Hernienchirurgie – von der Renaissance der netzfreien Nahtverfahren bis zur komplexen Bauchdeckenrekonstruktion unter besonderer Berücksichtigung der Lebensqualität

Habilitations-Schrift

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https://doi.org/10.18453/rosdok_id00005132

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Kumulative

Habilitations-Schrift

zur Erlangung des akademischen Grades

Doctor medicinae habilitatus

(Dr. med. habil.)

im Fachgebiet Chirurgie

der Universitätsmedizin Rostock

vorgelegt von:

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geboren am 1. April 1977 in Rostock

Rostock, März 2024

Datum der öffentlichen Verteidigung: 28.10.2024

Datum der öffentlichen Lehrprobe: 16.12.2024

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INHALTSVERZEICHNIS

1 Zusammenfassung

Prolog

Die Hernienchirurgie hat sich in den letzten 30 Jahren zu einem eigenständigen und ständig im Wandel befindlichen chirurgische Arbeitsgebiet entwickelt. Historisch hat sich ärztliches Handeln und die Entwicklung der Chirurgie sehr früh mit der Versorgung von Leistenhernien beschäftigt. Die erste Appendektomie erfolgte beispielsweise über eine Leistenhernie 1735 durch CLAUDIUS AMYAND. Heute werden in Deutschland jährlich ca. 300.000 Operationen aufgrund einer Hernie durchgeführt. Dabei handelt es sich um eine stabile Anzahl von Eingriffen. In anderen Arbeitsbereichen hat sich aufgrund einer strengeren Indikationsstellung (Schilddrüsenchirurgie), alternativen Behandlungsmethoden (Strahlentherapie des Ösophaguskarzinoms) oder verbesserten Therapien (*target therapies* in der Onkologie) ein rückläufiger Trend der Eingriffszahlen entwickelt.
Hernienchirurgie wird in diesem Kontext immer eine wichtige Disziplin der operativen Medizin sein, spezialisierte Hernienchirurgen sind schon lange ein geforderter Standard in Westeuropa und Deutschland. In manchen Ländern ist die Behandlung von Narbenhernien zertifizierten Zentren vorbehalten. Die zentrale Erfassung von Daten der an einer Hernie operierten Patienten in einem Register wurde in Deutschland nach skandinavischem Vorbild wegweisend von den Chirurgen initialisiert und wurde Grundlage für Zertifizierung und Zentrenbildung (Herniamed). Viele chirurgische Subdisziplinen sind diesem Beispiel gefolgt, um der Forderung gerecht zu werden, mit eigenen Daten Ergebnisse und Qualität des chirurgischen Handelns gegenüber ökonomischen und gesundheitspolitischen Aspekten darzustellen, insbesondere im Zusammenhang mit Mindestzahlen und *volume-outcome* Beziehungen.

„Bald wird die Zeit kommen, wo auch unsere Kollegen und Schüler strengere Anforderungen an uns und unser Handeln legen, wo man sich nicht mehr mit allgemeinen Bemerkungen über die Erfolge dieser oder jener Operation begnügen wird, sondern jeden Arzt für einen Scharlatan hält, der nicht im Stande ist, seine Erfahrungen in Zahlen auszudrücken."

THEODOR BILLROTH (1829-1894)

Komplexe Hernienchirurgie

In der Hernienchirurgie nimmt die Versorgung der Narbenhernien einen besonderen Stellenwert ein. Der Ausdruck *komplex* wird von manchen als Euphemismus belächelt. Tatsächlich können Hernienformationen ausgesprochen komplex sein. Inbegriffen sind dabei sehr große Bruchlücken mit u.U. verselbstständigtem viszeralem Bruchinhalt als sog. *loss of domain* bzw. einem „verlorenen Heimatrecht“, Parastomalhernien als eigene Entität oder in Kombination mit Narbenbrüchen, Hernien nach stattgehabter Infektsituation bzw. mit fortbestehenden Hautproblemen sowie laterale/lumbale Hernien.

Zumeist betreffen Narbenhernien allerdings die Medianebene der ventralen Bauchwand und sind nicht selten mit einer allgemeinen Neigung zu Instabilität des Bindegewebes verknüpft. Dabei kann es sich um individuelle Faktoren handeln, d.h. um eine genetisch determinierte Prädisposition im Sinne von Kollagensynthesestörungen. Diese können nicht unbedingt immer erfasst bzw. benannt werden, finden aber Ausdruck in Erkrankungen wie Aneurysmata von Gefäßen, Divertikulose des Darmes oder Hämorrhoidalleiden - oder eben der Neigung zur Ausbildung von Hernien, wofür sich der Begriff der Herniose etabliert hat.

Extrinsische Risikofaktoren für die Entstehung von Bauchwandhernien betreffen im Fall der Narbenhernie selbstredend die vorausgegangene chirurgische Prozedur, die auch nach vielen Jahren zu einem Bauchwandbruch führen kann. Wichtige Faktoren für das begünstigte Auftreten von Hernien sind komplexe abdominelle Voroperationen mit komplikativem Verlauf und der Notwendigkeit von erneuten kurzfristigen Laparotomien, Wundinfektionen sowie parallel erfolgte Anlagen von Stomata. Operationen am Magen-Darm-Trakt, insbesondere im Zusammenhang mit einer Tumorerkrankung und einer ggf. immunmodulierenden adjuvanten Therapie sind ebenso prädiktiv wie Erkrankungen und Operationen an der Aorta aufgrund eines Aneurysmas. Zusätzliche Risikofaktoren ergeben sich ebenfalls aus Komorbiditäten wie einem Diabetes mellitus, fortbestehendem Nikotinabusus, einer höhergradigen chronisch obstruktiven Lungenerkrankung (COPD) oder einem manifesten obstruktiven Schlafapnoe-Syndrom (OSAS).

In diesem Zusammenhang scheint es wichtig, außerhalb o.g. „blanker“ Registerdaten jeden Patienten individuell bzgl. der präoperativen Beschwerden infolge der Hernie, den relevanten Komorbiditäten, dem gewählten operativen Verfahren sowie dem postoperativen Ergebnis in einem Koordinatensystem der subjektiven Wahrnehmung abzubilden - dies führt schnell zu dem Begriff der Lebensqualität, dem der Verfasser eine besondere Bedeutung beimisst.

Alloplastisches Material

Die Frage nach der Notwendigkeit der Netzeinlage als alloplastisches Implantat bei der operativen Versorgung von Narbenhernien ist schon lange geklärt – die Wahrscheinlichkeit für eine Rezidiv beträgt 50%, wenn auf ein Netz verzichtet wurde. Dies hat u.a. mit den o.g. Risikofaktoren zu tun, d.h. bildet der Patient eine Narbenhernie aus, wird diese mit körpereigenem (Binde-)Gewebe nur ungenügend zu stabilisieren sein. Damit gilt es bereits seit über 20 Jahren als Standard, ein Netz zu implantieren. Dafür gibt es verschiedene operative Zugangswege und anatomische Präparationsebenen für die angestrebte Netzeinlage. Daher müssen verschiedene Techniken im Sinne eines breiten chirurgischen Armamentariums vorgehalten werden, um eine komplexe Hernienchirurgie anbieten bzw. durchführen zu können. Der Begriff des *tailored approach* ist hierbei kaum mit keiner anderen operativen Disziplin so eng verknüpft wie mit der Hernienchirurgie.
In einer spezialisierten Sprechstunde werden maßgeschneiderte Konzepte dem Patienten vorgeschlagen und geplant. Vor einer *one size fits all*-Strategie muss insbesondere in der Hernienchirurgie eindringlich gewarnt werden. Dies betrifft u.a. die Risiken der Verwendung alloplastischen Materials. Zum einen wird der chronische Schmerz in kausalem Zusammenhang mit einer Netzeinlage, insbesondere nach einer Leistenhernienreparation, möglicherweise aufgrund von Nervenirritationen oder Fremdkörpergefühl kontrovers diskutiert. Zum anderen birgt die Notwendigkeit der Implantation von alloplastischem Material die Gefahr der Infektion eines Netzes, z.B. im Gefolge einer tiefen Wundinfektes. Beides kann zu einer Netzexplantation führen. Die Explantation eines narbig eingeheilten Netzes ist anspruchsvoll und risikobehaftet, außerdem begünstigt es die Entstehung eines Rezidivs.
Für den spezialisierten Hernienchirurgen steht daher neben der primären Versorgung von Bauchwandbrüchen auch die Therapie o.a. postoperativer Probleme, möglichst unter Erhalt des Netzes, im Vordergrund.

Die vorliegende Arbeit befasst sich intensiv mit den wesentlichen Aspekten der Hernienchirurgie und leistet u.a. einen Beitrag zum Verständnis relevanter patientenindividueller Faktoren, insbesondere der postoperativen Lebensqualität.

2 Forschungsergebnisse

2.1 Prävention von postoperativen Wundinfektionen

Die auch in unseren Daten sehr hohe Rate an Wundinfektionen nach komplexer Narbenhernienreparation von ca. 10% hat zu der Überlegung geführt, wie man diesen wesentlichen postoperativen Parameter verbessern kann [1]. Mit der Einführung einer epikutanen und präventiv verwendbaren Vakuumschwammtherapie (Prevena®, Fa. KCI) im Jahr 2013 haben wir begonnen, diesen modernen Wundverband unmittelbar nach Wundverschluss unter sterilen Bedingungen im OP anzuwenden [2-4]. Die Ergebnisse sind in der Veröffentlichung [Leuchter M, Hitzbleck M, Schafmayer C, **Philipp M**. Use of incisional preventive negative pressure wound therapy in open incisional hernia repair: Who benefits? *Wound Repair Regen*. 2021 Sep;29(5):759-765.] dargestellt.

Es wurden in einem aufwendigen statistischen Verfahren 40 Patienten mit Prevena® (*negative wound pressure therapy*, NPWT) gegen 40 Patienten mit einer Standard Wundversorgung als *matched pair*-Analyse verglichen. Wichtige Prädiktoren für die Wundinfektionsrate waren die Größe der Bruchlücke sowie die Größe des implantierten Netzes. Beides korreliert mit einer ausgedehnteren Präparation, einer aufwendigeren OP-Technik sowie größeren Wundfläche und Hautwunde im Bereich der Bauchdecke. Es zeigt sich, dass die Verwendung der präventiven Vakuumtherapie ab einer Netzgröße von 400 cm^2 einen positiven Effekt auf die Wundinfektionsrate hat. Das Prinzip basiert auf der Erzeugung von Unterdruck auf Hautniveau mit konsekutiver Druckerhöhung im subkutanen bzw. epifaszialen Gewebe und fördert dadurch die Durchblutung, verbessert den Lymphabfluss und verringert die Serombildung [5]. Dadurch werden die wesentlichen Risikofaktoren für eine Wundinfektion antizipiert, allerdings funktioniert das Prinzip in präklinischen Untersuchungen nur bis zu einer bestimmten Wundtiefe [6].

Ergebnisse einer vergleichenden klinischen Untersuchung anhand von *matched pair*-Patientenkohorten mit den Voraussetzungen nicht-kontaminierter elektiver Chirurgie lagen bisher nicht vor [7]. Grundlage der prospektiven Anwendung und retrospektiven Untersuchung waren 386 Patienten, die im Zeitraum von 1/2014 bis 5/2019 an einer ventralen Bauchwandhernie mit einer Netzimplantation in Sublay-Position operiert wurden. Bei großen Bruchlückendefekten musste zusätzlich eine Komponentenseparation (modifizierte RAMIREZ-Plastik) durchgeführt werden, um die hintere Rektusscheide vor der Netzeinlage verschließen zu können. Diese Verfahren der komplexen Bauchwandreparation haben bekanntermaßen eine

deutlich erhöhte Infektionsrate [8] und waren entsprechend unserer *ex ante* Hypothese für die Verwendung des Prevena®-Verbandes vorzugsweise vorgesehen. Die individuelle Entscheidung zur Anwendung des neuartigen Verbandes blieb letztendlich auf dem Niveau einer *single center single surgeon*-Studie. Durch das *propensity score matching* konnte aber eine statistisch signifikante Aussage erbracht werden. Aufgrund der konsequenten und lückenlosen Eingabe und Verwendung einer Herniendatenbank (Herniamed®) in unserem Arbeitsbereich seit dem 1.1.2014 war auch das für diese Studie erforderliche *follow-up* mit einem Median von 38.5 Monaten sehr lang. Insbesondere wurden auch die postoperativen Verläufe von Patienten nach Entlassung aus dem Krankenhaus erfasst, eine in vielen Studien nur unzureichend repräsentierte Beobachtung [9,10].

Die gesamte Wundkomplikationsrate beider Patientenkohorten betrug 12% (n=54) und schloss Serom- und Hämatomformationen mit ein. Die Rate aller Wundinfektionen betrug 8.8% (n=34). In der Gruppe der Komponentenseparation (n=40) war diese Rate mit 15% (n=6) deutlich höher.

Unter Verwendung der NPWT war die Rate der Wundkomplikationen auf den ersten Blick ebenfalls deutlich erhöht, sie betrug während des Krankenhausaufenthaltes 14.8% (n=8) und stieg bei Erfassung des Verlaufes nach Entlassung bzw. mit erneuter stationärer Aufnahme nochmal deutlich auf 33.3% (n=18) an. Die Wundinfektionsrate bei Verwendung der NPWT war 14.8% (n=8) und führte in 7 Fällen (87%) zu einer operativen Revision. Die *matched pair*-Analyse ergab als wesentliche Risikofaktoren für Wundkomplikationen bzw. -infektionen die Dimensionen der Bruchlücke bzw. des Implantates. Es ergab sich abschließend, dass ein Benefit der NPWT für Patienten bestand, bei denen ein Netz >450 cm^2 implantiert wurde.

2.2 Erhalt von Netzmaterial in der Infektsituation

Wie bereits erläutert, gehört die Implantation von alloplastischem Material in der operativen Versorgung von Narbenhernien seit einigen Jahren zum Standard. Dies hat zu einer deutlich reduzierten Rezidivrate geführt und kann als evidenzbasiert bezeichnet werden [11,12]. Eine gefürchtete Komplikation bleibt die Infektion des eingebrachten Netzes, meist auf dem Boden bzw. in der Folge einer tiefen Wundinfektion, selten als Nebeneffekt einer ggf. unerkannten Verletzung viszeraler Organe, z.B. Enterotomie, während der Hernioplastik [13,14]. Aus der Konstellation einer Netzinfektion nach komplexer Bauchwandreparation ergibt sich ein erhebliches Dilemma, da eine Netzexplantation zur Beherrschung bzw. Sanierung des Infektes

eine nahezu unmögliche und komplikationsträchtige Prozedur darstellt [15]. Außerdem wird damit die Stabilität der Bauchwand gefährdet und der Ausbildung eines Rezidives Vorschub geleistet [16,17]. In unserer Publikation **[Philipp M**, Förster S, Klar E. Komplikationsmanagement in der Narbenhernienchirurgie: Erhalt von alloplastischem Material in der Infektsituation. *Viszeralmedizin.* 2012;28(2):138–141.] wurde dieses wichtige Thema adressiert und im eigenen Patientengut untersucht.

Wir haben anhand unserer retrospektiven Untersuchung an 198 konsekutiv operierten Patienten zeigen können, dass die konsequente therapeutische Strategie mit dem Ziel des Netzerhaltes mit den verfügbaren modernen Netzmaterialien und den neuen Techniken des Managements komplexer Wunden erfolgreich ist. Alle untersuchten Patienten wurden mit einem großporigen Polyester-Netz (Parietex®, Fa. Covidien) an einer ventralen Bauchwandhernie über einen Zeitraum von 5 Jahren operiert. In 10% der Fälle trat eine Wundinfektion auf, diese war in 6% der Fälle als tiefe Wundinfektion mit Netzbeteiligung klassifiziert. Bei n=10 konnte die Infektion folgenlos zur Ausheilung gebracht und das Netz erhalten werden, lediglich in 2 Fällen war eine Explantation notwendig. Die wesentlichen Pfeiler der Therapie waren die konsequente und radikale Sanierung des Infektes der Bauchdecke durch chirurgische Wunderöffnung, Evakuation von Eiter und regelmäßige Wundspülung, die resistenzgerechte antimikrobielle Behandlung sowie der Einsatz von Vakuumtherapie mit dem Ziel der sekundären Wundheilung.

2.3 Lebensqualität in der Hernienchirurgie

2.3.1 Demographische Aspekte der Lebensqualität in der Leistenhernienchirurgie

Die Lebensqualität in einer alternden Bevölkerung ist ein interessantes Kernelement der Demographie [18,19]. Um ein Schlüsselereignis für die Analyse der subjektiven Wahrnehmung von Wohlbefinden zu erfassen, ist ein chirurgischer Eingriff geeignet, indem man die prä- und postoperative Situation quantitativ erfasst [20]. Die häufig durchgeführte Operation einer Leistenhernie hat sich für diese Arbeit als ideal erwiesen, um einen signifikanten Zusammenhang der Lebensqualität auf der Zeitachse der chirurgischen Therapie festzustellen. Dies hat zu der für diese kumulative Habilitationsschrift zentrale Publikation [Leuchter M, Klar E, **Philipp M**. Die demografische Perspektive auf maßgeschneiderte Therapieansätze: Eine Analyse der Lebensqualität am Beispiel der Leistenhernie [Demographic perspective on the

concept of the tailored approach in surgery: Analysis of the quality of life exemplified by inguinal hernia repair]. *Chirurg.* 2020 Jan;91(1):60-66.] geführt. Insbesondere die Einbindung unserer Daten in eine Vergleichspopulation als sogenannte Normalbevölkerung verbindet demografische Aspekte mit denen der chirurgischen Grundversorgung [21].

Der konstante Anstieg der Lebenserwartung ist Ausdruck unserer modernen Gesellschaft. Der 80jährige Patient stellt heute im klinischen Alltag keine Ausnahme mehr dar. Diese Tatsache wirkt sich wesentlich auf diagnostische und therapeutische Leitlinien aus [22]. Neben quantitativen Faktoren (Komplikationen, Rezidivrate) muss in der elektiven Hernienversorgung auch die Lebensqualität (*quality of life*, QoL) als patientenzentrierter subjektiver Faktor bei der Therapieoption berücksichtigt werden [23,24]. Dazu bedarf es einer Standardisierung gegenüber einer Referenzbevölkerung [21].

Grundlage waren 310 an einer Leistenhernie operierte Patienten der Chirurgischen Universitätsklinik Rostock. Die präoperative Untersuchung und Befragung zur Lebensqualität wurde mit einer postoperativen Befragung korreliert. Dabei war mit einem medianen *follow-up* von 20 Monaten die Rate der Antworten 66%, was einem vergleichsweise sehr guten Ergebnis entspricht. Die Schmerzbelastungen wurden anhand der visuellen Analogskala (VAS) und die krankheitsunspezifische QoL durch den Erhebungsbogen EQ-5D evaluiert. Die Basis der Standardisierung bilden die repräsentativen Normwerte des EQ-5D für Deutschland [21,25].

Die Analyse der Patienten in den verschiedenen Therapiearmen (minimalinvasiv vs. offen-chirurgisch) zeigt signifikante Unterschiede in der Alterszusammensetzung und im Gesundheitszustand (ASA-Score). Der Vergleich der QoL zwischen den beiden netzbasierten Verfahren (TAPP vs. Lichtenstein) führt zu dem Ergebnis, dass eine vollständige Rekonvaleszenz nach 6 Monaten möglich ist [26]. Auffällig ist das leichte Absinken der QoL in der Lichtenstein-Kohorte, welches v.a. durch das hohe Lebensalter begründet ist.

Wir schlussfolgern, dass das Konzept der Evaluation der Lebensqualität in den aktuellen Bewertungen von Therapieverfahren eine immer wichtigere Rolle spielt. Bei einem Vergleich zwischen mehreren Verfahren muss allerdings eine Standardisierung vorgenommen werden, um die Heterogenität zwischen den Gruppen zu berücksichtigen bzw. auszugleichen. D.h. die gemessenen QoL-Werte sollten in das Verhältnis zu der alters- bzw. geschlechtsspezifischen Referenz der Allgemeinbevölkerung gesetzt werden, um den Effekt der beobachteten Erkrankung bzw. deren Therapie darzustellen.

Unsere Untersuchungen und Ergebnisse sowie deren Veröffentlichung können als Blaupause für andere Krankheitsentitäten bzw. Behandlungsmodalitäten genutzt werden.

2.3.2 Lebensqualität nach komplexer Bauchwandrekonstruktion

Weiterführend haben wir das Konzept der Analyse der Lebensqualität anhand operierter Patienten für die komplexe Rekonstruktion der Bauchwand durch netzverstärkende Hernioplastik untersucht [27,28]. Hierfür bildeten die Methoden der Untersuchungen zur Leistenhernie die Grundlage und es ergab sich in logischer Folge eine retrospektive Analyse einer sehr heterogenen Gruppe von Patienten mit der resultierenden Veröffentlichung [**Philipp M**, Leuchter M, Klar E. Quality of Life after Complex Abdominal Wall Reconstruction. *Visc Med.* 2020 Aug;36(4):326-332.].

Patienten mit großen Defekten der Bauchwand als ventrale Hernien haben häufig eine lange und komplizierte Krankheitsgeschichte [29,30,31]. Die Grunderkrankung, die zur Laparotomie und nicht selten zu einem komplikativen Verlauf führte, der meist die Ausbildung einer Hernie begünstigte, muss bei der Beurteilung der Lebensqualität berücksichtigt werden [32]. Insbesondere der Parameter Schmerz bewirkt häufig einen individuellen Leidensdruck, der den Patienten auch noch Jahre nach der ursprünglichen Operation zum Hernienchirurgen (im anglosächsischen Schrifttum übrigens auch etwas treffender als *abdominal wall surgeon* bezeichnet) führt. Dementsprechend ist auch der postoperative Schmerz ein wichtiger Verlaufsparameter, der die QoL wesentlich beeinträchtigt [27,28].

Die Anwendung der Komponentenseparation mit dem Ziel der Rekonstruktion der Mittellinie und konsekutiver Netzverstärkung dient der Reparation großer Herniendefekte [33]. Die Indikation und Durchführung sollte durch spezialisierte Hernienchirurgen erfolgen, da die postoperative Komplikationsrate erheblich ist und v.a. Probleme von Wundheilungsstörungen zur Folge hat (siehe 2.1). Die Methode wurde ursprünglich von Ramirez et al. [34] beschrieben und hat seitdem verschiedene Modifikationen erfahren, u.a. einen partiell minimalinvasiven Ansatz [35,36]. Eine systematische Untersuchung der langfristigen Lebensqualität nach diesen aufwendigen operativen Verfahren wurde meist nicht durchgeführt [27,28].

Wir haben in einer retrospektiven Analyse 35 Patienten untersucht, die im Zeitraum 2011 bis 2016 von uns konventionell offen bzw. mit einer endoskopischen Komponentenseparation operiert wurden. Bei allen Patienten konnte die Approximation der Faszienränder mit Verschluss der Mittellinie erreicht werden, was unserer Einschätzung nach für die Funktion der Bauchdecke und die konsekutive QoL entscheidend ist. Zusätzlich erfolgte eine Netzverstärkung in Sublay-Position.

Die Patientencharakteristika, die technischen Aspekte der Operation sowie der unmittelbare postoperative Verlauf wurden durch eine Erhebung der gesundheitsbezogenen QoL (EQ-5D)

einschließlich Schmerzevaluation (VAS) im Langzeitverlauf mit einem medianen *follow-up* von 19.5. Monaten komplettiert [37].

Von den 35 Patienten, die eine Komponentenseparation erhielten, wurden 25 konventionell offen und 10 endoskopisch assistiert operiert. Die endoskopisch assistierte Methode führte zu einer deutlich niedrigeren Rate an Wundheilungsstörungen (10% vs. 24%) und dementsprechend kürzeren Verweildauer im Krankenhaus (7.9 Tage vs. 16.6 Tage), allerdings waren die Herniendefekte auch signifikant kleiner (86 cm^2 vs. 169 cm^2), was a.e. Folge eines Selektionsbias in dieser *single centre single surgeon*-Studie ist. Interessanterweise war die Lebensqualität im Langzeitverlauf in beiden Gruppen gleich, sogar mit einem positiven Trend zum offenen Verfahren. Im Vergleich zur Referenzbevölkerung schnitten die Patienten bezüglich der QoL deutlich schlechter ab, obwohl von den 28 Patienten unter 65 Jahren 12 Patienten (42%) wieder ihre sozialversicherungspflichtige Beschäftigung aufnahmen. Bemerkenswert ist, dass der Unterschied zur Normalbevölkerung im EQ-5D bei der Evaluation der VAS-basierten subjektiven Gesundheitseinschätzung verschwindet, d.h. die Bauchdeckenrekonstruktion konnte das Schmerzniveau langfristig auf die Ebene der Referenzbevölkerung angleichen, ohne an den Beschwerden infolge der Grunderkrankung etwas zu ändern.

2.3.3 Lebensqualität nach Aorteneingriffen in Abhängigkeit von der Ausbildung einer Hernie

Ein besonderer Schwerpunkt in der Untersuchung von Hernien und Lebensqualität wurde durch uns mit der Analyse von Patienten nach offenem und interventionellem Aortenersatz aufgrund eines Bauchaortenaneurysmas (BAA) gesetzt. Die Arbeit fokussiert auf der systematischen Nachverfolgung von Patienten nach Eingriffen an der Bauchaorta, welche eine hohe Morbidität und Mortalität unmittelbar postoperativ/postinterventionell [38] nach sich ziehen und im Fall der offenen Versorgung eine besonders hohe Rate an Bauchwandhernien (bis 69%) im Langzeitverlauf aufweisen [39-43].

Die postoperative Lebensqualität nach Behandlung eines BAA stellt alleine schon einen wesentlichen Parameter zur Beurteilung des jeweiligen Therapieverfahrens dar [44-46]. Die gesundheitsbezogene QoL im Vergleich zur Referenzbevölkerung wird auch hier wieder zu einem wichtigen demografischen Aspekt in einer alternden Gesellschaft für eine spezifisch im hohen Alter häufig detektierte und behandelte Erkrankung (BAA) [47]. Die Überschneidung mit der konsekutiven Entwicklung einer ventralen Bauchwandhernie und deren Einfluss auf das

subjektive Wohlbefinden machen diese Untersuchung genuin und sind für die publizierten Daten [Gruel J, Grambow E, Weinrich M, Heller T, Groß J, Leuchter M, **Philipp M**. Assessment of quality of life after endovascular and open abdominal aortic aneurysm repair: a retrospective single center study. *J Clin Med*. 2022 May 27;11(11):3017.] von besonderem Wert.

Es konnten 83 Patienten, die zwischen 2008 und 2016 in der Universitätsklinik Rostock aufgrund eines BAA mittels offenem Aortenersatz (n=36) bzw. interventionell (EVAR, n=47) behandelt wurden, in die Analyse einbezogen werden. Die gesundheitsbezogene QoL wurde mittels SF-36 Fragebogen erhoben, das mittlere *follow-up* betrug 7.1 Jahre.

Die Inzidenz für die Ausbildung einer Narbenhernie betrug für die untersuchte Kohorte der offen operierten Patienten in dem o.g. sehr langen Nachbeobachtungszeitraum 30.6%. Während die gesundheitsbezogene QoL zwischen den beiden Therapiearmen zunächst keine signifikanten Vorteile ergab wurden von den Patienten, die eine Hernie im Verlauf ausgebildet hatten bestimmte Dimensionen im SF-36 deutlich schlechter bewertet. Die subjektive Gesundheitswahrnehmung wird schlussfolgernd wesentlich von dem Auftreten einer Bauchwandhernie infolge eines offenen Aortenersatzes aufgrund eines BAA beeinflusst.

2.4 Alternativen der konventionellen Netzverstärkung

2.4.1 Netzfreie Reparation der Leistenhernie nach DESARDA

Die Operation der Leistenhernie ist eine der ältesten durchgeführten Techniken in der Chirurgie. Die dazu verwendeten chirurgischen Methoden haben in den letzten 100 Jahren zahlreiche Modifikationen erfahren. Die Einführung von Implantaten und die Verwendung der Schlüssellochtechnik sind allerdings die fundamentalsten Entwicklungen in diesem Bereich. Die international geltenden Leitlinien zur operativen Versorgung einer Leistenhernie legen aktuell ein netzbasiertes Vorgehen für beide Geschlechter im Erwachsenenalter fest [48]. Dies hat in der sogenannten westlichen Welt dazu geführt, dass nahezu jeder Patient ein Implantat erhält, vorzugsweise minimalinvasiv (TAPP/TEP), alternativ offen als z.B. Lichtenstein-Operation. Allerdings dauert die Kontroverse an, ob ein netzfreies Verfahren, wie man es jahrzehntelang Patienten angeboten hat, nicht weiterhin einen Stellenwert haben sollte, insbesondere aufgrund der Bedenken bezüglich der Verwendung von Implantaten mit den Risiken der Infektion sowie des chronischen Leistenschmerzes. Zusätzlich ist vollkommen unklar, wie man mit

Empfehlungen internationaler Leitlinien umgeht, wenn damit große Teile der Weltbevölkerung von einer Versorgung mit den modernen und teuren Implantaten ausgeschlossen werden [49] (siehe 2.4.2).

2.4.1.1 Implementation einer neuen Methode an einer Universitätsklinik

Die Operationstechniken zur Versorgung der Leistenhernie weisen entsprechend der Statistik und den aktuellen Leitlinien eine deutliche Tendenz zum netzbasierten sowie laparoskopischen Vorgehen auf [48,54]. Entgegen diesem Trend zeigen wir eine Möglichkeit zur netzfreien Reparation der Leistenhernie unter Verwendung von autologem Faszienmaterial zur Verstärkung der Leistenkanalhinterwand, wie sie ursprünglich von Desarda et al. beschrieben wurde [50-53]. Bei dieser Publikation [**Philipp M**, Förster S, Klar E. Operation der Leistenhernie nach Desarda - Implementierung einer netzfreien Reparationsmethode an einer deutschen Universitätsklinik [Inguinal Hernia Repair According to Desarda - Implementation of a Mesh-Free Method in a German University Hospital]. *Zentralbl Chir.* 2015 Aug;140(4):373-4.] handelt es sich um ein Videopaper mit eingebundenem Lehrfilm in der Mediathek der Deutschen Gesellschaft für Chirurgie.
Die netzbasierte Versorgung des Leistenbruches entspricht auch dem operativen Standard in unserer Institution. Allerdings haben o.g. Bedenken dazu geführt, dass wir die Adhärenz zu dem leitliniengerechten Vorgehen im Rahmen der Beratung von Patienten in der spezialisierten Herniensprechstunde aufgeweicht haben. Damit folgen wir der Vorstellung des besonders in der Hernienchirurgie etablierten *tailored approach*. Dieses maßgeschneiderte Konzept beinhaltet, dass wir Patienten eine netzfreie offene Methode als Alternative anbieten. Dazu haben wir 2013 die Operationstechnik nach DESARDA adaptiert und in unserer Universitätsklinik implementiert. Diese Implementationsphase hat gezeigt, dass es sich um ein intuitives und leicht erlernbares Verfahren handelt.

2.4.1.2 Retrospektive multizentrische Auswertung

Wie bereits beschrieben, handelt es sich bei der Operationstechnik nach DESARDA um eine netzfreie Methode zur operativen Versorgung der Leistenhernie. Dem Grundprinzip aller Verfahren folgend wird die Hinterwand des Leistenkanals stabilisiert, dazu wird ein Streifen der Externusaponeurose als Faszienverschiebeplastik verwendet [50-53]. Der Begriff einer *pure tissue*-Technik hat sich hierfür international etabliert [55].

Unsere Bemühung, von der aktuell geltenden Leitlinie mit einer alternativen *pure tissue*-Technik abzuweichen, hat die Notwendigkeit ergeben, anhand von eigenen Daten die sichere Durchführung der Technik und Zuverlässigkeit der Reparation aufzuzeigen. Nach der Phase der Einführung (siehe 2.4.1.1) haben wir daher in einer retrospektiven Analyse 120 zwischen 2013 und 2020 operierte Patienten bezüglich ihres klinischen Outcomes sowie der postoperativen Lebensqualität untersucht und die Ergebnisse publiziert **[Philipp M**, Leuchter M, Lorenz R, Grambow E, Schafmayer C, Wiessner R. Quality of Life after Desarda Technique for Inguinal Hernia Repair–A Comparative Retrospective Multicenter Study of 120 Patients. *J Clin Med.* 2023 Jan 28;12(3):1001.].

Die Analyse und Auswertung beinhaltet die Patientencharakteristika, Dauer der Operation, stationäre Verweildauer sowie peri- und postoperative Komplikationen. Im Rahmen einer *matched pair*-Analyse wurde anhand der Variablen Geschlecht, Alter, ASA-Score, Lokalisation und Größe der Bruchlücke eine Kohorte aus dem eigenen Patientengut verglichen, die mittels TAPP operiert wurde. Zusätzlich erfolgte 12 Monate postoperativ die Evaluation der Lebensqualität (QoL) sowie der subjektiven Einordnung auf der Schmerzskala (VAS). Zusammenfassend fokussiert die Studie auf dem Vergleich der QoL von Patienten, die nach DESARDA operiert wurden mit Patienten, die mittels TAPP operiert wurden bzw. in Korrelation zu den Werten der Referenzbevölkerung [56,57].

Von den 120 operierten Patienten waren 106 männlich, das mediane Alter betrug 37.5 Jahre. Die Eingriffsdauer war 50 Minuten, die stationäre Verweildauer war 2 Tage, jeweils im Median. Innerhalb der 17 Monate Nachbeobachtungszeitraum zeigte sich ein Rezidiv (0.8%) und 2 Fälle mit einem chronischem Leistenschmerz (VAS > 3). Die 12 Monate postoperativ erhobene QoL zeigte keinen Unterschied zwischen DESARDA und TAPP. Allerdings hatten Patienten nach DESARDA-Operation eine signifikant höhere QoL im Vergleich zur Referenzbevölkerung.

Schlussfolgernd konnten wir anhand unserer eigenen Daten zeigen, dass die Operation nach DESARDA als *pure tissue* Verfahren eine gute Option in der operativen Behandlung der Leistenhernie darstellt.

2.4.2 Kompatibilität von Moskito-Netzen nach Dampfsterilisation

Wie bereits berichtet, hat sich in der Kontroverse um die Leitlinie zur Behandlung der Leistenhernie mit der klaren Empfehlung zur Netzimplantation ein weiteres Problem globalen Ausmaßes ergeben, welches national kaum Beachtung findet [58,59]. Während in Deutschland

Verfügbarkeit und Kosten der Implantate kein Problem darstellen, zeigt sich für die 3. Welt, insbesondere Afrika, ein eklatantes Missverhältnis zwischen Bedarf und finanzierbarer Verfügbarkeit [60].

In diesen Regionen hat sich die Verwendung von *low cost*-Netzen etabliert, zumeist handelt es sich dabei um handelsübliche Moskito-Netze [61]. Diese bestehen aus Polyester oder Polyethylen, was prinzipiell dem Material der kommerziellen Netze als Medizinprodukt entspricht. Allerdings müssen die *low cost*-Netze zunächst sterilisiert werden [62]. Inwieweit dieser Sterilisationsprozess das Material verändert, war Ziel und Inhalt unserer Untersuchungen. Hierbei wurden die Veränderungen der Biokompatibilität der Fibroblasten sowie mechanische und chemische Eigenschaften nach Gassterilisation analysiert. [Wiessner R, Lorenz R, Gehring A, Kleber T, Benz C, Sander M, Richter DU, **Philipp M**. Alterations in the mechanical, chemical and biocompatibility properties of low-cost polyethylene and polyester meshes after steam sterilization. *Hernia.* 2020 Dec;24(6):1345-1359.].

Proben des Netzmaterials aus Polyester bzw. Polyethylen wurden unsteril bzw. nach Dampfsterilisation mit 100°C, 121°C oder 134°C sowohl mechanischen Stabilitätstests, einer chemischen Analyse sowie einer Biokompatibilitätsprüfung gegenüber Fibroblasten unterzogen. Die Beurteilung beinhaltete konventionelle Mikroskopie, Elektronenmikroskopie, eine LDH-Zytotoxizitätstestung, eine Vitalitätstestung sowie die Bestimmung des pH-Wertes, Lactat und der Glycolyse. Bereits makroskopisch zeigte das Polyethylen-Netz eine deutliche Schrumpfung nach der Sterilisation, besonders nach 121°C und 134°C. Das Polyester-Netz wies keine mechanischen Veränderungen nach der Sterilisation auf. Die Zytotoxizität war am niedrigsten in den unsterilen Proben. Der Glukosemetabolismus war in beiden Varianten und unabhängig vom Sterilisationsprozess kaum beeinflusst.

Schlussfolgernd ändert die Dampfsterilisation erheblich die mechanischen und strukturellen Eigenschaften der *low cost*-Implantate. Auf der Grundlage unserer Untersuchungen kann eine Verwendung im Menschen nicht empfohlen werden.

Unsere Publikation in der Fachzeitschrift *Hernia* hat eine Debatte ausgelöst, die zeigt, wie kontrovers das Thema ist. Einem Kommentar von Stephenson *et al.* [63] zu unseren Ergebnissen im gleichen Journal sind wir entsprechend begegnet [Wiessner R, **Philipp M**, Lorenz R. The value and role of mosquito meshes in low resource and poor income settings: author's reply. *Hernia.* 2021 Oct;25(5):1379-1380.].

2.5. Situs-Lehre & Ausbildung chirurgischer Techniken

Operationen der Hernienchirurgie gelten als klassische Ausbildungseingriffe zur Erlangung des Facharztstatus (Facharzt für Chirurgie). Gleichzeitig ist dieser Arbeitsbereich mit immer neuen minimalinvasiven und offenen Operationstechniken national und international zu einer der innovativsten Disziplinen geworden. Die Einführung neuer Techniken in einer Universitätsklinik beinhaltet die Notwendigkeit, diese auch zügig an Kollegen zu vermitteln, vor allem die profunde Kenntnis der Anatomie des Leistenkanals und der Bauchdecke sind hierfür Voraussetzung.

Sowohl die komplexe Bauchwandreparation mit der Komponentenseparation und deren Modifikationen (OP nach RAMIREZ) als auch die inguinale Hernioplastik mit autologer Faszienverschiebeplastik als *pure tissue*-Verfahren (OP nach DESARDA), die im Zentrum dieser Arbeit stehen, konnten erfolgreich weitergegeben und ausgebildet werden.

Die Anatomie des Leistenkanals kann im Rahmen einer offenen Operation gut erklärt werden und das Verfahren nach DESARDA problemlos erlernt und nach wenigen Eingriffen bereits ohne Einschränkungen assistiert werden. Die Operationstechnik wurde durch Hospitationen zügig in anderen Kliniken implementiert und weitergeführt, außerdem auf der zentralen jährlichen Veranstaltung der Hernienchirurgie vor Live-Publikum voroperiert.

Eine Kooperation mit der Anatomie macht hier sogar eine frühzeitige Einbindung der Studenten der Humanmedizin möglich, auch diese Möglichkeit wurde intensiv genutzt.

Schwieriger stellt es sich bzgl. der Anatomie der Bauchdecke und der Technik der Komponentenseparation dar. Die großen, nicht selten monströsen, ventralen Bauchwandhernien, bei denen es sich meist um Narbenhernien handelt, stellen den Operateur vor Herausforderungen, die häufig erst während der OP abschätzbar sind.

Daher wurde in Kooperation mit dem Institut für Rechtsmedizin der Universitätsmedizin Rostock mit der Öffnung des Sektionssaales [64] für Kliniker eine ideale Voraussetzung für Lehre und Fortbildung von Anatomie und chirurgischen Techniken. Wir haben dies in der Zeitschrift *Chirurg* entsprechend erfolgreich publizieren können. [Hammer U, Blaas V, Büttner A, **Philipp M**. Autopsien mit Situs-Lehre in der klinischen Rechtsmedizin [Autopsies for anatomical teaching and training in clinical forensic medicine]. *Chirurg.* 2015 Dec;86(12):1128-31.]. Inhalt der Sektionen war neben dem primären rechtsmedizinischen Auftrag der Autopsie das Angebot einer gemeinsamen „Situs-Lehre“ für ärztliche Kollegen operativer und interventioneller Fächer, um sowohl dem jungen Weiterbildungsassistenten als auch dem fortgeschrittenen Operateur die Möglichkeit zu bieten, bewährte und innovative

Operationstechniken auf der Grundlage der Anatomie aufzuarbeiten [65,66]. In diesem Setting wurde am unfixierten Körper die Anatomie des Leistenkanals sowie der Bauchdecke studiert. Die Präparation der Rektusscheide mit Ablösung der *M. rectus abdominis* und Darstellung des vorderen und hinteren Blattes der Rektusscheide sowie die Präparation in den Schichten des *M. obliquus internus et externus* sowie das Ablösen der Fasern des *M. transversus abdominis* entspricht dabei bereits den Techniken der Komponentenseparation – diese konnten somit erfolgreich angewandt und weitervermittelt werden.

Die Kooperation wird durch uns weiterhin genutzt und derzeit im Rahmen der endokrinen Chirurgie fortgesetzt. [**Philipp M**, Reichenbach K, Manhart J, Lamp N, Schafmayer C, Büttner A. Feasibility of detecting altered parathyroid glands through interdisciplinary autopsy in a clinical forensic medicine setting. Abstract DGAV. *Innovative Surgical Sciences.* 2021;6(Special Suppl 1):S1-S80.]

3 Publikationsverzeichnis

(Angabe der Impact-Faktoren aus dem Jahr **2022** in Klammern)

3.1 Originalarbeiten

Gesamtanzahl der Originalarbeiten: 15

Anzahl der Originalarbeiten als Erst- oder Letztautor: 11

Kumulativer Impact-Faktor aller Originalarbeiten: 29

Kumulativer Impact-Faktor aller Originalarbeiten als Erst- oder Letztautor: 23.4

15:

Aldarwish S, Guda P, **Philipp M**, Schafmayer C, Hinz S.
Developing incisional hernia after open liver resection and liver transplantation: A single-center risk factor analysis.
Int J Abdom Wall Hernia Surg 2024;7(1):14-23. **(0.5)**

14:

Bürtin F, Ludwig T, Leuchter M, Hendricks A, Schafmayer C, **Philipp M**.
More than 30 Years of POSSUM: Are Scoring Systems Still Relevant Today for Colorectal Surgery?
J Clin Med. 2023 Dec 28;13(1):173. **(4.1)**

13:

Philipp M, Leuchter M, Lorenz R, Grambow E, Schafmayer C, Wiessner R.
Quality of Life after Desarda Technique for Inguinal Hernia Repair–A Comparative Retrospective Multicenter Study of 120 Patients.
J Clin Med. 2023 Jan 28;12(3):1001. **(4.1)**

12:

Witte M, Neese M, Leuchter M, **Philipp M**, Klar E, Schafmayer C.
Acute Mesenteric Ischemia: Preexisting Comorbidity Determines Short-Term Outcome and Quality of Life in Long-Term Survivors.
Visc Med. 2022 Dec;38(6):393-399. **(1.9)**

11:

Gruel J, Grambow E, Weinrich M, Heller T, Groß J, Leuchter M, **Philipp M**.

Assessment of quality of life after endovascular and open abdominal aortic aneurysm repair: a retrospective single center study.

J Clin Med. 2022 May 27;11(11):3017. **(4.1)**

10:

Leuchter M, Hitzbleck M, Schafmayer C, **Philipp M**.

Use of incisional preventive negative pressure wound therapy in open incisional hernia repair: Who benefits?

Wound Repair Regen. 2021 Sep;29(5):759-765. **(2.9)**

9:

Wiessner R, Lorenz R, Gehring A, Kleber T, Benz C, Sander M, Richter DU, **Philipp M**.

Alterations in the mechanical, chemical and biocompatibility properties of low-cost polyethylene and polyester meshes after steam sterilization.

Hernia. 2020 Dec;24(6):1345-1359. **(2.9)**

8:

Philipp M, Leuchter M, Klar E.

Quality of Life after Complex Abdominal Wall Reconstruction.

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7:

Schwandner F, Hinz S, Witte M, **Philipp M**, Schafmayer C, Grambow E.

Intraoperative assessment of gastric sleeve oxygenation using hyperspectral imaging in esophageal resection: a depiction of a case series.

Visc Med. 2021 Jun;37(3):165-170. **(1.9)**

6:

Leuchter M, Klar E, **Philipp M**.

Die demografische Perspektive auf maßgeschneiderte Therapieansätze: Eine Analyse der Lebensqualität am Beispiel der Leistenhernie [Demographic perspective on the concept of the tailored approach in surgery: Analysis of the quality of life exemplified by inguinal hernia repair].

Chirurg. 2020 Jan;91(1):60-66. **(0.9)**

5:

Hammer U, Blaas V, Büttner A, **Philipp M**.

Autopsien mit Situs-Lehre in der klinischen Rechtsmedizin [Autopsies for anatomical teaching and training in clinical forensic medicine].

Chirurg. 2015 Dec;86(12):1128-31. **(0.9)**

4:

Philipp M, Förster S, Klar E.

Operation der Leistenhernie nach Desarda - Implementierung einer netzfreien Reparationsmethode an einer deutschen Universitätsklinik [Inguinal Hernia Repair According to Desarda - Implementation of a Mesh-Free Method in a German University Hospital].

Zentralbl Chir. 2015 Aug;140(4):373-4. **(0.7)**

3:

Kühn F, **Philipp M**, Klar E, Witte M.

Versorgung einer spät entdeckten, iatrogenen Kolonperforation via minimalinvasivem Rendezvous-Verfahren [Treatment of a subsequently detected, iatrogenic colonic perforation via minimal-invasive rendezvous procedure].

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2:

Philipp M, Förster S, Klar E.

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Chirurg. 2014 Nov;85(11):1005-9. **(0.9)**

1:

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Viszeralmedizin. 2012; 28 (2): 138–141. **(–)**

3.2 Letter mit Originaldaten

Anzahl der Arbeiten: 1
kumulativer Impact-Faktor: 2.9

Wiessner R, **Philipp M**, Lorenz R.
The value and role of mosquito meshes in low resource and poor income settings: author's reply.
Hernia. 2021 Oct;25(5):1379-1380. **(2.9)**

3.3 Publizierte Kongressbeiträge

Philipp M, Reichenbach K, Manhart J, Lamp N, Schafmayer C, Büttner A.
Feasibility of detecting altered parathyroid glands through interdisciplinary autopsy in a clinical forensic medicine setting. Abstract DGAV.
Innovative Surgical Sciences. 2021;6(Special Suppl 1):S1-S80. **(–)**

Philipp M, Leuchter M, Klar E.
Does the statistical analysis of quality of life change our view on the tailored approach for treatment in inguinal hernia repair?: Lichtenstein vs. Tapp vs. Desarda. Poster P1222 International Hernia Congress 2018.
Hernia. 2018;22(Suppl 1):S94–S189. **(–)**

3.4 Addendum: Publikationen, nicht peer-reviewed

Philipp M, Reichenbach K, Heuschkel M, Krause BJ, Willenberg HS, Schafmayer C.
Neuroendokrine Tumoren des Gastro- intestinaltraktes - Bericht aus einem NET-Zentrum.
Ärzteblatt Mecklenburg-Vorpommern. Ausgabe 10/2023, S.365-370

Philipp M, Fromhold-Treu S, Leuchter M, Schafmayer C, Lamprecht G.
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Diagnostik & Therapie von Erkrankungen der Nebenschilddrüse - der primäre Hyperparathyreoidismus.
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Philipp M, Reichenbach K, Plath R, Schwarzenböck S, Krause BJ, Schafmayer C, Willenberg HS. Aktuelle Diagnostik und minimalinvasive Therapie von Tumoren der Nebenniere - Bericht aus einem Zentrum.
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5 Curriculum vitae

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6 Danksagung

Ich danke Herrn Prof. Dr. med. C. Schafmayer für die stetige Ermutigung und die uneingeschränkte Förderung meiner wissenschaftlichen Betätigung.

Mein Dank gilt ebenfalls Prof. em. Dr. med. E. Klar für den Impuls, meine Leidenschaft für Chirurgie auch wissenschaftlich fortzuführen.

Mein herzlicher Dank gilt meinem ehemaligen Mitstreiter und Freund Dipl.-Demogr. Matthias Leuchter, der wesentlichen Anteil an dem Gelingen und der Publikation der Ergebnisse der wissenschaftlichen Projekte dieser Arbeit hat.

Mein besonderer Dank gilt meinen Eltern Marita und Otto Philipp sowie meinen Kindern Anouk und Julika, die durch ihre Toleranz und liebevolle Unterstützung die Entstehung dieser Arbeit erst ermöglicht haben.

Diese Arbeit ist meinen Mädchen Anouk & Julika Philipp gewidmet.

7 Selbstständigkeitserklärung

Hiermit erkläre ich an Eides statt, dass die vorliegende Arbeit von mir selbstständig und ohne fremde Hilfe sowie nur unter Benutzung der angegebenen Quellen und Hilfsmittel erstellt worden ist. Die den benutzten Werken wörtlich oder inhaltlich entnommenen Stellen sind als solche kenntlich gemacht.

Ich versichere, diese Arbeit nicht vorher und auch nicht gleichzeitig bei einer anderen als der genannten Fakultät zur Eröffnung des Habilitationsverfahrens eingereicht zu haben.

Weiterhin erkläre ich an Eides statt, dass ich die deutsche Staatsbürgerschaft besitze und mir die Bestimmungen der Habilitationsordnung bekannt sind.

Rostock, März 2024 Dr. med. Mark Philipp

8 Anhang: Originalarbeiten

Received: 18 November 2020 | Revised: 17 May 2021 | Accepted: 25 May 2021

DOI: 10.1111/wrr.12948

ORIGINAL RESEARCH-CLINICAL SCIENCE

Wound Repair and Regeneration — WILEY

Use of incisional preventive negative pressure wound therapy in open incisional hernia repair: Who benefits?

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Abstract

Complex surgery of abdominal wall hernia continues to bear the major concern of wound healing disorders. Technical modifications have not been able to sufficiently prevent wound healing impairments or infections, even in clean elective cases, especially when dealing with large-scale hernia defects. Incisional negative pressure wound therapy (iNPWT) in its intentional use as a preventive tool has recently found its way from theoretical and experimental advantages to the clinical routine. Different indications have been defined but evidence is lacking. We performed a retrospective analysis (1/2014–5/2019) of all ventral hernia repairs ($n = 386$) done in our institution as open sublay mesh reinforcement, partially requiring component separation (CS), receiving iNPWT in selected cases based on single surgeon experience. Pre- and perioperative data included patient and hernia characteristics as well as the employed mesh sizes. Postoperative follow-up (median 38.5 months [interquartile range: 23.4, 53.3]) extended beyond patient dismissal and included the rate of re-admission due to wound healing disorders. The primary outcome was the incidence of surgical site occurrences (SSO). Secondary endpoints included wound-related readmissions, reoperations and recurrences. Patients were matched based on propensity scores in a 1:1 ratio. Propensity scores were calculated based on five preoperative variables, including sex, body-mass-index, American Society of Anesthesiology classification, recurrent hernia repair and operation technique, to identify significant parameters. The rate of SSO was 12% ($n = 46$) for all operated cases, and the rate of surgical site infection (SSI) was 8.8% ($n = 34$). In the subgroup of CS ($n = 40$), the rate increased to 15% ($n = 6$). The usage of iNPWT ($n = 54$) led to an in-hospital SSO rate of 14.8% ($n = 8$) but increased to 33.3% ($n = 18$) when including the re-admission rate. The SSI rate for the iNPWT cohort was 14.8% ($n = 8$) with a consecutive need for reoperation (Clavien-Dindo IIIb) in 87.5% ($n = 7$). In the matched-pair analysis, the hernia-size and mesh-size were the main risk factors for SSO.

Abbreviations: ASA, American Society of Anesthesiology; AUC, area under the (ROC) curve; BMI, Body-Mass-Index; CI, confidence interval; CS, component separation; iNPWT, Incisional negative pressure wound therapy; IQR, Interquartile Range; LOS, length of stay; ROC, receiver operating characteristic; SD, standard deviation; SSI, surgical site infection; SSO, surgical site occurrences.

The use of iNPWT significantly reduced this statistical effect ($p = 0.405$). In a large and representative patient cohort, we were able to demonstrate that the advantage of iNPWT used after complex abdominal wall repair does not come first hand. Especially in the follow-up, we found a relevant increase in wound healing problems after dismissal. To proof the benefit of iNPWT in these heterogeneous patients, we could identify hernia size and mesh size as individual risk factors that were nihilated by the use of iNPWT. We found it to be favourable to use iNPWT when mesh-size exceeded 450 cm^2.

KEYWORDS
abdominal wall, hernia, iNPWT, matched pair, ROC, surgical site infection, wound healing

1 | INTRODUCTION

Innovation in complex surgery of (incisional) ventral abdominal wall hernia mainly aims at the reduction of wound healing disorders in the immediate postoperative course. Technical modifications have not been able to sufficiently prevent impaired wound healing or surgical site infections—even in clean elective operative cases, especially when dealing with large hernia defects.[1]

Incisional negative pressure wound therapy (iNPWT) in its intentional use as a preventive tool has recently found its way from theoretical and experimental advantages to the clinical routine. Different indications have been defined but proof of evidence is lacking.[2]

The theoretical advantages of incisional or preventive negative pressure (vacuum) therapy are the improvement of microcirculation and consecutive improved perfusion in the tissue with higher oxygen saturation. Additionally, the wound tension especially in the lateral margins is reduced up to 50%. This may lead to normalisation of the shear forces of the wound-area that pose as a relevant result from closing hernia gaps of the ventral abdominal wall.[3] Another experimental advantage lays in the improved lymph drainage leading to a reduced swelling of the wound area. Compared to a conventional wound dressing, the formation of seroma and hematoma is significantly reduced under these conditions.[4] The iNPWT used in our study is the Prevena™ dressing (Fa. Acelity/KCI) introduced in 2013 in Germany and used for various indications. This led to the use of prophylactic negative pressure vacuum therapy in elective hernia surgery, applying the foam to the primarily closed incision.

We aimed at investigating the advantages of iNPWT in our patients focussing on the statistical analysis of risk factors and the effect of the novel therapy in this setting.

2 | METHODS

In our specialised department (certified for quality-assured hernia surgery by the German Hernia Society), incisional hernia of all sizes and difficulties are being operated on. In a single-centre setting with a single surgeon experience, iNPWT has been implemented since 2014. The individual decision to use iNPWT was based on parameters such as patient characteristics, the intraoperative aspect, the size of the hernia defect and the mode of surgical technique.

All consecutive patients who underwent ventral hernia repair (VHR) by an experienced surgeon between January 2014 and May 2019 were retrospectively reviewed. Anonymous data acquisition was based on patient's informed consent with registry data survey.

Three hundred eighty-six patients received open mesh-based repair in sublay position. Prevena™, Fa. KCI/Acelity, was used as iNPWT in 54 selected cases; the iNPWT was applied directly after skin closure and continued for 7 days with 125 mmHg negative pressure. In the patients of the control group, a standard sterile wound dressing was used. Only elective clean cases with primary wound closure and without Stoma were included.

The necessity to perform CS was decided upon the inability to primarily close the posterior sheath, therefore avoiding bridging when putting the mesh in sublay position.

The primary outcome of this study was the SSO rate including SSI, seroma, hematoma, wound dehiscence and/or enterocutaneous fistula. Secondary endpoints included wound-related readmissions, reoperations and recurrences. All postoperative complications were based on clinical symptoms and physical exam findings observed during the follow-up. Next to compulsory follow-up appointment, mailed surveys were sent to all included patients. The Clavien-Dindo classification was used to compare the severity of the occurred postoperative complications.[5] We listed all complications and multiple counts were possible. The highest Clavien-Dindo was considered and included complications not associated to SSO.

Baseline patient characteristics were collected from electronic medical records including age, sex, body mass index (BMI), previous VHR and comorbidities (smoking, diabetes, immunosuppression, chronic obstructive pulmonary disease). Defect size was measured intraoperatively calculated by an elliptic formula.

Perioperative data acquisition included American Society of Anesthesiology (ASA) classification, operative time, surgical repair technique and length of stay.

Patients were matched using propensity scores incorporating multiple preoperative variables. To generate valid statistical comparisons, we performed an optimal 1:1 pair matching. The matching is optimal in the sense that the sum of the absolute pairwise distances in the matched sample is as small as possible. The matched-pair analysis equalised potential distorting parameters. Matching was performed by calculating propensity scores for the following predictors: sex, BMI, ASA classification, recurrent hernia repair and operation technique.

Continuous variables are presented as mean ± standard deviation (SD) or median ± interquartile range (IQR), whilst categorical variables are presented as the number of patients. *p*-Values for continuous variables were calculated using the Kruskal–Wallis rank-sum test. *p*-Values for categorical variables were calculated using the Fisher's exact test for testing the independence of rows and columns in a contingency table. For statistical evaluation, the data were analysed using 'R!' software (esp. pROC-package).[6,7] To compare the performance of potential parameters for SSO, the receiver operating characteristic (ROC) curve analysis was performed. The mesh and defect size of the two patient subgroups were used for SSO prediction and the area under the ROC curve (AUC) including the 95% confidence interval (CI) was calculated. ROC curves are able to graph the sensitivity of a diagnostic test.[8] The AUC of 100% means that the parameter is perfect to discriminate between the patients with or without a wound healing disorder, whereas a value of 50% indicates no discriminative power for this parameter.

3 | RESULTS

The postoperative wound complication rate for the whole patient cohort undergoing open ventral mesh-based hernia repair ($n = 386$) was 12%. The need for performing a component separation (CS) elevated this rate to 15% in those patients.

The subgroup of patients receiving iNPWT had a 14.8% in-hospital wound impairment rate leading to four cases of surgical intervention (according to Clavien-Dindo IIIb). One patient died because of a missed small bowel injury. The median hospital stay was 8.5 days (IQR 7-11d) when using iNPWT.

In the matched-pair analysis, 54 patients receiving iNPWT could be matched to 54 patients with conventional wound dressing. Table 1 displays a full synopsis of all patients' and operative characteristics.

The two subgroups were similar with respect to sex, BMI, ASA score and comorbidities. Individual risk factors regarding comorbidity known for increased risk of wound complications and SSI, such as smoking or diabetes mellitus, did not significantly differ between both

TABLE 1 Patient and operative characteristics

	Full cohort	Prevena	Control	*p*
Patients (*N*)	108	54	54	
Median follow-up time (months)[a]	38.5 (23.4–53,3)	38 (22.8,-54)	39.8 (25–53)	0.848
Sex-ratio (m/f)	63/45	31/23	32/22	1.000
BMI (kg/m^2)[b]	30,98 (±7.4)	31.3(±7.6)	30.6(±7.3)	0.692
Age (years)[b]	59.86 (±77.9)	56.6 (±11.8)	63.13 (±11.12)	0.034
ASA score	2/44/58/4	1/23/27/3	1/21/31/1	0.790
Operative time (min)[a]	140 (104–187)	150 (112–196)	123(100–168)	0.083
LOS (days)[a]	8 (6–11)	8.5 (7–11)	7 (6–10.5)	0.078
Defect size (cm^2)[b]	109.9 (±111.1)	133.1 (±112)	84.5 (±105.5)	0.029
Mesh size (cm^2)[a]	450 (375–600)	450 (450,600)	450 (300,600)	0.001
Type of operation (sublay/CS)	68/40	29/25	39/15	0.073
Recurrent hernia repair	15 (14%)	7 (13%)	8 (15%)	1.000
Smoking	35 (32%)	21 (39%)	14 (26%)	0.217
COPD	19 (18%)	6 (11%)	13 (24%)	0.128
Diabetes	26 (24%)	13 (24%)	13 (24%)	1.000
Aortic aneurysm	7 (7%)	4 (7%)	3 (6%)	1.000
Immunosuppression	23 (21%)	14 (26%)	9 (17%)	0.347
Corticosteroid use	11 (10%)	7 (13%)	4 (7%)	0.526
Clotting disorder	7 (7%)	3 (6%)	4 (7%)	1.000
Co-medication anticoagulants	37 (34%)	18 (33%)	19 (35%)	1.000

Note: Defect size = length × width × $\pi/4$.

Abbreviations: ASA, American Society of Anesthesiologists physical status classification system; BMI, body-mass index; COPD, chronic obstructive pulmonary disease; LOS, length of stay.

[a]Values are reported as median (interquartile range).

[b]Values are reported as mean ± SD.

	Prevena	Control	*p*
SSO (patients)	18 (33.3%)	11 (20.2%)	0.192
SSO in-hospital	8 (14.8%)	6 (11.1%)	0.776
SSO after discharge	10 (18.5%)	5 (9.3%)	0.265
Clavien-Dindo (I/II/III/IV/V)	7/4/10/0/1	3/1/5/3/0	0.054
Skin dehiscence	2 (3.7%)	0	0.495
Necrosis	2 (3.7%)	3 (5.6%)	1.000
Surgical site infections	8 (14.8%)	4 (7.4%)	0.359
Seroma	11 (20.2%)	3 (5.6%)	0.042
Hematoma	3 (5.6%)	1 (1.9%)	0.618
Hernia recurrence	2 (3.7%)	3 (5.6%)	1.000
Reoperations	12 (22.2%)	10 (18.5%)	0.812

TABLE 2 Postoperative outcome: inherits all qualities of wound healing disorders and duplicate values were possible. The reoperation rate included the need for elective surgery in case of recurrent hernia. Data are expressed as number (percentage)

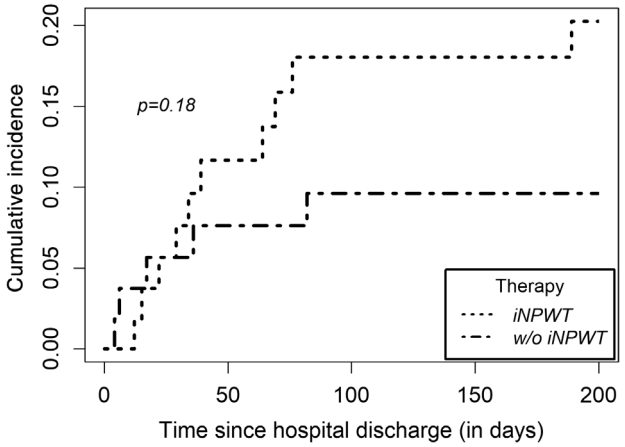

FIGURE 1 Cumulative incidence of readmissions

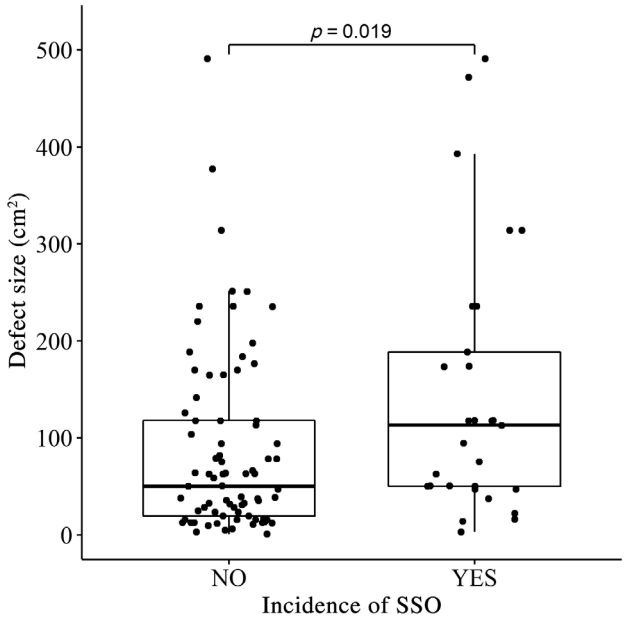

FIGURE 2 Overall comparison of the defect size by the incidence of surgical site occurrence (SSO)

groups.[9–11] The proportion of patients experiencing CS followed by mesh reinforcement was more common in the Prevena group but did not reach statistical significance ($p = 0.14$). Though, significant differences in the defect-size and mesh-size were detectable.

Table 2 inherits all qualities of wound healing disorders; multiple inclusions in the various categories were possible. The reoperation rate included the need for elective surgery in case of recurrent hernia.

The median follow-up of the matched-paired patients ($n = 108$) was 38.5 months (IQR 23.4, 53.3). In the matched-pair analysis, the standard wound dressing cohort had an in-hospital rate of SSO of 11% (6/54), the follow-up detected 10% (5/49) additional cases of SSO and therefore the total number of cases cumulated to 21% (11/54). In the iNPWT group, the in-hospital rate of SSO was 14.8% (8/54). The follow-up included another 18.5% (10/44) cases of SSO, leading to a rate of 33.3% (18/54) (Table 2).

In this context, we evaluated whether the occurrence of SSO had a correlation to the time-period after operation or hospital discharge. Figure 1 shows that readmission caused by SSO occurred up to 180 days after dismissal. In the event-history analysis, SSO did not significantly differ between the matched groups. The latest event occurred 180 days after dismissal from hospital.

We subsequently looked at the general cohort of patients undergoing operation for VHR. Independent to the use of specific wound dressing, we tried to identify and exclude factors influencing the wound healing. We found that the defect size of the hernia-gap significantly differed ($p = 0.02$) regarding the rate of SSO (Figure 2). This correlation consecutively applied ($p > 0.001$) to the size of the implanted mesh (Figure 3). The dashed horizontal line at 450 cm^2 marked the limit of the 3rd quartile of patients without SSO and the 1st quartile of patients with a SSO. Other potentially determining factors did not influence the wound healing in either group (Table 1).

Further analysis of the match-paired cases showed that the use of iNPWT could level out the negative effect of hernia size and even more that of the mesh-size. In the matched-pair subgroups, the effect of the hernia gap size was not statistically significant connected to

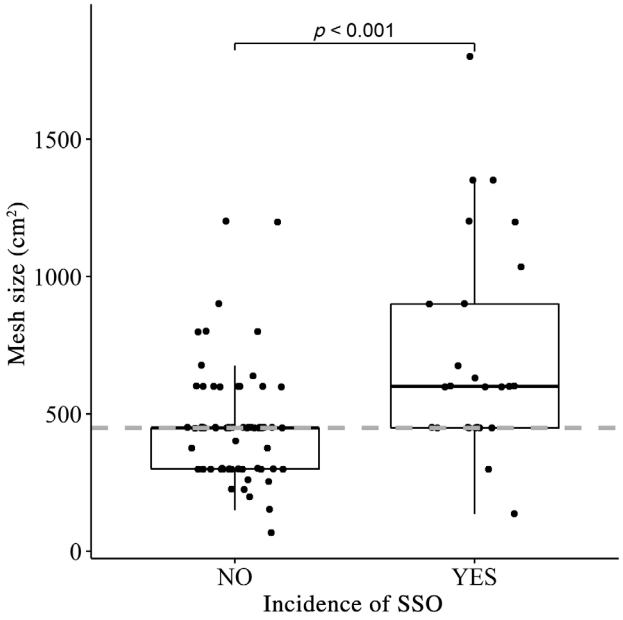

FIGURE 3 Overall comparison of the mesh size by the incidence of surgical site occurrence (SSO)

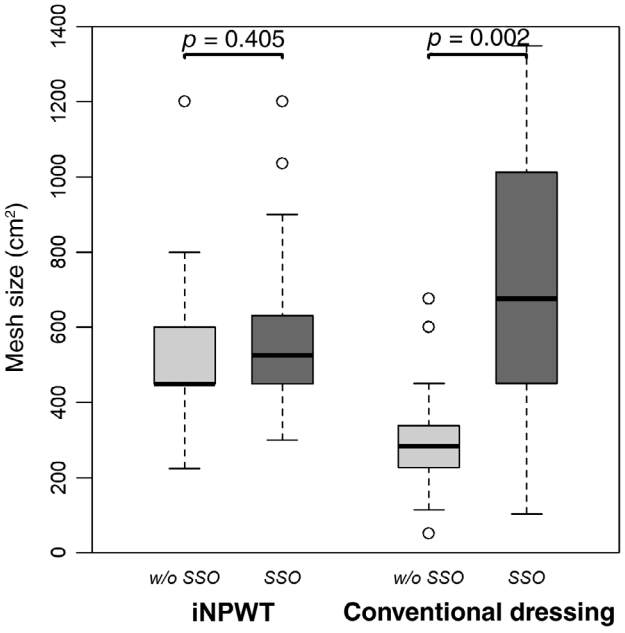

FIGURE 5 Comparison of the subgroups regarding mesh size and incidence of surgical site occurrence (SSO)

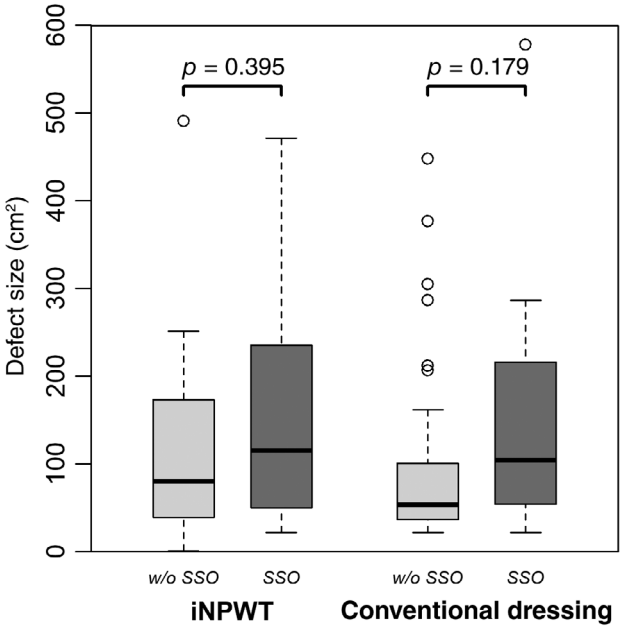

FIGURE 4 Comparison of the subgroups regarding defect size and incidence of surgical site occurrence (SSO)

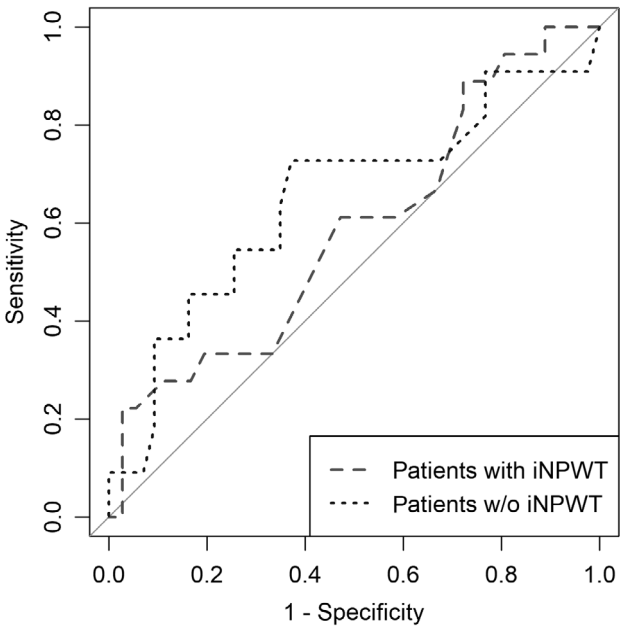

FIGURE 6 Receiver operating characteristic (ROC) curves analysis of the defect size for surgical site occurrence (SSO) after incisional hernia surgery. Defect size was a predicator for SSO in in the conventional group (area under curve: 0.648, 95% CI: 0.440–0.846, $p = 0.600$). Incisional negative pressure wound therapy (iNPWT) (area under curve: 0.583, 95% CI: 0.417–0.749, $p = 0.900$)

SSO (Figure 4). In contrast, the mesh size was statistically relevant connected to SSO in the conventional group only ($p = 0.002$). Mesh size does not alter the SSO rate ($p = 0.405$) in the iNPWT group (Figure 5).

Despite the low number of patients, we were able to statistically evaluate the effect of iNPWT. For this purpose, we used the ROC curve analysis. As shown in Figure 6, the percentage of defect size change displayed a low discriminative power for both subgroups; the patients with iNPWT had a sensitivity of 22.2% and the specificity of 97.2%, the area under the curve = 0.583, $p = 0.9$, 95% CI = (0.417,

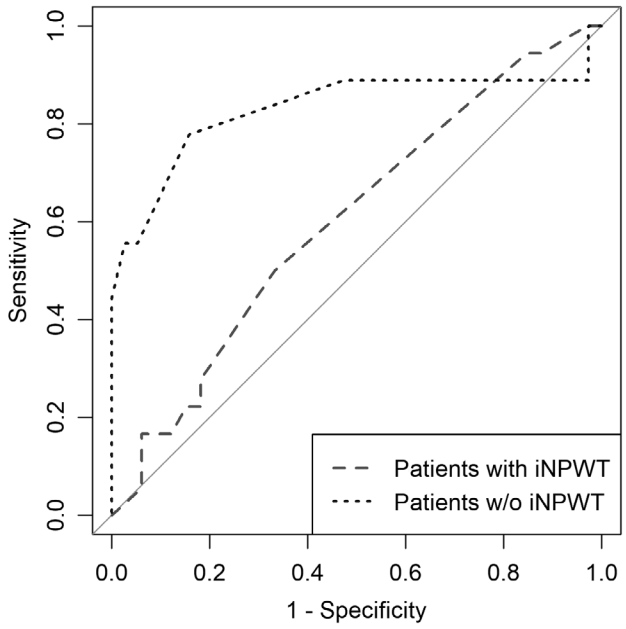

FIGURE 7 Receiver operating characteristic (ROC) curves analysis of the mesh size for surgical site occurrence (SSO) after incisional hernia surgery. Mesh size was a predicator for SSO in in the conventional group (area under curve: 0.832, 95% CI: 0.621–1.000, $p < 0.005$). Incisional negative pressure wound therapy (iNPWT) (area under curve: 0.603, 95% CI: 0.450–0.755, $p = 0.650$)

0.749), respectively; patients with conventional wound dressing had a sensitivity of 72.7% and the specificity of62.8%, the area under the curve = 0.648, $p = 0.6$, 95% CI = (0.440, 0.846). The test of the null hypothesis of equality of the two AUCs was not significant ($p = 0.68$).

Consecutively, the comparison of these groups regarding mesh-size underlines the effect of iNPWT, showing an AUC of 0.603 (95% CI: 0.450–0.755, $p = 0.188$) in the iNPWT group and an AUC of 0.832 (95% CI: 0.621–1.000, $p = 0.005$) in the conventional group (Figure 7). The differences between the area under the ROC curve of the iNPWT and conventional group, did not reach statistical significance ($p = 0.08$). The optimal cut point of the mesh-size in the conventional group was 450 cm^2 or larger with a sensitivity of 77.8% and specificity of 84.2%.

The mesh-size in the iNPWT group identified about 50% of patients with a SSO (sensitivity) and about 66.6% of subjects without a SSO (specificity).

4 | DISCUSSION

We initialised a single-centre single-surgeon trial after the hypothesis of improving wound healing by iNPWT. We chose patients with the need of VHR and fully standardised the operative procedure to minimise the limitations of other studies.[12,13] In an attempt to show the potential advantage of iNPWT in the management and prevention of SSO, we chose the mesh-based reparation of ventral hernia as a rather standardised setting of clean surgery. This was previously reported in other studies with heterogeneous results.[14–16]

Several studies suggest that the use of INPWT leads to decreased postoperative complications for clean-contaminated and contaminated operations.[15,17] In contrast, Pauli et al. focused on contaminated cases in hernia surgery and found no significant difference regarding postoperative wound infections.[12]

In general, the clinical picture of ventral hernias is heterogeneous. They can greatly vary in size which then inferentially conducts disparate techniques of closure and additional mesh-reinforcement.

Since the indication to use iNPWT was highly individual and had a high potential of a negative selection bias, we were not surprised to find a high wound impairment rate despite the use of iNPWT. In discordance to other publications, we monitored a high rate of complications after the patients' dismissal.[14,17] Possibly, this has not been thoroughly enough investigated in similar studies.[15] Another explanation could be the long period of follow-up that we reported in our study. Hopkins et al. also demonstrate a dependency of duration of follow-up and clinical outcome. The incidence of deep SSI between the iNPWT and conventional group only differs significantly within 30 days and the effect diminishes after 180 days of follow-up.[13]

The reason for prolonged wound problems in spite of iNPWT might be due to the physical properties of iNPWT. In deeper layers of the scarred tissue, the effectiveness of iNPWT significantly decreases and therefore does not substantially impede long-term effects on epifascial seroma, especially after removing the dressing. The commonly used duration and amount of negative pressure of iNPWT was adopted in our study although their impact remains unclear.

Our study was limited by its retrospective and observational design. We decided to exclude patients involving bowel or stoma surgery. Another important limitation of our study is that the choice of iNPWT or conventional dressings was based on the preference of the surgeon, which likely favours a higher incidence of SSO/SSI in the iNPWT group. We try to diminish this selection effect by employing a matched-pair analysis.[13]

We inaugurated iNPWT in a large patient cohort receiving elective surgery and dealing with large wounds in a non-contaminated field. We were not able to lower the wound impairment rate in our selected patients but levelled out a very heterogeneous patient cohort by a matched-pair analysis to continue further studies.

In this matched-pair analysis, we could not show that the use of iNPWT could lower the absolute risk of the occurrence of SSO in our patients. Remarkably, the independent risk factor of mesh-size was annihilated by the use of iNPWT when the mesh-size exceeded 450 cm^2. We conclude that the use of iNPWT is a good additional tool to prevent SSO in cases of complex hernia repair, especially when a high-risk constellation is present. Our cohort only inherited clean cases of surgery, but we identified a mesh-size of larger than 450 cm^2 to be beneficial for the use of iNPWT.

5 | CONCLUSION

The preventive strategy of using iNPWT in abdominal wall hernia repair is feasible. Moreover, evidence for the benefit in the clinical routine is missing. Complex but clean abdominal wall hernia repair seems to be a good basis for proving this fairly new therapy to be beneficial. Wound healing is strongly dependent on hernia gap size, supposedly reflecting the technical need of implanting large meshes, while the use of iNPWT nearly equals out the risk of wound healing disorder.

ACKNOWLEDGMENT

Open access funding enabled and organized by Projekt DEAL.

CONFLICT OF INTEREST

M.L., M.H., C.S. declare that there is no conflict of interest. M. P. received a speaker honorarium from KCI/Acelity and declares no conflict of interest.

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How to cite this article: Leuchter M, Hitzbleck M, Schafmayer C, Philipp M. Use of incisional preventive negative pressure wound therapy in open incisional hernia repair: Who benefits? *Wound Rep Reg*. 2021;29(5):759–765. https://doi.org/10.1111/wrr.12948

Viszeralmedizin
Gastrointestinal Medicine and Surgery

Originalarbeit · Original Article

Viszeralmedizin 2012;28:138–141
DOI: 10.1159/000338010

Online publiziert: 13. April 2012

Komplikationsmanagement in der Narbenhernienchirurgie: Erhalt von alloplastischem Material in der Infektsituation

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Schlüsselwörter
Narbenhernie · Wundinfektion · Komplikationsmanagement bei Netzinfektion · Netzexplantation

Zusammenfassung

Hintergrund: Die Implantation von alloplastischem Material in der operativen Versorgung von Narbenhernien gehört heute zum Standard. Dies hat zu einer deutlich reduzierten Rezidivrate geführt; eine gefürchtete Komplikation bleibt die Infektion des eingebrachten Netzes. **Patienten und Methoden:** Wir berichten über unsere Erfahrungen und retrospektiv erhobenen Ergebnisse in der alloplastischen (Polyester; Parietex™) Narbenhernienversorgung. Wir untersuchten die Rate der Wundinfektion sowie den Anteil der tiefen Infektionen mit Netzbeteiligung bei 198 konsekutiven Patienten. Auf dieser Grundlage erläutern wir unser Komplikationsmanagement mit Einsatz der Vakuumtherapie bei postoperativ infizierten Netzimplantaten. **Ergebnisse:** Die Wundinfektionsrate über einen Zeitraum von über 5 Jahren mit 198 offen chirurgisch mit einem Polyester-Implantat (Parietex) versorgten Narbenhernien betrug 10%, davon in 6% der Fälle mit einer Netzbeteiligung; lediglich 2 Netze mussten im Behandlungsverlauf explantiert werden. **Schlussfolgerung:** Moderne Netzmaterialien und neue Techniken im Management komplexer Wunden ermöglichen den Erhalt alloplastischer Netze in der Infektsituation.

Keywords
Incisional hernia · Surgical site infection · Complication management of mesh infection · Mesh explantation

Summary

Complicational Management Following Surgery of Incisional Hernia: Preservation of Alloplastic Material in the Case of Infection

Background: The standardized implantation of an alloplastic mesh graft in the open surgical repair of incisional hernia significantly reduces the rate of recurrence but bears the imminent problem of a mesh infection. **Patients und Methods:** We are sharing our experiences and retrospectively gained results with 198 consecutive patients who underwent a polyester mesh-based (Parietex™) repair of their incisional hernia. Thus, we are reporting about the rate and management of deep infections involving the mesh. **Results:** The rate of surgical site infections over a 5-year period with 198 patients undergoing open surgery because of their incisional hernia using alloplastic material (polyester mesh Parietex) was 10%, whereas the mesh-involving rate was 6%. Using a vacuum-based wound management, only 2 meshes had to be explanted. **Conclusion:** Modern mesh materials as well as new techniques in the management of complex wounds have led to the possibility of preserving alloplastic meshes in the event of an infection.

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Einleitung

Ungeachtet der bisherigen Fortschritte in der offenen Narbenhernienreparatur mittels Netzaugmentation [1] wird in den verfügbaren prospektiv randomisierten Studien über Infektionsraten von 5% [2] bis zu 27% [3] berichtet [4]. Die dabei erfassten tiefen Infekte mit Netzbeteiligung resultieren zu einem hohen Anteil in einer Netzexplantation [5]. Generell besteht die Hauptursache für eine Netzexplantation nach alloplastischer Versorgung einer Narbenhernie in einer Infektion [6]. Die konsekutive Wahrscheinlichkeit des Auftretens eines Rezidivs der Hernie nach infektbedingter Netzexplantation ist deutlich erhöht [7]. Moderne Salvage-Strategien haben dazu geführt, dass der Netzausbau nur im Einzelfall notwendig ist [8]. Die publizierten Erfahrungen diesbezüglich stammen aus einzelnen Zentren und sind dementsprechend limitiert [9].

Insbesondere die laparoskopische Reparation von abdominellen Narbenhernien und ventralen Bauchwandhernien hat zu einem Paradigmenwechsel in der Hernienchirurgie geführt und die Infektionsrate deutlich gesenkt [10–12]. Der zunehmende Einsatz dieser Technik in der eigenen Klinik hat uns dazu veranlasst, unsere konventionell operierten Patienten retrospektiv zu untersuchen. Wir berichten über eigene Erfahrungen im Komplikationsmanagement von tiefen Wundinfektionen mit Netzbeteiligung nach offen chirurgischer Reparatur von ventralen Narbenhernien.

Patienten und Methoden

Die im Zeitraum 01/2005 bis 09/2010 konventionell offen chirurgisch operierten Patienten mit Narbenhernien der ventralen Bauchwand wurden retrospektiv ausgewertet. Als Standardverfahren der Reparation diente die retromuskuläre Netzaugmentation mit Verschluss der vorderen Faszie über dem eingebrachten Netz. Weitere Reparationsverfahren bestanden im Bauchdeckenersatz («bridging») mit entweder retromuskulärer oder intraperitonealer Implantatlage. Nur in begründeten Ausnahmesituationen wurde das Netz epifaszial als Onlay-Plastik platziert. Bei den verwendeten Netzimplantaten handelte es sich ausschließlich um Polyestermaterial (Parietex™; Covidien Deutschland GmbH, Neustadt a.d. Donau, Deutschland).

Bei Nachweis einer postoperativen tiefen Wundinfektion mit Netzbeteiligung erfolgte die frühzeitige Intervention mit Einsatz der Vakuumtherapie unter resistenzgerechter Antibiose und anschließender feuchter Wundbehandlung unter Verwendung spezifisch absorbierender und granulationsfördernder Materialien.

Ergebnisse

Insgesamt wurde im Auswertungszeitraum bei 198 Patienten mit ventraler Narbenhernie eine offen chirurgische Reparation mit dem Einsatz von nichtresorbierbaren, alloplastischen Netzmaterialien durchgeführt. Die lokale Wundinfektionsrate betrug 10,6% (n = 21). In 6,1% der Fälle (n = 12) war durch den tief reichenden Wundinfekt eine direkte Netzinfektion zu verzeichnen. Unter den oben angegebenen Maßnahmen des Komplikationsmanagements konnten 83,3% der lokal infizierten alloplastischen Implantate in situ belassen (n = 10/12) und folgenlos zur Ausheilung gebracht werden.

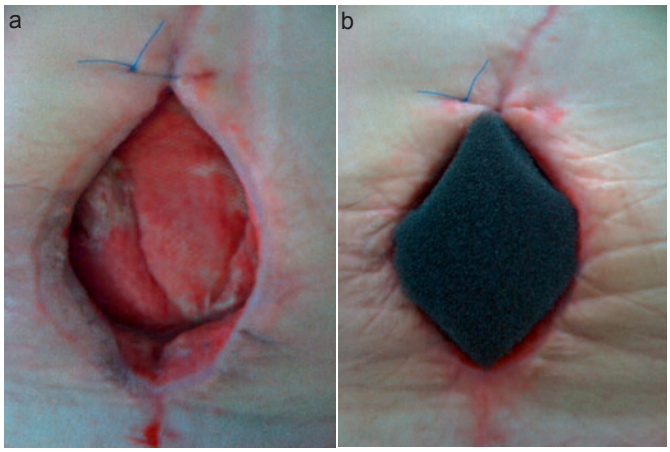

Abb. 1a,b. Wundverhältnisse nach initialer Vakuumanlage.

In einem standardisierten Protokoll erfolgte der Wechsel des Vakuumschwamms in einem 3-Tages-Intervall; die durchschnittliche Dauer der Vakuumtherapie betrug 28 Tage und die mittlere Krankenhausverweildauer 36,1 Tage (21–58 Tage). In der Folge werden unsere Ergebnisse exemplarisch anhand einer Kasuistik dargestellt.

Kasuistik

Wir sahen einen 71-jährigen Patient mit einer abdominellen ventralen Rezidivnarbenhernie monströser Konfiguration. Es bestand ein Zustand nach aortalem Prothesenersatz 3 Jahre zuvor und Versorgung einer konsekutiven Narbenhernie 1 Jahr später als minimal invasive Hernioplastik ventralis in IPOM-Technik (intraperitoneales Onlay-Mesh).

Wir führten eine Hernienreparatur mit Netzaugmentation im Unterbauch in Sublay-Technik mit präperitonealer Fixierung als Stoppa-Modifikation durch. Das verwendete Polyesterimplantat war ein Parietex-Netz in der Dimension 30 × 25 cm.

Die Wiederaufnahme des Patienten erfolgte nach initial problemlosem postoperativem Verlauf und Entlassung am 8. postoperativen Tag erneut am 15. postoperativen Tag mit klinischen und paraklinischen Zeichen einer Wundinfektion. Die umgehende operative Wundrevision in Intubationsnarkose ergab eine tief reichende putride Infektion mit Netzbeteiligung. Wir entschlossen uns zur Anlage einer Vakuum-Versiegelung der Firma KCI™ (KCI Medizinprodukte GmbH, Wiesbaden, Deutschland) (Abb. 1). Nach Erhalt des Antibiogramms behandelten wir testgerecht adjuvant mit Clindamycin (Sobelin®; Pharmacia GmbH (Pfizer), Berlin, Deutschland).

Nach einem stationären Aufenthalt über weitere 14 Tage mit gut durchführbarem bettseitigem Wechsel des Vakuumsystems im dreitägigen Intervall und beginnender Granulation auf dem Mesh gaben wir den Patienten in die ambulante Betreuung und führten den Vakuumschwammwechsel intervallgemäß im Rahmen unserer Sprechstunde zweimal wöchentlich durch. Nach weiteren 2 Wochen konnten wir bei vollständig von Granulationsgewebe bedecktem Netz eine offene Wundver-

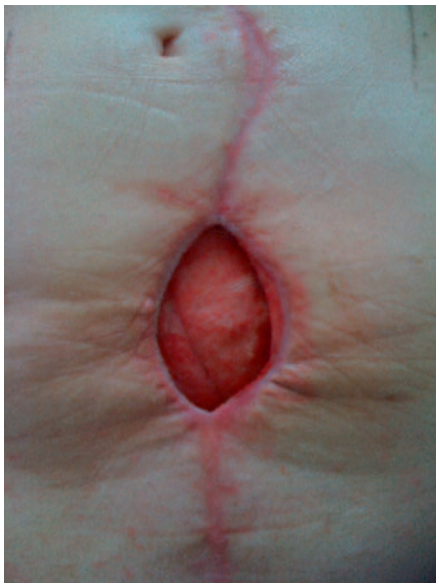

Abb. 2. Wundsituation 3 Wochen nach Wiederaufnahme.

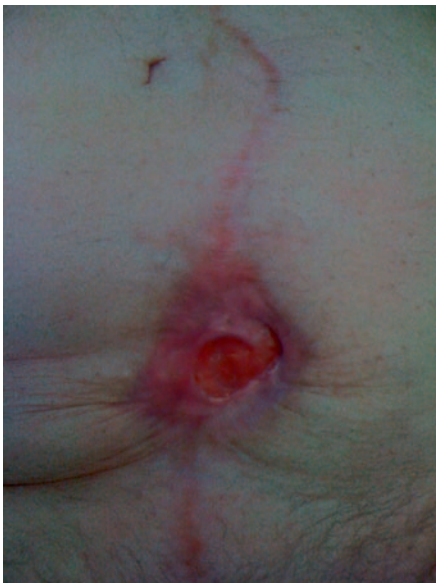

Abb. 3. Wundsituation 6 Wochen nach Wiederaufnahme.

sorgung mit Cutimed Sorbact® (BSN medical GmbH, Hamburg, Deutschland) durchführen. Die Wunde war innerhalb von 12 Wochen vollständig verschlossen (Abb. 2, 3).

Diskussion

Die Darstellung unserer retrospektiven Ergebnisse in der offen chirurgischen Reparation von Narbenhernien ergibt ein homogenes Bild im Vergleich zur aktuellen internationalen Datenlage. Die alloplastische Augmentation der ventralen Bauchwand, die in der Mehrzahl der Fälle in Sublay-Technik unter leitliniengerechter perioperativer Antibiose erfolgte [13], führte in unserem Patientengut in 10,6% der Fälle zu einer Wundinfektion [14]. Diese vergleichsweise hohe Infektionsrate führte nicht nur zu einer Fokussierung auf minimal invasive Verfahren, sondern primär auch zur Durchführung eines standardisierten intraoperativen Handschuhwechsels vor Netzverwendung.

Die notwendige Identifikation von Risikopatienten für eine Wund- bzw. Netzinfektion gelingt generell nicht ohne Einschränkungen. Der in unserer Kasuistik vorgestellte Patient besitzt jedoch die Stigmata für ein deutlich erhöhtes Risiko einer tiefen Wundinfektion [14]. In diesem Zusammenhang wird diskutiert, ob die Kenntnis um diese Risikopatienten zu einer besseren postoperativen Überwachung führen sollte [15]. Die Reparation einer Unterbauchnarbenhernie in der Rives-Stoppa-Technik [16] ist bei Auftreten einer Wundinfektion mit einer 50%igen Wahrscheinlichkeit der Netzinfektion belegt [17].

Wir haben das laparoskopische IPOM-Verfahren unter Verwendung eines Polyesternetzes mit Kollagenbeschichtung (Parietex Composite (PCO) Mesh) als minimal invasive Alternative zur Reparation von Narbenhernien bereits seit 2005 implementiert und sehen deutlich geringere Infektionsraten. Dies entspricht dem Stand der internationalen Literatur [10–12]. Große prospektiv randomisierte Studien hierzu fehlen. In Vorbereitung einer eigenen solchen Erhebung haben wir daher zunächst die offen chirurgisch operierten Patienten ausgewertet.

Die aktuelle Literaturrecherche ergibt unterschiedliche Berichte über das Vorgehen bei einer Infektion mit Netzbeteiligung infolge einer Wundinfektion nach alloplastischer Reparation von Narbenhernien. Die Explantation des Netzes als Ultima Ratio führt in Abhängigkeit von der Dimension der ursprünglichen Hernie zu einem Rezidiv, das ein aufwendiges plastisch-rekonstruktives Verfahren erfordert [18]. Einzelfallberichte betreffen die antibiotikahaltige Irrigation von infizierten Netzen [19].

Die Verwendung von Systemen zur Vakuumversiegelung als Salvage-Strategie ist in wenigen Publikationen mit kleinen Fallzahlen etabliert [9, 14]. Es ist ein sicheres Vorgehen, das zu einem hohen Anteil zum Netzerhalt führt. Unserer Ansicht nach sind die prinzipielle Durchführbarkeit im ambulanten Bereich sowie der mögliche Wechsel auf eine moderne Wundversorgung nach initialer Konditionierung die wesentlichen Gründe, dieses Konzept weiterzuverfolgen.

Schlussfolgerung

Der Paradigmenwechsel, Netzimplantate trotz nachgewiesener Infektion zu erhalten, erfordert ein stratifiziertes Vorgehen zur Beherrschung der Infektion von Wunde und Implantat ohne Gefährdung der Bauchwandreparatur. Insbesondere leichtgewichtige, großporige Implantate können selbst bei fortgeschrittenen Wundinfektionen belassen und komplett zur Ausheilung gebracht werden.

Auf eine befundadaptierte Terminierung der initialen Vakuumtherapie ist besonders deshalb zu achten, um den Patienten zum frühestmöglichen Zeitpunkt in die ambulante Betreuung mit konsekutiver offener Wundbehandlung entlassen zu können.

Disclosure Statement

Es bestehen keine Interessenkonflikte.

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Der Chirurg

Originalien

Chirurg 2020 · 91:60–66
https://doi.org/10.1007/s00104-019-01049-x
Online publiziert: 29. Oktober 2019

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Die demografische Perspektive auf maßgeschneiderte Therapieansätze

Eine Analyse der Lebensqualität am Beispiel der Leistenhernie

Hintergrund

Die Steigerung der Lebenserwartung ist in den letzten Jahrzehnten zu einem Großteil auf den Sterblichkeitsrückgang in den höchsten Altersstufen zurückzuführen [1, 2, 3]. Diese gewonnenen Lebensjahre sind aber nicht unbedingt gesunde Lebenszeit. Die Anzahl der in Krankheit verbrachten Lebensjahre, in Abhängigkeit der Definition von Gesundheit bzw. Krankheit und der sozialen Schicht, steigt zwar in Deutschland an, allerdings langsamer als die Gesamtlebenserwartung [4, 5]. Diese Kompression des Anteils kranker Lebensjahre hat aber keinen Einfluss auf die steigende Anzahl älterer multimorbider Patienten aufgrund der demografischen Alterung.

Nach Berechnung des Statistischen Bundesamtes wird sich der Anteil der über 80-Jährigen bis 2030 um ca. 60 % erhöhen [6]. Die Steigerung der Lebenserwartung ist neben den verbesserten hygienischen Lebensbedingungen zum Großteil auf den medizinischen Fortschritt zurückzuführen [7–10]. Das Hauptaugenmerk lag dabei auf Verbesserungen der primären und sekundären Prävention, dem Screening, der Diagnosestellung sowie der resultierenden Behandlung. In der medizinischen Forschung wie auch in der Demografie verschiebt sich der Fokus zur Beurteilung von Behandlungsoptionen weg von den rein quantitativen Bewertungsparametern hin zu einer Berücksichtigung der Qualität. Hier wird das subjektive Empfinden/Wahrnehmung des Patienten in die Bewertung einer Therapieoption mit einbezogen. Dabei findet das mehrdimensionale theoretische Konstrukt der Lebensqualität („quality of life“, QoL) in immer mehr klinischen Studien Anwendung. Bei diesem Index unterscheidet man hinsichtlich des Spektrums der einbezogenen Lebensbereiche in generische und krankheitsspezifische Lebensqualität. Die generische QoL soll dabei alle Bereiche des Lebens einbeziehen, hingegen die krankheitsspezifische QoL auf die Effekte der Krankheit und Therapie(folgen) fokussieren. Beeinflusst wird das Niveau der Lebensqualität von den individuellen Erfahrungen, Glauben, Erwartungen und Wahrnehmungen [11]. Folgend ist eine hohe Lebensqualität nicht nur von der Abwesenheit einer spezifischen Erkrankung oder Gebrechen abhängig, sondern vom ganzheitlichen physischen, mentalen und sozialen Wohlbefinden. Ziel dieser Studie ist die Einbeziehung der Alters- und Geschlechterzusammensetzung in die Bewertung der Lebensqualität und Gesundheitswahrnehmung von Hernienpatienten.

Leistenhernien

Eine Umfrage auf dem 18. Congress Of The European Association Of Endoscopic Surgery ergab, dass 82 % der Chirurgen ein differenziertes Vorgehen (sog. „tailored approach“) in Abhängigkeit der Risikokonstellation des Patienten und der Erfahrung des Operateurs unterstützen [12, 13].

Dem gegenüber stehen die restriktiven Empfehlungen der internationalen Guidelines zum Einsatz netzbasierter Techniken zur Behandlung der Leistenhernie [14]. In Abhängigkeit der Erfahrung des Operateurs und der vorhanden medizinisch-technischen Ausstattung ist ein minimal-invasiver Ansatz (TAPP [transabdominell präperitoneal]/TEP [total extraperitoneal]) zu präferieren. Der Benefit für den minimal-invasiv operierten Patienten liegt in der perioperativen Phase, was durch zahlreiche Studien belegt ist [15]. Die bessere Befindlichkeit mit weniger Schmerz, die frühe Mobilität und die insgesamt raschere Rekonvaleszenz bedingen einen schnelleren Anstieg der Lebensqualität. Netzfreie Methoden sollen nur (noch) in Ausnahmesituationen (Patient mit ablehnender Haltung bezüglich eines implantierten Fremdkörpers bzw. mangelnde Verfügbarkeit von Netzen) Anwendung finden. Damit manifestiert sich ein Paradigmenwechsel, dessen Entwicklung nicht nur evidenzbasiertes chirurgisches Vorgehen ist, sondern als Triebfeder auch das industrielle Angebot widerspiegelt. Allerdings lässt die aktuelle Studienlage ebenfalls eine Renaissance der Pure-tissue-Verfahren erkennen. Der Chirurg steht damit im Spannungsfeld bei der Wahl der besten therapeutischen Maßnahme.

Operationen mit höherer Behandlungsintensität (z. B. Intubationsnarko-

Tab. 1 Kennzahlen unseres Patientenkollektivs

	TAPP	Lichtenstein	*p*-Wert
Fallzahl	194	116	–
Follow-up (Median, in Monaten)	22,5	25	n. s.
ASA-Score (I/II/III/IV)	94/70/29/1	17/41/55/3	<0,001
Alter (Median, in Jahren)	58	73,5	<0,001
Geschlechterverhältnis (m/w)	166/28	108/8	0,046
BMI (Median, kg/m^2)	25,7	25,3	n. s.
Hernientyp (lateral/medial/femoral/skrotal)	109/67/17/1	61/50/0/5	<0,001
Bruchlückengröße (<1,5, 1,5–3, >3 cm)	78/108/8	29/69/18	<0,001
Operationsdauer (Median, in Minuten)	57,5	70	<0,001
Chronische Schmerzen >3 Monate (m/w)	17 (13/4)	10 (10/0)	n. s.
Postoperative Komplikationen (*n*)	9	8	n. s.
Rezidive	2	2	n. s.
Reoperation (*n*)	3	2	n. s.

ASA American Society of Anesthesiologists, *BMI* Body-Mass-Index, *TAPP* transabdominell-präperitoneale Technik

se und Kapnoperitoneum) lassen sich dementsprechend auf alte (morbide) Patienten mit erhöhtem Risikoprofil nicht einfach übertragen.

Patienten und Methoden

In unserer Klinik wurden zwischen 2014 und 2016 insgesamt 310 Patienten mit einem Leistenbruch operiert. In allen Fällen erfolgte eine präoperative Risikoevaluation in Anlehnung an den ASA-Score (American Society of Anesthesiologists) und vorhandene Risikofaktoren (Body-Mass-Index [BMI], kardiopulmonales Risikoprofil, Voroperationen).

Das primär favorisierte Operationsverfahren war die netzbasierte minimalinvasive Hernioplastik in TAPP-Technik. Als Standardimplantat wurde das seitenadaptierte anatomisch geformte Parietex™-Netz (Covidien, Mansfield, MA, USA) in der Dimension 10 × 15 cm verwendet, welches ausschließlich mit Evicel® (1 ml, Johnson & Johnson Wound Management, Ethicon, Somerville, NJ, USA) fixiert wurde.

Bei Patienten ab einem ASA-Score III wurde vorrangig ein offener Zugang gewählt, um eine Spinalanästhesie zu ermöglichen, außerdem wurden relevante Voroperationen als relative Kontraindikationen für die TAPP gewertet. Standardimplantat war in diesen Fällen das VyproII-Netz (Ethicon GmbH, Hamburg, Deutschland).

Alle Patienten wurden angeschrieben und zu ihrem aktuellen Gesundheitszustand inkl. der generischen Lebensqualität anhand des EQ-5D befragt. Zur Berücksichtigung der Heterogenität zwischen den Vergleichsgruppen wurde in Anlehnung an das Konzept des „relativen Überlebens" aus der Krebsepidemiologie das Verhältnis aus gemessenen Werten und den alters- und geschlechtsspezifischen (repräsentativen) Normwerte für die Allgemeinbevölkerung gebildet [16]. Ziel dieses Ansatzes ist, den Effekt/die Korrelation des Alters und des Geschlechts auf den Zielparameter zu berücksichtigen [17]. Die Unterschiede zwischen zwei Gruppen stellen dann den alleinigen Effekt der Therapieform dar.

Ergebnisse

Von den 310 Patienten wurden 194 (62,5 %) minimal-invasiv behandelt. **Tab. 1** zeigt Typ und Größe der Bruchlücken in beiden Therapiearmen. Das mediane Follow-up betrug 24 Monate (Bereich 6–36 Monate). In beiden Gruppen konnten 66 % aller Patienten nachuntersucht werden.

Das Durchschnittsalter aller Patienten betrug 65 Jahre. Zwischen den TAPP-Patienten mit einem Medianalter von 58 Jahren (Gruppe A) und denen, die nach Lichtenstein operiert wurden, bestand ein signifikanter Altersunterschied von etwa 15 Jahren. Betrachtet man die Altersverteilung der Patienten unserer beiden Operationstechniken ist eine eindeutige Abhängigkeit zu erkennen (**Abb. 1**). Die Überschneidung im höheren Alter lässt eine negative Risikoselektion zugunsten der TAPP vermuten. Entsprechend unterschieden sich die beiden Gruppen hoch signifikant in der Risikozusammensetzung (nach ASA). Weiterhin war das Geschlechterverhältnis unterschiedlich. In der Gruppe der offen Operierten dominierte das männliche Geschlecht stärker. Bei allen Operationen handelte es sich um elektive Eingriffe. Eine Konversion zur offenen Reparationstechnik war nicht erforderlich.

Eine Reoperation infolge eines Rezidivs erfolgte in beiden Gruppen gleich häufig, dabei handelte es sich in beiden Gruppen jeweils um ein mediales und ein laterales Rezidiv. Bei einem Patienten in der TAPP-Gruppe trat eine operationspflichtige Trokarhernie auf. Die postoperative Komplikationsrate betrug insgesamt 5,5 % (TAPP 4,6 % vs. Lichtenstein 6,9 %), erfasst wurden Nachblutungen, Wundinfektionen, Darmverletzungen, Serome und Hämatome.

In **Abb. 2** sind die angegebenen Lebensqualitätsniveaus der Patienten in Abhängigkeit der Follow-up-Dauer abgebildet und anhand einer Regressionsgerade der zeitliche Trend (inkl. 95 %-Konfidenzintervall) dargestellt. Das konstante Niveau (schwarze Regressionsgerade) über die gesamte postoperative Follow-up-Dauer lässt den Rückschluss zu, dass eine Evaluierung nach einer postoperativen Nachbeobachtungszeit von 6 Monaten ausreichend ist, den Erfolg einer Therapie anhand der QoL zu bewerten. Im Hinblick auf die Rekonvaleszenz der beiden Operationsverfahren zeigt sich ein überraschendes Bild. Während bei den laparoskopisch behandelten Patienten ein Anstieg der QoL über die Beobachtungsdauer (rote Regressionsgerade) feststellbar ist, zeigt sich bei den offen behandelten Patienten ein gegenläufiger Trend (blaue Regressionsgerade).

Die Analyse unseres Patientengutes zur Lebensqualität und der subjektiven Gesundheitswahrnehmung führt zu dem Ergebnis, dass Patienten mit einer transabdominalen präperitonealen

Chirurg 2020 · 91:60–66 https://doi.org/10.1007/s00104-019-01049-x

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Die demografische Perspektive auf maßgeschneiderte Therapieansätze. Eine Analyse der Lebensqualität am Beispiel der Leistenhernie

Zusammenfassung

Einleitung. Der konstante Anstieg der Lebenserwartung seit über 170 Jahren ist eine der größten Leistungen der modernen Gesellschaft. Die Wahrscheinlichkeit, dass ein 80-Jähriger 100 Jahre wird, hat sich in Deutschland seit 1950 verzwanzigfacht. Dieser Sachverhalt hat verschiedenste Implikationen für den klinischen Alltag und therapeutische Leitlinien. In der Hernienversorgung sollte neben quantitativen Faktoren (Komplikationen, Rezidivrate) auch die Lebensqualität („quality of life", QoL) als patientenzentrierter subjektiver Faktor bei der Therapieoption berücksichtigt werden. Um heterogene Patientengruppen im Hinblick auf die QoL vergleichen zu können, muss eine Standardisierung gegenüber einer Referenzbevölkerung vorgenommen werden.
Material und Methoden. Datengrundlage bilden 310 nachverfolgte Patienten der Chirurgischen Universitätsklinik Rostock. Die Patienten wurden präoperativ klinisch untersucht und befragt sowie postoperativ auf postalischem Weg (Follow-up-Rate 66 %) eingebunden. Die mediane Nachverfolgungsdauer beträgt 20 Monate. Die Schmerzbelastungen wurden anhand der visuellen Analogskala (VAS) und die krankheitsunspezifische QoL durch den Erhebungsbogen EQ-5D evaluiert. Die Basis der Standardisierung bilden die repräsentativen Normwerte des EQ-5D für Deutschland.
Ergebnisse. Eine Analyse der Patienten in den verschiedenen Therapiearmen zeigt signifikante Unterschiede in der Alterszusammensetzung und im Gesundheitszustand (nach American Society of Anesthesiologists, ASA). Der Vergleich der QoL zwischen den beiden netzbasierten Verfahren (TAPP [transabdominell präperitoneal]/Lichtenstein) führt zu dem Ergebnis, dass eine vollständige Rekonvaleszenz nach 6 Monaten möglich ist. Auffällig ist das leichte Absinken der QoL in der Lichtenstein-Kohorte, welches durch die Methode und das hohe Lebensalter begründet ist. Eine Berücksichtigung dieser Altersunterschiede führt zu einem veränderten Outcome.
Fazit. Das Konzept der Lebensqualität (QoL) spielt in den aktuellen Bewertungen von Therapieverfahren eine immer wichtigere Rolle. Bei einem Vergleich zwischen mehreren Verfahren muss eine Standardisierung vorgenommen werden, um die Heterogenität zwischen den Gruppen zu berücksichtigen. Ähnlich dem Konzept des „relative survival" in der Krebsepidemiologie sollten die gemessenen QoL-Werte in das Verhältnis zu der alters- bzw. geschlechtsspezifischen Referenz der Allgemeinbevölkerung gesetzt werden, um den Effekt der beobachteten Erkrankung bzw. deren Therapie darzustellen.

Schlüsselwörter

Lebensqualität · Hernienchirurgie · TAPP · Lichtenstein · Demographie

Demographic perspective on the concept of the tailored approach in surgery. Analysis of the quality of life exemplified by inguinal hernia repair

Abstract

Introduction. The constant increase in life expectancy for over 170 years is one of the biggest achievements of modern society. In Germany the probability of an 80-year-old person becoming 100 years old has increased by a factor of 20 since the 1950s. This fact has various implications for the clinical routine and therapeutic guidelines. In addition to the quantitative factors (e.g. complications, recurrence rate), the quality of life (QoL) as a patient-centered subjective factor should be taken into consideration in the treatment options for hernia repair. To compare heterogeneous cohorts of patients regarding the QoL, a standardization based on representative reference values is absolutely essential.
Material and methods. The study was based on data from the follow-up of 310 patients who underwent inguinal hernia repair at the surgery department of the University Hospital Rostock. The preoperative clinical examination of the patients and a questionnaire were supplemented by a postal follow-up survey postoperatively at a median of 20 months (follow-up rate 66%). Patient pain level was assessed by a visual analogue scale (VAS) and health-unspecific QoL by the EQ-5D questionnaire. Standardization of the EQ-5D was based on a survey on a normative German reference population.
Results. Analysis of the patients in the various treatment arms showed significant differences in age composition and health states (American Society of Anesthesiologists, ASA scores) of the patient cohorts. A comparison of the QoL between the two mesh-based procedures, the transabdominal preperitoneal (TAPP) procedure and the Lichtenstein procedure, showed that complete recovery is possible after 6 months. A slight decrease in the QoL of the Lichtenstein cohort patients was ascertainable, which can be explained by the method and the higher age of the group. Taking the differences in age of the two groups into account led to a change of the QoL outcome.
Conclusion. The concept of QoL is currently becoming increasingly more important in the assessment of treatment procedures. When comparing several therapeutic procedures, a standardization must be undertaken to take the heterogeneity of patient cohorts into consideration. Analogous to the relative survival in cancer epidemiology, the measured QoL scores should be put in the relationship to the age and sex-specific reference of the general population in order to demonstrate the actual effect of the disease in question and its treatment.

Keywords

Quality of life · Hernia surgery · TAPP · Lichtenstein · Demography

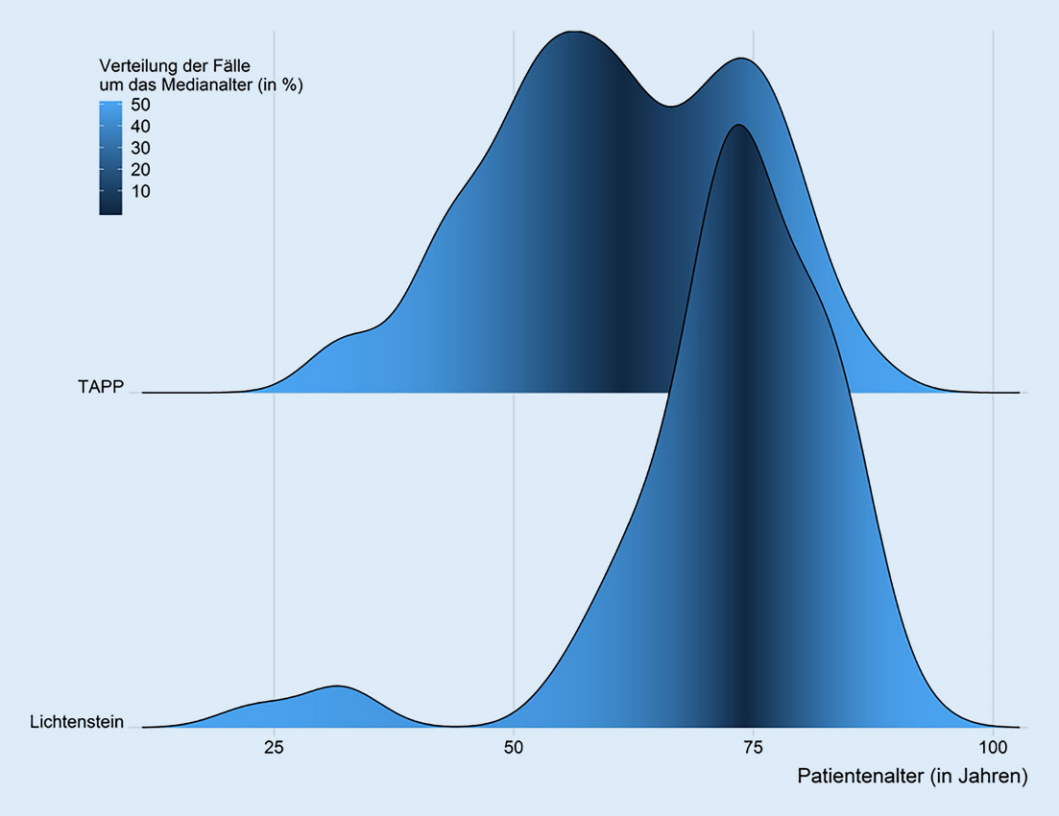

Abb. 1 ◀ Altersverteilung nach Operationsmethode. *TAPP* transabdominell-präperitoneale Technik

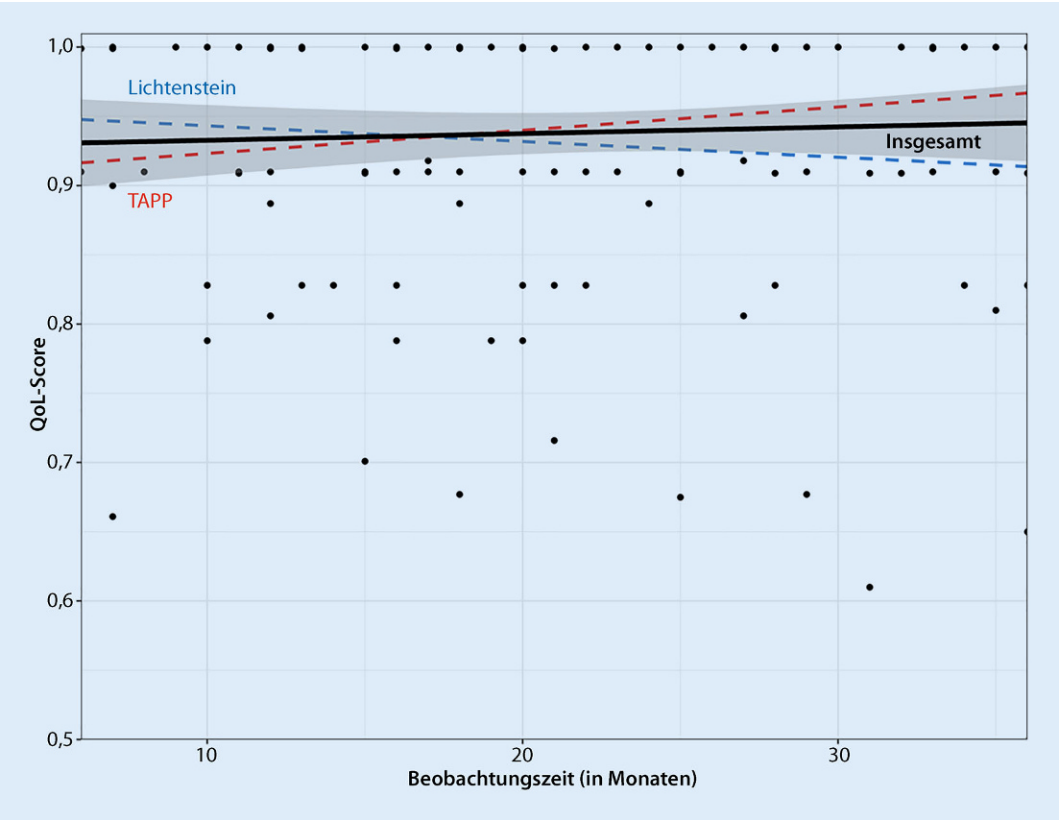

Abb. 2 ◀ Niveau der Lebensqualität im Zeitverlauf (6–36 Monate). *QoL* „quality of life", *TAPP* transabdominell-präperitoneale Technik

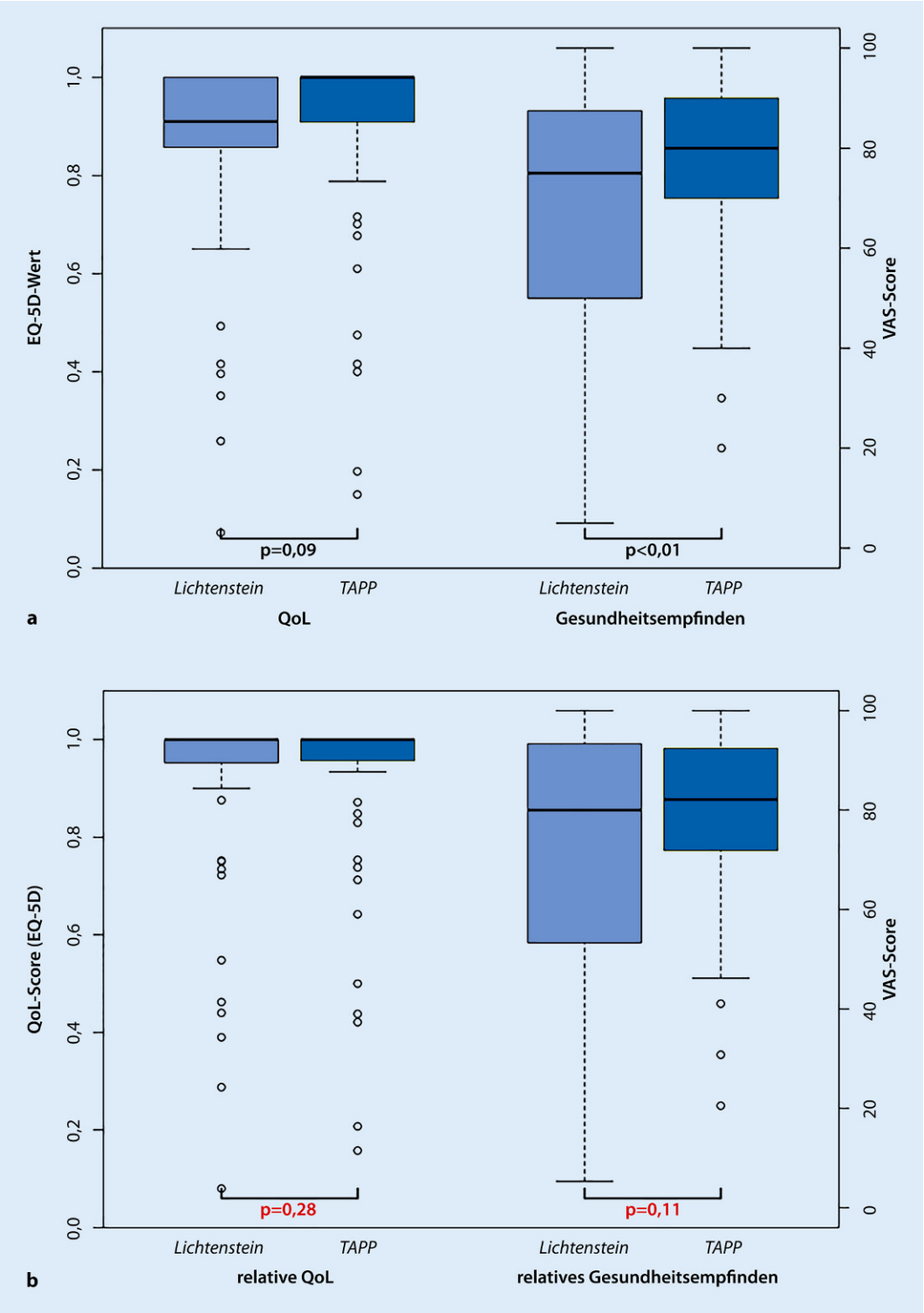

Abb. 3 ◀ Vergleich der Lebensqualität und der subjektiven Gesundheitseinschätzung zwischen den netzbasierten Verfahren **a** ohne **b** mit Berücksichtigung der Alters und Geschlechtsunterschiede im Patientenkollektiv. *QoL* „quality of life", *TAPP* transabdominell-präperitoneale Technik, *VAS* visuelle Analogskala

Netzimplantation ein signifikant höheres subjektives Gesundheitsempfinden haben, als offen operierte Patienten (**Abb. 3a**).

Die Berücksichtigung der Alters- und Geschlechterzusammensetzung in den beiden Vergleichsgruppen führt zu einem relativ stärkeren Anstieg der Messwerte in der Lichtenstein-Gruppe und zu einer veränderten Bewertung der beiden chirurgischen Ansätze (**Abb. 3b**).

Grund ist das vergleichsweise höhere Alter der Patienten und der damit einhergehenden höheren Wahrscheinlichkeit einer Komorbidität. Bezieht man die Korrektur ein, führt es zu einer angeglichen (relativen) Lebensqualität und einer Eliminierung der Unterschiede im (subjektiven) Gesundheitsempfinden zwischen den Gruppen.

Diskussion

Da der Prozess des Alterns individuell sehr unterschiedlich ist, muss demzufolge der individuelle biologische Zustand des alten Patienten bei der Verfahrenswahl im Vordergrund stehen. Trotz der negativen Risikoselektion (nach Alter und ASA-Score) zugunsten der TAPP gab es zwischen den beiden chirurgischen Ansätzen keinen signifikanten Unterschied in Bezug auf die Rezidivhäufigkeit und postoperative Komplikationen. Entsprechend der in der aktuellen Literatur kontrovers diskutierten erhöhten Rate an chronischen Schmerzpatienten nach Lichtenstein-Operation konnten wir dies in unserem Patientengut (Lichtenstein 8,6 % vs. TAPP 8,8 %) nicht verifizieren [18–20]. Die Darstellung der Lebensqualität im Langzeitverlauf führt zu unterschiedlichen Trends. Eine mögliche Ursache könnte die Heterogenität der zwei Gruppen sein. Die ältere und kränkere Vergleichsgruppe wird mit einer höheren Wahrscheinlichkeit durch ihre Komorbiditäten, gerade im Langzeitverlauf, an nicht (ursächlich) therapierelevanten Erkrankungen Einbußen in der Lebensqualität haben. Trotz Analogie zu vielen anderen chirurgischen Disziplinen wurden bisher nur wenige Arbeiten, die sich mit dem Zusammenhang zwischen Alter und Hernienchirurgie befassen, publiziert [21].

Ebenso wie Gutlic et al. konnten wir die Gleichwertigkeit der Operationsverfahren bezüglich der QoL belegen [22]. Die Abkehr von rein quantitativen Bewertungskriterien von Therapien ist in vollem Gange. Subjektive Kennzahlen unterliegen unterschiedlichsten Verzerrungen, können aber durch eine Standardisierung anhand von Referenzwerten der Allgemeinbevölkerung korrigiert werden. In unserer Analyse können wir die Vergleichbarkeit der beiden chirurgischen Verfahren, trotz signifikanter Alters- und Geschlechterunterschiede und einer geringen Fallzahlen, herstellen.

Während die Vorteile der minimalinvasiven Technik bei jungen gesunden Patienten anerkannt und belegt sind, wird die offene netzfreie Reparation trotz guter Langzeitergebnisse hinsichtlich der Rezidivraten nur in Ausnahmefällen empfohlen [13]. Im Gegensatz dazu wird die Indikation zum minimal-invasive Verfahren bei komorbiden Patienten relativiert, obwohl der Vorteil ebenso vorliegt.

Fazit für die Praxis

Die Lebensqualität ist ein geeigneter Parameter zur Bewertung einer Therapieoption, der nach einer Nachbeobachtungsdauer von 6 Monaten eine aussagekräftige Kennzahl darstellt. Der Heterogenität zwischen den Patientengruppen und der damit verbundenen Unterschiede in Morbidität und Lebensqualität kann durch Standardisierung auf die Allgemeinbevölkerung Rechnung getragen werden. Dadurch zeigt sich in unserer Studie trotz des retrospektiven Designs mit dem entsprechenden Evidenzlevel, dass die offene Reparation einer Leistenhernie zu einem gleichwertigen Ergebnis gegenüber der laparoskopischen Hernienchirurgie führt.

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Einhaltung ethischer Richtlinien

Interessenkonflikt. M. Leuchter, E. Klar und M. Philipp geben an, dass kein Interessenkonflikt besteht.

Alle beschriebenen Untersuchungen am Menschen oder an menschlichem Gewebe wurden mit Zustimmung der zuständigen Ethikkommission, im Einklang mit nationalem Recht sowie gemäß der Deklaration von Helsinki von 1975 (in der aktuellen, überarbeiteten Fassung) durchgeführt. Von allen beteiligten Patienten liegt eine Einverständniserklärung vor.

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Visceral Medicine

Research Article

Visc Med 2020;36:326–332
DOI: 10.1159/000505247

Received: July 22, 2019
Accepted: December 4, 2019
Published online: January 14, 2020

Quality of Life after Complex Abdominal Wall Reconstruction

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Keywords

Endoscopic component separation · Ventral hernia repair · Quality of life · Abdominal wall reconstruction · Ramirez

Abstract

Background: Component separation (CS) for tension-free approximation of fascial edges is the established technique for the repair of large ventral hernias mostly regarding midline defects. Recent studies suggest lower complication rates following a modified version of this technique using a partially endoscopic-assisted approach, whereas little is known about the quality of life (QoL) in the long-term evaluation of these patients. ***Methods:*** A retrospective study and analysis of patients undergoing hernia repair using an open CS (OCS) and endoscopically assisted CS (ECS) technique, respectively, from 2011 to 2016 at the Rostock University Medical Center. Patients underwent a mesh-based sublay reinforcement following a distinct CS with closure of the linea alba. Patient characteristics, technical details, and short-term postoperative outcomes were determined by a physician chart review. A health-related QoL survey (EQ-5D) including a pain assessment was evaluated at a median of 19.5 months postoperatively. ***Results:*** Thirty-five patients had a CS: 25 OCS and 10 ECS. Perioperative variables were comparable except for the median defect size (169 cm^2 OCS vs. 86 cm^2 ECS; $p < 0.05$) and maximum width of hernia (25 vs. 13 cm). Hospitalization lasted 16.6 days in the OCS group and 7.9 days in the endoscopic group ($p = 0.04$). Wound complications occurred in 24% of OCS and 10% of ECS patients. ***Conclusions:*** Patients in the ECS group had a shorter hospital stay and less minor and major wound complications. These advantages led to a faster recovery directly affecting the QoL in the ECS group. This effect diminishes in the long-term follow-up with a positive trend towards the OCS technique.

Introduction

Incisional hernias are a common postoperative complication with an incidence of 5–20% following open abdominal procedures [1–3] and 1–3% following minimally invasive abdominal procedures [3–5]. Several risk factors including obesity, smoking habits, genetic disposition, and particularly the type and approach of previous surgical procedures with a focus on postoperative wound healing impairments increase the risk for incisional hernia occurrence up to 55% [6]. Musculofascial component separation (CS), initially described by Ramirez et al. [7], offers theoretically physiological advantages for the repair of abdominal wall defects. Initially described as a mesh-free method of approximation of the rectus muscle and reconstruction of the *linea alba*, it now follows the current standard of mesh reinforcement [8, 9] with the crucial aim of leaving no bridging defect for the mesh by full coverage of the alloplastic material with tissue on both sides.

Open anterior CS (OCS) has considerable consequences for midline skin perfusion and wound healing, particularly in contaminated, irradiated, and/or previously surgically altered abdominal walls. Recently published guidelines have taken this into account and de-

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clared OCS a technique with limited recommendation [10].

Prior to this, several groups have described less invasive CS approaches recognizing the above-mentioned limitations [11–13]. This led to the approach that provides direct access to the lateral abdominal wall by using balloon dissectors and endoscopic visualization. The technical feasibility of this procedure has been described recently [14–16]. A disadvantage of the endoscopically assisted CS (ECS) is the reduced gain of abdominal wall advancement [17]. When assessing results of ventral hernia surgery, it is important to consider the full range of outcome parameters that are important to the individual patient: postoperative surgical complications, short-, mid-, and long-term general mortality analogous to visceral surgery, recurrence, patient satisfaction, and functional outcomes affecting quality of live (QoL). Long-term pain, patient satisfaction, and function have been reported in only a few small observational studies [18, 19]. Some authors even imply that there is no significant benefit of mesh utilization in the long term [9, 20].

Methods

After obtaining Institutional Review Board approval, all patients undergoing OCS or ECS for complex abdominal wall reconstruction from January 2012 to October 2016 at the University Medical Center of Rostock were reviewed retrospectively. Patients had to sign a consent form in order to take part in this study and the consecutive follow-up.

When feasible, ECS was offered to patients. The clinical characteristics of the abdominal wall and the defect size were the main parameters for the decision towards ECS. Ultrasound and/or CT were not obligatory and were only primarily done to evaluate hernia sac content and a possible "loss of domain" situation when clinically assumed. According to Harth and Rosen [21], the open approach was selected in patients who required skin advancement or removal, and in patients who were expected to require extensive adhesiolysis, mostly after open abdominal treatment. Medical records were analyzed for patient demographics, including gender, age, comorbidities, body mass index, prior abdominal surgeries, surgical indication, and preoperative pain scores. Perioperative data included the American Society of Anesthesiology (ASA) classification, defect size of the hernia, CS technique used, and mesh type and size required. Outcomes were evaluated for hospital length of stay, postoperative complications including major and minor wound complications, need for reoperation, and hernia recurrence.

Wound complications were classified as major when either a surgical procedure or percutaneous drainage was required, and minor when local bedside debridement, oral/intravenous antibiotics, and/or use of negative pressure therapy were used for treatment. The classification of Dindo et al. [22] was adopted to achieve a comparable grouping.

The follow-up consisted of outpatient visits or mailed surveys. At the time of this report, 32 of 35 patients were available for evaluation. Average length of follow-up was 20.7 months (median 18, IQR 6–28). The validated German version of the EQ-5D Health Questionnaire, which consists of 2 scores: the EQ-5D descriptive system and the EQ visual analogue scale (EQ-VAS), was used. The EQ-5D descriptive system consisted of 5 dimensions (mobility, self-care, daily activities, pain, or discomfort, and psychological state) in 5 levels (no problems, slight, moderate, severe, and extreme problems). We compared these items with their levels in a reference population that originates from an evaluation of a sample of 3,552 persons [23]. König et al. [23] used time to trade-off techniques to determine valuations (perfect health and death have utilities of 1 and 0, respectively) [24]. The EuroQol also contains an EQ VAS on which persons can rate their overall health state by placing a mark on a vertical scale which ranges from 0 (worst imaginable health state) to 100 (best imaginable health state).

Additionally, we included in our questionnaire the time span from operation to full return to work when applicable (potentially or formerly employed patients).

Hernia recurrence was determined using our follow-up evaluation. All patients had a postoperative physical examination within 3 months after surgery. In case a further surgical or interventional procedure was indicated, indication and type of treatment were noted when required. Statistical analysis was performed using R! software [25]. Percentages were evaluated using either the χ^2 test or the Fisher exact test. Continuous variables were evaluated using the Mann-Whitney test. A p value of less than 0.05 was considered significant.

Surgical procedures were performed as follows. Patients were operated in back-spine position. A single-shot of antibiotic (cefazolin 2 g i.v.) was given just before incision; this was repeated when operation time exceeded 3 h. The use of incision foil was not generally adopted.

When performing ECS, we started preparing the dissection plane between the internal and external oblique muscles using a trocar balloon (Spacemaker Dissection Balloon; Covidien Ltd., Dublin, Ireland) and consecutive blunt dissection. An insufflation pressure of 20 mm Hg was used to maintain the space. Trocar positioning started with an 11-mm port above the costal arch in midclavicular line, meticulously aiming lateral to the hernia and sparing the rectus sheath and muscle. Another 11-mm port was then introduced under vision through an incision above the inguinal ligament in midclavicular line; an additional 5-mm trocar was used halfway between the first two, entered in the anterior axillary line. This setting allowed the individual switching of the camera and instruments (scissors and hook), with a final incision in the external oblique aponeurosis [26, 27] (Fig. 1–3). The procedure was performed bilaterally and ended with the placement of suction drains (Ch 12). Then the defect was approached using an open midline incision.

The open procedure started by wide excision of the scar tissue intentionally performing a median laparotomy; a panniculectomy was necessary in case of former open abdomen situation with secondary wound healing or skin mesh use. The abdominal cavity was opened stepwise avoiding enterotomy. Meticulous adhesiolysis was done if needed. A systematic interenteric adhesiolysis was not generally performed. The hernia sac in its subcutaneous position stayed primarily untouched. Instead, the rectus muscle was manually identified, and the anterior fascial sheath of the rectus muscle was approached by transecting through the hernia sac approximately 1 cm atop of the hernia ring usually at the level of the maximum width of the defect. Following this plane, the anterior rectus sheath could be dissected beyond the linea semilunaris when performing an anterior CS. When a transverse abdominis release was planned or the CS was already done by the endoscopic technique, the anterior sheath was only defined and followed to the xyphoid and pubic bone for further processing. The anterior CS led to the complete identification of the linea semilunaris sparing perforator vessels if possible and leaving remnants of fatty tissue on the

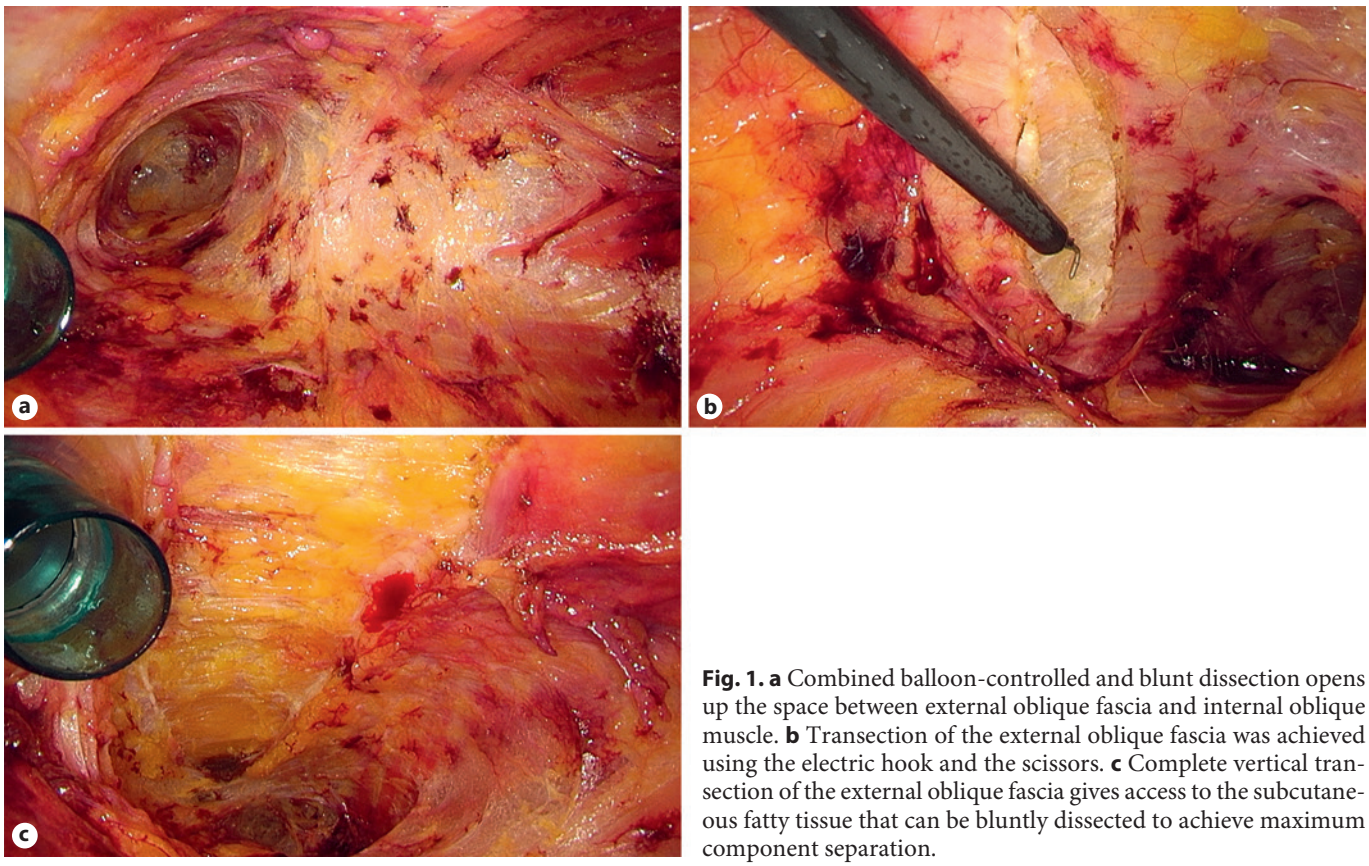

Fig. 1. a Combined balloon-controlled and blunt dissection opens up the space between external oblique fascia and internal oblique muscle. **b** Transection of the external oblique fascia was achieved using the electric hook and the scissors. **c** Complete vertical transection of the external oblique fascia gives access to the subcutaneous fatty tissue that can be bluntly dissected to achieve maximum component separation.

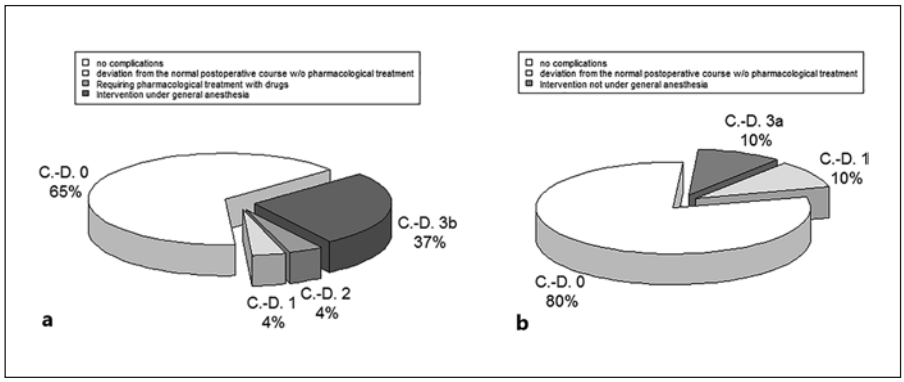

Fig. 2. Postoperative complications according to Clavien-Dindo for open component separation (**a**) and endoscopic anterior component separation (**b**) [22].

fascia if feasible. The following incision of the external oblique fascia 1–2 cm lateral to the linea semilunaris was vertically completed from the costal arch to the inguinal ligament. A blunt dissection achieved a medial advancement of the rectus-fascial muscle complex. This procedure was done bilaterally. The next step was opening of the rectus sheath by incision of the anterior fascia just at the edge of the former hernia ring and completion vertically from the retroxyphoid space (fatty triangle) to the retropubic space (Retzius). The resulting retrorectus space for the mesh augmentation was dissected bluntly sparing the epigastric vessels.

When performing a transversus abdominis muscle release, the posterior fascia was incised 1 cm medially to the linea semilunaris, and the M. transversus abdominis became visible. A combination of transecting the muscle fibers by coagulation and blunt dissection gave the necessary gain to the midline advancement. Whether an anterior or posterior (transversus abdominis muscle release) procedure was necessary or feasible was mainly decided intraoperatively.

In case of excessive intraoperative abdominal pressure monitored by blood pressure, respiration pressure, or the missed chance to close the posterior and/or anterior fascia, a combination of anterior and posterior CS was inevitable ($n = 2$). In case of ECS, the medial gain was automatically achieved when opening the rectus sheath. The posterior sheath was closed by resorbable continuous suture loops (MonoMax®; B. Braun Melsungen AG) after placement of an intraabdominal drainage.

The placement of the mesh in the sublay (retrorectus) position covered full midline using a Parietex Progrip Mesh (Covidien), alternatively Dynamesh CICAT (Dahlhausen), and in 1 case the biologic mesh Strattice (LifeCell Corp., Branchburg, NJ, USA). As

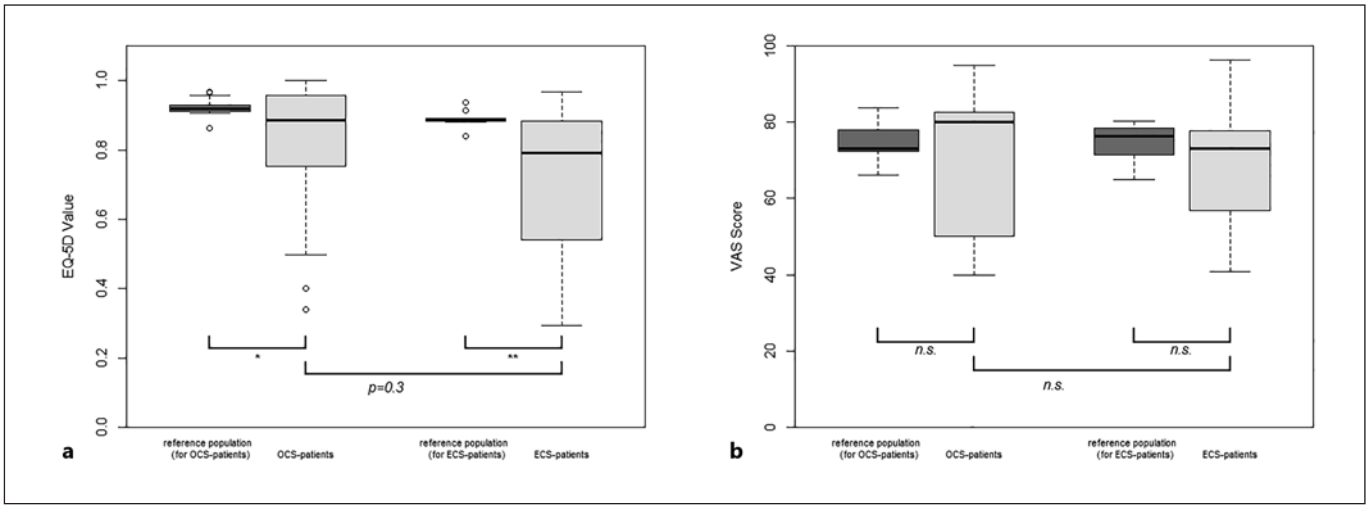

Fig. 3. Health-related quality of life (**a**) and self-rated health (**b**) compared to the reference population.

Table 1. Demographics and perioperative parameters (medians)

	Overall	OCS	ECS	*p* value
Follow-up, months	19.5	21	13	0.12
Age, years	58	56	59	0.954
Sex, males/females	21/14	15/10	6/4	1
BMI, kg/m^2	29.7	29.7	29.3	0.5
Smokers, *n*	12	9	3	1
ASA score, I/II/III	0/12/23	0/9/16	0/3/7	1
Length of stay, days	14	16.6	7.9	0.04
Duration of operation, min	187	187	184	0.21
Defect size, cm^2	126	169	86	0.001
Width, cm	12	14.5	10	0.013
Previous incisional hernia repair	5	4	1	1
Impending abdominal compartment	4	3	1	1
C-reactive protein, mg/L				
Preoperatively	3.4	3.51	2.45	0.412
Postoperative day 3	160	179.5	117	0.33
Postoperative day 7	74.8	75.65	69.2	0.8

ASA, American Society of Anesthesiologists; defect size, length × width × π/4.

above, the mesh suction drains (Ch 16) were placed, and the hernia sac was excised. The anterior rectus sheath was closed analogous to the posterior one. The subcutaneous space was drained and reconstructed by interrupted sutures; skin closure was performed with tacks.

Results

Among the 35 patients operated on during the study period, 32 (91.4%) were successfully contacted for long-term evaluation and represent the study population. Two patients died; the causes of death were not related to the repair but were linked to acute or chronic liver failure; 1 person refused to cooperate due to communication problems.

There were 25 patients who had OCS and 10 who had ECS. No conversion of the minimally invasive approach was necessary. The demographics of the patients were comparable in both groups (Table 1).

Regarding the perioperative parameters, the median hernia size was significantly smaller in the ECS group with 86 cm^2 compared to 169 cm^2 in those that had undergone open repair (OCS). Accordingly, the median width of the hernia was more than 30% smaller in the ECS group (OCS 14.5 [IQR: 10–18] vs. ECS 10 [IQR: 8–12]). In contrast, no difference in the median operation time was noted (187 vs. 184 min).

The mean length of hospital stay postoperatively was 7.9 versus 16.6 days in open repair ($p < 0.04$). Overall, there were no statistical differences in complication rates when comparing both groups.

One patient (10%) in the minimally invasive group experienced postoperative wound complications in comparison with 6 patients (24%) in the open group ($p = 0.53$) (Table 2).

Hematoma/seroma was seen in 1 patient (10%) in the endoscopically (assisted) group and required CT-guided drainage (Fig. 1a, b). Three patients (12%) in the open group had a clinically evident hematoma ($p = 1$) but required no further treatment. Four patients in the open group (16%) had prolonged seroma formation that persisted up to 4 months following abdominal wall repair but were managed conservatively.

The only recurrence was detected in the ECS group. However, at the time of the operation, this patient had an epicystostomy in situ, and the abdominal wall could not be completely reinforced by a mesh.

Three patients in the OCS group suffered severe pulmonary complications requiring tracheotomy and prolonged ICU support (max. 21 days).

The median EuroQol and VAS scores evaluated during the follow-up are summarized in Figure 2. No significant differences between OCS and ECS patients were observed except for a slight tendency towards a better outcome in the OCS group. Both groups showed significant differences ($p < 0.05$ for OCS/$p < 0.01$ for ECS) compared to the standardized reference population (Fig. 2a). Surprisingly, these differences diminished when measuring the overall health state on VAS basis (Fig. 2b).

Regarding age, 28 patients were <65 years; 12 of these 28 (42%) patients were postoperatively returning to employment. With respect to the duration of return to work, it was only 0.5 weeks shorter (6 vs. 6.5 weeks) for the ECS group.

Table 2. Complications after component separation

	ECS	OCS
Surgical complications		
Superficial	0	2
Subfascial	0	1
Necrosis	0	3
Hematoma	1	3
Seroma	1	4
Others	0	3
Recurrence	1	0
Reoperation	1	6

Discussion

When assessing results of ventral hernia surgery, it is important to consider the full range of outcome parameters that significantly affect the individual patient: postoperative surgical complications, short-, mid-, and long-term general mortality analogous to visceral surgery, recurrence, patient satisfaction, and functional outcome affecting QoL.

Recurrence may always occur but even more so in the course of time. In contrast to other hernia types, the complete recurrence rate will show their full amount rather on a 10-year follow-up [28]. Long-term pain, patient satisfaction, and functional parameters have been reported only in a few, small, observational studies [18, 19]. Even large comprehensive long-term studies in ventral hernia repair lack dependable elementary statements [9]. The call for multicenter studies with long-term follow-up remains [29].

To our knowledge, this study represents the first study comparing ECS with OCS for abdominal wall defects regarding QoL. While our experience confirms that the endoscopic approach is safe, our data suggest that there may be advantages for the open approach. In our small cohort, clinical outcome and QoL did not significantly differ for each CS method in a systematic follow-up.

The additional focus regarding QoL in our setting of abdominal wall reconstruction as an extraordinary effort to involve endoscopically assisted techniques does not only point to acceptable clinical outcomes but also asks for better QoL for these patients.

We found, as others have, that CS techniques generally improve the QoL in patients with large ventral hernias [30–32]. The use of a global health-related QoL index has been established [30], but the number of patients is still low [31]. There seems to be consensus that the restoration of the linea alba does not only improve abdominal wall function but also QoL [31, 32]. There are no published studies comparing long-term QoL outcomes for different CS techniques.

The difference in wound complications between the 2 techniques reaches statistical significance, which have clinically important implications. Major wound complications can result in prolonged hospital stay, costly reoperations and expensive long-term wound therapy. We give evidence that ECS is associated with a decreased likelihood of requiring subsequent surgical procedures. This is evident in the 8.7-day reduction in hospitalization in the endoscopic group.

There is a negative effect of hernia width and subsequently used mesh size to the occurrence of complications [33].

The decision to perform an ECS in our study led to a selection bias because very large hernias were approached primarily conventionally (OCS). Therefore, the superior-

ity of ECS over OCS might be related to the maximum width of the defect. Taking the differences in the defect size into account by removing patients with the biggest defect size, the OCS results in a postoperative complication rate similar to the ECS.

The low recurrence rate in our cohort of CS is based on the principle of stabilizing the whole abdomen vertically and is therefore not the issue we struggle with when closing smaller defects [34, 35].

Evolution of complex abdominal wall reconstruction shows a trend toward posterior CS techniques, especially transversus abdominis muscle release [36, 37], but ECS still remains an attractive approach [29]. We were able to include defects of up to 122 cm^2, with a maximum defect width of 13 cm. It seems unfavorable to include patients with the above-mentioned limitations, but if CS is necessary, ECS may be the best indication to prevent wound healing disorders.

We conclude that a precise description of the technique is crucial but will raise even more questions about the use of CS in ventral hernia repair. In our opinion, analysis of postoperative QoL after an appropriate time span is the best option to control the quality of surgery.

Statement of Ethics

The study protocol was approved by the Institutional Review Board.

Disclosure Statement

The authors have no conflicts of interest to declare.

Funding Sources

The authors declare that there is no funding of any research relevant to the preparation of data or the manuscript.

Author Contributions

M.P. wrote the main parts of the manuscript and made the final structure and corrections of the manuscript.

M.L. developed the structure of the manuscript, reviewed the literature, wrote parts of the manuscript, and created figures; E.K. gave substantial implications for the manuscript and revised the manuscript critically.

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Assessment of Quality of Life after Endovascular and Open Abdominal Aortic Aneurysm Repair: A Retrospective Single-Center Study

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Abstract: Postoperative quality of life is an important outcome parameter after treatment of abdominal aortic aneurysms. The aim of this retrospective single-center study was to assess and compare the health-related quality of life (HRQoL) of patients after open repair (OR) or endovascular treatment (EVAR), and furthermore to investigate the effect of incisional hernia (IH) formation on HRQoL. Patients who underwent OR or EVAR for treatment of an abdominal aortic aneurysm between 2008 and 2016 at a University Medical Center were included. HRQoL was assessed using the SF-36 questionnaire. The incidence of IH was recorded from patient files and by telephone contact. SF-36 scores of 83 patients (OR: n = 36; EVAR: n = 47) were obtained. The mean follow-up period was 7.1 years. When comparing HRQoL between OR and EVAR, patients in both groups scored higher in one of the eight categories of the SF36 questionnaires. The incidence of IH after OR was 30.6%. In patients with postoperative IH, HRQoL was significantly reduced in the dimensions "physical functioning", "role physical" and "role emotional" of the SF-36. Based on this data, it can be concluded that neither OR nor EVAR supply a significant advantage regarding HRQoL. In contrast, the occurrence of IH has a relevant impact on the HRQoL of patients after OR.

Keywords: aortic aneurysm; vascular surgery; incisional hernia; EVAR; OR quality of life

Citation: Gruel, J.; Grambow, E.; Weinrich, M.; Heller, T.; Groß, J.; Leuchter, M.; Philipp, M. Assessment of Quality of Life after Endovascular and Open Abdominal Aortic Aneurysm Repair: A Retrospective Single-Center Study. *J. Clin. Med.* **2022**, *11*, 3017. https://doi.org/10.3390/jcm11113017

Academic Editors: Manuel Martínez-Sellés and Sheldon Goldberg

Received: 31 March 2022
Accepted: 24 May 2022
Published: 27 May 2022

1. Introduction

Cardiovascular diseases are currently the leading cause of death worldwide [1]. Abdominal aortic aneurysms (AAA), along with vascular pathologies such as peripheral artery disease (PAD) and stenoses of the carotid artery, are among the five most frequent vascular diagnoses in German hospitals [2]. Treatment of AAA includes open repair (OR) or endovascular aortic repair (EVAR). Both procedures are considered equivalent with the respective benefits of each technique [3]. While endoleak formation is a specific complication after EVAR [4], one of the most important specific complications after OR is the development of an incisional hernia (IH). The incidence of IH in AAA patients varies from 10 to 38% [5–7], while studies with a longer follow-up period even showed incidences of up to 69% after OR [8,9]. Risk factors for IH include the AAA itself, obesity, malnutrition, corticosteroid medication, connective tissue disease, smoking, and pulmonary diseases such as

chronic obstructive pulmonary disease (COPD), bronchial asthma, or chronic cough [10–13]. IH, in turn, often require secondary surgery. To prevent the development of IH after OR, the current European Society for Vascular Surgery (ESVS) guidelines on the management of abdominal aorto-iliac artery aneurysms as well as the German S3-guideline on screening, diagnosis, therapy, and follow-up of AAA, recommend considering prophylactic mesh reinforcement after median laparotomy for patients at high risk for IH [3,14]. In contrast, the Society for Vascular Surgery (SVS) practice guidelines on the care of patients with an abdominal aortic aneurysm and the British National Institute for Health and Care Excellence (NICE) guideline on 'Abdominal aortic aneurysm: diagnosis and management' do not state any recommendations regarding prophylactic mesh reinforcement [15,16].

To evaluate the benefit of aortic aneurysm repair, the health-related quality of life (HRQoL) became an important parameter in recent years [17–19]. The reason for this is that most procedures are performed electively on asymptomatic patients. Furthermore, the quality of life after therapy is as important as the technical success.

The aim of this study was to evaluate the HRQoL of patients after OR and EVAR. Furthermore, the effect of IH on HRQoL was investigated within the OR group.

2. Materials and Methods

This retrospective cohort study was approved by the local ethics committee (A2020-0168). All patients were included who underwent either OR or EVAR due to an AAA at the study site, a University Medical Center, between 2008 and 2016. The local database SAP (Walldorf, Germany) was screened for the OPS codes 5-38a, 5-384.5, 5-384.6, and 5-384.7 of the German Operationen- und Prozedurenschlüssel (version 2020). Additionally, digital and analog record search was conducted.

2.1. Assessed Data

Documented data included age, gender, body mass index (BMI), preexisting hernia, and concomitant diseases (coronary artery disease (CAD), PAD, COPD, smoking, chronic kidney disease, hyperlipidemia (HLP) and diabetes) at the time of OR or EVAR. In addition, data including the performed operation or intervention, whether it was emergency or elective treatment, and the incidence of postoperative complications, including IH and the respective management, were studied. All data were documented with Excel (Microsoft Excel 2019, Microsoft, Redmond, WA, USA).

2.2. Quality of Life Assessment

For the survey of patients' HRQoL, the 36-item short-form health survey (SF-36) was used. This health questionnaire consists of 36 questions that reflect eight domains. These are physical functioning (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (V), social functioning (SF), role emotional (RE), and mental health (MH) [20].

Due to contact restrictions at the time of data collection patients were contacted by phone only. After consenting to take part, patients received the SF-36 by post and were asked about their current health status and the occurrence of IH by phone. Subsequently, the questionnaire and a written consent form were completed and returned by post.

2.3. Aortic Access in OR and Routine Follow-Up

As intraoperative access route median laparotomy was performed in 72.2%, retroperitoneal access in 16.7%, and initial laparoscopy in 11.1%. In all cases, fascia closure was performed in standardized continuous fashion using two running CT-1 PDS (polydioxanone) loop sutures (Ethicon™, Raritan, NJ, USA) in the small bites technique. No mesh was primarily applied for hernia prevention. For follow-up after surgery, patients were offered annual readmissions to our vascular outpatient clinic, which included an ultrasound examination of the aorta and femoral/popliteal arteries in addition to clinical examination.

2.4. Conduction of EVAR and Routine Follow-Up

Strictly following our internal institutional standard all EVAR-procedures have been performed either in the hybrid operation theater or in a dedicated cath lab under general anesthesia with open surgical access in both groins by an interdisciplinary team of anesthesiologists, interventional radiologists, and vascular surgeons. Depending on anatomical characteristics of the aneurysm and extension to the common iliac arteries the following endograft systems were used: Excluder® (W. L. Gore and Associates, Flagstaff, AZ, USA) in 20/47 cases, Endurant II™ (Medtronic, Dublin, Ireland) in 21/47 cases, Zenith Flex® (Cook Medical Inc, Bloomington, IN, USA) in 5/47 cases and Ovation™ (Endologix, Irvin, CA, USA) in 1/47 cases. After the intervention, all patients are transferred to the recovery room for monitoring.

Routine follow-up included CTA before discharge as well as 6 resp. at 12 months after EVAR. This was followed by annual control by means of sonography or CTA depending on aneurysm size, kidney function, and sonographic assessability of the aorta.

2.5. Statistics

Program R was used for statistical analysis [21]. Both groups, OR and EVAR, were examined for differences within the above-mentioned parameters. When comparison of the groups involved whole numbers in terms of patient numbers (n), Fisher's exact test was used to determine significance. Data of each subscale were compared between the groups using the Students' t-test. Data from the SF-36 were compared using Mood's median test. Binary logistic regression was performed to examine the effect of certain patient characteristics on the incidence of IH. Selected characteristics were sex, age, whether the surgery was elective or emergent, nicotine abuse, BMI, HLP, CAD, diabetes, and preoperatively existing hernia. p-values < 0.05 were considered significant.

3. Results

Out of the initially identified 258 patients treated for an AAA, 175 cases had to be excluded due to missing contact data, failed contact, death, inability, or denial to participate. In total, questionnaires of 83 patients were available, of whom 36 were treated by OR and 47 by EVAR (Figure 1).

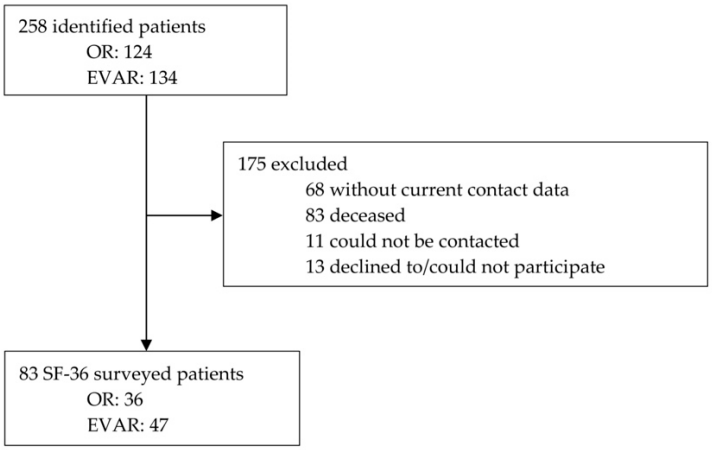

Figure 1. Trial profile. From 2008 to 2016, 258 patients were treated with open or endovascular repair at the University Medical Center. After exclusion of 175 cases, 83 patients were included in the study. Health-related quality of life was assessed by means of the SF-36 questionnaire. OR: open repair; EVAR: endovascular aortic repair.

3.1. Patient Characteristics

The mean age was 64.0 ± 8.8 years in the OR group at the time of operation and significantly lower compared to 70.2 ± 6.9 years in the EVAR group ($p < 0.05$). The groups

also showed a significant difference in frequency of current smoking (OR: 27.8%, EVAR: 19.1%, $p < 0.05$) and prevalence of diabetes (OR: 30.5%, EVAR: 10.6%, $p < 0.05$). Arterial hypertension was the most common concomitant disease in both groups (OR: 91.7%, EVAR: 72.3%, $p < 0.05$). Other concomitant diseases, gender distribution, and mean follow-up did not differ significantly between the groups (Table 1).

Table 1. Baseline characteristics at the time of data collection and follow-up time of patients after open repair or endovascular aortic repair of an abdominal aortic aneurysm. Data are given as *n* (%) or mean ± SD. Fisher's exact test.

	OR *n* = 36		**EVAR *n* = 47**	
	n	**%**	***n***	**%**
Age	64 ± 8.8		70.2 ± 6.9 *	
Male	32	88.9	45	95.7
Female	4	11.1	2	4.3
CAD	14	38.9	19	40.4
Arterial hypertension	33	91.7	34	72.3 *
HLP	18	50.0	16	34.0
Smoking	10	27.8	9	19.1 *
Diabetes	11	30.5	5	10.6 *
COPD	6	16.7	6	12.8
BMI	28.01 ± 3.62		29.29 ± 3.05	
Elective intervention	30	83.3	46	97.9 *
Emergent intervention	6	16.6	1	2.1 *
Follow-up (years)	7.8 ± 2.7		6.6 ± 1.9	
Min. follow-up (years)	3.6		3.6	
Max. follow-up (years)	12.1		12.4	

* $p < 0.05$ vs. OR. SD: Standard deviation; OR: open repair; EVAR: endovascular aortic repair; CAD: coronary artery disease; HLP: hyperlipoproteinemia; COPD: chronic obstructive pulmonary disease; BMI: body mass index.

For elective AAA repair ($n = 76$) EVAR ($n = 46/47$) was performed significantly more often compared to OR ($n = 30/36$, $p < 0.05$). For emergent interventions ($n = 7$) OR ($n = 6/36$) was performed significantly more frequent (EVAR: $n = 1/47$, $p < 0.05$).

3.2. Complications after EVAR and OR

After EVAR, the most frequent complication was the occurrence of endoleaks (21.3%) in ten patients, nine of whom underwent successfully revised endovascularly. Type I endoleaks were found in four patients (8.5%), and type II endoleaks in six patients (12.8%).

Other complications included one case of AAA rupture 8 years after intervention (2.1%), one thrombotic occlusion of a prosthetic leg 19 months after EVAR (2.1%), stenosis of a prosthetic leg in three cases (6.4%), and one inguinal wound infection (2.1%). Each of these complications required at least one reintervention. No complications occurred in 32 patients (68.1%).

The most common early postoperative complication after OR was postoperative bleeding. One patient (2.8%) suffered postoperative bleeding as well as abdominal compartment syndrome. Two patients (5.6%) had isolated postoperative bleeding. One patient developed colonic ischemia (2.8%). Relaparotomy was necessary in each of these four cases (11.2%). No complication occurred in 32 patients (88.9%).

Three patients (8.3%) in OR had a history of abdominal wall hernia prior to AAA detection (two umbilical, one inguinal hernia). Two of them developed an IH after OR. Overall, eleven patients (30.6%) in the OR group developed an IH. Three of them (27.3%) were treated by mesh-based hernioplasty in sublay technique. None of the characteristics gender ($p = 0.19$), age ($p = 0.75$), elective or emergency operation ($p = 0.87$), current smoking ($p = 0.35$), BMI $</\geq 30$ ($p = 0.49$), HLP ($p = 0.63$), CAD ($p = 0.66$), diabetes ($p = 0.67$), and preexisting hernia ($p = 0.17$) had a significant impact on IH development in the studied population.

3.3. HRQoL after EVAR and OR

The average follow-up time between the first intervention (OR or EVAR) and the survey of the SF-36 questionnaire was 7.1 years (OR: 7.8 years, EVAR: 6.6 years). The time ranged from a minimum of 3.6 years (OR and EVAR) to a maximum of 12.4 years (OR: 12.1 years, EVAR: 12.4 years).

Significantly higher values in the SF-36 were found in the OR group in the domain MH (OR: 62 (60–64) compared to EVAR: 60 (60–60), $p < 0.05$) (Figure 2). In the domain PF, there was no significant difference, but a trend with higher scores after EVAR (EVAR: 80 (55–90) compared to OR: 65 (43.75–85), $p = 0.05$). In the other six domains, no significant difference was detected.

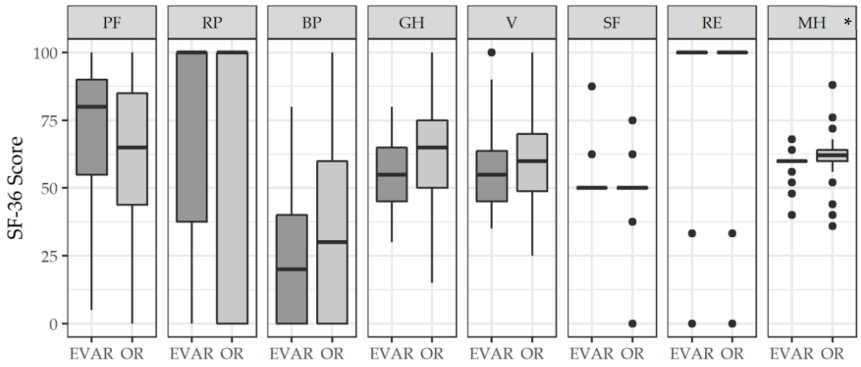

Figure 2. Health-related quality of life in patients after endovascular (EVAR) and open repair (OR) of an abdominal aortic aneurysm was assessed by means of the SF-36 questionnaire. Data are given as median and IQR (25% and 75% percentile). Dots represent suspected outliers (≥1.5 IQR). Mood's median test. * $p < 0.05$ vs. EVAR. IQR: interquartile range; PF: physical functioning; RP: role physical; BP: bodily pain; GH: general health; V: vitality; SF: social functioning; RE: role emotional; MH: mental health.

3.4. Effects of IH on HRQoL after OR

A significant difference was found in three of eight domains of the questionnaire between HRQoL of patients with and without IH (Figure 3). Significantly higher values were obtained by patients without IH in the domains PF (IH: 65 (40–65) compared to w/o IH: 70 (45–90), $p < 0.05$), RP (IH: 25 (0–100) compared to w/o IH: 100 (25–100), $p < 0.05$) and RE (IH: 100 (100–100) compared to w/o IH: 100 (100–100), $p < 0.05$).

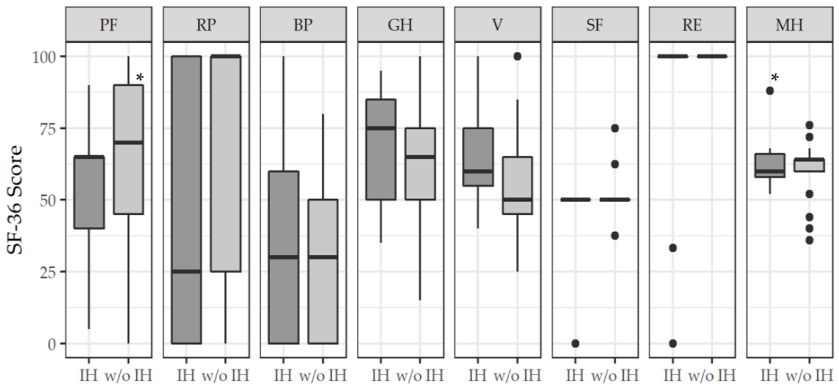

Figure 3. SF-36 score in patients after open repair of an abdominal aortic aneurysm. The health-related quality of life was assessed depending on the occurrence of incisional hernia (IH) compared to patients without incisional hernia (w/o IH), respectively. Data are given as median and IQR (25% and 75% percentile). Dots represent suspected outliers (≥1.5 IQR). Mood's median test. * $p < 0.05$ vs. IH. IQR: interquartile range; PF: physical functioning; RP: role physical; BP: bodily pain; GH: general health; V: vitality; SF: social functioning; RE: role emotional; MH: mental health.

4. Discussion

This retrospective single-center analysis found that the choice of surgical procedure for AAA repair did not differ in terms of HRQoL in EVAR and OR. In contrast, in patients after OR developing an IH the HRQoL is affected significantly.

In sense of patient-centered medicine, recording the effect of a specific therapy on patients is crucial [22]. A suitable method is the analysis of quality of life as subjectively experienced health from the patient's point of view [23]. With decreased morbidity and mortality in various treatment techniques, HRQoL became a more important parameter in clinical trials [18,24,25]. The SF-36 is currently the most widely used and fast performable questionnaire for surveying HRQoL [26]. Its reliability has been confirmed in several studies [27–29]. Answering the questionnaire takes an average of ten minutes. Due to its validity and reliability, the SF-36 has been recommended as the preferred questionnaire instrument for patients with vascular disease [29]. However, HRQoL is not an objectively measurable variable [18]. Still, in a long-term follow-up design of a retrospective study, it seems crucial to include HRQoL because reliable outcome parameters are scarce.

In the present study, a significant difference was only found in the domain MH of the SF-36 with lower values in patients after EVAR. In comparison, the EVAR group in the prospective DREAM study reached significantly higher HRQoL values than the OR group in the SF-36 domains PF, SF, and RP at three weeks postoperatively. In contrast, after twelve months, patients in the OR group revealed significantly higher scores in the domains PF, SF, RE, BP, and GH [30]. In the EVAR-1-trial, the early postoperative period of up to three months also showed slightly higher HRQoL in the EVAR group compared to the OR group. However, the results of the HRQoL survey after one to two years revealed no significant difference between the two groups [31]. The need for continuous follow-up due to the risk of endoleaks in EVAR patients, requiring additional interventions, was discussed as a factor affecting HRQoL in the DREAM study [18]. In contrast, no evidence was found in the EVAR-1-trial that post-interventional monitoring affected HRQoL after EVAR [31]. In the present study, all patients were recommended annual follow-up after surgery by physical examination and sonography. In comparison, endovascularly treated patients received a CTA within five days after EVAR. In the case of type II endoleak not requiring therapy immediately, CTA was repeated after six months. If no endoleak was detected, routine follow-up was performed by CTA 12 months after EVAR, followed by annual controls by sonography or CTA. Although the effects of follow-up assessments were not specifically investigated in this study, the more frequent CT examinations for endoleak detection after EVAR could have a long-term effect on quality of life, leading to the significantly lower scores in the domain MH in patients after EVAR.

High rates of endoleaks requiring close follow-up assessments and additional re-interventions are significantly more frequent when endovascular therapy is not performed within the manufacturer's instructions for use (IFU) of implanted stent-graft [32]. Thereby the most frequent reasons why patients are ineligible for EVAR are too short aortic neck length and too small diameters of the distal aorta and the iliac access arteries. In order to extend endovascular therapies for a broader range of aorto-iliac anatomies, new low-profile endografts have been developed [33]. Like the Ovation, these endostent grafts allow EVAR in patients whose vascular anatomy does not meet the IFU criteria of previous stent grafts. Therefore, it might be assumed that more frequent use of these low-profile devices, which are even eligible for aortic necks with a diameter of 0.7 mm, could lead to fewer endoleaks and in turn to fewer re-interventions. In this context, Zavatta et al. recently showed that the use of the Incraft (Cordis Corporation, Bridgewater, NJ) ultra-low-profile endograft revealed both sufficient technical success rates and freedom from re-interventions [34]. Similar positive results were recently reported in a retrospective analysis of the low profile endografts Ovation, Zenith LP, and Incraft [35]. This could also positively affect patients' quality of life.

In addition to follow-ups and re-interventions, the vascular access performed for EVAR also affects the quality of life. Surgical access to the common femoral artery was

performed for all EVARs in our study. Although percutaneous access was shown to be beneficial on complication rates, procedure time and hospital length of stay [36,37], its effect on patients' quality of life has not been extensively studied yet. However, it might be assumed that although percutaneous access could improve quality of life, this effect might only be evident in the early post-interventional phase and not in a long-term follow-up.

There are only a few studies with a follow-up time of more than one year. In the DREAM study, the HRQoL of patients was collected over 5 years, in another study the median was 5.2 years [15,29]. In the present work, the median time between treatment and collection of the SF-36 was 7.8 years after OR and 6.5 years after EVAR. As a limitation, it should be noted that due to the study design, the time between treatment and SF-36 assessment varied among patients, limiting comparability with data from prospective studies. Thus, the minimum time span was 3.6 years for both OR and EVAR and the maximum was 12.1 and 12.4 years for OR and EVAR, respectively.

Another important aspect is that all the patients studied suffer from other diseases besides abdominal aortic aneurysm, which could additionally affect the HRQoL studied. However, the comparison performed on concomitant diseases between the two groups revealed no differences except for the diagnosis of diabetes, arterial hypertension, and smoking, which were significantly more frequent in the OR group. Since this comparison is based on preoperative findings, it is possible that patients might have developed other concomitant diseases postoperatively. Due to the retrospective design of our study, no SF-36 survey before treatment is available to show a baseline HRQoL.

In this study, the incidence of complications and respective surgical or endovascular revisions differed markedly between EVAR and OR. Thereby both complications and revisions were more frequent after EVAR. A significantly higher proportion of complications and reinterventions were also observed in the EVAR-1-trial after EVAR. Here, 41% of the patients after EVAR had at least one complication, compared to 9% after OR. At least one reintervention was performed in 20% after EVAR but only in 6% after OR [31]. The lower complication and reintervention rate after OR in our study reflects this benefit of OR. However, the assessed HRQoL does not reflect this advantage relevantly.

No statistically significant difference was found with respect to gender distribution between EVAR and OR. However, patients in the EVAR group had a significantly higher mean age. This is in line with the general recommendation of national and international guidelines to prefer OR in younger healthier patients [3,14].

The occurrence of IH is usually assessed and documented during clinical follow-up. In our department, all patients after EVAR and OR are offered annual follow-up. However, only 63.9% of patients after OR attended such appointments. Therefore, it is still unclear whether the incidence of IH recorded in this study corresponds to the actual incidence. Although all patients were also asked about the occurrence of IH during the phone contact, it remains unclear, whether the patient-side assessment was correct. It is known that more than 30% of patients with IH were not aware of their presence. This observation involved especially older patients whose IH was small [38].

In our study, 30.6% developed an IH after OR. Comparable results were found by Musella et al., who found an IH of 31.7% after OR was [6]. In contrast, van Ramshorst et al. described an incidence of IH of only 20%. However, the median follow-up period of 1.3 years was short in this study [39]. In contrast, markedly higher incidences after OR were observed in two other studies with 59.4% [9] and 69.1% [8].

While most IH occurs within the first two years after surgery [40], the majority of IH develops in the first three postoperative years [39,40]. Consequently, a corresponding long-term follow-up is necessary [10,39,41]. In our study, the median duration after OR was 7.8 years. Due to the retrospective study design, the shortest period was 3.6 years after OR in two patients. However, even this time should have been sufficient to detect an existing hernia [42].

Several risk factors are associated with IH. In our study, no significant influence on the appearance of IH was found for any of the studied diseases. Another retrospective

study demonstrated that AAA patients with a BMI above 25 had a significantly higher risk for IH than patients with a BMI below 25. Both male sex and positive smoking history were not significantly associated with the occurrence of IH, as this was also found in the present study.

We found, a significant influence on HRQoL in patients with IH after OR in the three domains PF, RP, and RE of the SF-36. In the PRIMA trial, after a two-year follow-up period, HRQoL assessed by the SF-36 revealed no significant differences between patients with and without IH after median laparotomy in seven domains. Only in the domain PF, do patients without IH have significantly higher scores. In addition, patients with IH had significantly higher scores on the visual analog score for postoperative pain [43]. In another study, addressing the effect of IH on HRQoL and body image after open abdominal surgery by means of SF-36, after one year, patients with IH had significantly lower scores in the domains PF and RP than patients without IH [39]. Symptoms caused by IH range from aesthetic discomfort and skin problems to mild discomfort due to abdominal and lower back pain, constipation, pulmonary dysfunction, limitations in daily and work life, and serious complications such as obstruction, incarceration, and strangulation [39,44–47]. In contrast, half of the patients with IH are completely asymptomatic [38]. This circumstance might explain the unaffected domains of the SF-36 questionnaire in patients with IH in the present work.

Muysoms et al. found a highly significant reduction of IH after OR when a mesh was implanted compared to conventional fascia closure. After two years, the incidence of IH was 28% after conventional closure versus 0% after mesh insertion [48]. The AIDA trial also demonstrated a significant reduction in the incidence of IH with prophylactic mesh insertion. One year after OR, the incidence was 4.55% in the mesh group and 21.74% in the conventional closure group [49]. These results show that prophylactic use of mesh insertions after OR is an effective way to prevent IH.

Other studies reported mesh infections in almost 20% after hernioplasty [48,49]. However, data specific to the preventive use of mesh show that the rate of surgical wound infections does not differ significantly between patients with and without mesh insertion [50–52]. In the PRIMA study, the only disadvantage of mesh insertion was the incidence of intrabdominal abscesses, which occurred more frequently in the mesh group [53].

5. Conclusions

In summary, we found that occurrence of IH after OR revealed a significant impact on HRQoL. Further scientific evidence is needed to evaluate the impact of IH after OR on HRQoL more comprehensively. With a view on the ongoing development of low-profile and ultra-low-profile devices in recent years, studies on the HRQoL of these new, promising devices are needed to assess their impact on patients' quality of life. For this purpose, prospective studies with larger patient cohorts are needed. In the context of the present work, the importance of a continuous follow-up regarding both vascular complications and the documentation of late complications, such as IH, must be emphasized.

Author Contributions: Conceptualization, E.G., M.P. and J.G. (Johanna Gruel); methodology, E.G. and J.G. (Johanna Gruel); formal analysis, M.L.; investigation, J.G. (Johanna Gruel); resources, E.G.; writing—original draft preparation, J.G. (Johanna Gruel); writing—review and editing, E.G., M.P., M.W., J.G. (Justus Groß) and T.H.; visualization, M.L. and J.G. (Johanna Gruel); supervision, E.G.; project administration, E.G. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Ethics Committee of the Medical University of Rostock (protocol code A2020-0168; 28 July 2020).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data presented in this study are available on request from the corresponding author. The data are not publicly available.

Acknowledgments: The authors sincerely give their thanks to all patients who consented to take part in this study.

Conflicts of Interest: The authors declare no conflict of interest.

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Operation der Leistenhernie nach Desarda – Implementierung einer netzfreien Reparationsmethode an einer deutschen Universitätsklinik

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Inguinal Hernia Repair According to Desarda – Implementation of a Mesh-Free Method in a German University Hospital

Zusammenfassung

Die Operationstechniken zur Leistenhernienreparation weisen entsprechend der Statistik und den aktuellen Leitlinien eine deutliche Tendenz zum netzbasierten sowie laparoskopischen Vorgehen auf. Entgegen diesem Trend zeigen wir eine Operationsmethode zur netzfreien Reparation der Leistenhernie unter Verwendung von autologem Faszienmaterial zur Verstärkung der Leistenkanalhinterwand, wie sie von Desarda beschrieben wurde.

Einleitung

Die Entwicklung der operativen Versorgung der Leistenhernie hat in den letzten 20 Jahren in Deutschland bzw. Europa zur breiten Anwendung von alloplastischem Material und minimalinvasiven Implantationstechniken geführt. Statistische Datenbanken und Leitlinien spiegeln diese Tatsache wider [1]. Patienten äußern dennoch regelmäßig Bedenken gegenüber körperfremden Materialien, aber auch Umfragen unter den behandelnden Chirurgen belegen die Skepsis gegenüber der Verwendung von Implantaten, insbesondere in Hinsicht auf den postoperativen chronischen Leistenschmerz. Wir haben seit 2013 eine neue Operationsmethode zur netzfreien Reparation der Leistenhernie unter Verwendung von autologem Faszienmaterial zur Verstärkung der Leistenkanalhinterwand, wie sie von Desarda beschrieben wurde, an unserer Universitätsklinik implementiert. Im vorliegenden Video zeigen und erklären wir diese Methode.

Falldarstellung

Die Indikationsstellung für die Durchführung der ersten 20 Operationen nach Desarda erfolgte altersadaptiert sowie in Anerkennung der möglichen Ausbildung eines Rezidivs bzw. eines chronischen Schmerzsyndroms als die für uns wesentlichen Parameter der Nachbeobachtung. Weiterhin galt der Wunsch nach einem netzfreien Vorgehen durch den Patienten sowie eine Risikokonstellation in der Schmerzanamnese als Indikation.

In dem von uns im Video gezeigten Fall handelt es sich um einen 45-jährigen Mann mit einem linksseitigen reponiblen Leistenbruch ohne wesentliche Schmerzsymptomatik, der aufgrund von Sekundärliteratur einem netzbasierten Vorgehen skeptisch gegenüberstand. Bezüglich Komorbidität und individuellem Aktivitätsniveau bestanden keine Risikofaktoren.

Wir operieren Patienten regelhaft in Intubationsnarkose oder Spinalanästhesie, eine Therapie in Lokalanästhesie ist problemlos möglich, wurde aber von uns bisher für die Desarda-Methode nicht durchgeführt. Die geringe Anzahl der Operationen in Lokalanästhesie betrifft meist Patienten mit hohem kardiopulmonalem Risikoprofil, die für uns dann nicht für die selektionierte Versorgung in der Desarda-Technik qualifizieren.

Operationsverfahren

Das Verfahren nach Desarda wird vom Namensgeber selber publiziert [2–5] und propagiert. Studien aus anderen Arbeits-

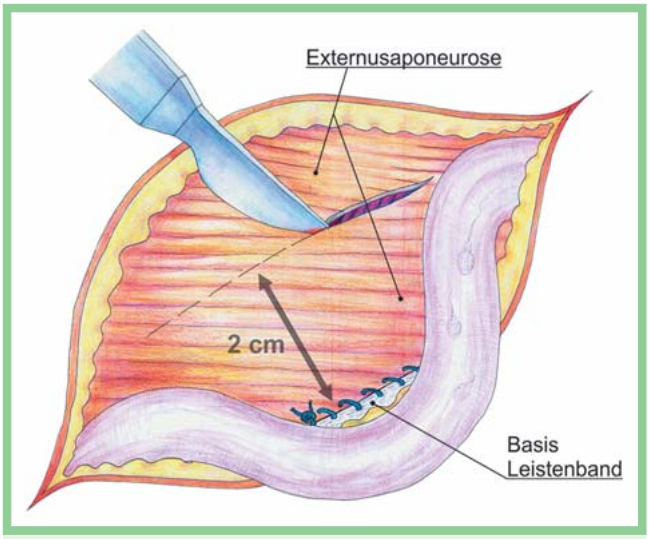

Abb. 1 Doppelpfeil zeigt kraniokaudale Ausdehnung des Faszienstreifens.

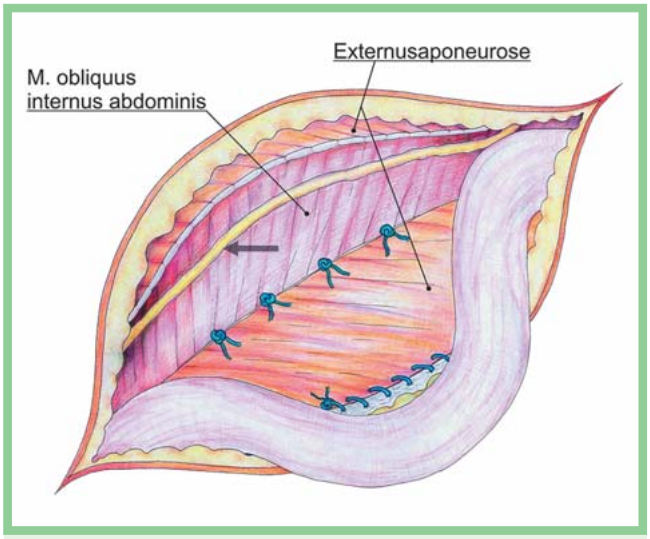

Abb. 2 Pfeil verweist auf N. iliohypogastricus.

Abstract

Inguinal hernia repair shows a clear tendency towards mesh-based as well as laparoscopic approaches. This is widely reflected in data-based statistics and guidelines. In contrast we have initiated and hereby illustrate the surgical method according to Desarda using autologous fascia to repair inguinal hernia.

gruppen lassen bisher nur eingeschränkte Aussagen zu den wesentlichen Parametern zu bzw. haben kurze Nachbeobachtungsintervalle [6–9]. Wir wollen dies in unserer Arbeitsgruppe aufgreifen und hierzu weiterführend publizieren.

Die wesentlichen Schritte der Präparation der Bauchwand mit Eröffnung des Leistenkanals sowie der Versorgung des Bruchsacks entsprechen den bekannten offen-chirurgischen Verfahren. Der entscheidende Teil der Operation besteht aus der Präparation und Verwendung eines Faszienstreifens der Aponeurose des M. obliquus externus abdominis zur Verstärkung der Hinterwand. Die Externusaponeurose wird zunächst an der Basis des Leistenbands fixiert (fortlaufend mit spätresorbierbarem monophilem Nahtmaterial [PDS2/0]). Dann erfolgt ca. 2 cm kranial die parallele Inzision der Faszie mit Bildung eines Streifens, der medial und lateral am originären Fasziengewebe verbunden bleibt. (**Abb. 1**) Der Oberrand dieses Streifens wird in Einzelknopfnahttechnik [PDS3/0] auf dem M. obliquus internus abdominis fixiert. (**Abb. 2**) Der Verschluss des Leistenkanals erfolgt mit dem de novo entstandenen Unterrand der Externusaponeurose an den freien Rand des Leistenbands und das weitere Vorgehen entspricht wieder den bekannten Techniken.

In den Publikationen von Desarda [2–5] wird zunächst die Verwendung nicht resorbierbaren Nahtmaterials beschrieben. Die Weiterentwicklung der Methode durch Desarda selbst führte dann zum Einsatz resorbierbarer Nähte [5]. Bezüglich der Nahtführung in fortlaufender bzw. Einzelknopftechnik wechseln in den vorliegenden Publikationen die Beschreibungen [2–5]. Wir haben unsere Methode an die Demonstration durch Desarda im Rahmen einer Liveoperation 2013 angelehnt.

Für uns ist die Verwendung spät resorbierbaren Nahtmaterials eine logische Folge einer netzfreien autologen Methode. Die fortlaufende Fixierung am Leistenband erzeugt die notwendige Stabilität. Der De-novo-Oberrand der Hinterwand ist wesentlich weniger mechanischem Stress ausgesetzt und die Durchführung von Einzelknopfnähten ist hier zur Vermeidung einer Nervenirritation (N. iliohypogastricus) sinnvoll.

Fazit

In Anlehnung an die von Desarda beschriebene und publizierte Methode haben wir im Februar 2013 begonnen, an der Chirurgischen Universitätsklinik Rostock nach entsprechender Patientenselektion diese Operation durchzuführen. Im Gegensatz zur derzeitigen Entwicklung der Hernienversorgung handelt es sich bei der Operation nach Desarda um eine gut zu erlernende und bei geeigneter Patientenselektion mit einer geringen Komplikationsrate durchführbare Methode. Unsere Implementierungsphase mit 20 operierten Patienten und einem Follow-up von 6 Monaten hat in unserer Klinik zu einer Ausweitung der Indikation und Verbreiterung der Anzahl der Operateure geführt. Das Wesen der Operation soll in dem Video demonstriert werden.

Der **Link zum Video**: http://www.tiny.cc/zbc_Video_4_2015

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DOI http://dx.doi.org/10.1055/s-1545865

Zentralbl Chir 2015; 140: 373–374

ISSN 0044-409X

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Quality of Life after Desarda Technique for Inguinal Hernia Repair—A Comparative Retrospective Multicenter Study of 120 Patients

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Abstract: Inguinal hernia repair, according to Desarda, is a pure tissue surgical technique using external oblique fascia to reinforce the posterior wall of the inguinal canal. This has provided an impetus for the rethinking of guideline adherence toward minimally invasive and mesh-based surgery of inguinal hernia. In this study, a retrospective analysis of this technique was conducted in two German hospitals. Between 6/2013 and 12/2020, 120 operations were performed. Analysis included patient characteristics, duration of operation, length of hospital stay, and perioperative complications. Data were used to achieve a matched-pair analysis comparing Desarda to laparoscopic transabdominal preperitoneal (TAPP) hernia repair. Propensity scores were calculated based on five preoperative variables, including sex, age, American Society of Anesthesiology classification, localization, and width of the inguinal hernia in order to achieve comparability. Additionally, we assessed pain level and quality of life (QoL) 12 months postoperatively. The focus of our study was a comparison of QoL to a reference population and TAPP cohort. The study population consisted of 106 male and 14 female patients, and the median age was 37.5 years. The median operation time was 50 min, and the median length of hospital stay was 2 days. At a follow-up of 17 months, the median recurrence rate was 0.8%, and two cases of chronic postoperative pain were recorded. Postoperative QoL does not significantly differ between Desarda and TAPP. In contrast, Desarda patients had a significantly higher QoL compared with the reference population. In summary, Desarda's procedure is a good option as a pure tissue method for inguinal hernia repair.

Keywords: Desarda; TAPP; pure tissue; inguinal hernia; quality of life

Citation: Philipp, M.; Leuchter, M.; Lorenz, R.; Grambow, E.; Schafmayer, C.; Wiessner, R. Quality of Life after Desarda Technique for Inguinal Hernia Repair—A Comparative Retrospective Multicenter Study of 120 Patients. *J. Clin. Med.* **2023**, *12*, 1001. https://doi.org/10.3390/jcm12031001

Academic Editor: Sergio Huerta

Received: 2 December 2022
Revised: 20 January 2023
Accepted: 24 January 2023
Published: 28 January 2023

1. Introduction

The repair of inguinal hernia has been modified in numerous ways over the last 100 years. Recent worldwide guidelines base their recommendations on meta-analyses and randomized control trials (RCTs), but they are still controversial [1]. The minimally invasive approach and mesh-based repair receive a strong recommendation, and it has become challenging to perform a mesh-free (pure tissue) technique in primary inguinal hernia regardless of sex, age, or other factors [2,3].

Despite guideline recommendations, the pure tissue repair of the inguinal canal has never lost popularity, especially in low-resource countries where mesh implants are rare and expensive, as availability is limited [4]. Nevertheless, even in high-income countries, there are still arguments for a renaissance of pure tissue repair, especially when addressing

the problem of chronic pain and the disadvantages of foreign body implants [5,6]. A tailored approach to inguinal hernia repair should include a mesh-free option.

A novel approach for mesh-free inguinal hernia repair was introduced by M.P. Desarda in 2001 [7]. The term pure tissue evolved and has led to an intense debate among hernia surgeons [5]. The first self-reported results of M.P. Desarda were promising but based on a single surgeon's experience [8]. In the course of defining a true pure tissue method, Desarda used only long-term resorbable sutures [9]. Since then, his intuitive technique has been characterized by the use of only autologous external oblique fascia and long-term absorbable sutures to stabilize the posterior inguinal wall in order to avoid chronic pain. This seems important, as numerous variations in inguinal hernia repair have been historically described and scientifically established, and even reinforcement strategies have used biological mesh material as pure tissue [10,11].

Although most well-trained hernia surgeons should be familiar with all techniques, we nowadays face the problem of the inferior ability to perform pure tissue procedures. [12]. Current guidelines propose Shouldice to be the preferred technique and state that Desarda needs further supporting data [1]. However, in the available studies, systematic reviews, and meta-analyses, Desarda is usually compared with Lichtenstein [13,14].

This study followed the implementation of Desarda's operation in a tertiary institution, as it was previously published by our group [15]. It was designed as a retrospective study that aimed to demonstrate equivalent results compared with a proven and established technique and was conducted at two German hospitals. The study evaluated perioperative parameters next to patient-reported outcomes measures (PROMs) in the context of quality of life (QoL).

2. Materials and Methods

Based on the description of M.P. Desarda and available publications, we introduced Desarda's repair in a tertiary hospital (Department of General, Visceral, Thoracic, Vascular and Transplantation Surgery, Rostock University Medical Center) in 2013 and extended it to a regional hospital in 2016 (Department of General and Visceral Surgery, Bodden-Kliniken Ribnitz-Damgarten). Anonymous data acquisition was based on patients' written informed consent and permission for registry participation. The retrospective cohort study was approved by the Institutional Review Board (A2022-0128).

On behalf of our own experience, we initially offered the treatment to selected patients, including males under 40 years and females under 50 years, as well as to patients who had risk factors for chronic pain or prejudices toward implants. After successful implementation of the method, we expanded the inclusion criteria.

A total of 120 patients underwent inguinal hernia repair according to Desarda. All cases were performed as elective surgery. Since TAPP is the standard procedure for inguinal hernia repair in our institutions, a mesh-based operated cohort was used as a benchmark.

2.1. Operation Technique

The technique was adapted from Desarda's description using long-term resorbable sutures only [9]. Following a conventional approach to the inguinal canal, an indirect hernia sac was ligated using Vicryl 2/0, preferably hiding the stump under the internal oblique muscle. A direct defect was minimized by gathering the transversal fascia using Vicryl 2/0. A relevant femoral hernia was precluded by digital exploration inferiorly of the inguinal ligament toward the vascular lacuna. The external oblique fascia was sewn using continuous PDS 2/0 to the basis of the inguinal ligament, starting at the pecten ossis pubis and continuing to the internal inguinal ring. A 2 cm wide strip of external oblique fascia was incised and left attached medially and laterally, thus forming a new posterior wall of the inguinal canal. The superior edge of the strip was fixed to the internal oblique muscle fibers using PDS 3/0, meticulously avoiding the hypogastric nerve.

2.2. Outcome Parameters

Parameters proving our assumption were the evaluation of the duration of the operative procedure, the learning curve, and the length of stay in hospital. Supplementary data reinforcing our study objectives were obtained by the associated hospital where this technique was implemented and later applied simultaneously.

The primary endpoint of the study was the rate of recurrence and PROMs, including pain level and quality of life (QoL), in the long-term follow-up. For QoL analysis, the validated German version of the EQ-5D Health Questionnaire was used. The EQ-5D descriptive system consisted of 5 dimensions (mobility, self-care, daily activities, pain or discomfort, and psychological state) in 5 levels (no problems, slight, moderate, severe, and extreme problems). We compared these items with their levels in a reference population that originates from an evaluation of a sample of 3552 persons [16] Numeric analog scales (NASs) were used to assess postoperative pain.

The follow-up was scheduled 12 months postoperatively and conducted either through compulsory postoperative appointment or postal questionnaire and included a survey regarding QoL. The survey was used and established in our institution with numerous other hernia patients [17]. Our reference cohort (TAPP) received follow-up questionnaire, including QoL survey, under identical conditions.

All postoperative complications were based on clinical symptoms and physical exam findings observed during the follow-up. Only if patients stated problems in their returned postal questionnaire were they invited for clinical examination.

2.3. Statistics

For continuous data with a normal distribution, means are presented with standard deviations. When data were not normally distributed, data are given as median with interquartile range (IQRs, i.e., 25th and 75th percentiles). The Kolmogorov–Smirnov test was performed to assess normality of data. The *p*-values for continuous outcome measurements with a normal distribution were calculated using the Kruskal–Wallis rank sum test. If data were not normally distributed, we used Mood's median test to analyze significant differences between study groups. The Fisher exact test or the χ^2 test was used to determine the significance of intergroup differences for categorical variables. Statistical reports and analyses were carried out using the statistic software "R!" [18]. Patients were matched using propensity scores incorporating multiple preoperative variables. To generate valid statistical comparison, we performed an exact matching. This technique matches each Desarda patient to all possible TAPP patients with exactly the same values on all the covariates. Hence, matched records will have identical characteristics except for their treatment status.

3. Results

3.1. Patient Characteristics

In the Desarda group, the median age was 37.5 years (range: 16–80) overall. For men, the median age was 38 years (range: 17–80), and for women, 32 years (range: 24–75). Compared with our standard group of inguinal hernia repair, the age was significantly different. In the TAPP group, the median age was 60 years (range: 19–87), clearly exemplifying our general patient recruitment. Median age was 60 years for males and 63 years for females (Figure 1).

Desarda's procedure was performed on 120 patients, 106 males (86.5%) and 14 females (13.5%). A total of 246 patients were treated by TAPP (210 male (84%), 36 female (16%), $p = 0.518$). The ASA score in the Desarda group was I ($n = 56$), II ($n = 52$), and III ($n = 12$). The median BMI was 24.7 (range: 19.1–37.1) in the Desarda group. TAPP-treated patients had a median BMI of 25.7 (range: 17.9–42.7); for the *p*-values, see Table 1. In the Desarda group, we included 62 cases of right-sided and 58 cases of left-sided inguinal hernia. The type of hernia was direct/medially in 40 cases, indirect/laterally in 71 cases, and combined in 9 cases. Half of all patients had a defect size of <1.5 cm, 50 1.5–3 cm, and 10 >3 cm.

Five patients in the Desarda group had had a prior operation and were classified as having a recurrent hernia.

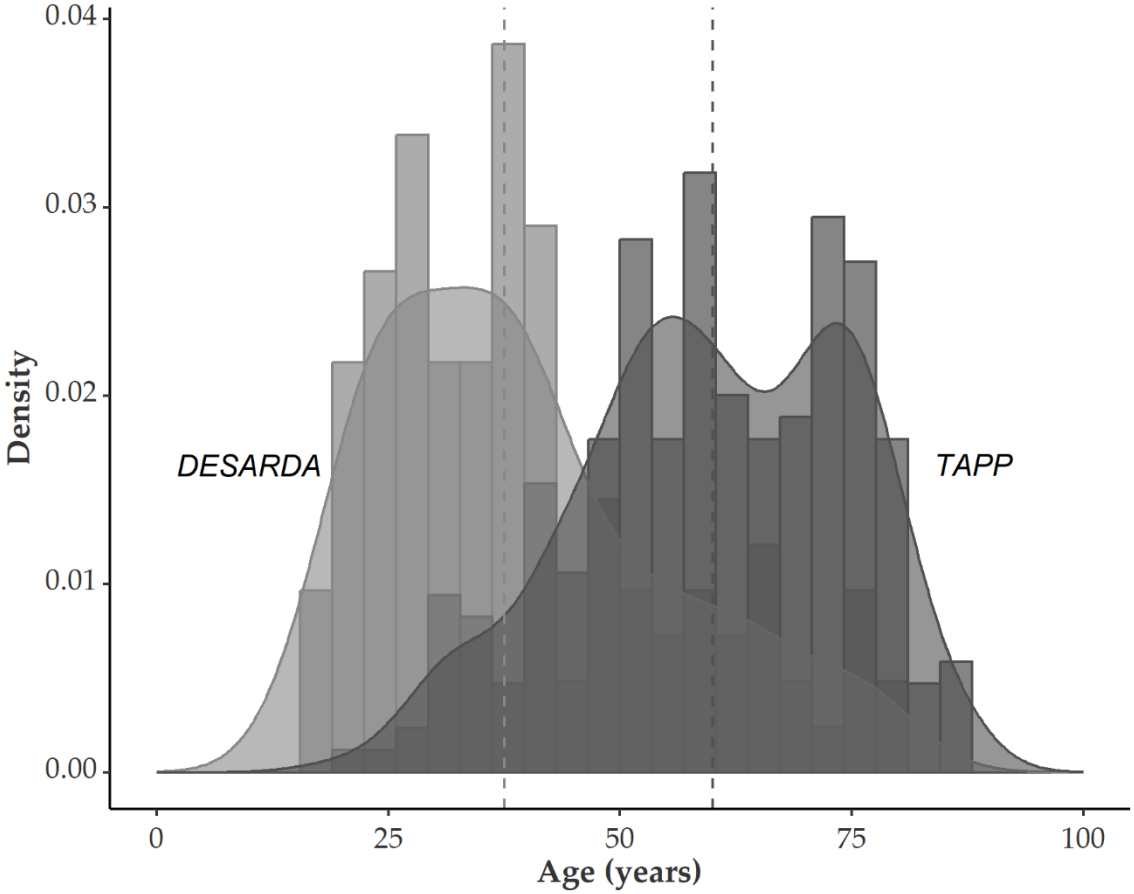

Figure 1. Distribution of age in patients undergoing inguinal hernia repair in our hospital, comparing transabdominal preperitoneal patch plasty (TAPP) to Desarda. The TAPP cohort reflects the age distribution of the patients in our tertiary hospital.

Table 1. Baseline characteristics of unmatched patient cohorts by operative method. Data are given as *n* (%) or median (IQR). Chi-square test or Mood's median test.

Characteristic	Desarda	TAPP	*p*
n	120	246	
Age	37.5 (26.8,49.0)	60 (51,73)	<0.001
Sex			0.518
Male	106 (88)	210 (85)	
Female	14 (12)	36 (15)	
BMI	24.6 (22.2,26.8)	25.7 (24.0,27.8)	0.126
ASA score (I/II/III/IV)	56/52/12/0	113/92/40/1	0.328
Hernia side (right/left)	62/58	127/119	1
Type of hernia			0.02
Medial	40 (33)	73 (30)	
Lateral	71 (59)	132 (54)	
Combined	9 (8)	41 (17)	
Defect size			0.007
<1.5 cm	60 (50)	85 (35)	
1.5–3 cm	50 (42)	145 (59)	
>3 cm	10 (8)	16 (7)	

TAPP: laparoscopic transabdominal preperitoneal; BMI: body mass index; ASA: American Society of Anesthesiologists Physical Status Classification System.

3.2. Perioperative Outcome

The duration of the operative procedure was 50 min (median) for Desarda repair (range: 30–87), which was significantly shorter than for the transabdominal preperitoneal patch plasty (TAPP) procedure (median, 60 min; range: 21–160; $p < 0.001$) (Figure 2).

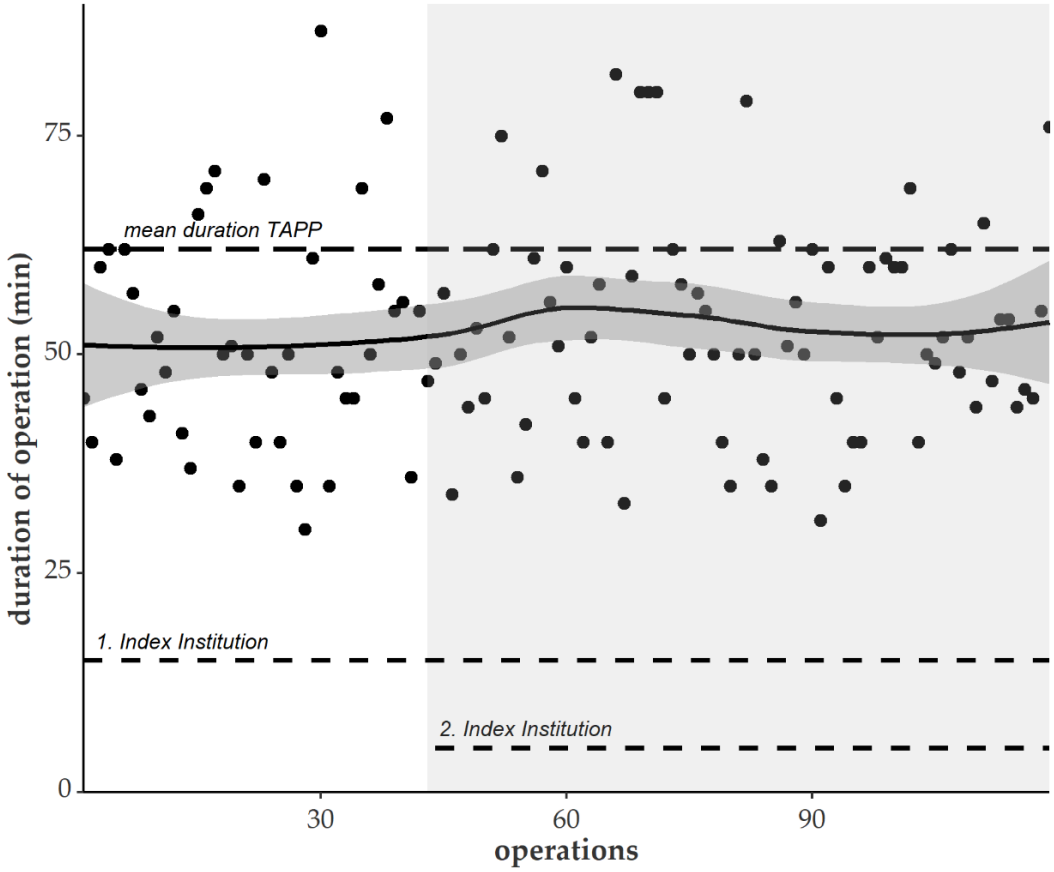

Figure 2. Correlation of operation time and number of procedures performed. The white area indicates single center results, and the area shaded light gray includes results from both hospitals. Dashed lines show mean duration of transabdominal preperitoneal patch plasty (TAPP) operation.

Desarda's repair was performed throughout all stages of teaching and learning and still outperformed routine inguinal hernia surgery. Involving additional trainees increased the length of surgery, but after about 80 operations, the mean time decreased and stabilized at 50 min (see above). Eventually, the procedure was accomplished by seven surgeons; three surgeons reached the level of teaching the novel technique to fellow colleagues.

The median postoperative length of stay at hospital was shorter after hernioplasty by means of Desarda at 2 days (range: 0–8) compared to TAPP at 3 days (range: 0–15).

3.3. Quality of Life

The matched-pair analysis equalized potential distorting parameters. Included matching predictors were age, sex, ASA classification, location, and defect size (EHS classification) of the inguinal hernia (Table 2).

The time span of follow-up regarding QoL after the treatment was 17 months (IQR 12–22). The index of QoL postoperatively was significantly better in patients who underwent Desarda before matching. When aligning QoL data in propensity score matching, these significant differences vanish. Figure 3 shows the EQ-5D questionnaire scores after matched-pair analysis. The median in the treatment group was 0.999 and 0.959 in the TAPP group, leading to a p-value of 0.149. Significant differences between the Desarda patients compared to the standardized reference population are verifiable.

Table 2. Baseline characteristics of matched patient cohorts by operative method. Data are given as *n* (%) or median (IQR). Chi-square test or Mood's median test.

Characteristic	Desarda	TAPP	*p*
n	98	143	
Age	43 (32.7,57)	43 (32.7,57)	1.000
Sex			1.000
Male	92 (94)	134 (94)	
Female	6 (6)	9 (6)	
BMI	25.1 (23.2, 26.8)	25.7 (23.8, 27,5)	0.359
ASA score (I/II/III/IV)	46/42/9	67/63/13	1.000
Hernia side (right/left)	51/47	73/70	0.896
Type of hernia			0.260
Medial	22 (22)	44 (31)	
Lateral	67 (68)	83 (58)	
Combined	9 (9)	16 (11)	
Defect size			0.993
<1.5 cm	52 (53)	76 (53)	
1.5–3 cm	43 (44)	63 (44)	
>3 cm	3 (3)	4 (3)	

TAPP: laparoscopic transabdominal preperitoneal; BMI: body mass index; ASA: American Society of Anesthesiologists Physical Status Classification System.

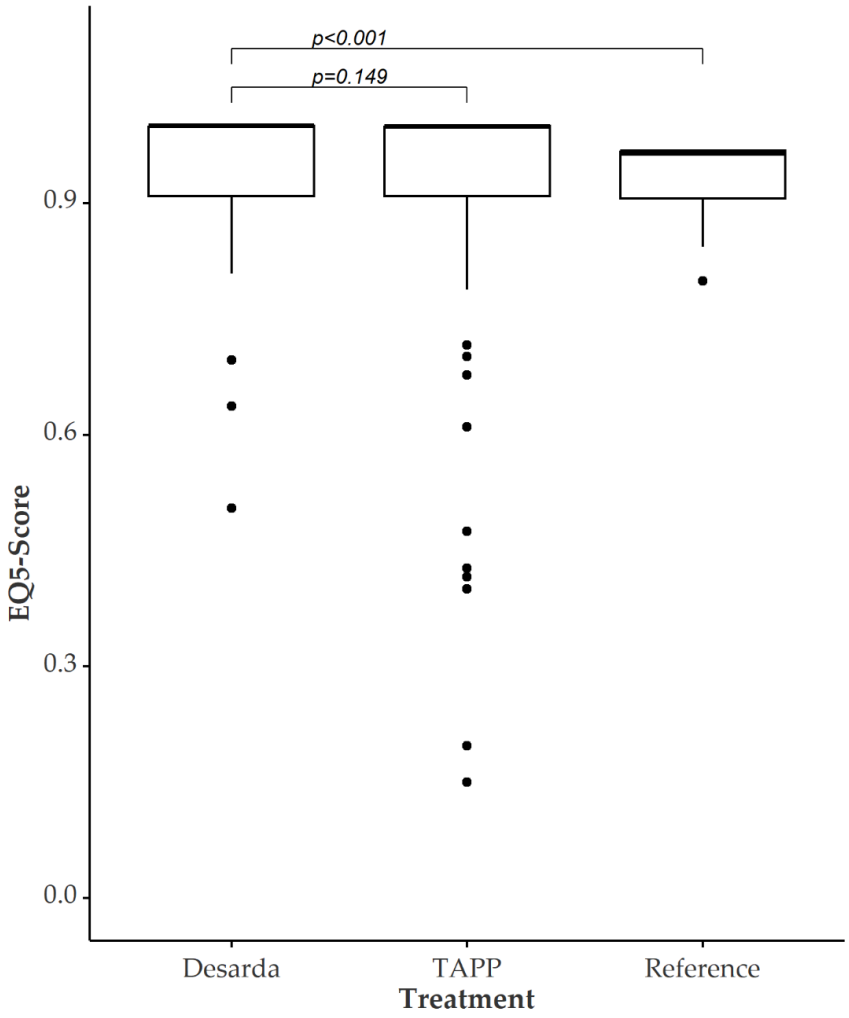

Figure 3. QoL after Desarda vs. TAPP vs. reference population after propensity score matching. *n* = 241 (Desarda = 98, TAPP = 143); data are given as median and IQR (25% and 75% percentile). Dots represent suspected outliers (≥1.5 IQR).

3.4. Follow-Up

In the immediate postoperative assessment, we found a significant ($p < 0.001$) higher pain level (NAS) on the first postoperative day in the Desarda group (4, IQR 2–5) compared with TAPP (3, IQR 2–3).

At a median follow-up of 17 months (range: 5–36), we found one recurrence (0.8%) and two patients with chronic (prolonged, >3 months) pain (1.7%) in the Desarda group. In one case, persisting pain could not finally be differentiated from preexisting hip arthrosis.

The extended questionnaire showed faster recovery after TAPP during the first 14 days after the operation. In addition, 50% of recovery (self-reported inability to work) was reached after 21 days following TAPP and 28 days following Desarda. After 60 days, 2% of the patients treated with the technique according to Desarda and 10% of the patients with a TAPP hernia repair were still unable to perform their work (Figure 4).

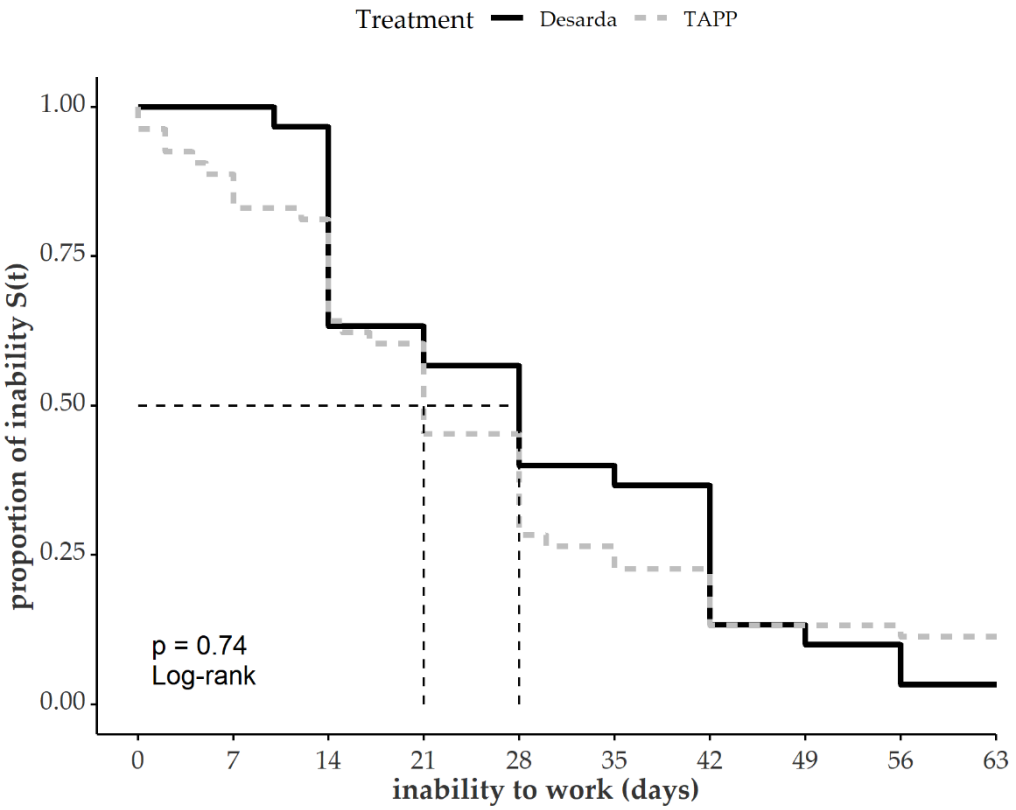

Figure 4. Self-reported time of inability to work after operation, $n = 83$.

4. Discussion

Reasons for renewed interest in pure tissue repair for inguinal hernia are numerous. There are persisting concerns associated with implanted hernia meshes regarding chronic postherniorrhaphy pain, visceral complications following minimally invasive and mesh-based techniques, as well as long-term uncertainties toward later surgical procedures, e.g., radical prostatectomy [19–21].

Nevertheless, the Hernia Surge Guideline states a weak recommendation for pure tissue inguinal hernia repair [1]. One problem could be the consistency and standardization of the surgical technique, which remains the main risk factor for the failure of mesh-free inguinal hernia repair [12]. Prospectively, the individual advantages and risks remain, and the idea of a tailored approach to hernia surgery might be exemplified by the discussion about pure tissue repair regarding Desarda's technique [22].

A systematic review including 14 randomized controlled trials (RCTs), though of a very heterogenous quality, overseeing 2791 patients concluded Desarda to be a valuable alternative to Shouldice with a need for further studies [23]. A few prospective and

comparative studies show comprehensible results and include a comparison to Lichtenstein repair or the Bassini technique but lack long-term follow-up [24,25]. The first prospective data comparing Desarda to Lichtenstein included a 3-year follow-up and was published by Szopinski et al. [26]. In the context of the discussion toward a renaissance of pure tissue inguinal hernia repair, a few questions remain unclear, especially the selection of patients and a reliable long-time follow-up [27].

Despite the rather minimal evidence, we introduced the method of Desarda's repair in our German university hospital in 2013 and initially reported preliminary results in 2015 [15]. The consecutive selection of suitable patients was originally intended to identify the ideal indication for a pure tissue technique in inguinal hernia repair, especially under the pressure and dominance of guideline-derived, mesh-based, and minimally invasive techniques in the Western world [10]. Our cohort study was designed to retrospectively follow up patients who underwent Desarda's repair in a standardized setting.

The considerable difference in median age in our Desarda and TAPP cohort led to a relevant longer length of stay. It was adjusted by using propensity score matching. A further prospective trial should eliminate this bias.

By applying QoL questionnaires, we were able to demonstrate comparable outcomes regarding patient comfort, and in particular, the short-term advantages of minimally invasive mesh-based (TAPP) repair were leveled out when looking beyond a 180-day follow-up survey. The postoperative self-reported return-to-work analysis was comparable to the data from Szopinksi et al., with 28 days as the median. In the same Polish study group, the recurrence rate was 2%, and the rate of chronic pain was stated at 4.8% [26]. We identified fewer patients with chronic pain when using Desarda's repair. From our knowledge, this study is the first to report on PROM and QoL after Desarda's repair.

Selecting suitable patients to offer the Desarda procedure was at the discretion of the surgeon and, therefore, affected the outcome of our study. We were not able to identify the ideal patient, but we also did not see an exclusion criterion in age, sex, or BMI. We found an increasing interest in mesh-free techniques. Therefore, it is a limitation of our study that it was not randomized. We see these results as a basis for initiating a prospective randomized trial.

5. Conclusions

In an observational study to introduce the operation according to Desarda's technique, we were able to show that the novel operation was successfully implemented. The results were equal, even in a low-volume prerequisite. This was underlined by an additional survey of the postoperative QoL, showing that Desarda was equal to TAPP and superior compared to the reference population.

Author Contributions: Conceptualization, R.W. and M.P.; methodology M.P. and R.W.; formal analysis, M.L.; investigation, R.L. and R.W.; resources, M.P.; writing—original draft preparation, M.P., R.W. and M.L.; writing—review and editing, E.G., M.P., R.W. and R.L.; visualization, M.L. and E.G.; supervision, C.S.; project administration, M.P. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Ethics Committee of the Medical University of Rostock (protocol code A2022-0128).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data presented in this study are available on request from the corresponding author. The data are not publicly available.

Acknowledgments: The authors sincerely give their thanks to all patients who consented to take part in this study.

Conflicts of Interest: The authors declare no conflict of interest.

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Hernia (2020) 24:1345–1359
https://doi.org/10.1007/s10029-020-02272-w

ORIGINAL ARTICLE

Alterations in the mechanical, chemical and biocompatibility properties of low-cost polyethylene and polyester meshes after steam sterilization

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Received: 14 May 2020 / Accepted: 17 July 2020 / Published online: 25 September 2020

Abstract

Introduction In Africa and other Low Resource Settings (LRS), the guideline-based and thus in most cases mesh-based treatment of inguinal hernias is only feasible to a very limited extent. This has led to an increased use of low cost meshes (LCMs, mostly mosquito meshes) for patients in LRS. Most of the LCMs used are made of polyethylene or polyester, which must be sterilized before use. The aim of our investigations was to determine changes in the biocompatibility of fibroblasts as well as mechanical and chemical properties of LCMs after steam sterilization.

Material and methods Two large-pored LCMs made of polyester and polyethylene in a size of 11 x 6 cm were cut and steam sterilized at 100, 121 and 134 °C. These probes and non-sterile meshes were then subjected to mechanical tensile tests in vertical and horizontal tension, chemical analyses and biocompatibility tests with human fibroblasts. All meshes were examined by stereomicroscopy, scanning electron microscopy (SEM), LDH (cytotoxicity) measurement, viability testing, pH, lactate and glycolysis determination.

Results Even macroscopically, polyethylene LCMs showed massive shrinkage after steam sterilization, especially at 121 and 134 °C. While polyester meshes showed no significant changes after sterilization with regard to deformation and damage as well as tensile force and stiffness, only the unsterile polyethylene mesh and the mesh sterilized at 100 °C could be tested mechanically due to the shrinkage of the other specimen. For these meshes the tensile forces were about four times higher than for polyester LCMs. Chemical analysis showed that the typical melting point of polyester LCMs was between 254 and 269 °C. Contrary to the specifications, the polyethylene LCM did not consist of low-density polyethylene, but rather high-density polyethylene and therefore had a melting point of 137 °C, so that the marked shrinkage described above occurred. Stereomicroscopy confirmed the shrinkage of polyethylene LCMs already after sterilization at 100 °C in contrast to polyester LCMs. Surprisingly, cytotoxicity (LDH measurement) was lowest for both non-sterile LCMs, while polyethylene LCMs sterilized at 100 and 121 °C in particular showed a significant increase in cytotoxicity 48 hours after incubation with fibroblasts. Glucose metabolism showed no significant changes between sterile and non-sterile polyethylene and polyester LCMs.

Conclusion The process of steam sterilization significantly alters mechanical and structural properties of synthetic hernia mesh implants. Our findings do not support a use of low-cost meshes because of their unpredictable properties after steam sterilization.

Keywords Inguinal hernia repair · Low cost mesh · Sterilization · Shrinking · Biocompatibility

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Introduction

With up to 20 million operations per year, inguinal hernia repair is one of the most frequently performed operations in general surgery worldwide [1]. Almost one third of all men and about 3% of all women can develop an inguinal hernia during their lifetime [2]. The prevalence of inguinal hernia is high in low income countries (LICs). Because the health care system in LICs is mostly underdeveloped and elective hernia repair is rare. Most repairs are performed as emergencies; the resulting mortality is as high as 40% [3, 4]. In addition, there are significantly more scrotal hernias in LICs than in higher-income countries (HICs), as most patients undergo surgery late. In these cases, a pure-tissue technique is often not feasible [5, 6]. Large hernia defects lead to the necessity of synthetic mesh reinforcement. On the one hand, these are unaffordable for large parts of the population, and on the other hand the implantation techniques often have not been learned by the few surgeons available in LICs [7–10].

The current HerniaSurge Guidline also focuses on the problem of surgery of inguinal hernias in LRSs [2]. The recommendations of the HerniaSurge Guidline apply to every patient worldwide. For most of the inguinal hernias the Lichtenstein-Technique with use of Low Cost Meshes under local anesthesia was recommended. The chemical and physical properties of the LCMs should be known.

While the studies carried out on patients show equivalent results in comparison to commercial meshes (CMs) [5, 11–13], other studies show inadequate results of the different LCMs after steam sterilization [14]. The LCMs from Ethiopia, Ghana and India tested by Mitura et al. shrink massively after sterilization at 121 °C and could therefore not be recommended for use in patients [14].

The aim of this work was to investigate the influence of steam sterilization at different temperatures on the mechanical and chemical properties as well as the biocompatibility of fibroblasts in two LCMs made of polyethylene and polyester.

Material and methods

Material

Two mosquito meshes made of polyethylene (Amsa Plastic, India) and polyester (Brettschneider Moskitonetze, Germany) were used for the mechanical, chemical and biocompatibility tests.

- **Low cost mesh** made of **polyethylene**, large-pored (1.5 × 1.9 mm), monophilic, lightweight (53.7 g/m^2) polyethylene mesh (Amsa Plastic, India). The mesh was kindly provided by Jessica Beard (M.D., M.P.H., Temple University, Philadelphia, USA).
- **Low cost mesh** made of 100% polyethylene terephthalate (**polyester**), large-pored (1.4 × 1.9 mm) with a weight of 30 g/m^2 (Brettschneider Moskitonetze, Germany).

The LCMs were cut to the size of 11 × 6 cm to represent the average implantation size of a mesh when using the Lichtenstein hernioplasty technique (Fig. 1a, b). The mosquito meshes were sterilized by steam sterilization at 100 °C (29 min), 121 °C (18 min) and 134 °C (5 min). For the 100 °C sterilization we used a steam sterilizer (NübyTM, Natural TouchTM, Monroe, Louisiana, USA), which is conventionally used for sterilizing baby bottles. This steam sterilization was also intended to represent, among other things, the situation of sterilization with limited resources (boiling of instruments as in the nineteenth century, occasional power failures) in remote regions in Africa or other LICs. The use of non-sterile polyester and polyethylene meshes as a control was essential for our investigations to detect any material changes caused by sterilization. Since fibroblasts quickly

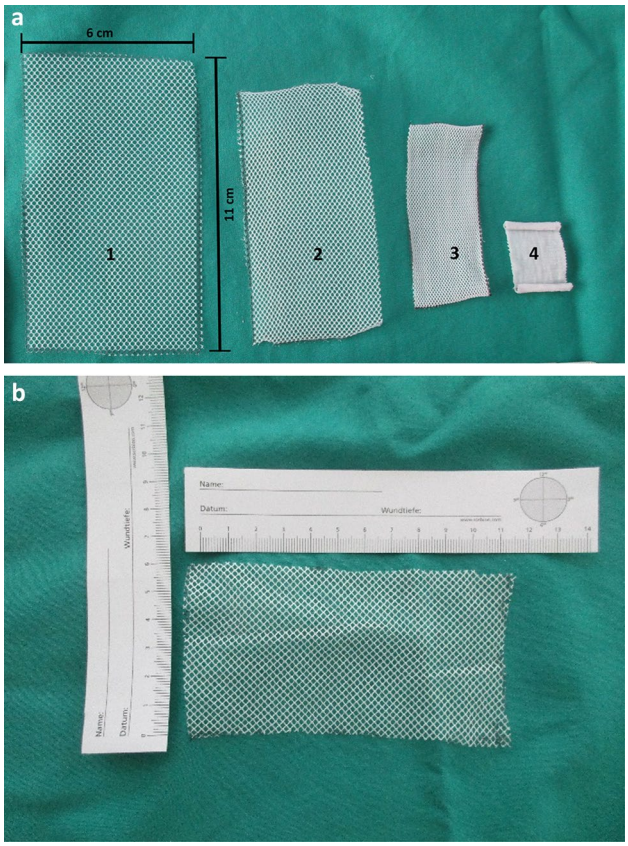


Fig. 1 Photograph **a** shows the 6 × 11 cm polyethylene mesh unsterile (**1**), after sterilization at 100 °C (**2**), 121 °C (**3**) and 134 °C (**4**). A significant shrinkage occurs already at 100 °C horizontally and vertically. At 134° C, no grid structure can be detected. Picture **b** shows a polyester (mosquito) mesh of 6 × 11 cm after sterilisation at 134 °C

contaminate in a non-sterile environment, the surrounding environment (nutrient medium) was mixed with antibiotics/antifungals. The unsterile meshes were also treated with an antibiotic and an antifungal agent. Penicillin/Streptomycin (100 × dilution; Sigma-Aldrich) was used as an antibiotic and Amphotericin B (250 µl/ml; PAN Biotech GmbH) as an antimycotic.

The following results are shown in the diagrams and figures as follows:

1. Polyethylene non-sterile
2. Polyethylene 100 °C
3. Polyethylene 121 °C
4. Polyethylene 134 °C
5. Polyester unsterile
6. Polyester 100 °C
7. Polyester 121 °C
8. Polyester 134 °C

For the biocompatibility tests, 10 × 10 mm pieces of meshes were punched out of the first cut pieces of mesh and then placed in the reservoirs of a 12-well cell culture plate (Biochrom AG, Berlin, Germany) without wrinkles [15, 16].

Mechanical testing

Tensile tests were performed for both materials: both as unsterile and also following their different conditions of sterilization. Rectangular specimens were cut from the mosquito meshes. A schematic drawing of the specimen size and the characteristic measures of the clamping facility is given in Fig. 4a. The specimens were cut from the mesh in two orthogonal orientations (*O1* and *O2*) to investigate the influence of the orientations of the fiber (mesh) structure in relation to the loading direction. At least four specimens were tested for each condition ($2 \times n = 4$). A uniaxial servo hydraulic testing machine INSTRON 8800 (Instron, USA) with a total actuator stroke of 150 mm was used for the tests. The forces were measured with a HBM load cell U2A (Hottinger Baldwin Messtechnik, Germany) load cell with a load range of ± 500 N. The tests were performed in position control mode with an actuator velocity of 1 mm/min. Each specimen was clamped with the same clamping pressure, since the screws of the clamping mechanism were tightened at the same moment. Additionally, the tests were documented with an industrial 5MP monochromatic camera (isi-sys GmbH, Germany) which was controlled by the software VIC-Snap (correlated solutions, USA).

Chemical analyses

The chemical composition of the meshes was identified using differential scanning calorimetry, microtome section and infrared (IR)-spectroscopy. Sample preparation: the meshes were cut to a size of 2 cm^2 and analyzed using a headspace preparation ($n = 1$).

Differential scanning calorimetry

The samples were characterized for their thermal properties using differential scanning calorimetry analysis (Mettler Toledo DSC823e, Switzerland). The samples were heated under a flow of dried air from 30 to 190 °C at 10 °C/min, cooled down to 30 °C at 20 °C/min and subsequently heated for a second cycle up to 300 °C at 5 °C/min.

Microtome sections

Suitable microtome sections were photographed at variable magnification (10 ×, 20 × or 40 ×) by means of a Leica DMLS microscope and a Leica EC3 camera (Leica Biosystems, Germany).

IR-spectroscopy

The infrared spectra were collected by a Nicolet 380 FT-IR spectrometer (Nicolet™, USA) with a Smart Orbit ATR diamond accessory (30,000–200 cm^{-1}) at room temperature.

IR parameter:
Number of scans: 32.
Scan width: 4.000–525 cm^{-1}.
Resolution: 4 cm^{-1}.

Biocompatibility research methods

We have already described in detail a large proportion of the test methods we used (Scanning Electron Microscopy (SEM), cytotoxicity/LDH, pH-value determination and glycolysis test) and would like to refer to our explanations [15, 16]. One analysis per parameter was performed ($n = 1$).

Fibroblasts

We cite our earlier, detailed remarks [15, 16]. To study the biocompatibility properties of the meshes, tissue-specific human fibroblasts were available. Fibroblasts synthesize the components of the intracellular substance, the matrix and

the fibers. They are in the organism both in the developing and growing connective tissue, as well as in the differentiated loose connective tissue. For culturing the cells, a section of approximately 30 mm^2 of sub-epithelial tissue from female donors was used. Each individual tissue sample was divided into three to four smaller segments and prepared with enzymes with collagenase (PAA; 3–4 h; 37 °C). Subsequently, the sample was cultivated in culture medium flasks (culture surface area 25 cm^2, Sarstedt) until a monolayer formed. An ethics committee approval by the University of Rostock is available.

Stereo microscopy and scanning electron microscopy for the end-point determination

We used scanning electron microscopy and, in addition, stereomicroscopy to visualize the structures of materials. Before incubation with fibroblasts, the different LCMs were examined by means of a stereomicroscope (Stemi DV4, Fa. Zeiss, Jena, Germany). This review was carried out by co-author Dagmar-Ulrike Richter (Research Laboratory of the University Women's Hospital, University Medicine Rostock). At the end of the long-term experiment (12 weeks), scanning electron microscopy (SEM) was used to determine the endpoint [15, 16]. We refer to our earlier detailed test descriptions [16].

Biochemical assays of the biocompatibility

It is known that biomaterials can be cytotoxic if cell damage occurs during their use. Therefore, the determination of cytotoxicity and viability is an integral part of testing for biocompatibility of materials.

Viability test (mitochondrial activity of fibroblasts)

The CellTiter-Glo® Luminescent Cell Viability Assay (Promega Corporation, Madison USA) is a cell-based assay for the detection of cell viability. The principle is based on the measurement of the ATP content in an ATP-dependent luciferase reaction. The determined ATP content is a measure for metabolic cell activity. The conversion of luciferin by means of a recombinant luciferase (Ultra-Glo™Luciferase) produces oxyluciferin and light. The strength of the light signal is measured with a luminometer (Promega Glomax Multi Detection Microplate Reader) and is proportional to the number of living cells. The measurements were performed with the respective mesh materials after 48 h incubation. This incubation time was derived from previous pilot studies from which it is known that fibroblasts react very quickly to foreign materials.

Cytotoxicity testing (LDH; Roche)

In this study, the cytotoxicity was analyzed using the Roche ELISA KIT. The ubiquitous LDH is very well suited for this testing procedure, not only because of its stability in the culture medium; an additional aspect is its resistance to proteases and its sufficient quantity in the target cells. We refer to our earlier detailed test descriptions [15].

Metabolism of the cells

pH value determination

The pH value analyses were performed with the ORION 3 STAR electrode (Fa. Thermo Scientific) in the cell culture supernatant. The pH reference value corresponded to the pH value of the pure culture medium (medium + fetal calf serum + antibiotics). After the addition of cells and wetting samples, a pH value difference of 0.30–0.45 arose from medium change to medium change, which is caused by metabolic processes in the cells. This pH value change remained constant the entire time. The measurement was performed after 48 h incubation time. Here we refer to our earlier, detailed remarks [16].

Glycolysis

The determination of the extracellular glucose content in the cell culture supernatant is a measure for the glycolytic degradation of glucose in the cells. If the glucose content is lowered, this indicates that the cell's metabolism is good. If the cell is decomposed, there is an increase in glucose in the cell culture supernatant. The glucose analyses during the network contact provide an indirect indication of cell vitality. Here we refer to our earlier, detailed remarks [16].

Lactates

Lactate is the salt of lactic acid and is formed when, during intensive exercise, contact is made with mesh material. In this case, the oxygen absorbed via cell respiration is no longer sufficient to cover the energy requirement. This means that the normal aerobic metabolism is no longer sufficient to produce energy, and consequently, anaerobic metabolism increases (glycolysis). This then results in increased lactate.

Principle: enzymatic LOD method L-lactate is oxidized by lactate oxidase (LOD) to pyruvate and hydrogen peroxide (H2O2). The reaction of peroxidase (POD), hydrogen peroxide (H2O2), 4-aminoantipyrine (4-AA) and a hydrogen

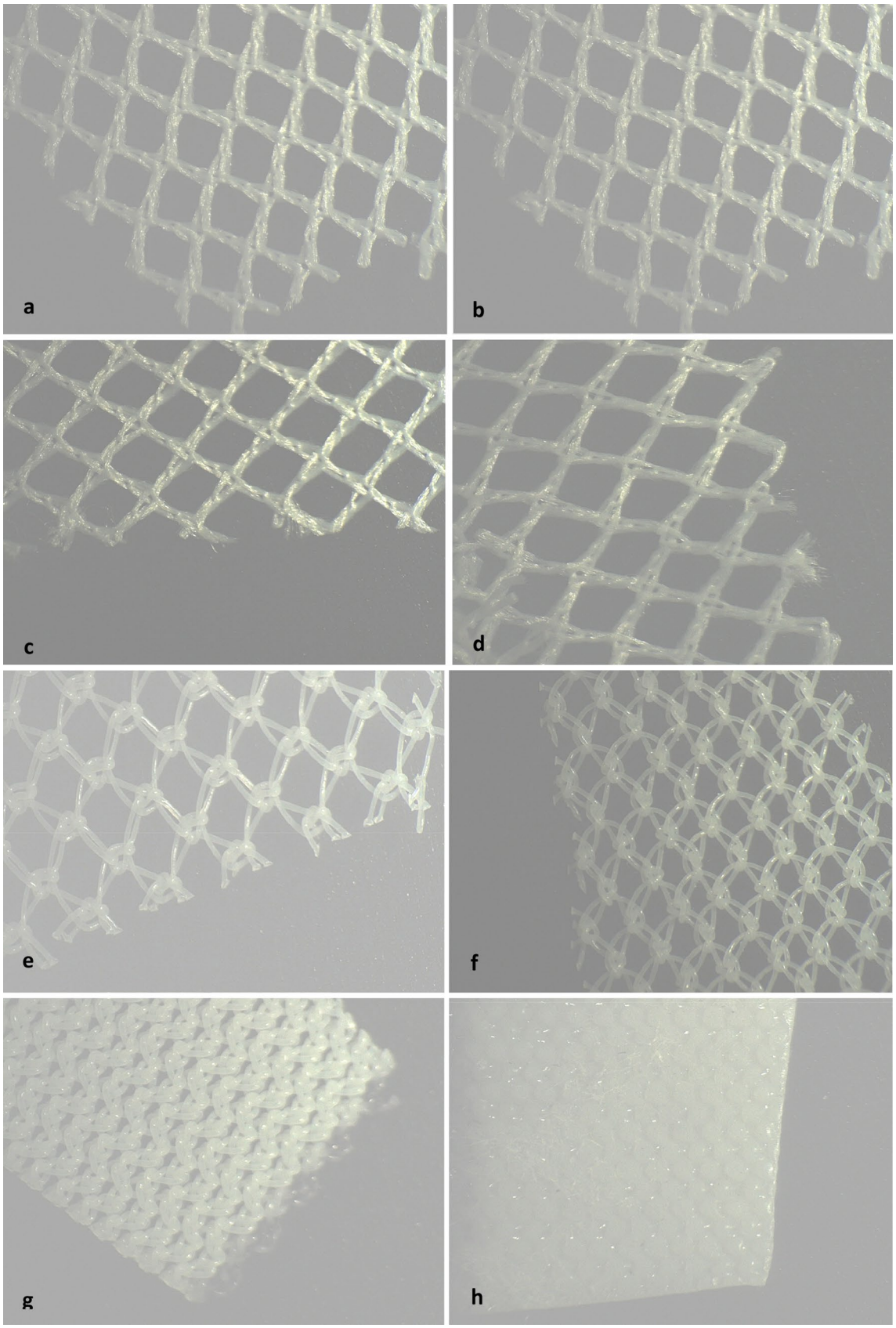
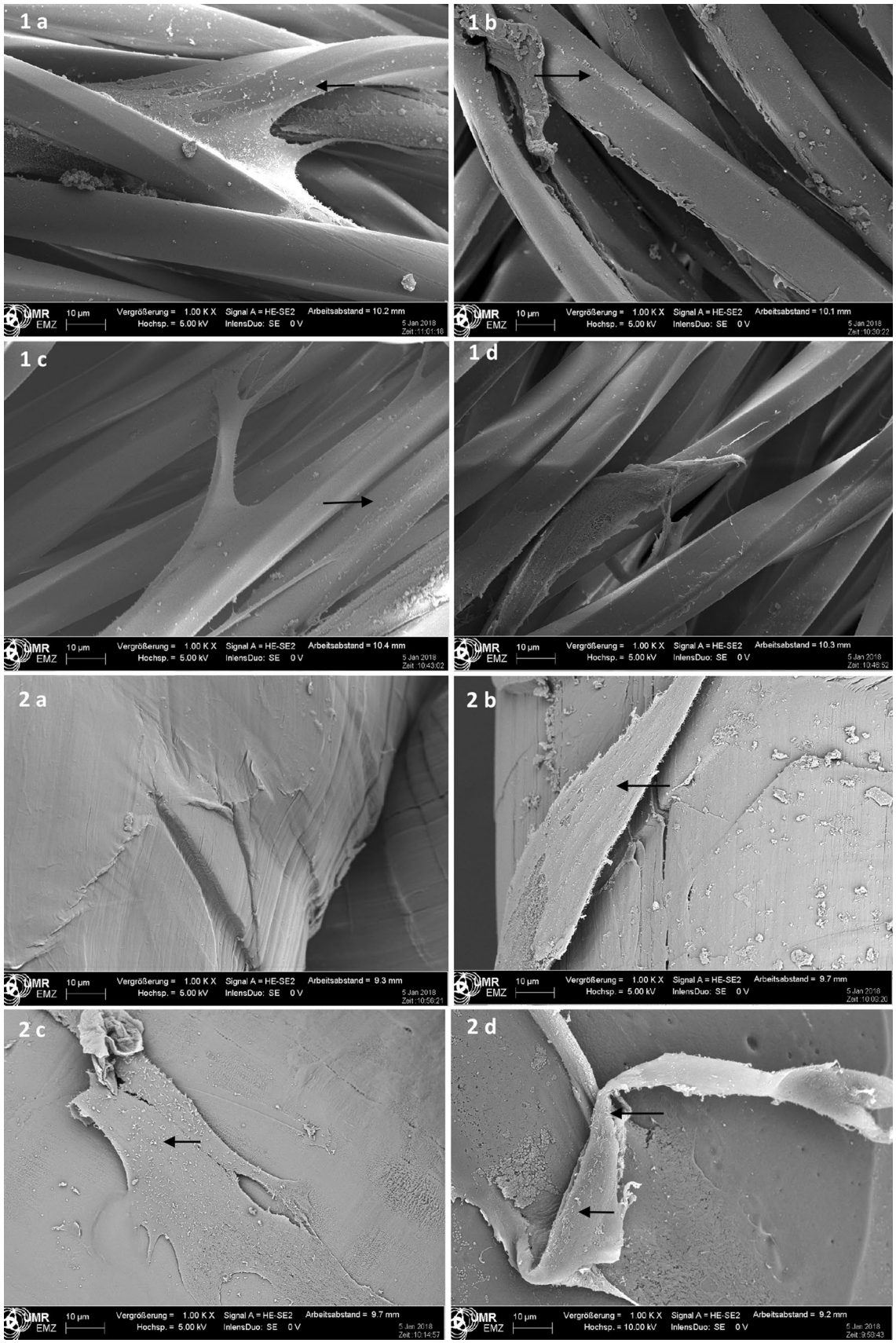


Fig. 2 Stero microscopy (40×magnification) of polyester LCMs: **a** unsterile; **b** sterilized at 100 °C; **c** at 121 °C; **d** at 134 °C. Stero microscopy (40×magnification) of polyethylene LCMs: **e** unsterile; **f** sterilized at 100 °C; **g** at 121 °C; **h** at 134 °C. *LCMs* low-cost-meshes


1 a
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2 d

◂**Fig. 3** Scanning electron microscopy 12 weeks after incubation with fibroblasts at polyester (**1**) and polyethylene (**2**) LCMs. **1**. **a** unsterile; **b** sterile at 100 °C; **c** sterile at 121 °C; **d** sterile at 134 °C. **2. a** unsterile; **b** sterile at 100 °C, **c** sterile at 121 °C. a **d** sterile at 134 °C . *LCMs* low-cost-meshes

donor (H-donor) produces a colored product. The intensity of the color is proportional to the lactate concentration.

1. $L-\text{lactate} + O_2 \longrightarrow LOD_{\text{pyruvate}} + H_2O_2$
2. $H_2O_2 + 4-AA + H-\text{donor} \longrightarrow_{POD} \text{chromogen} + 2\,H_2O$

Just like the glucose determination, lactate analyses were carried out in cell culture supernatants. Beckman Coulter (Beckman Coulter GmbH; Krefeld; Germany) was used for the lactate measurements. Double determinations were also performed here. As with glucose, the lactate analysis was performed after 48 h incubation time.

Results

Macroscopy and microscopy

Even macroscopically, a shrinkage of the polyethylene LCMs after steam sterilization can be observed (Fig. 1a). The polyethylene mesh showed a slight shrinkage of the meshes by about 1/3 in width and 1/5 in length even at only 100 °C. At 121 °C the polyethylene mesh structure is still visible, but extremely deformed. The meshes have shrunk considerably. It has a stiff and polygonal consistency. At 134 °C the mesh structure is no longer visible (Fig. 1a, 2 h). On the other hand, the macroscopy and stereomicroscopy at 40 × magnification showed no structural changes in the polyester LCMs after sterilization compared to the unsterile mesh (Fig. 1b and 2a ,b, c, d).

The stereomicroscopy of unsterile and sterilized (100 °C) polyethylene LCMs showed a good mesh structure with a slight shrinkage (Fig. 2e, f). After sterilization at 121 °C the mesh structure is still visible, but extremely deformed and has shrunk considerably. It showed a distinct alteration of the fiber-texture (Fig. 2g). After sterilization at 134 °C the mesh structure is no longer visible and the fibers agglutinated. The haptic aspect of the mesh is a rigid consistency with sharp edges (Fig. 2h).

The SEM of the polyester LCM showed a moderate, heterogeneous growth of fibroblasts on all meshes, independent of the sterilization procedure. A complete closure of the meshes by proliferating fibroblasts could not be detected 12 weeks after incubation. All polyester LCMs showed a good thread structure with moderate heterogeneous growth of fibroblasts. The unsterile and the polyethylene LCM sterilized at 100 °C showed a delicate, thin fibroblast growth. The polyethylene LCMs sterilized at 121 and 134 °C showed a very thin growth of fibroblasts while the net structure was lifted (Fig. 3).

Mechanical testing

Polyester

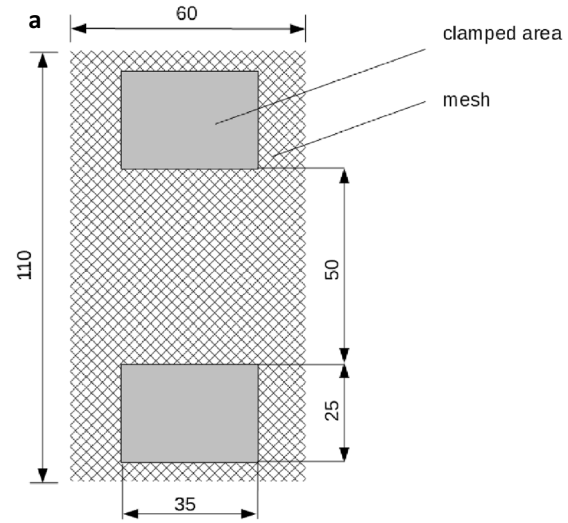
Deformation and damage The polyester meshes showed a significant contraction during the tests; see Fig. 4b. Since the clamping prevents the contraction, the fibers in this region are highly stressed. The failure always initiated close to the clamping region. Failure of fibers in the other regions of the specimens could not be observed macroscopically.

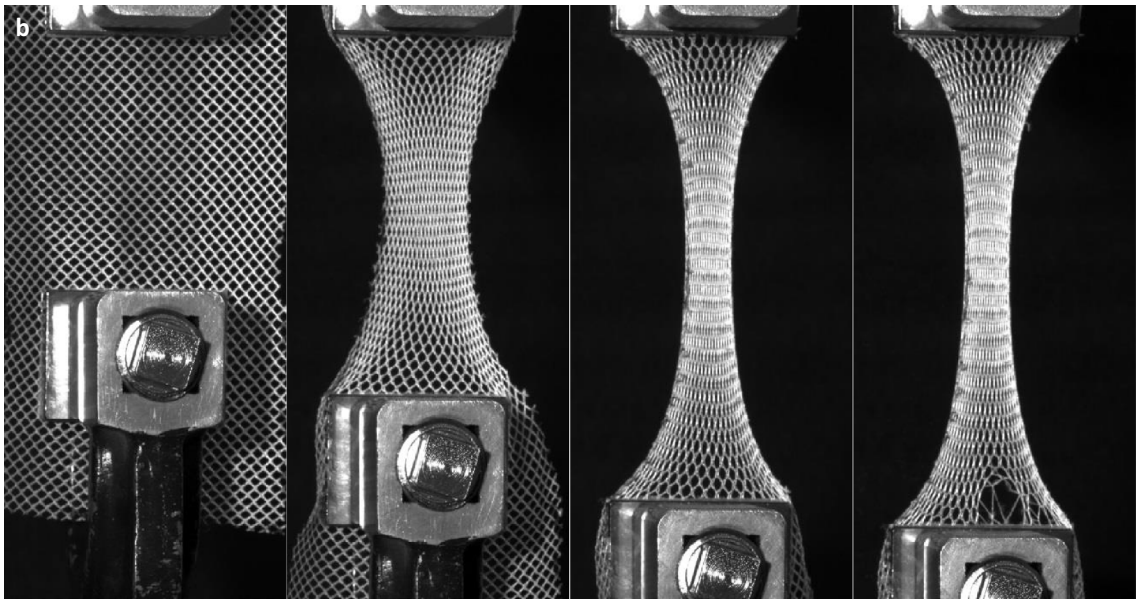
Tensile force and stiffness Figure 4c shows the force–displacement curves for unsterilized meshes and after sterilization at 134 °C. At the beginning of the test, the force does not increase. After a few millimeters of elongation, the force increases progressively until it reaches a certain slope. The slopes of the different specimen are quite similar. It must be noted that the curves have a distinct linear region. The stiffness is quite constant until the specimen fails. The average slope/stiffness is approximately 3.7 N/mm. After reaching a maximum, the tensile forces decrease significantly due to failure of several fibers. The direction in which the specimen were taken from the basic mesh (orthogonal directions designated as *O1* and *O2* in Fig. 4c, e) showed no significant influence on the mechanical behavior. The meshes are thus equally strong, both vertically and horizontally.

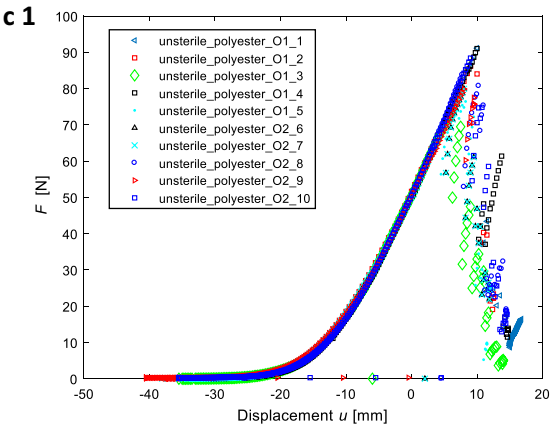
Table 1 gives an overview on the variation of the maximum tensile force for all tested specimen. The sterilization at 100 °C leads to a decrease of the maximum tensile force. For the other three conditions the maximum, minimum and the arithmetic mean value do not differ significantly. However, for "100 °C" all values are approximately 10 N lower than for the other conditions. The standard deviation is significantly higher for the sterilization at 100 °C than for the others.

Polyethylene

Deformation and damage Two differences could be observed during the polyethylene tests in comparison to the polyester tests. First, the polyethylene specimen does not contract as much as the polyester specimen during the tests. Second, the initiation of failure is not only limited to the clamping region (compare Fig. 4d, arrows) from a macroscopic point of view. However, the final failure of the specimen is also based on the failure of multiple fibers in the clamping region.







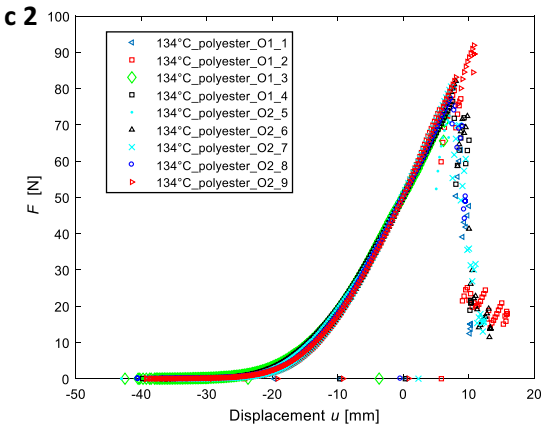


Fig. 4 **a** Schematic illustration of the specimen and clamping at the beginning of the tensile tests. **b** Typical deformation and damage behavior in the unsterile polyester mesh. **c** Force–Displacement curves of polyester: one unsterile; two sterilized at 134 °C. (*O1* and *O2* designate two orthogonal directions in which the specimen were cut from the basic mesh) **d** Typical deformation and damage behavior in the unsterile polyethylene mesh. **e** Force–Displacement curves of polyethylene: one unsterile; two sterilized at 100 °C. (*O1* and *O2* designate two orthogonal directions in which the specimen were cut from the basic mesh)

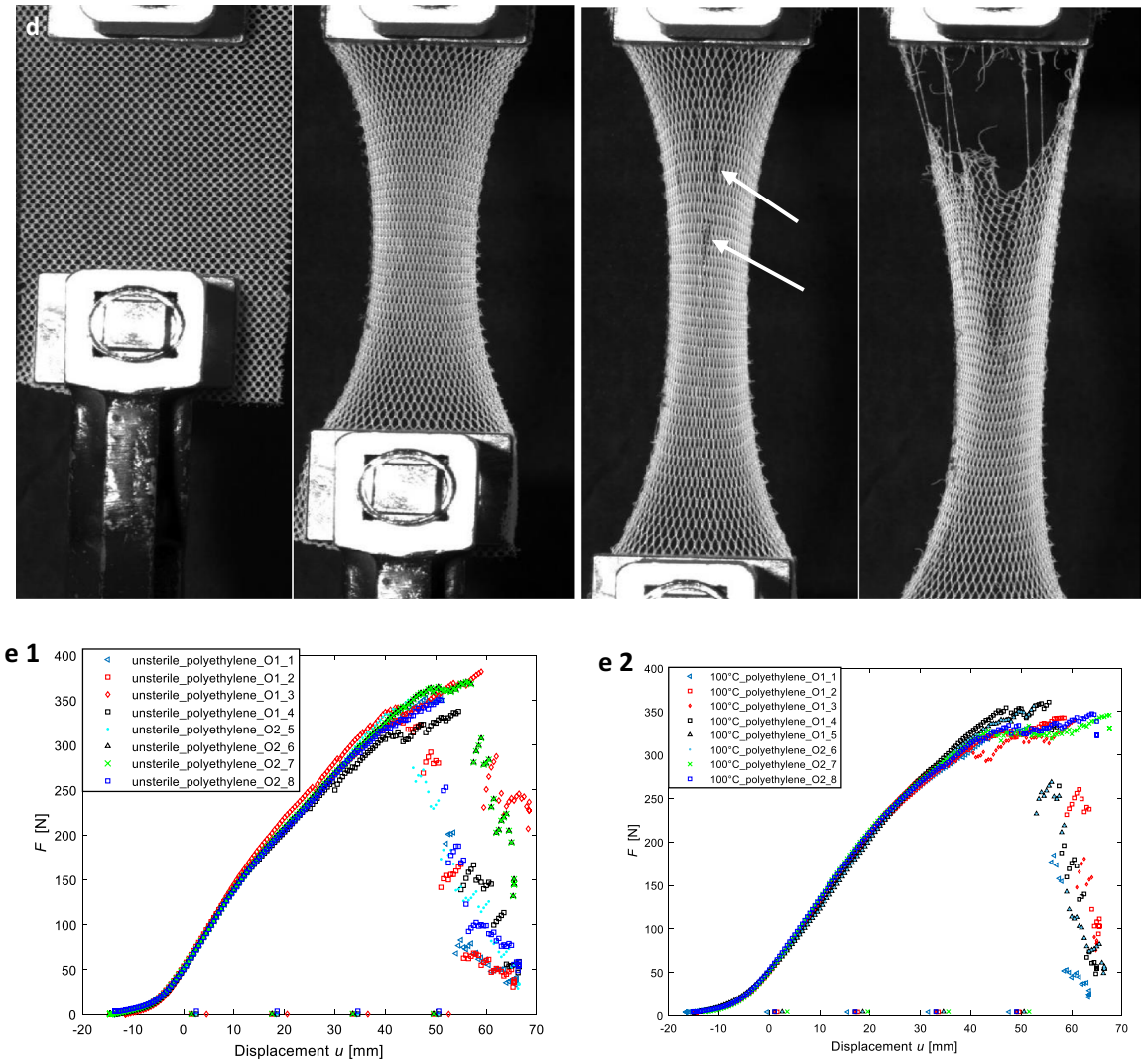


Fig. 4 (continued)

Table 1 Overview of the maximum tensile forces for all tested polyester specimens

	Unsterile	100 °C	121 °C	134 °C
Maximum value	91.1	84.8	90.8	91.9
Minimum value	74.1	60.8	73.8	72.5
Artihmetic mean	84.0	72.2	81.0	79.4
Standard deviation	5.8	8.3	6.0	5.4

All values given in [N]

Table 2 Overview of the maximum tensile forces for all tested polyethylene specimens

	Unsterile	100 °C
Maximum value	381.8	361.1
Minimum value	329.2	336.9
Artihmetic mean	356.7	347.3
Standard deviation	18.0	7.1

All values given in [N]

Tensile force and stiffness Figure 4e shows the force–displacement curves for the tests of the unsterile specimen and the sterilized specimen at 100 °C, respectively. The curves of both diagrams correlate quite well. The maximum tensile forces are approximately four times higher than for the polyester specimen. Another difference in the results for polyethylene is that the slopes of the curves are not constant, but the slopes show a declining characteristic until the maximum force is reached. After the force has reached its maximum value, multiple fiber failures occur (compare Fig. 4d). However, there is a linear region for forces up to approximately 200 N. The average stiffness in the linear region is about

Table 3 Results of the chemical tests

Sample name	Deformation	Melting point/ transition [°C]	Identified materials
Polyethylene unsterile	No	137	HDPF
Polyethylene 100 °C	No	137	HDPF
Polyethylene 121 °C	Yes	137	HDPF
Polyethylene 134 °C	Yes	–	HDPF
Polyester unsterile	No	256	PET
Polyester 100 °C	No	256	PET
Polyester 121 °C	No	254	PET
Polyester 134 °C	No	259	PET

8.8 N/mm, which is more than twice the stiffness of the polyester specimen.

Table 2 gives an overview of the variation of the maximum tensile force for all tested specimens, where the maximum, minimum, arithmetic mean value and standard deviation for the maximum tensile force are listed. The standard deviation for the unsterile specimen is significantly higher than for the specimen sterilized at 100 °C. The minimum and the arithmetic mean values are quite similar, while the maximum value is higher for the unsterile condition.

Chemical testing

All meshes are produced as monolayers. The polyester LCM has a characteristic melting point for polyethylene terephthalate (PET) in a range of 254–269 °C. Therefore, no deformation (shrinkage) during sterilization is observed. The LCM made of polyethylene does not consist of low-density polyethylene but rather of high-density polyethylene with a characteristic melting point of 137 °C (Table 3). The polyethylene mesh sterilized at 134 °C was not suitable for microtome section due to massive shrinkage.

The characteristic vibrational bands in the IR spectra confirm the chemical composition of the meshes (Fig. 5).

Biocompatibility of fibroblasts

The measurement of the viability of the fibroblasts 48 h after incubation showed no significant changes between the unsterile and sterilised meshes. The vitality of the fibroblasts was greater than 80% in all meshes. Interestingly, compared to the unsterile meshes, both the sterilized polyester and polyethylene meshes showed a lower mitochondrial activity (Fig. 6a). The LDH measurement also showed the lowest cytotoxicity for both unsterile LCMs, while in particular the sterilized polyethylene meshes with 18.35% (polyethylene LCM 100 °C) and 16.0% (polyethylene LCM 121 °C) showed a significant increase in cytotoxicity after 48 h incubation with fibroblasts compared to the medium/cells (0.3%) (Fig. 6b).

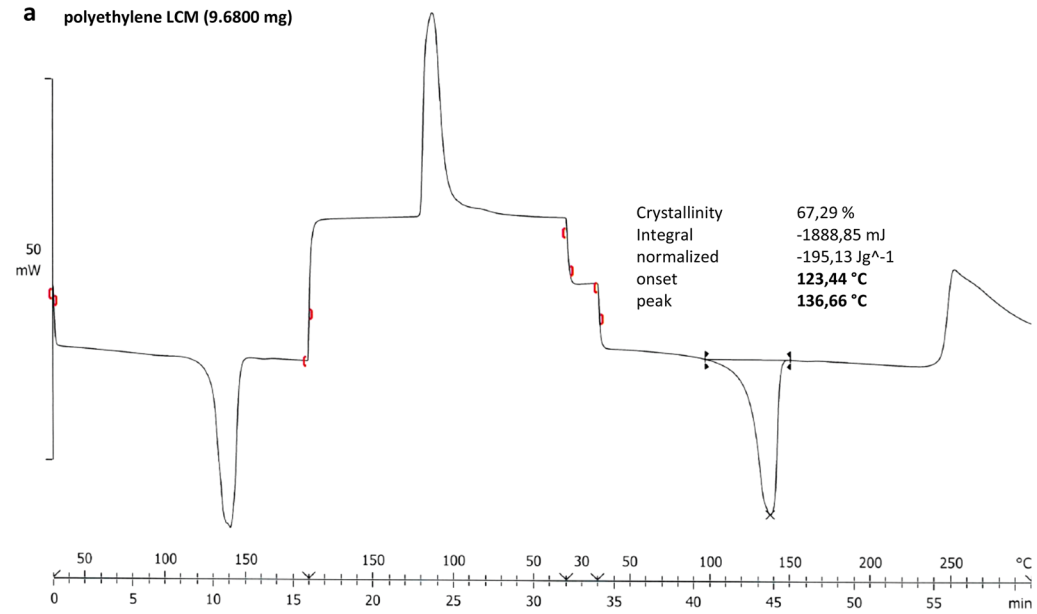
Measurement of the glucose metabolism showed normal metabolism of the fibroblasts without significant change on all unsterile and sterilized polyethylene and polyester low cost meshes (Fig. 7a). The pH value of non-sterilized LCMs (LCM polyethylene pH value 7.7; LCM polyester pH value 7.76) was the lowest in comparison to the medium/cells (pH value 7.78), where there are ideal conditions for the fibroblasts (Fig. 7b). Measurement of the lactate metabolism showed the highest lactate production in fibroblasts on polyethylene (7.7 mmol/l) and polyester (8.6 mmol/l) meshes sterilized at 100 °C (Fig. 7c).

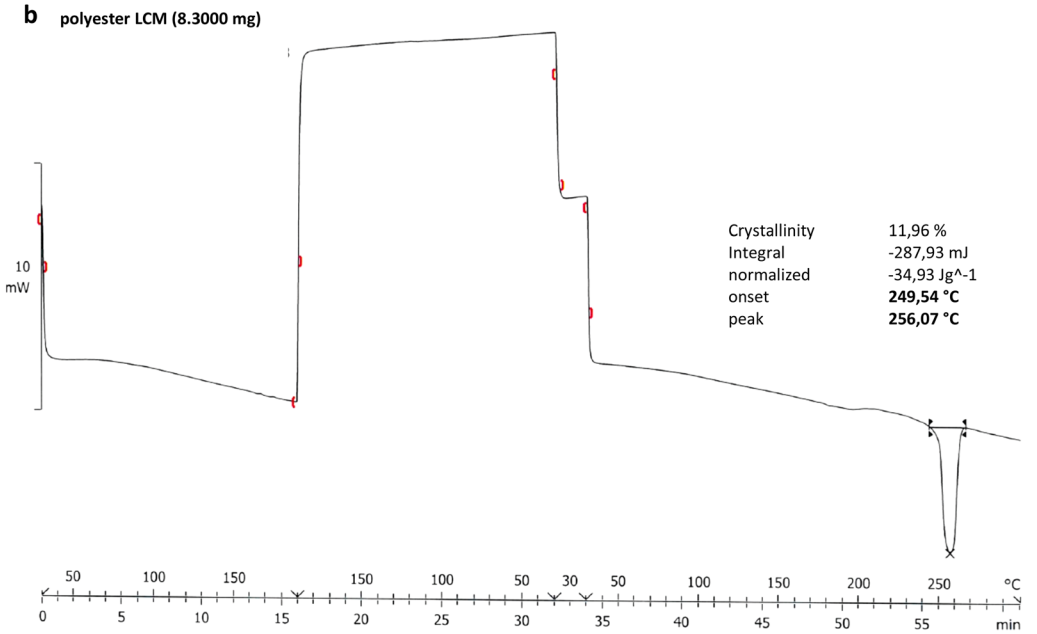
Discussion

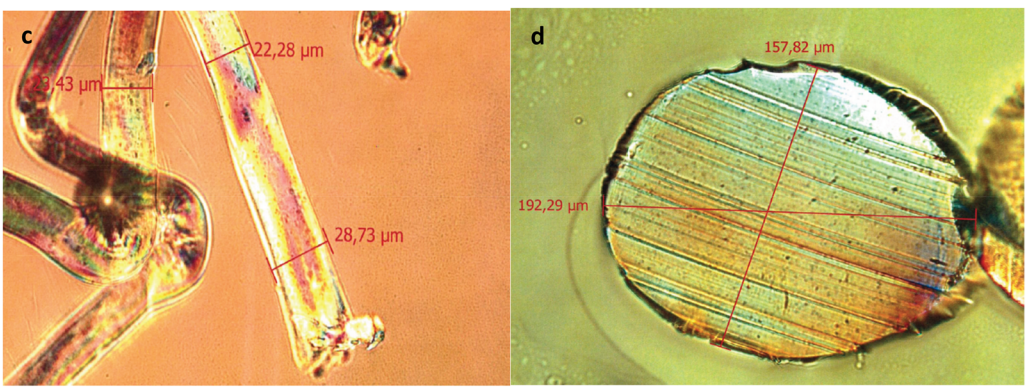
The HerniaSurge Guidline recommends the use of meshes for hernias also for LICs [2]. In LICs, however, the conventional commercial meshes are unaffordable for the majority of the patients, so that due to the lack of alternatives, cost-effective alternatives were sought [11]. Tongaonkar, in particular, is considered a pioneer in the use of mosquito meshes and has shown excellent results in more than 700 patients over 10 years with a follow-up of 12–18 months [17]. Several research groups were also able to demonstrate equivalent results in comparison to CMs [5, 7, 12, 13, 18], so that the current guideline makes the (weak) recommendation for the use of LCMs in the Lichtenstein technique [2]. In the guideline, the problem of sterilization of LCMs is only briefly described [2]. However, the literature used to prepare the recommendation shows slight changes (shrinkage) in polyethylene LCMs after steam sterilization at 121 °C [19].

The only prospective randomized study does not describe any changes in low density polyethylene LCMs sterilized at 121 °C for 20 min [12]. The randomized prospective study published by Löfgren et al. with a follow-up of one year showed no differences in the clinical results (recurrence rate, p. o. complications) compared to the commercial polypropylene mesh used in the comparison group [12]. The polyethylene LCMs were cut into 10 cm × 15 cm pieces and reference was made to the studies by Stephenson and Kingsnorth, who in their publication demonstrated the minimal structural changes described above [19].

Fig. 5 Chemical analysis. **a** differential scanning calorimetry analys ▶ of unsterile polyethylene mesh. **b** differential scanning calorimetry analysis of unsterile polyester mesh. **c** microtome section of unsterile polyethylene. **d** microtome section of unsterile polyester. **IR-analysis** of unsterile polyester (cm^{-1}): ν(C–H) 2957 (strong), ν(C–H) 2955 (strong), $\nu(CH_2)$ 1447 (deformation in plan). **IR-analysis** of unsterile polyethylene (cm^{-1}): ν(C–H) 2998 (strong), ν(C–H) 2934 (strong), ν(C=O) 1722 (strong), ν(C–C–O) 1326 (strong), ν(O–C–C) 1093 (strong), ν(C=C) 722 (very strong)


a
polyethylene LCM (9.6800 mg)
50
mW
Crystallinity 67,29 %
Integral -1888,85 mJ
normalized -195,13 Jg^-1
onset 123,44 °C
peak 136,66 °C
50 100 150 150 100 50 30 50 100 150 200 250 °C
0 5 10 15 20 25 30 35 40 45 50 55 min


b
polyester LCM (8.3000 mg)
10
mW
Crystallinity 11,96 %
Integral -287,93 mJ
normalized -34,93 Jg^-1
onset 249,54 °C
peak 256,07 °C
50 100 150 150 100 50 30 50 100 150 200 250 °C
0 5 10 15 20 25 30 35 40 45 50 55 min


c
22,28 µm
23,43 µm
28,73 µm
d
157,82 µm
192,29 µm

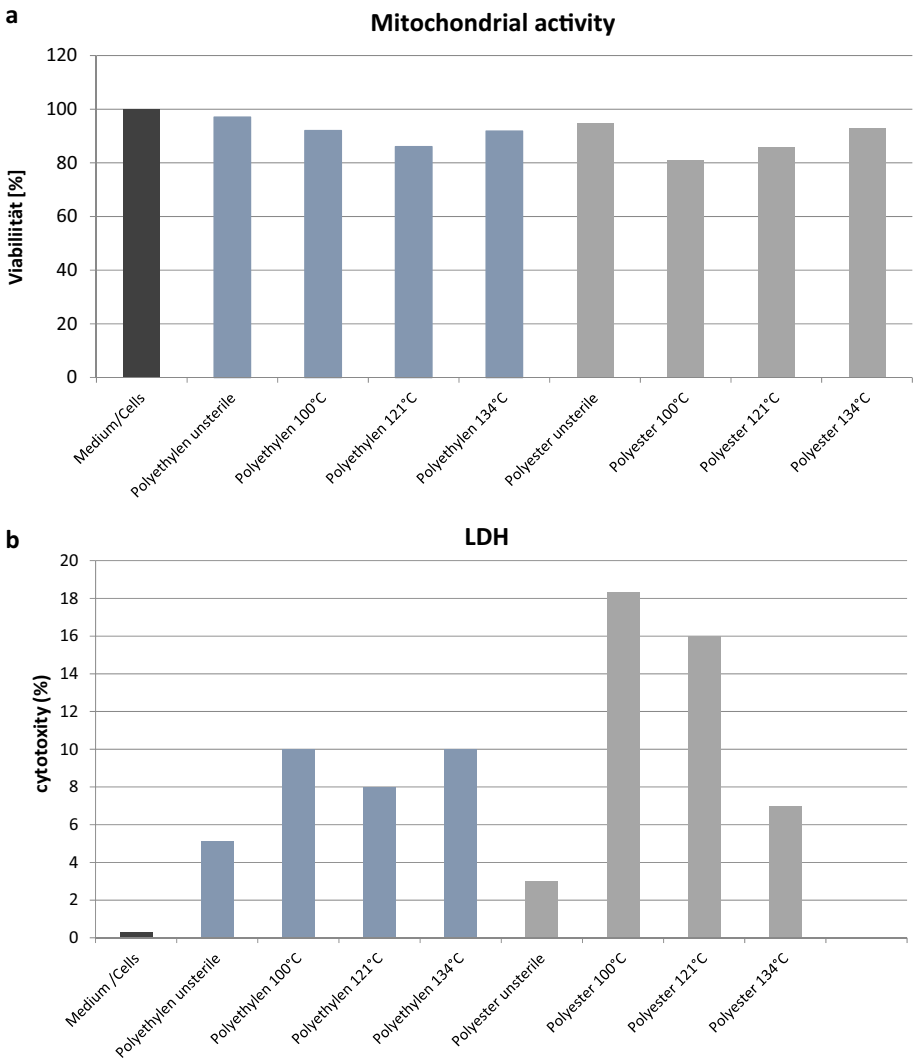


Fig. 6 Biochemical analyses. **a** Measurement of the viability of the fibroblasts 48 h after incubation. **b** Measurement of the cytotoxicity of the fibroblasts 48 h after incubation

To further substantiate these results, which were obtained directly from the patient, in in-vitro experiments and, if necessary, animal experiments, we have also tried to obtain a low density polyethylene mesh, as these meshes were used most frequently in previous studies [11, 12, 17, 19]. Our aim was to prove in vitro that LCMs made of polyethylene and polyester are safe to use, as described in the introduction. Thus, our former investigations of cell proliferation, cytotoxicity, oxidative stress, pH and glycolysis including SEM did not show significant differences between the polyester LCM, which is also used currently, and various commercial meshes (inter alia Ultrapro™ (Ethicon, Norderstedt, Germany), Parietex^{R} (Medtronic GmbH, Meerbusch, Germany)) [15].

It is well known that different sterilization processes for synthetic materials also lead to very different changes in the individual polymers [20]. For example, Müller et al. demonstrated in 1999 that only γ radiation should be used to sterilize polyethylene, since sterilization with steam at 121 and 134 °C leads to deformation and destruction of polyethylene. The polyethylene used, which had a crystal melting point of 118 °C, showed pronounced changes in the fibrils even at 121 °C [20]. Sterilization with 3% formaldehyde for one hour at 60 °C also led to changes in the polyethylene sample [20]. Our results of the chemical analysis show that the polyethylene LCM examined was high density polyethylene (HDPE) and not low-density polyethylene (LDPE), as described above. HDPE is even more resistant to heat and chemicals than LDPE [21]. In their 2011 work, Stephenson et al. also investigated a mosquito mesh from India, which consisted of 50% polypropylene and 50% polyethylene [19]. Steam sterilization of the initial 7×5 inch (17.8×12.7 cm) mesh at 134 °C led to massive shrinkage, as in our investigations. Sterilization at 121 °C for 20 min resulted in a shrinkage of 30%, which is lower than in our tests (Fig. 1c, 2c) [19]. These (shrunken) meshes were then implanted in 51 patients (54 hernias) in a size of 10×12 cm [19]. The 6-month follow-up showed no complications [19]. A shrinkage of 30% naturally leads to a change in mesh size and thus in effective porosity. In their prospective randomized

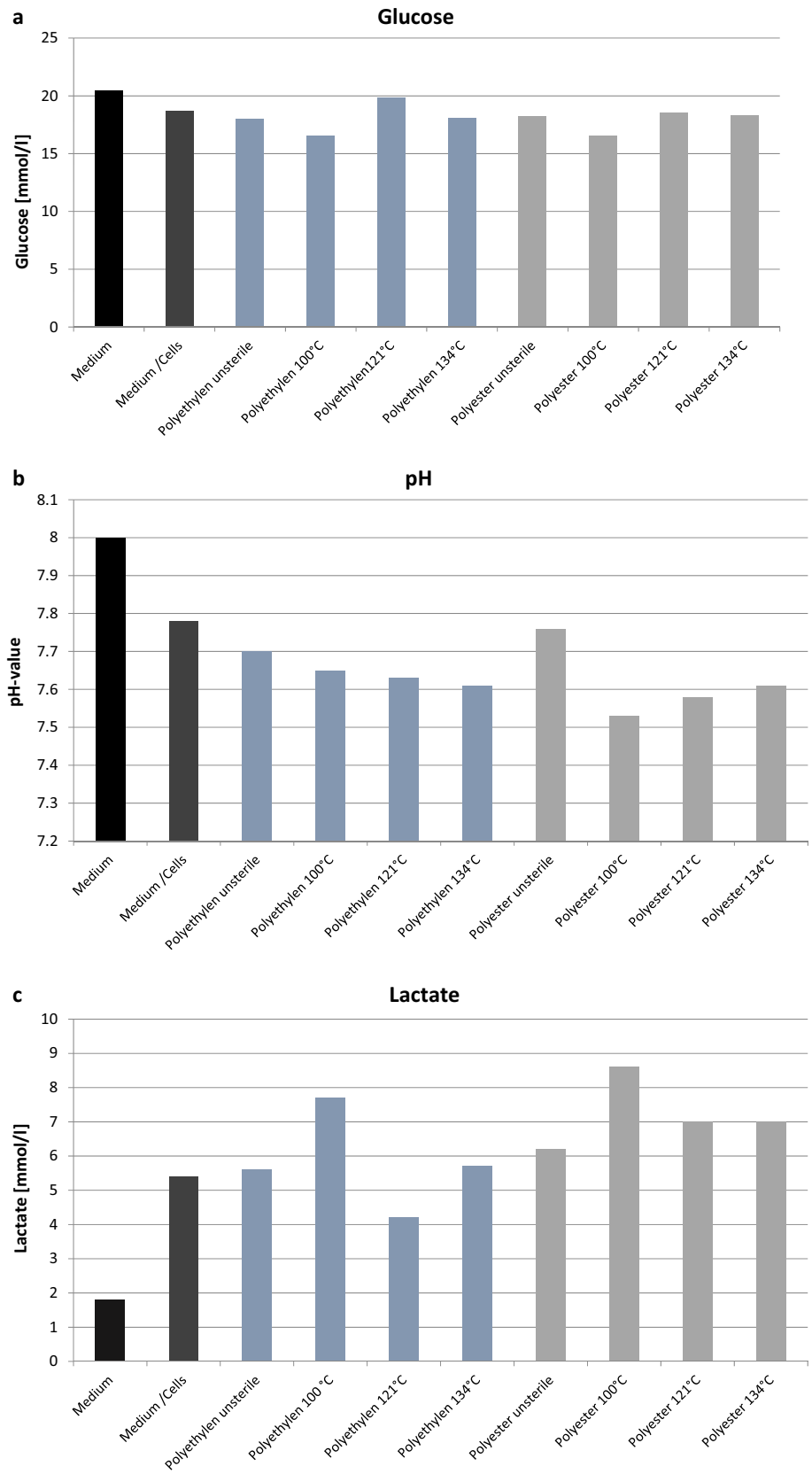


Fig. 7 Metabolism of the cells. **a** Measurement of the glucose metabolism of the fibroblasts after 48 h of incubation. **b** Measurement of the pH value of the fibroblasts after 48 h of incubation. **c** Measurement of the lactate metabolism of the fibroblasts after 48 h of incubation

study Löfgren et al. also implanted these (shrunken) meshes in 150 patients, whereby the initial size of the meshes before sterilization at 121 °C was approx. 10×15 cm (with approx. 30% shrinkage after sterilization then approx. 7×11.5 cm; assuming the same chemical composition of the Amsa Plastic mesh used as that of Stephenson et al. 2011) [12]. For a hernia repair using the Lichtenstein technique, this mesh size is just barely acceptable. However, the mesh size is only one parameter that can change due to sterilization of synthetic materials.

Thus, the aim of our mechanical investigations was to identify the influence of different sterilization methods on the mechanical properties of two different meshes. Since the focus was on the comparison of the unsterile conditions to different sterilized specimen, the test setup was chosen to be intriguingly simple rather than to mimic a complex condition after implantation in a human body. The investigations served this purpose very well. It was found that the difference of the mechanical properties in unsterile and sterile conditions was relatively small for most of the investigated specimens. In general, the maximum loads are higher for the unsterile meshes compared to the sterilized specimens. The most significant effect was observed for polyester sterilized at 100 °C (Table 1). The polyethylene specimen could not be tested at 121 and 134 °C due to significant shrinkage effects. However, a sterilization at 100 °C led to a small reduction of the maximum load (approximately 2.5% for the arithmetic mean value, Table 2).

It seems that 100 °C sterilization has a deeper impact on lactate production, LDH cytotoxicity test, and moreover, there is a decrease of the maximum tensile force. We neither have an explanation for our results nor have we found an association for this effect at 100 °C in our literature research.

The biocompatibility of the fibroblasts also changed during our investigations due to sterilization, both for the polyethylene LCMs and the polyester LCMs. Thus, all sterilized LCMs showed the lowest mitochondrial activity as a sign of cell death compared to the unsterilized meshes. The cytotoxicity (LDH measurement) was also lowest in the unsterilized meshes, while it increased significantly after steam sterilization, particularly in the case of polyester LCMs. Similarly, cell metabolism showed a greater drop in pH and an increase in lactate in the sterilized meshes. This corresponds to the results already published by Broll et al. in 2002 [22]. They showed in vitro experiments with human fibroblasts that resterilized polypropylene meshes after steam sterilization at 121 °C showed both a significant decrease in the proliferation index and a significant increase in the apoptosis rate of the fibroblasts compared to the control and the unsterilized meshes [22]. As in our experiments, the sterilization process changes the growth behavior of the cells. The authors assume that the thermal treatment of the meshes damages the DNA and conclude that a malignant transformation of the tissue surrounding the sterilized meshes is possible over years or decades and could lead to the induction of sarcomas [22].

Mitura et al. also showed that massive shrinkage of mosquito meshes can occur [14]. The authors also carried out chemical and mechanical tests on the various LCMs and found massive changes (shrinkage, deformation) in meshes from Ethiopia, Ghana and India after sterilization at 121 and 134 °C [14]. Mitura et al. clearly stated that the chemical composition of the locally acquired meshes is not known, so that a certain risk is present and therefore the unrestricted use of LCMs cannot be recommended [14]. For the local producers of mosquito meshes, the suppliers of the raw materials can change every year, e.g. for cost reasons, so that an externally identical mesh can now change significantly during steam sterilization due to the change in composition. This is no problem for the producers of LCMs—they do not produce their nets for use as medical devices in humans! Löfgren et al. have also recommended that the mesh used in a randomized prospective study should no longer be used in its current form [23]. A general use of LCMs, as recommended in the current HerniaSurge Guideline, is, despite all the known economic problems in LICs, only recommended with very severe limitations and should be critically reviewed.

In our view, two approaches should be pursued.

On the one hand, the training of local surgeons, especially for suture-based procedures, should be intensively promoted. For example, Mitura et al. showed that there are anatomical differences in the inguinal region between Africans and Caucasians and that therefore pure tissue repairs could be promising, especially for African patients [24]. A recent Cochrane analysis also recommends mesh-free methods for LICs [25].

Since only suture-based procedures are not always feasible for the very large inguinal hernia gaps, which are often very common, and thus meshes are urgently required, we also see, like Löfgren et. al., a possibility to solve the problem by establishing a manufacturing facility in Central Africa [23].

Conclusion

The sterilization of LCMs leads to significant changes in the growth behavior of human fibroblasts in vitro as well as in the chemical and mechanical properties of the meshes. Since manufacturers of LCMs do not produce certified medical devices, the chemical composition of meshes that have already been used clinically for positive results can change practically every day, so that for ethical (and legal) reasons alone a general use of LCMs cannot be recommended. A change to the, albeit, weak recommendation in the HerniaSurge Guideline is urgently recommended.

Acknowledgement Our special thanks go to Jessica Beard (M.D., M.P.H., Temple University in Philadelphia, USA) from whom we received the polyethylene low cost mesh.

Compliance with ethical standards

Conflict of interest RW, RL, AG, TK, CB, MS, DR and MP declare that they have no conflict of interest. RW declares conflict of interest not directly related to the submitted work. He has given two OP training courses for Company Medtronic.

Human and animal rights All authors confirm that no experiments with humans or animals have been carried out.

Informed consent For this type of stdy, formal consent is not required.

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Hernia
https://doi.org/10.1007/s10029-020-02363-8

LETTER TO THE EDITOR

The value and role of mosquito meshes in low resource and poor income settings: author's reply

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Received: 30 November 2020 / Accepted: 23 December 2020

We would like to thank Stephenson and Kingsnorth for the critical examination of our publication and would like to comment on the criticism expressed [1, 2].

Our research group has been working on the biocompatibility of mosquito and commercial meshes for several years, primarily to prove the equivalence of these meshes [3, 4]. During our investigations it became more and more apparent that the sterilization process itself is of crucial importance. Thus, we discovered that the process of steam sterilization also leads to changes in commercial meshes. We have recently tested mosquito meshes made of polyester and those made of polyethylene. The polyester mesh was purchased in Germany; the polyethylene mesh was sent to us from the USA with the information, documented several times, that it was manufactured by the company Amsa-Plastic in India. Despite several attempts, we have not succeeded in acquiring a mesh directly on the Internet or by telephone order from the company directly. From all of these meshes, 24 pieces of 6 × 11 cm size were produced and sterilized for the mechanical tests. The sterilization at 134 °C and 121 °C was performed in the central sterilization department of the Südstadt Clinic Rostock by the CE certified autoclave ECS 209 (WEBECO, Spain). Temperature fluctuations, as assumed by the authors, do not occur with this constantly maintained device. A sterilization temperature of 100 °C cannot be set with these autoclaves because they are not permitted in Europe, so we had to improvise. It was thus only for this particular relatively low temperature (100 °C) that we used the baby bottle steam sterilizer. As explained in our article, this temperature had been chosen in addition to the conventional sterilization temperatures mentioned above (134 °C, 121 °C) to simulate the situation in areas without electricity (and thus without autoclaves).

The treatment of the meshes with penicillin/streptomycin and amphotericin took place with all mesh pieces only AFTER the sterilization and leads thus also to no impairment or even denaturation of the meshes.

In contrast to the information provided by Stephenson et al., our chemical analyses showed that the mosquito mesh from India was not made of low-density polyethylene (LDPE) but instead of high-density polyethylene (HDPE). As described in our article, polyethylene is not optimally suited for steam sterilization. The thermal properties of polyethylene are very limited, as it starts to soften at 80 °C. The melting point of LDPE is 105 °C; that of HDPE is 137 °C. We cannot understand from our data why there was little or no shrinkage in the mesh used by both Stephenson et al. and Tongaonkar, both of whom we hold in high esteem. The chemical and physical properties of polyethylene cannot be influenced. It is possible that, as assumed in our article, other polymers (e.g. polypropylene) were temporarily part of the mesh, so that the degree of shrinkage was lower.

We consider the argument that if a mesh shrinks, it should be discarded because of the low costs, to be debatable. As described in our investigations, sterilization changes the mechanical and chemical properties of the nets including the biocompatibility of the fibroblasts. If shrinkage is still acceptable, the effective porosity, elasticity and flexibility of the mesh will still change compared to the non-sterile mesh. Mitura et al. also showed nearly identical results for locally acquired meshes [5]. As already explained in our article, the composition of a manufacturer's polymers can theoretically change daily due to new suppliers, so that a previously successfully implanted mesh suddenly no longer meets the minimum requirements. Therefore, Löfgren et al.

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Published online: 11 January 2021

recently advised against using the Amsa-Plastic mesh they had previously used [6].

We would very much like to re-examine the polyethylene mesh you analyzed and would be therefore be pleased if you could send us a piece measuring approximately 50 × 50 cm.

Since the meshes used are not primarily designed for use on humans, the material composition may change. Unfortunately, there is often no transparency of the production process. Today, there is also another problem, especially in regard to liability laws. Due to the worldwide introduction of the Medical Device Regulation, the medical device manufacturer is basically liable for the implanted mesh for life; in this case the sterilizing surgeon is responsible for the low-cost mesh. As also recommended by the Cochrane Database 2018, we believe that a possible way out for selected patients in low income countries would be to use mesh free surgical techniques [7].

Compliance with ethical standards

Conflict of interest The authors declare no competing interests.

Human and animal rights There are no issues to declare.

Informed consent For this study formal consent is not required.

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Chirurg 2015 · 86:1128–1131
DOI 10.1007/s00104-015-2992-2
Online publiziert: 22. März 2015

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Autopsien mit Situs-Lehre in der klinischen Rechtsmedizin

Die Deutsche Gesellschaft für Rechtsmedizin führt folgende Arbeitsgemeinschaften mit klinischen Bezügen: Forensische Altersdiagnostik, Forensische Gerontologie, Forensisch-pädiatrische Diagnostik, Forensische Psychopathologie und Ethik, Klinische Rechtsmedizin [6]. Die forensische Psychiatrie nimmt im Grenzbereich zwischen Medizin, Rechtswissenschaften, Kriminologie, Soziologie und Psychologie bei großer Nähe zur Rechtsmedizin eine Sonderstellung ein [7].

Am weitesten reichen Arbeiten der klinischen Rechtsmedizin zur Befunddokumentation und Begutachtung nach fraglicher Gewalt gegen Kinder zurück [10], bis zu jüngsten Empfehlungen der Arbeitsgemeinschaft Klinische Rechtsmedizin bei Verdacht auf Misshandlung und Missbrauch [2, 5].

Klinische Rechtsmedizin kann zur Gratwanderung werden. Das zeigen die Bestattungsgesetze der Bundesländer ([3] für Mecklenburg-Vorpommern) mit der Verpflichtung jeden Arztes, auch des Rechtsmediziners, nichtnatürliche Todesfälle inklusive des Verdachtes, der örtlich zuständigen Polizei/Staatsanwaltschaft anzuzeigen. Klinische Sektionen durch die Rechtsmedizin, über entsprechend strukturierte Autopsieanträge, werden dennoch mehr und mehr zu einer selbstverständlichen Option nach einem Sterbefall im Krankenhaus. Klinikinterne Fortbildungen durch die Rechtsmedizin zu Todesursache, Todesart, Meldepflichten sowie zur korrekten Ausstellung von Todesbescheinigungen erleichtern die fallbezogene Orientierung.

Die Öffnung des Sektionssaales für Lehre und Fortbildung fördert gegenseitiges Verständnis [4]. Aus der Tradition, die Ergebnisse klinischer Sektionen in klinisch-pathologischen bzw. klinisch-rechtsmedizinischen Konferenzen zu besprechen und der gelegentlichen Teilnahme von Klinikern an Sektionen, insbesondere nach Komplikationen medizinischer Eingriffe, entwickelte sich nach Abstimmung mit dem Institut für Anatomie der Universitätsmedizin Rostock unser Angebot einer „Situs-Lehre“ für ärztliche Kollegen operativer und interventioneller Fächer der Universität Rostock, um dem jungen Weiterbildungsassistenten und auch dem fortgeschrittenen Operateur die Möglichkeit zu bieten, bewährte und innovative Operationstechniken auf der Grundlage der Anatomie aufzuarbeiten.

Dabei muss jedem bewusst sein, dass ein vergangenes Leben die Möglichkeit bietet, für mehr Patientensicherheit zu lernen und dass die ethischen Grundsätze zum Umgang mit Verstorbenen zu beachten sind. Die besondere Situation bedeutet die Übernahme einer speziellen Verantwortung und damit eine besondere Herausforderung. Das Vorhaben wurde von der Ethikkommission der Universitätsmedizin Rostock und der Stabsstelle Recht der Rostocker Fakultät für Medizin positiv bewertet.

Methode

Das Konzept sieht vor, dass zu Beginn geplanter Obduktionen (Eröffnung aller Körperhöhlen, vollständige Sektion gemäß der Leitlinie Obduktion der Deutschen Gesellschaft für Rechtsmedizin [1]) operative/interventionelle Zugänge und Punktionswege sowie topografisch-anatomische Verhältnisse, unter Leitung der Obduzenten, in Kleingruppen von 2 bis 4 Personen, zunächst manuell exploriert werden. Mehrmalige Teilnahmen zu verschiedenen Themen sind möglich.

Bei einer Bedarfsermittlung im Klinikum reagierten Kolleginnen und Kollegen

Infobox 1 Klinisch gefragte Themen für die Situs-Lehre

- *Technik:*
  - Punktionen großer Gefäße und liquorführender Räume
  - Koniotomie
  - Drainage von Thorax und Abdomen
  - Komponentenseparation der Bauchwandmuskulatur
  - Magenresektion
- *Topografische Anatomie:*
  - Lagebeziehungen thorakaler und abdomineller Organe
  - Verläufe von Gefäßen und Nerven
  - Chirurgische Engen: Mediastinum, sub- und retrohepatische Räume, Bursa omentalis, Leistenkanal, kleines Becken, retroperitonealer Raum
  - Leitstrukturen im Kontext von Operationen

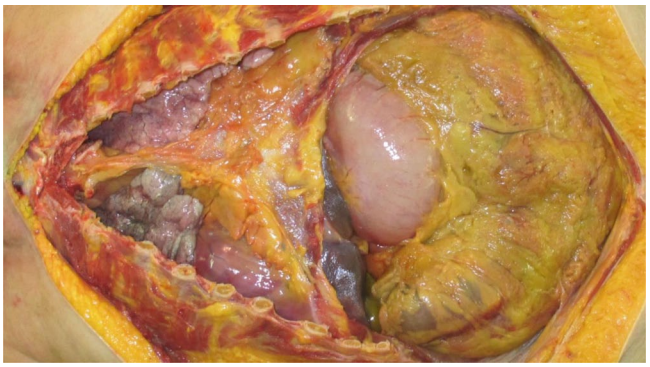

Abb. 1 ▲ Thorakaler und abdominaler Situs nach Präparation der Rumpfwand und Entnahme des Brustbeins

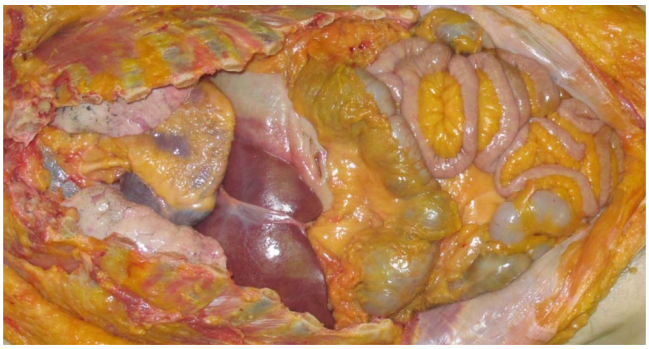

Abb. 2 ▲ Thorakaler und abdominaler Situs nach Präparation der Rumpfwand, Entnahme des Brustbeins sowie Teilentfernung von Herzbeutel, Zwerchfell und großem Netz

der Fächer Chirurgie, Orthopädie, Gynäkologie, Hals-Nasen-Ohren-Heilkunde, Anästhesie/Intensivmedizin und Radiologie (◘ **Infobox 1**).

Der Bedarf wurde beispielgebend für die Viszeralchirurgie so begründet, dass die fundierte Kenntnis der Anatomie des Leistenkanals und der ventralen Bauchwand Grundlage wesentlicher Ausbildungseingriffe für Chirurgen verschiedener Fachrichtungen, aber vor allem Bestandteil der Allgemein- und Viszeralchirurgie ist. Die traditionellen Operationstechniken der Hinterwandverstärkung des Leistenkanals und die Komponentenseparation der Muskulatur der Bauchdecke (Ramirez) zum Zweck der Versorgung monströser und komplexer Hernien seien ideale Anwendungsbeispiele für den Bedarf an Aus- und Fortbildung aus der operativen Praxis heraus zur Kooperation mit einem Institut für Rechtsmedizin. Zudem sei die Aufarbeitung der anatomischen Lagebeziehungen der abdominellen und retroperitonealen Organe und Leitstrukturen im besonderen Kontext der Operationen an Magen, Leber, Pankreas, Milz, Nebennieren oder Nieren mit wesentlichen präparatorischen Schritten nahezu analog zum Operieren eine einmalige Gelegenheit für junge und fortgeschrittene Chirurgen [8, 9].

In einem bedarfsorientierten Zeitraum von 1–2 h wird bis zur Organentnahme vorgegangen (◘ **Abb. 1, 2**), wobei chirurgische und sektionstechnische Schritte zusammenfließen, ohne den Sektionsauftrag zu überschreiten, der in jedem Fall die Öffnung aller Körperhöhlen sowie die Entnahme und Sektion aller inneren Organe vorsieht.

Ergebnisse

Zum Termin erschienen sowohl Einzelpersonen als auch Interessengruppen. Bisher erfolgten die Explorationen am vorbereiteten, thorakalen und abdominalen Situs manuell oder mit instrumenteller Unterstützung aus dem Sektionssaal. Die Erweiterung auf spezielle Instrumente aus den jeweiligen Fachgebieten ist denkbar.

Die bisher fünf Veranstaltungen boten optimalen Raum für die individuellen, sehr fachspezifischen Themen und endeten mit großem Erkenntnisgewinn für alle Beteiligten.

Der Verlauf der klinischen Sektionen wurde durch die Kurse moduliert, aber ohne negativen Einfluss auf die Befunderhebung.

Statistische Angaben zu den Kursteilnehmern mit Spezifizierung des Kurserfolges können erst nach Erreichen größerer Fallzahlen erfolgen.

Diskussion

Der früh postmortale, noch realitätsnahe Situs und der Status der Kollegen in Weiterbildung bieten nähere, klinisch relevante Bezüge als die lange zurückliegenden Präparierkurse für Studenten in den Instituten für Anatomie. Hierin begründet sich eine wiederholende Situs-Lehre bzw. ein Kurs zur topographischen Anatomie durch Institute für Rechtsmedizin oder Pathologie.

Nach Prüfung durch die Stabsstelle Recht und Grundsatzangelegenheiten der Universitätsmedizin Rostock bestehen keine zivilrechtlichen, strafrechtlichen und datenschutzrechtlichen Bedenken. Zwar werde in die Unversehrtheit eines Leichnams eingegriffen, dieser Eingriff sei aber nicht rechtswidrig. Selbst wenn im Rahmen des Kurses z. B. durch Punktionen der Sektionsauftrag überschritten werden würde, sei damit kein weiterer Eingriff in die Unversehrtheit des Leichnams verbunden, da diese als eine Einheit zu verstehen sei. Nach einer Sektion liegt keine Unversehrtheit des Leichnams mehr vor. Im Einzelfall könne es geboten sein, eine Einwilligung der Angehörigen einzuholen, z. B. vor einer geplanten, simulierten Operation oder einer Koniotomie [4].

„Angebot und Nachfrage“ ließen sich inhaltlich bisher sehr gut abstimmen. Die Obduzenten standen zunächst im Vordergrund, demonstrierten den Situs und blieben auch bei gegebenenfalls aufkommender praktischer Dominanz der Kliniker anwesend. Sie tragen die Verantwortung für eine lege artis durchgeführte Sektion.

Problematisch ist die geringe Zahl geeigneter Sektionsfälle (mittleres Sterbealter, kurze Liegezeit, weitgehender Erhalt der physiologischen Anatomie), die rechtzeitige Terminierung in potenziell günstige Phasen des Stationsbetriebes außerhalb der Operationsprogramme und die Eingliederung in den laufenden Betrieb des Institutes.

Der Sektionssaal eines Institutes für Rechtsmedizin gehört zum akkreditierten Bereich des Gerichtsärztlichen Dienstes. Alle damit verbundenen Regularien und Dokumentationsformen bleiben erhalten, auch wenn es sich nicht um eine gerichtlich angeordnete Obduktion handelt.

Wichtig erscheint, die individuellen Interessenlagen der Teilnehmer in Klau-

Chirurg 2015 · 86:1128–1131 DOI 10.1007/s00104-015-2992-2

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Autopsien mit Situs-Lehre in der klinischen Rechtsmedizin

Zusammenfassung

Hintergrund. Klinische Rechtsmedizin bedeutet neben der Untersuchung und Begutachtung lebender Gewaltopfer auch die Option klinisch beauftragter Sektionen, z. B. nach nicht meldepflichtigen Komplikationen medizinischer Eingriffe, nach Sterbefällen zeitnah zu medizinischen Eingriffen oder nach Sterbefällen als Folge von Verletzungen, wenn sich die zuständige Staatsanwaltschaft gegen eine gerichtlich angeordnete Sektion entscheidet. Aus dieser Praxis entwickelte das Institut für Rechtsmedizin der Universitätsmedizin Rostock das Angebot einer wiederholenden Situs-Lehre: topografische Anatomie für Ärztinnen und Ärzte in Weiterbildung zu operativen/interventionellen Fächern.
Methode. Zu Beginn geplanter Obduktionen können in Kleingruppen zu 2 bis 4 Personen, in einem bedarfsorientierten Zeitraum von 1–2 h, zum einen die Zugänge interventioneller Punktionstechniken exploriert, zum anderen operative Techniken und deren grundlegende Anatomie unter Anleitung erfahren werden. Das Format der Situs-Lehre ist im Wesentlichen auf die frühe Weiterbildungszeit abgestimmt, erfüllt aber auch die Voraussetzungen zur Exploration komplexer Operationstechniken. Die Explorationen erfolgen nach Eröffnung der Körperhöhlen unter Leitung der Obduzenten manuell durch die Teilnehmer oder mit instrumenteller Unterstützung aus dem Sektionssaal.
Ergebnisse. Die Veranstaltungen boten optimalen Raum für die individuellen, sehr fachspezifischen Themen und endeten mit großem Erkenntnisgewinn für alle Beteiligten. Eine statistische Bewertung kann erst nach Erreichen größerer Fallzahlen erfolgen.
Schlussfolgerungen. Die klinische Rechtsmedizin hat sich als wesentliches Teilgebiet seit vielen Jahren etabliert. Die Öffnung des Sektionssaales für Lehre und Weiterbildung ergänzt ihr Profil. Eine topografische Situs-Lehre zu Beginn von Obduktionen gibt viel Raum für die Weiterbildung zugunsten der Patientensicherheit. Es erscheint wichtig, die Themen der Teilnehmer in wertungsfreier Klausur zu begleiten. Ethische Grundsätze, der Sektionsauftrag und die Regularien eines akkreditierten Arbeitsbereiches sind zu beachten.

Schlüsselwörter

Klinische Rechtsmedizin · Autopsie · Topografische Anatomie · Operativer Zugang · Patiensicherheit

Autopsies for anatomical teaching and training in clinical forensic medicine

Abstract

Background. Clinical forensic medicine does not only entail examination of patients after physical violence but also the option of clinical autopsies, e.g. after non-notifiable complications of medical interventions, after fatalities closely following medical interventions or fatalities as a result of injuries when the public prosecutor decides not to order a medicolegal autopsy. Based on this routine the Institute of Forensic Medicine at the University of Rostock offers a training course in topographical anatomy to physicians for further training in interventional and surgical disciplines.
Methods. At the beginning of autopsies the participants can explore the approaches of interventional puncture techniques as well as surgical techniques and the basic topographical anatomy in small groups of 2–4 persons under the supervision of forensic examiners. The format is essentially oriented to the early further training period but fulfils the requirements for the exploration of complex operative techniques. The course was adapted for physicians and offered separately to students. The explorations are performed manually or by support with autopsy instruments.
Results. The courses offer an ideal room for individual, discipline-specific topics and result in a great benefit for all participants. A statistical assessment can only be achieved with a larger number of participants.
Conclusion. Making autopsy rooms available for teaching and further training represents an additional feature to the profile of clinical forensic medicine. Lessons in topographical anatomy provide a great benefit for patient safety. It seems to be important to offer the opportunity to address individual interests in a closed meeting to consolidate skills and abilities in a non-judgemental environment.

The post-mortem examiners have to ensure that the autopsy is carried out lege artis. Basic ethical principles and all regulations from an accredited scope have to be adhered to.

Keywords

Clinical forensic medicine · Autopsy · Topographical anatomy · Surgical procedure · Patient safety

sur zu begleiten. Gerade klinisch tätigen Kollegen in früher Weiterbildungszeit soll die Möglichkeit gegeben werden, die eigenen Kenntnisse und Fähigkeiten in einem wertungsfreien Raum zu vertiefen.

Fazit für die Praxis

- **Die klinische Rechtsmedizin hat sich als wesentliches Teilgebiet der Rechtsmedizin seit vielen Jahren etabliert.**
- **Die Öffnung des Sektionssaales für Lehre und Weiterbildung ergänzt ihr Profil.**
- **Das Institut für Rechtsmedizin der Universitätsmedizin Rostock bietet operativen und interventionellen Fächern zu Beginn von Obduktionen die Möglichkeit zur Wiederholung topografischer Anatomie.**
- **Eine Situs-Lehre in gefahrloser, wertungsfreier Klausur gibt viel Raum für die individuellen und fachspezifischen Themen zugunsten der Patientensicherheit.**
- **Ethische Grundsätze, der Sektionsauftrag und die Regularien eines akkreditierten Arbeitsbereiches sind zu beachten.**

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Einhaltung ethischer Richtlinien

Interessenkonflikt. U. Hammer, V. Blaas, A. Büttner und M. Philipp geben an, dass kein Interessenkonflikt besteht.

Dieser Beitrag beinhaltet keine Studien an Menschen oder Tieren.

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