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Neuartige minimalinvasive Osteosynthesen zur Versorgung von Frakturen des Beckenrings: Eine biomechanische Versuchsreihe

Dissertation
zum Erwerb des Doktorgrades der Medizin
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Vorgelegt von
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Einleitende Zusammenfassung

der schriftlichen, kumulativen Promotion

gemäß §4a der Promotionsordnung der LMU vom 1.Juni 1983 in der konsolidierten Fassung der elften Änderungssatzung vom 15. September 2016

Eidesstattliche Versicherung

Cavalcanti Kußmaul, Adrian

Name, Vorname

Ich erkläre hiermit an Eides statt,

dass ich die vorliegende Dissertation mit dem Titel

Neuartige minimalinvasive Osteosynthesen zur Versorgung von Frakturen des Beckenrings: Eine biomechanische Versuchsreihe

selbständig verfasst, mich außer der angegebenen keiner weiteren Hilfsmittel bedient und alle Erkenntnisse, die aus dem Schrifttum ganz oder annähernd übernommen sind, als solche kenntlich gemacht und nach ihrer Herkunft unter Bezeichnung der Fundstelle einzeln nachgewiesen habe.

Ich erkläre des Weiteren, dass die hier vorgelegte Dissertation nicht in gleicher oder in ähnlicher Form bei einer anderen Stelle zur Erlangung eines akademischen Grades eingereicht wurde.

München, 15.07.2021 Adrian Cavalcanti Kußmaul

Ort, Datum Unterschrift Doktorand

Inhaltsverzeichnis

1. Abkürzungsverzeichnis:

ANOVA: Analysis of Variance

AO: Arbeitsgemeinschaft für Osteosynthesefragen

ARDS: Acute respiratory distress syndrome

INFIX: Anteriorer (ventraler) subkutaner Fixateur interne

N: Newton

NCFL: Nervus cutaneus femoris lateralis

SI: Sakroiliakal (-gelenk)

SIRS: Systemic inflammatory response syndrome

SWK: Sakralwirbelkörper

TIFI: Transiliakaler Fixateur interne

3D: Dreidimensional

2. Publikationsliste

2.1. Publikation I

Christopher A. Becker, Christian Kammerlander, Adrian Cavalcanti Kußmaul, Matthias Woiczinski, Christoph Thorwächter, Christian Zeckey, Fabian Sommer, Christoph Linhart, Simon Weidert, Eduardo M. Suero, Wolfgang Böcker, Axel Greiner.
Modified less invasive anterior subcutaneous fixator for unstable Tile-C-pelvic ring fractures: a biomechanical study. BioMedical Engineering OnLine. 2019 Mar 29;18(1):38. doi: 10.1186/s12938-019-0648-z.

2.2. Publikation II

Adrian Cavalcanti Kußmaul, Axel Greiner, Christian Kammerlander, Christian Zeckey, Matthias Woiczinski, Christoph Thorwächter, Clara Gennen, Christian Kleber, Wolfgang Böcker, Christopher A. Becker.
Biomechanical comparison of minimally invasive treatment options for Type C unstable fractures of the pelvic ring. Orthopaedics & Traumatology: Surgery & Research. 2020 Feb;106(1):127-133. doi: 10.1016/j.otsr.2019.09.032. Epub 2019 Dec 18.

2.3. Publikation III

Christopher Alexander Becker, Adrian Cavalcanti Kussmaul, Eduardo Manuel Suero, Markus Regauer, Matthias Woiczinski, Christian Braun, Wilhelm Flatz, Oliver Pieske, Christian Kammerlander, Wolfgang Boecker, Axel Greiner.
Tape suture for stabilization of incomplete posterior pelvic ring fractures—biomechanical analysis of a new minimally invasive treatment for incomplete lateral compression pelvic ring fractures. Journal of Orthopaedic Surgery and Research 2019 Dec 27;14(1):465. doi: 10.1186/s13018-019-1509-y.

3. Einleitung

3.1. Hintergrund, Problematik und übergreifende Zielsetzung

Beckenringfrakturen gehören mit einer Inzidenz von ca. 0,3 bis 6% zu den selteneren Frakturen in der Unfallchirurgie [1]. Bei polytraumatisierten Patienten steigt die Inzidenz jedoch auf etwa 20% an [1].

Beckenfrakturen umfassen eine Vielzahl verschiedener Verletzungsmuster und reichen von stabilen, gering dislozierten und größtenteils durch Niedrigenergietraumata hervorgerufenen Typ A-Frakturen, bis hin zu instabilen, lebensbedrohlichen Typ C-Frakturen, welche oftmals durch Hochrasanztraumata entstehen und eine sofortige chirurgische Intervention benötigen [2].

Die Einteilung solcher Frakturen erfolgt entsprechend der AO-(Arbeitsgemeinschaft für Osteosynthesefragen) Klassifikation in A-, B- oder C-Frakturen.

Bei Frakturen vom Typ A ist die biomechanische Kraftübertragung des Beckenrings intakt und dieser damit stabil, während bei Typ B-Frakturen eine rotatorische Instabilität bei erhaltener vertikaler Stabilität besteht [3]. Typ C-Frakturen repräsentieren die Maximalvariante von Beckenringfrakturen und weisen durch die komplette Instabilität des hinteren und vorderen Beckenrings sowohl einen vertikalen als auch rotatorischen Stabilitätsverlust auf [2,3].

Aufgrund ihrer Komplexität sowie der mannigfaltigen Begleitverletzungen stellt die Versorgung von Beckenringfrakturen bis heute eine der anspruchsvollsten unfallchirurgischen Herausforderungen dar [4].

Zwar herrscht Konsens über die Notwendigkeit der operativen Versorgung von instabilen Beckenringfrakturen, die Auswahl des optimalen

Osteosyntheseverfahrens wird jedoch kontrovers diskuiert und befindet sich in stetiger Weiterentwicklung [3,5,6].

Aktuell stehen für den hinteren Beckenring unter anderem folgende Verfahren zur Verfügung: Beckenzwinge [7], offene Reposition und Stabilisierung mittels Platten- und Schraubenosteosynthesen, perkutane SI-Schrauben [8], transiliakaler Fixateur interne [9,10] sowie trianguläre oder lumbopelvine Stabilisationssysteme [11,12].

Auch für den vorderen Beckenring existieren verschiedene operative Osteosynthesemöglichkeiten, wie die Transfixation mittels Fixateur externe, retro- oder anterograde transpubische Schraubenosteosynthesen, Plattenosteosynthesen des frakturierten Ramus pubis [2] oder interne Fixateursysteme wie der 2009 von Kuttner et al. beschriebene subkutane ventrale Fixateur interne (INFIX) [13].

Zwar befinden sich unter den oben genannten Osteosynthesen auch minimal-invasive Versorgungsmöglichkeiten, jedoch liegen in der Literatur bisher nur wenige Daten vor, bei welchem Frakturmuster welche der Osteosynthesen sinnvoll eingesetzt werden kann [14].

Zum einen fehlen Untersuchungen, welche diese Osteosyntheseverfahren hinsichtlich ihrer Stabilität und Belastbarkeit untereinander vergleichen [15].

Zum anderen gibt es kaum Studien bezüglich möglicher Kombinationen dieser Techniken zur Versorgung von Frakturen des vorderen und hinteren Beckenringes [14].

Die Relevanz der simultanen Versorgung des vorderen und hinteren Beckenringes im Bezug auf die frühe Mobilisierung des Patienten zur Prävention von Langzeitschäden des Beckens wurde jedoch bereits von McLachlin et. al [2] beschrieben.

Patienten profitieren hinsichtlich ihres Outcomes aber nicht nur von der größtmöglichen Stabilität in Form der Versorgung ihrer Frakturen [9,16], sondern auch von einer möglichst geringen Gesamtinvasivität des Eingriffes [17]. Diese beinhaltet besonders die Minimierung intra-und postoperativer Risiken und Komplikationen [18], wie beispielsweise die Reduktion des Verletzungsrisikos für Weichteil- oder neurovaskuläres Gewebe [9] sowie des Blutverlusts und postoperativer Schmerzen, welche folglich eine frühere Mobilisierung ermöglichen [11,19].

Ebenfalls entscheidend für das Outcome der Patienten hinsichtlich ihrer traumaassoziierten Morbität und Mortalität ist die mit der Invasivität des Eingriffes korrelierende Immunantwort, unter anderem die des Komplementsystems, welche in einer 2020 von Lackner et al. veröffentlichen Studie untersucht wurde [20]. So kommt es bei polytraumatisierten Patienten zu einer raschen traumainduzierten Aktivierung mehrerer Achsen des Immunsystems, welche mit einer massiven Immunantwort korrelieren [21]. Diese birgt vor allem das Risiko eines posttraumatischen Auftretens eines „systemic inflammatory response syndrome“ (SIRS) und / oder einer Sepsis bis hin zum Multiorganversagen [20].

Zudem kann es im Verlauf durch die Durchführung ausgedehnter chirurgischer Maßnahmen zu der Auslösung einer zweiten Immunantwort im Sinne eines „second hits“ kommen [22]. Die Intensität einer solchen „Zweitaktivierung“ korreliert mit der Invasivität des Eingriffes und kann folglich ebenso zur Induktion eines „systemic inflammatory response syndrome“ (SIRS) mit Multiorganversagen bis hin zum Tod führen [23]. Dementspreched ist die Invasivität des chirurgischen Eingriffes, insbesondere bei polytraumatisierten Patienten, von entscheidender Bedeutung für die Entwicklung intensivmedizinscher Komplikationen und damit für das Gesamtüberleben [20].

Das Ziel dieser Dissertation ist, verschiedene minimal-invasive Osteosynthesetechniken an unterschiedlichen Frakturmustern des Beckenringes einzeln und in Kombinationen auf ihre Stabilität und biomechanische Belastbarkeit hin zu untersuchen, um durch die Entwicklung neuer und Verbesserung etablierter minimal-invasiver Osteosynthesen das Outcome der Patienten mit Beckenringfrakturen zu verbessern.

3.2. Zielsetzung Publikation I

(Modified less invasive anterior subcutaneous fixator for unstable Tile-C-pelvic ring fractures: a biomechanical study. [15]*)*

Die externe Transfixation (Fixateur externe) zur notfallmäßigen Stabilisierung von Beckenringfrakturen gilt als schnelles und effektives Verfahren in Akutsituationen [24].

Die damit einhergehende Einschränkung der Mobilisation sowie das erhebliche Risiko von durch Schanz-Schrauben verursachten Infektionen jedoch führten im Verlauf zur Entwicklung des internen Fixateurs [24,25].

Diese minimal-invasive Osteosynthese vereint durch die subkutane Einbringung die Stabiliät eines Fixateurs bei gleichzeitiger Erleichterung der Mobilisation und Minimierung des Infektionsrisikos [24,26].

Jedoch kann es bei der Implantation sowohl externer als auch interner Fixationssysteme zu Läsionen des Nervus cutaneus femoris lateralis (NCFL) kommen [27,28].

Da der in der Literatur verwendete INFIX aber meist bilateral angebracht wurde, sahen wir insbesondere die Gefährdung der Gefäß-Nervenstrukturen, vor allem des NCFL, auf der intakten Seite des Beckens als problematisch und potenziell vermeidbar an [15].

Daher modifizierten wir zur Versorgung einer unilateralen AO Typ C1.3-Fraktur den Fixateur interne zu einem unilateralen INFIX oder einem „extended“ (erweiterten) unilateralen INFIX, bei dem eine zusätzliche Pedikelschraube symphysennah in den kontralateralen Schambeinast eingebracht wurde, um so den NCFL der nicht frakturierten Seite des Beckens bei gleichzeitig gesicherter Stabilität zu schonen (siehe Bild 1 a & b) [15].

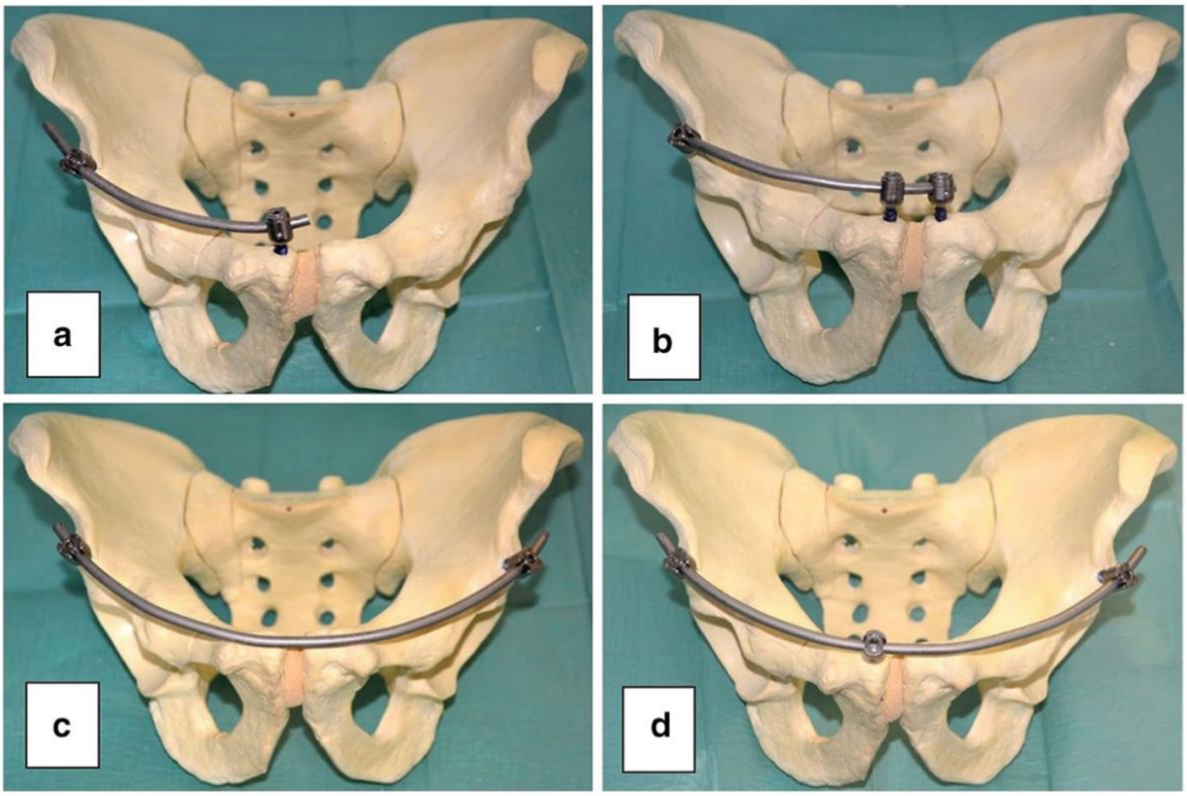

Bild 1:

a) unilateraler INFIX + 2 SI-Schrauben, b) „extended“ unilateraler INFIX + 2 SI-Schrauben

c) bilateraler INFIX + 2 SI-Schrauben, d) „extended“ bilateraler INFIX + 2 SI-Schrauben

3.3. Zielsetzung Publikation II

(Biomechanical comparison of minimally invasive treatment options for Type C unstable fractures of the pelvic ring. [14]*)*

Während bei der zur ersten Veröffentlichung führenden Studie der Fokus auf der Versorgung des vorderen Beckenringes lag, wurde in dieser Studie die Versorgung des hinteren Beckenringes, ebenfalls bei einer AO-Typ C1.3-Beckenringfraktur, experimentell miteinbezogen [14,15].

Die Bedeutsamkeit der gemeinsamen Versorgung sowohl des vorderen als auch des hinteren Beckenringes zur frühen postoperativen Mobilisierung, Prävention von Langzeitschäden und damit einhergehender Verbesserung des Gesamtoutcomes der Patienten, konnte 2018 von McLachlin et. al bereits gezeigt werden [2].

Dazu wurden in dieser Veröffentlichung sowohl am vorderen als auch am hinteren Beckenring je zwei verschiedene Osteosynthesen in ihren vier möglichen Kombinationen getestet und sowohl untereinander als auch zu einer fünften Referenzgruppe, bestehend aus einem intakten Becken, hinsichtlich ihrer biomechanischen Stabilität verglichen (siehe Bild 2) [14].

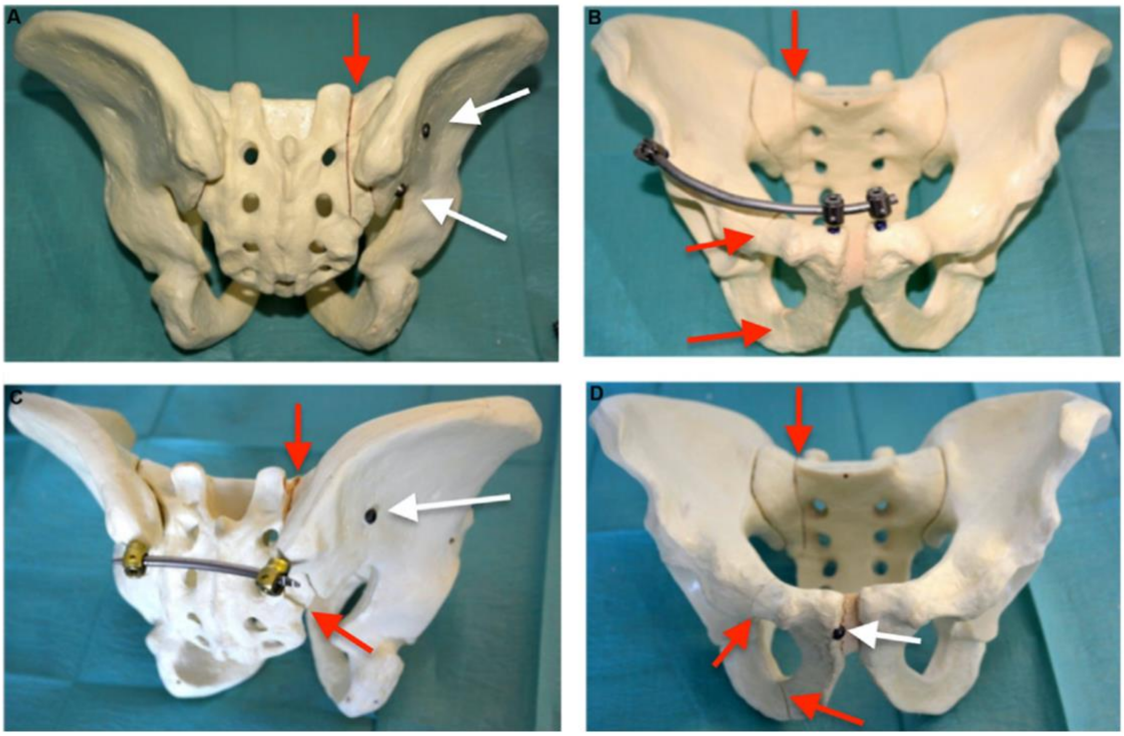

Bild 2:

A: 2 SI-Schrauben, B: Modifizierter unilateraler INFIX aus Publikation I

C: TIFI + 1 SI-Schraube, D: retrograde transpubische „Kriechschraube“

Die weißen Pfeile zeigen die Richtung der Schraubenosteosynthesen, die roten Pfeile markieren den Verlauf der C1.3 Fraktur

Das Ziel dieser Studie bestand darin, die Kombination verschiedener Osteosynthesetechniken mit der größten Stabilität bei gleichzeitig möglichst geringer Invasivität zu identifizieren.

3.4. Zielsetzung Publikation III

(Tape suture for stabilization of incomplete posterior pelvic ring fractures—biomechanical analysis of a new minimally invasive treatment for incomplete lateral compression pelvic ring fractures. [29]*)*

In dieser Studie wurde eine bei der Versorgung von Beckenringfrakturen in der Literatur noch nicht beschriebene Osteosynthesetechnik, das FiberTape® (FiberTape 2 mm, Arthrex, Naples, FL, USA), biomechanisch untersucht.
Dieses Polyethylenband wird bereits in der Versorgung von Verletzungen der vorderen Syndesmose des Sprunggelenks, der Rotatorenmanschette und der ligamentären Strukturen des Knies eingesetzt [30–32].
Die stabilisierende Wirkung durch das FiberTape® beruht auf einer „Schienung" der Verletzung im Sinne einer Bandaugmentation [30], sprich einer Verstärkung der vorhandenen Bandstrukturen.
Das FiberTape® wurde in dieser Studie zur Versorgung einer AO Typ B2.1-Beckenringfraktur verwendet, da es sich bei dieser Frakturform um eine inkomplette laterale Kompressionsfraktur des Sakrums mit erhaltenen ligamentären Strukturen handelt, welche die Testung der zugrunde liegenden Wirkung des Tapes überhaupt ermöglicht [33]. Um durch erhaltene Bandstrukturen die Wirkung der Bandaugmentation überhaupt untersuchen zu können, wurde das FiberTape® in dieser Studie an Leichenbecken biomechanisch getestet [29].
Das Ziel dieser Studie bestand in der Etablierung eines weniger invasiven, aber ähnlich stabilen Verfahrens im Vergleich zur bisher verwendeten SI-Schraubenosteosynthese des hinteren Beckenringes [34].

3.5. Eigenanteil an den vorgelegten Veröffentlichungen

Zunächst wurde die wissenschaftliche Problematik, welche dieser Dissertation zu Grunde liegt, nach Sichtung der aktuellen Literatur meinerseits recherchiert. Es folgten die Ausarbeitung der einzelnen Fragestellungen sowie die Konzipierung des Studiendesigns in Absprache mit Dr. med. Christopher A. Becker und Prof. Dr. Wolfgang Böcker.

Die Planung der Durchführbarkeit der Versuche erfolgte in Zusammenarbeit mit den beiden Ingenieuren Dr. rer. nat. Matthias Woiczinski und Christoph Thorwächter des biomechanischen Labors der LMU München.

Nach Konstruktion des jeweiligen Versuchsaufbau und dem Erwerb der für die Versuche notwendigen Materialien folgte die selbstständige Durchführung aller oben beschriebenen Versuche und die damit einhergehende Akquirierung der Daten durch mich.

Anschließend wertete ich die ermittelten Daten mittels Excel (Version 16.31 für Mac OS X, Microsoft Corporation, Redmond) eigenständig aus.

Diese Daten wurden dann gemeinsam mit den Koautoren der Publikationen mittels Statistikprogrammen (IBM SPSS Statistics, Version 24, Armonk, New York, USA; sowie R version 3.5.1, R Foundation for statistical Computing, Wien, Österreich) analysiert.

Eine erste Interpretation der Statistiken vor dem Hintergrund der wissenschaftlichen Fragestellung erfolgte daraufhin zunächst durch mich und wurde im Anschluss gemeinsam mit Dr. med. Christopher A. Becker besprochen.

Die vorgelegte Erstautorenschaft wurde initial von mir verfasst und daraufhin in Rücksprache mit Dr. med. Christopher A. Becker und den anderen Ko-Autoren überarbeitet.

Die Niederschrift der beiden anderen Veröffentlichungen erfolgte zum Teil eigenständig durch mich (vor allem Methoden und Ergebnisse), zum Teil in Zusammenarbeit mit den Ko-Autoren.

Im Anschluss an die Review-Verfahren aller Veröffentlichungen wurden die gewünschten Änderungen durch mich durchgeführt und den entsprechenden (Ko-)Autoren zur erneuten Durchsicht vorgelegt.

4. Zusammenfassung

Frakturen des Beckenringes stellen als seltene und oft schwerwiegende Verletzungen eine besonders anspruchsvolle chirurgische Herausforderung dar [1,14].

In den letzten Jahren wurden zu ihrer Versorgung verschiedene minimal-invasive Osteosyntheseverfahren entwickelt, um durch die Reduktion der peri- und postoperativen Risiken und Komplikationen das Outcome der Patienten signifikant zu verbessern [2]. Erreicht wird dies vor allem durch die Schonung des umliegenden Gewebes, die Reduktion des Blutverlustes, die Verkürzung der Eingriffsdauer sowie die frühere Mobilisierung [2,9,26,35,36].

Allerdings existieren bisher nur wenige Studien, welche die entwickelten Osteosynthesen hinsichtlich ihrer biomechanischen Eigenschaften untereinander vergleichen [14,15].

Der anteriore subkutane Fixateur interne (INFIX) beispielsweise zeigt vielversprechende biomechanische Eigenschaften, birgt jedoch durch die bislang bilaterale Installation ein hohes Risiko unter anderem für die Verletzung des Nervus cutaneus femoris lateralis der intakten Seite [27,28].

Daher erfolgte in der Studie, welche der Veröffentlichung “*Modified less invasive anterior subcutaneous fixator for unstable Tile-C-pelvic ring fractures: a* *biomechanical study"* zugrunde liegt, die Modifikation des Fixateur interne zu einem unilateralen INFIX oder einem „extended" (erweiterten) unilateralen INFIX mit additiver symphysennaher Pedikelschraube im kontralateralen Schambeinast [15].

Diese zwei neuen Osteosynthesekonstrukte wurden dann mit einem bilateralen, aus zwei Pedikelschrauben bestehenden INFIX und mit einem „extended" (erweiterten) bilateralen aus drei Pedikelschrauben bestehenden INFIX zur Versorgung einer unilateralen AO Typ C1.3-Beckenringfraktur hinsichtlich ihrer biomechanischen Eigenschaften verglichen [15].

Die Versorgung der Fraktur des posterioren Beckenringes bestand bei allen Versuchen aus zwei SI-Schrauben (siehe Bild 1, S.10) [15].

Nach Durchführung der jeweiligen Osteosynthese und Einbringung in das elektrodynamische Prüfsystem (Instron ElectroPulsTM E10000 Linear-Torsion, Norwood, USA) wurden alle Becken zyklisch zwischen 100 N und 200 N belastet. Im Anschluss erfolgte eine Maximalbelastung bis 300 N (siehe Bild 3) [15].

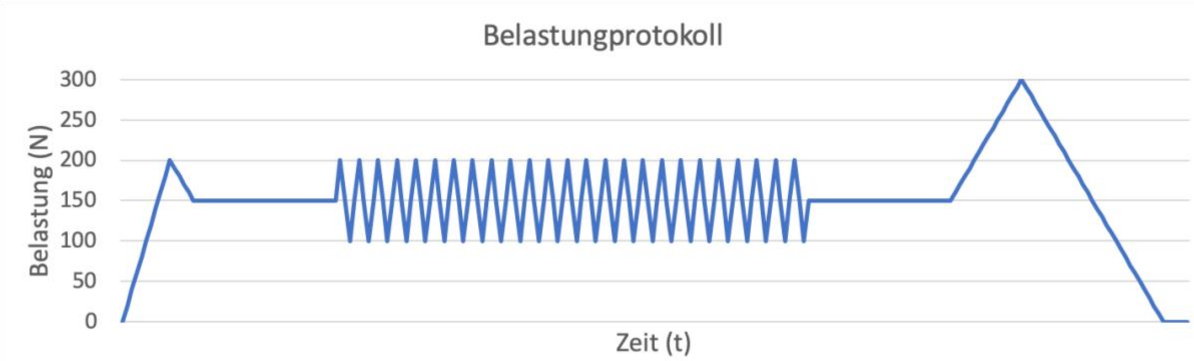

Bild 3:

Schematisches Belastungsprotokoll

Die Dislokation der Frakturfragmente wurde mittels eines 3D-Ultraschall-Systems (Zebris CMS20, Gilching, Germany) gemessen und mit Hilfe linearer Regression paarweise statistisch miteinander verglichen. Anschließend wurde die Steifigkeit (N/mm) aus dem Quotienten aus angewandter Kraft (N) und der daraus hervorgerufenen Dislokation (mm) errechnet [15].

Der „extended“ unilaterale INFIX stellte sich in den durchgeführten Versuchen als stabilste Osteosynthese, gemessen an der im Mittelwert geringsten Dislokation der Frakturfragmente zueinander, dar. Im Vergleich zum „standard“ bilateralen INFIX beispielsweise zeigte er eine signifikant höhere Rotationsstabilität (p = 0,04). Verglichen zum unilateralen INFIX zeigte die symphysennahe Einbringung einer weiteren Pedikelschraube (dem „extended“ unilateralen INFIX entsprechend) eine signifkante Verbesserung der Stabilität der anterioren Frakturdislokation (p = 0,01) [15].

Durch die Entwicklung dieser Technik könnte folglich bei Einbringung in vivo sowohl die Invasivität des INFIX reduziert, als auch die Schonung des NCFL der intakten Seite gewährleistet werden [15].

Eine weitere Schwierigkeit bei der Etablierung minimal-invasiver Osteosynthesen zur Versorgung instabiler Beckenringfrakturen stellt die unzureichende Studienlage hinsichtlich der Kombinationsmöglichkeiten der bislang entwickelten Verfahren dar [14].

Die Studie *„Biomechanical comparison of minimally invasive treatment options for Type C unstable fractures of the pelvic ring“* vergleicht vier verschiedene Osteosynthesetechniken hinsichtlich ihrer biomechanischen Eigenschaften, um die Kombination mit der größtmöglichen Stabilität bei möglichst geringer Invasivität zur Versorgung einer AO Typ C1.3-Beckenringfraktur zu identifizieren (siehe Bild 2) [14].

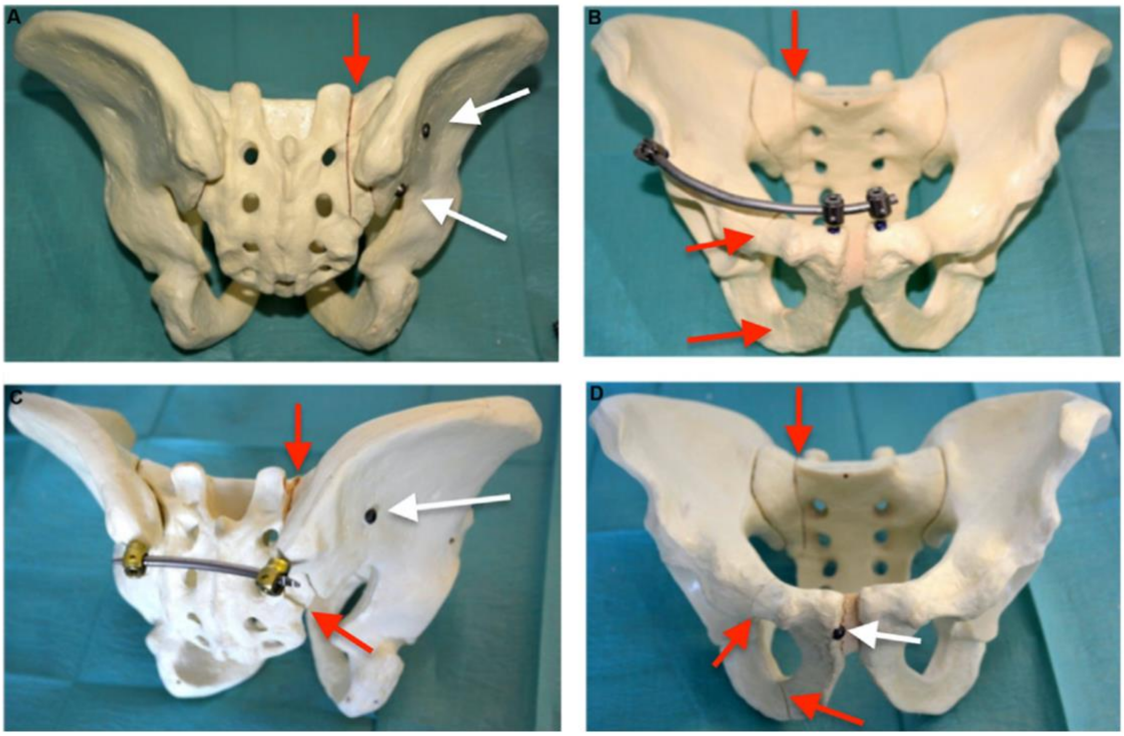

Bild 2:

A: 2 SI-Schrauben, B: Modifizierter unilateraler INFIX aus Publikation I

C: TIFI + 1 SI-Schraube, D: retrograde transpubische „Kriechschraube“

Die weißen Pfeile zeigen die Richtung der Schraubenosteosynthesen, die roten Pfeile markieren den Verlauf der C1.3 Fraktur

Als Gruppe 1 wurde in diesem Projekt der bereits beschriebene modifizierte „extended“ unilaterale INFIX miteinbezogen [15].

Als weitere Osteosynthesetechnik für den vorderen Beckenring wurde eine retrograde transpubische Schraubenosteosynthese („Kriechschraube“) (siehe Bild 2 – D) verwendet, da diese bereits zuvor in der Literatur aufgrund ihrer intramedullären Fixierung und des damit einhergehenden Widerstandes gegenüber Rotationsbewegungen des Beckens als stabile minimal-invasive Osteosynthese beschrieben wurde [2,37–39].

Für die Versorgung des hinteren Beckenringes wurden entweder zwei SI-Schrauben, welche in den Sakralwirbelkörpern (SWK) SWK1 und SWK2 platziert wurden (siehe Bild 2 – A), oder ein transiliakaler Fixateur interne (TIFI) mit einer SI-Schraube (im SWK 1 liegend) verwendet (siehe Bild 2 – C) [14].

In dieser Studie ersetzt der TIFI die zweite SI-Schraube, um durch die Unterbindung einer Rotation um die Transversalachse als zusätzliche Stabilisierung der Beckenringfraktur zu dienen (siehe Bild 4) [14].

So verbindet dieses Konstrukt sowohl die Stabilität von SI-Schrauben als auch verringert es das Risiko für Gefäß-/ Nervenverletzungen sowie für Schraubenlockerungen [14].

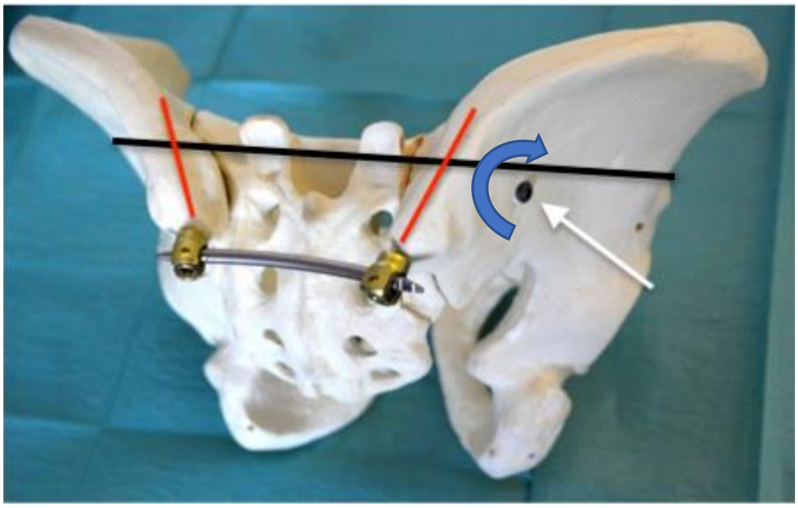

Bild 4:

Durch die möglichst senkrecht zur Transversalachse (schwarze Linie) verlaufenden Pedikelschrauben des TIFIs (rote Linien) wird die Rotation um die SI-Schraube (weißer Pfeil) verhindert

Die Aufteilung der verschiedenen Osteosynthesen erfolgte in folgende Gruppen (siehe Tabelle 1):

Versuchsgruppe	Osteosynthesekombinationen
1	INFIX + 2 SI Schrauben (Bild 2 A+B)
2	INFIX + TIFI + 1 SI-Schraube (Bild 2 B+C)
3	Retrograde transpubische „Kriechschraube“ + 2 SI-Schrauben (Bild 2 A+D)
4	Retrograde transpubische „Kriechschraube“ + TIFI + 1 SI-Schraube (Bild 2 C+D)
5	Intaktes Becken (Referenzgruppe)

Tabelle 1

Die Becken wurden im Anschluss mit dem in der ersten Veröffentlichung bereits erprobten Belastungsprotokoll zyklisch zwischen 100 N und 200 N belastet (siehe Bild 3, Seite 16).
Die Dislokation (mm) der Frakturfragmente wurde gemessen und mit Hilfe der einwirkenden Kraft (N) die Steifigkeit (N/mm) berechnet. Die statistische Auswertung erfolgte mit Hilfe einer Analysis of Variance (ANOVA) sowie einer Bonferroni Anpassung.
Die biomechanische Prüfapparatur sowie das Messsystem entsprachen denen der ersten Publikation [15].
Alle getesteten minimal-invasiven Osteosynthesen erwiesen sich als biomechanisch stabil und zeigten keine signifikanten Unterschiede untereinander (anteriore Dislokation $p = 0{,}61$; posteriore Dislokation $p = 0{,}88$).

Die Kombination zweier SI-Schrauben mit einer retrograden transpubischen Schraubenosteosynthese (Gruppe 3) zeigte jedoch die geringste absolute Dislokation (anterior und posterior 1,8 ± 0,2 mm) sowie die höchste absolute Steifigkeit (anterior 56,0 N/mm; posterior 55,9 N/mm) [14].

Die absolute Dislokation entspricht hier dem Mittelwert der maximalen Abstände aller Frakturfragmente im dreidimensionalen Raum zueinander während der zyklischen Belastung.

Folglich könnten sich alle Kombinationen dieser Osteosynthesetechniken dazu eignen, das Outcome der Patienten durch die minimale Invasivität und die geringere Operationszeit bei gleichzeitig vielversprechender biomechanischer Stabilität deutlich zu verbessern [14].

Nach erfolgreicher Modifizierung und Kombination bereits beschriebener Osteosynthesetechniken in der ersten und zweiten Veröffentlichung erfolgte die kritische Auseinandersetzung mit den bisher getesteten Therapieoptionen.

Aufbauend auf der bisher gewonnen biomechanischen Erfahrung entstand die Idee, neue, bisher am Beckenring noch nicht beschriebene aber bei anderen unfallchirurgischen Indikationen erfolgreich eingesetzte Therapieoptionen bei Beckenringfrakturen erstmalig einzusetzen [29].

Hierzu erfolgte in der Studie *„Tape suture for stabilization of incomplete posterior pelvic ring fractures—biomechanical analysis of a new minimally invasive treatment for incomplete lateral compression pelvic ring fractures“* die Testung einer bei Beckenringfrakturen noch nicht beschriebenen Osteosynthesetechnik, dem FiberTape® [29].

Das aus Polyethylen bestehende Band, dessen Wirkung auf einer Verstärkung von ligamentären Strukturen und damit einhergender „Schienung“ der Verletzung basiert [30], wurde hier zur Versorgung einer AO Typ B2.1-Beckenringfraktur zwischen den Spinae iliacae posteriores superiores eingebracht [29].

Als Vergleich diente die bei solchen Frakturen bisher etablierte SI-Schraube, hier im SWK 1 liegend [40].

Die biomechanische Testung erfolgte, wie in den vorherigen Studien auch, durch eine zyklische, axiale Belastung der Becken zwischen 150 N und 250 N. Auch hier wurde die Dislokation (mm) der Frakturfragmente gemessen und mit der einwirkenden Kraft (N) die Steifigkeit (N/mm) berechnet. Der Vergleich der daraus ermittelten Daten erfolgte statistisch mittels linearer Regression.

Anhand der in der Studie ermittelten Daten konnte gezeigt werden, dass das FiberTape® mit einer Dislokation von 2,2 ± 0,8 mm und einer Steifigkeit von 52,2 ± 18,0 N/mm der SI-Schraube (Dislokation 2,1 ± 0,6 mm; Steifigkeit 50,8 ± 13,0 N/mm) im Bereich der hinteren Beckenringfraktur nicht signifikant ($p > 0,999$) unterlegen war [29].

Auch an der vorderen Fraktur zeigte sich das FiberTape® hinsichtlich Dislokation und Steifigkeit der SI-Schraube nicht signifikant unterlegen (Dislokation: $p = 0,22$; Steifigkeit: $p = 0,07$) [29].

Aufgrund der aufgezeigten vergleichbaren biomechanischen Stabilität bei gleichzeitig aber mutmaßlich in vivo geringerem Verletzungsrisiko relevanter Strukturen sowie voraussichtlich geringerer intraoperativer Strahlenbelastung stellt sich das FiberTape® daher als vielversprechende minimal-invasive Osteosynthese zur Versorgung von inkompletten Beckenringfrakuren dar [29].

Abschließend lässt sich sagen, dass, trotz der vielversprechenden biomechanischen Eigenschaften aller in dieser Arbeit gestesteten Osteosyntheseverfahren im experimentellen Setting, es zuvor noch klinischer Studien bedarf, um abschließende Rückschlüsse auf die klinische Umsetzbarkeit ziehen zu können.

4. Summary

Pelvic fractures are rare and often severe injuries and as such represent one of the most challenging surgical procedures [1,14].

Recently, various minimally invasive techniques have been developed in order to significantly improve the patient's outcome through the reduction of peri-and postoperative risks and complications [2]. This especially includes the conservation of the surrounding tissue, the reduction of blood loss and surgical procedure time and the earlier mobilization of the patient [2,9,26,35,36].

However, only few studies compare the newly developed osteosynthesis techniques regarding their biomechanical properties [14,15].

The anterior subcutaneous internal fixator (INFIX) for example shows promising biomechanical results, yet due to its in literature described bilateral installation on the pelvis displays a significant risk of injuring the NCFL of the intact side of the pelvis [27,28].

Consequently, in the study leading to the first publication "*Modified less invasive anterior subcutaneous fixator for unstable Tile-C-pelvic ring fractures: a biomechanical study"* the internal fixator was modified to a unilateral INFIX or to an "extended" unilateral INFIX with an additional pedicle screw close to the symphysis in the contralateral pubic ramus [15].

The biomechanical properties of these two constructs were then compared to either a bilateral INFIX with two pedicle screws or to an "extended" bilateral INFIX with three pedicle screws for the fixation of a unilateral AO type C1.3-pelvic fracture [15].

The fixation of the posterior pelvic ring fracture consisted of two SI screws in all groups (see figure 1, page 10) [15].

After osteosynthesis and attachment of the pelvises to the electrodynamic testing system (Instron ElectroPulsTM E10000 Linear-Torsion, Norwood, USA), all pelvises were cyclically loaded between 100N and 200N. Afterwards, a maximum loading of 300N was applied to the pelvises (see figure 3, page 16) [15].

The dislocation of the fracture fragments was detected with a 3D ultrasound system (Zebris CMS20, Gilching, Germany). The statistical comparison was made using linear regression. The stiffness (N/mm) was then calculated by the ratio of the applied force (N) and the resulting dislocation (mm) [15].

In this study, the “extended” unilateral INFIX proved to be the osteosynthesis with the highest stability based on the least mean dislocation between the fracture fragments. Compared to the “standard” bilateral INFIX, the “extended” unilateral INFIX displayed a significantly higher rotational stability (p = 0,04). Also, the “extension” of the unilateral INFIX with an extra pedicle screw on the contralateral pubic ramus close to the symphysis proved to significantly improve the stability of the anterior fracture dislocation (p = 0,01) [15].

When applied in vivo, the development of this technique could consequently not only lead to the reduction the invasiveness of the INFIX but also to the preservation the NCFL of the intact side of the pelvis [15].

Another difficulty when establishing minimally invasive treatment options for pelvic ring fractures is the lack of biomechanical studies investigating the possible combinations of the already developed osteosynthesis techniques [14,15].

Hence, the study *“Biomechanical comparison of minimally invasive treatment options for Type C unstable fractures of the pelvic ring”* compares the biomechanical properties of four different osteosynthesis methods in order to identify the combination merging the highest stability with the lowest possible invasiveness for the treatment of an AO type C1.3-pelvic ring fracture (see figure 2, page 18) [14,15,29].

The already described “extended” unilateral INFIX was included as group 1 in this study [15].

A retrograde transpubic screw was used as an alternative osteosynthesis for the fixation of the fracture of the anterior pelvic ring (see figure 2 – D, page 18). This method has previously been described as a stable minimally invasive osteosynthesis due to its intramedullary fixation and therefore its resistance to rotational forces [2,14,37–39].

The posterior fracture of the pelvic ring was fixed with either two SI screws, which were placed in the first and second sacral vertebra (see figure 2 – A, page 18), or a transiliac internal fixator (TIFI) in combination with one SI screw being placed in the first sacral vertebra (see figure 2 – C, page 18) [14].

In this study, the TIFI functioned as a substitute for the second SI screw in order to provide additional stability by preventing rotation around the transversal axis (see figure 4, page 19) [14]. Therefore, it combines the stability of SI screws with a reduced risk of tissue injuries or screw loosening [14].

The different osteosynthesis methods were divided in the following groups (see table 1, page 20).

Next, all pelvises were periodically loaded between 100N and 200N based on the testing protocol of the first publication (see figure 3, page 16).

The dislocation (mm) of the fracture fragments was measured and with the applied force (N) the stiffness (N/mm) calculated. The statistical analysis was performed with an Analysis of Variance (ANOVA) and a Bonferroni adjustment [14].

The biomechanical testing machine and the measuring system corresponded to the first publication.

All minimally invasive osteosynthesis methods proved to be biomechanically stable and did not show any significant difference among each other (anterior dislocation p=0,61; posterior dislocation p=0,88).

The combination of two SI screws with a retrograde transpubic screw (group 3) however displayed the least absolute dislocation (anterior and posterior 1,8 ±

0,2 mm) and the highest absolute stiffness (anterior 56,0 N/mm; posterior 55,9 N/mm) [14].

The absolute dislocation corresponds to the average of the maximum distances between all fracture fragments during the cyclic loading.

Consequently, all combinations could possibly improve the patient's outcome based on their reduced invasiveness and surgical procedure time in combination with their promising biomechanical stabilities [14].

After successful modification and combination of existing osteosynthesis methods in the first and second publication, a critical analysis was performed concerning the so far tested osteosynthesis methods.

Based on the gathered biomechanical experience, the idea emerged of testing a new osteosynthesis which has not yet been applied in pelvic surgery but successfully utilized in other surgical fields [29].

Consequently, a not yet described osteosynthesis technique in pelvic surgery, the FiberTape®, was tested in the study "*Tape suture for stabilization of incomplete posterior pelvic ring fractures—biomechanical analysis of a new minimally invasive treatment for incomplete lateral compression pelvic ring fractures*" [29].

The effect of the polyethylen band is based on the reinforcement of ligamental structures and concomitant "splinting" of the injury [30].

In this study, the tape was applied to an AO type B2.1 pelvic fracture spanning between both superior posterior iliac spines [29] and compared to a SI screw placed in the first sacral vertebra, representing the current treatment method of choice in such fractures [40].

Similar to the other studies, a cyclic axial loading between 150N and 250N was then applied to all pelvises. The dislocation (mm) of the fracture fragments was measured and with the applied force (N) the stiffness (N/mm) calculated. The results were then compared using linear regression.

Based on the data acquired in this study, we could demonstrate that with a dislocation of 2,2 ± 0,8 mm and a stiffness of 52,2 ± 18,0 N/mm, the FiberTape® showed similar biomechanical properties considering the posterior fracture site compared to a SI screw (dislocation 2,1 ± 0,6 mm; stiffness 50,8 ± 13,0 N/mm) (p > 0,999) [29]. When taking the anterior fracture side into account, the FiberTape® again was not significantly inferior to the SI-screw regarding its dislocation (p = 0,22) and stiffness (p = 0,07) [29].

Based on the comparable biomechanical properties of the FiberTape® detected in this experiment in combination with its in vivo assumed lower risk of injury of relevant structures and expected fewer intraoperative radiation, the FiberTape® presents as a promising minimally invasive osteosynthesis method for the treatment of incomplete pelvic fractures [14].

Finally, despite the promising biomechanical properties of all osteosynthesis methods tested in the studies above in an experimental setting, clinical studies are needed prior to drawing conclusions concerning their clinical feasibility.

5. Veröffentlichungen

5.1. Veröffentlichung I

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Modified less invasive anterior subcutaneous fixator for unstable Tile-C-pelvic ring fractures: a biomechanical study

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Abstract

Background: Operative procedures for unstable pelvic ring fractures remain controversially discussed. Minimally invasive treatment options for pelvic ring fractures have several benefits for the patient. But they can also provide disadvantages. Anterior subcutaneous pelvic fixation (INFIX) has shown promising biomechanical results in pelvic ring fractures, but there is a high complication rate of nerve injuries. An additional screw to the INFIX seems to be more stable. The aim of this study is to compare biomechanical stability of a new modified unilateral INFIX fixing the unilateral injured pelvic ring with the standard INFIX.

Methods: 24 composite synthetic full pelvises were used in this study. 4 groups each with a number of six pelvic specimens were randomly assigned. A C1.3-type pelvic fracture was made with an osteotomy of the sacrum and an osteotomy of the anterior pelvic ring. Fracture fixation was performed within the four groups: (1) unilateral INFIX, (2) "extended" unilateral INFIX + additional pubic ramus pedicle screw, (3) bilateral INFIX, (4) "extended" bilateral INFIX + additional pubic ramus pedicle screw. All specimens were cyclic loaded with 200 N until maximum of 300 N. Distance/dislocation of the fracture fragments were detected with 3D-ultrasound measuring system. Stiffness was calculated.

Results: Extended unilateral INFIX showed the lowest mean dislocation. Lowest rotational stability was displayed by the standard bilateral INFIX. A significant difference ($P = 0.04$) was shown between the extended unilateral INFIX and the "standard" bilateral INFIX in terms of rotational stability. Extended unilateral INFIX showed significantly improved stability of anterior fracture dislocation ($P = 0.01$) and unilateral INFIX showed the highest rotational stiffness. Anterior fixation stiffness of the unilateral INFIX was significantly improved using an additional symphysis/pubic ramus screw ($P = 0.002$).

Conclusion: Extended unilateral INFIX (+ additional pubic ramus pedicle screw) is a feasible minimally invasive treatment for anterior pelvic ring fractures. Higher stability and lower probability of bilateral nerve damage is provided by the extended unilateral INFIX compared to the standard bilateral INFIX.

Keywords: Pelvic ring fracture, Biomechanical study, Tile-C-fracture, Minimally invasive fixation

Introduction

While consensus exists on the need of surgical treatment of unstable pelvic ring fractures, the choice of the ideal strategy for osteosynthesis remains controversial [1–3]. Current clinical research shows that minimally invasive strategies may have several benefits for patients compared to the more invasive plate osteosynthesis [4, 5]. The anterior subcutaneous pelvic fixator (INFIX) has formerly been described as a treatment option for unstable pelvic ring fractures and biomechanical studies reveal a superior stability of the INFIX compared to a supraacetabular external fixator [6]. Clinical data show that the stability and the clinical outcome of patients with pelvic ring fracture treated with an INFIX (or INFIX with three screws) is sufficient compared to standard open plate osteosynthesis [7].

Nonetheless, some clinical data also hints towards increased complication rates for the INFIX as well as supraacetabular external fixation, the main complication being damage to the superficial femoral cutaneous nerve [8, 9]. This nerve is at risk on both sides of the pelvic ring as it is situated closely to the lateral screw and it can easily be crushed between the bone cortex and the rod.

The configuration providing optimal stability when using the INFIX is debatable. A very limited number of papers demonstrated that it might be useful to add a third screw next to the pubic symphysis [7]. Another option to improve stability while reducing the risk of nerve damage on the contralateral side could be the connection between the unilateral supraacetabular screw with two screws on both side of the pubic symphysis.

The purpose of this study was to evaluate the stability of the unilateral INFIX compared to a bilateral INFIX with two variations of each. We hypothesize that both configurations offer a comparable stability and stiffness of a unilateral and a bilateral INFIX, rendering the unilateral INFIX a viable option for unstable pelvic ring fractures.

Methods

24 composite synthetic full pelvises (Model: Full Pelvis 1301, Sawbones®; Pacific Research Laboratories, Vashon, WA, USA) were used in this study. Each specimen was randomly assigned to one of four fixation groups each, yielding six pelvic specimens per each of the following groups: unilateral INFIX (Group 1); "extended" unilateral INFIX + additional pubic ramus pedicle screw (Group 2); bilateral INFIX (Group 3); "extended" bilateral INFIX + additional pubic ramus pedicle screw (Group 4) (Fig. 1).

After randomization, an AO Classification type C1.3 pelvic ring fracture was simulated in each specimen by performing an osteotomy of the sacrum (lateral of the foramen, Denis I-type) and an osteotomy of the anterior pelvic ring (complete fracture of pubic ramus and ischium) using a hacksaw.

Once the fracture models were created, INFIX fixation was applied using two or three pedicle screws (6.5 × 50 mm, Viper, Synthes, USA) and a connection rod (cobalt chrome 5.5 mm, Synthes, USA) depending on the osteosynthesis in the anterior inferior iliac spine and symphyseal part of the ramus ossis pubis uni- or bilateral. In every group the SI-joint was unilaterally fixed with two cannulated iliosacral screws (7.5 × 70 mm, Königsee Implantate GmbH, Allendorf, Germany) placed into S1.

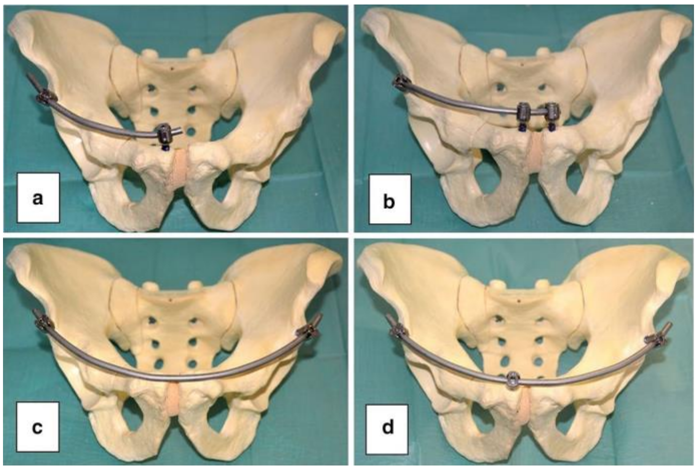

Fig. 1 **a** Unilateral INFIX + 2 iliosacral screws, **b** extended unilateral INFIX + 2 iliosacral screws, **c** bilateral INFIX + 2 iliosacral screws, **d** extended bilateral INFIX + 2 iliosacral screws

Tension banding of the iliotibial tract is simulated with the use of cable pulls fixed ipsilateral to the iliac crest.

Our biomechanical test protocol was conducted according to McDonald et al. [10]. A bipolar hemi-prosthesis was inserted into the acetabulum in order to simulate axial skeletal loading.

Fracture fragment displacement were measured using a 3D ultrasound tracking system with an error margin of 0.1 mm (Zebris CMS20; Zebris Medical GmbH, Isny, Germany). A total of three sensors were fixed onto the acetabulum, the symphysis and the sacrum.

An all-electric industrial loading machine (ElectroPulsTM E10000 Linear-Torsion) was used in this study with the following test protocol: (1) axial loading up to 200 N; (2) loading to 150 N for 30 s; (3) cyclic loading of 25 cycles with a frequency of 0.25 Hz between 100 and 200 N; (4) loading to 150 N for 30 s; (5) maximal loading up to a force of 300 N or until reaching a displacement limit of −28 mm; (6) system back to its original position of +28 mm. Due to the lower load capacity of the synthetic pelvic models, a force of a maximum of 300 N (approximately 1/2 body weight) was used for the cyclical tests in order not to jeopardize the integrity of the osteosynthesis. This should be taken into account when interpreting the results of the current study and for any in vivo considerations. The relative distance of each the three sensors to each other was recorded. A maximum distance of the sensors was defined as the maximum displacement of the fragments in a certain direction (mm). Stiffness was defined as the loading force divided by the maximum displacement distance (N/mm) (Fig. 2).

Fig. 2 Biomechanical setup with the pelvis fixed onto the testing machine. Sensors were fixed at the sacrum, the pubic symphysis and the acetabulum

Statistical analysis

We used linear regression to test for an effect of fixation techniques on fracture fragment displacement and construct stiffness. Robust standard errors were calculated to decrease to chance of a type I error. Pairwise comparisons were performed between techniques and a Holm correction was applied to all P-values. Alpha was set to 0.05 for all tests. Descriptive statistics are presented as mean and standard deviation or 95% confidence interval (95% CI) wherever appropriate. All testes were conducted using R version 3.5.1 (R Foundation for Statistical Computing, Vienna, Austria).

Results

Displacement

Mean displacement (distance Symphysis—Sacrum) was 7.4 ± 2.9 mm and mean anterior displacement was 3.6 ± 1.1 mm.

Extended unilateral INFIX showed the lowest mean displacement. The highest rotational stability was displayed by both the unilateral INFIX as well as the extended unilateral INFIX. The lowest rotational stability was displayed by the classic bilateral INFIX (Fig. 3).

A significant difference ($P = 0.004$) was shown between the extended unilateral INFIX and the "standard" bilateral INFIX in terms of rotational stability.

Additional symphysis/pubic ramus pedicle screws installed to the unilateral INFIX (= extended unilateral INFIX) showed significantly improved stability of anterior fracture dislocation ($P = 0.01$).

Anterior stability of the fracture of the bilateral INFIX is slightly, not significantly improved by an additional symphysis/pubic ramus pedicle screw ($P = 0.7$).

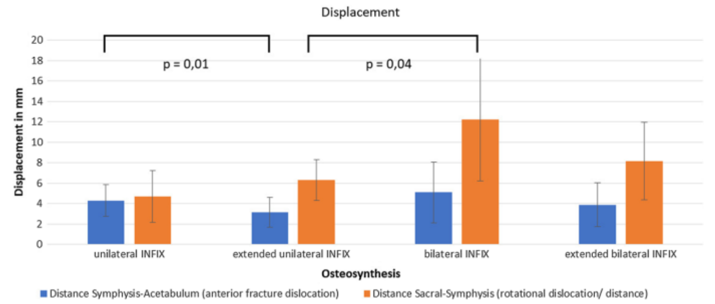

Fig. 3 Average displacement (mm) of the four different groups: (1) unilateral INFIX, (2) extended unilateral INFIX, (3) bilateral INFIX, (4) extended bilateral INFIX

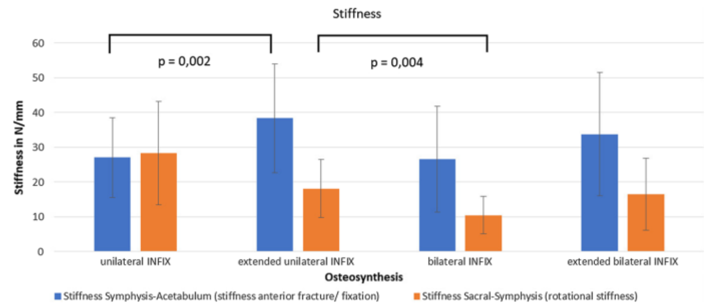

Fig. 4 Mean stiffness (N/mm) of the four different groups: (1) unilateral INFIX, (2) extended unilateral INFIX, (3) bilateral INFIX, (4) extended bilateral INFIX

Stiffness

Mean rotational stiffness (Stiffness Symphysis—Sacrum) was 48.7 ± 17.5 N/mm and the mean anterior fracture/fixation stiffness was 84.6 ± 21.5 N/mm (Fig. 4).

The highest rotational stiffness was seen with the unilateral INFIX. There was also a significant difference ($P = 0.004$) of the unilateral INFIX with an additional symphysis/pubic ramus pedicle screw compared with the bilateral INFIX.

Anterior fixation stiffness of the unilateral INFIX was significantly improved using an additional symphysis/pubic ramus screw ($P = 0.002$).

Discussion

Optimal fixation strategy in unstable pelvic fractures remains controversial topic in orthopaedic trauma care. In the last decade, minimally invasive approaches have shown promising results. The aim of the current study was to evaluate the biomechanical stability of a unilateral and extended unilateral INFIX compared to the a bilateral INFIX for fixation and stabilization of unstable pelvic fractures. The main findings of the current study were that. The biomechanical stability of the extended unilateral INFIX was significantly superior to that of the bilateral INFIX. He addition of a pubic ramus or symphysis pedicle screw to the unilateral INFIX provided significantly better anterior stiffness and decreased anterior fracture fragment displacement.

These results show that, in cases of unilateral pelvic ring instability, the classic bilateral INFIX could be replaced by the extended unilateral INFIX, reducing the risk of nerve damage on the contralateral, uninjured site. Furthermore, we see the potential for using the additional pubic ramus pedicle screw for reduction of the fracture, as it offers good control of the medial fragment. Due to the three-point-attachment, the rod could play a role in reducing the intermediate fragment attached to the screw in the middle, similar to spine surgeries.

Preliminary results of ongoing biomechanical have demonstrated good biomechanical stability of a modified INFIX for acetabular T-type-fractures, simultaneously using this device for the reduction of the anterior acetabular column.

Displaced fractures of the anterior pelvic ring often require open reduction and internal fixation. For this procedure, anterior approaches such as the modified Stoppa approach can be used [11]. These approaches have many disadvantages, such as high blood loss and the risk of nerve damage due to traction [11–13].

Minimally invasive treatment options of the anterior pelvic ring are normally performed with a retrograde transpubic screw, a supraacetabular external fixator or, as a new method, with the INFIX. These treatments also have some disadvantages, mainly regarding difficulties to achieve a proper reduction in displaced fractures. An additional supraacetabular external fixator may help to reduce the fracture but may introduce a higher risk of infection of the pin screws, loosening of the screws, loss of reduction, as well as a massive discomfort of the patient who has to cope with this construction in his or her daily routine [14, 15]. The INFIX also seems more effective than external fixation at reducing postoperative surgical site pain [16]. Other disadvantages of the external pelvic fixator include worse outcomes in diabetic and obese patients [17].

Biomechanically, the INFIX is more stable compared to the external fixator and provides better stability [6]. The symphysis-fixed INFIX (extended unilateral INFIX) could provide improved rotational stability compared to the bilateral INFIX with fixation of the symphysis. A finite element study by Song et al. [17] showed better rotational stability of the plate fixation fixed to the symphysis compared to the bilateral INFIX. It was concluded that this could be due to the fixation to the symphysis [17].

Our results also underline that the extended unilateral INFIX could provide better rotational stability than the standard bilateral INFIX, possibly because fixation next to the symphysis provides more anterior stability when using the INFIX for anterior pelvic ring fractures. Further biomechanical studies should follow especially in human pelves to confirm these findings.

We assume that the extended unilateral INFIX has better stability than the bilateral INFIX with the possible advantage of performing a reduction of the fracture with the pre-bend rod.

A problem of the extended INFIX, and also the classic INFIX, is the anterior fixation near the pubic symphysis. Anatomically, the anterior fixation site is located near the urinary bladder, therefore having the potential for irritating it, especially when filled. The potential bladder damage is also a problem when performing INFIX or extended INFIX

[2]. In clinical situations, another problem of the INFIX is the potential damage to nerve and vessel structures like the lateral femoral cutaneous nerve, the femoral artery or the femoral vein during the operation. On the other hand, the more invasive Stoppa approach for ORIF is more challenging for the surgeon and has high potential for damaging blood vessel structures or the peritoneum [12].

Our study has a number of potential limitations. The composite bones do not fully resemble the biomechanical conditions in a human body, but they do have the advantage of providing reproducible and comparable biomechanical testing, thus avoiding the variability inherent to cadaveric specimens. In terms of fracture reduction, the synthetic bones are by far easier to reduce than human in vivo pelvic bones. However, previous studies have already demonstrated that the INFIX is a feasible technique of reduction and fixation of fractures in patients with pelvic trauma.

Conclusion

The extended unilateral INFIX with an additional pubic ramus pedicle screw is a feasible minimally invasive alternative treatment for anterior pelvic ring fractures, especially in Tile-C unstable pelvic fractures. Further in vivo studies are warranted to evaluate the use of the extended unilateral INFIX in anterior pelvic ring fractures in a clinical setting.

Abbreviation

INFIX: internal fixator.

Authors' contributions

ACK, MW, CT and CL carried out the experiments. CAB wrote the manuscript with support from CK, CZ, SW and WB. FS and ES helped to supervise the project and the statistics. CAB and AG supervised the project. All authors read and approved the final manuscript.

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Competing interests

The authors declare that they have no competing interests.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Consent for publication

All authors give their consent for publication.

Ethics approval and consent to participate

Since this is an experimental study on the artificial bone, no ethics approval and consent to participate are necessary.

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Original article

Biomechanical comparison of minimally invasive treatment options for Type C unstable fractures of the pelvic ring

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ABSTRACT

Background: The definite treatment of pelvic C fractures presents a widely discussed issue and undergoes continuous evolution. While the stabilization of the posterior ring has been studied extensively, the fixation of the anterior pelvic ring continuous to be rarely investigated. The importance of the simultaneous stabilization however lays in the earlier mobilization and prevention of long-term damage to the pelvis. Therefore we investigated four combinations of minimally invasive fixation techniques for unstable type C1-3 pelvic injuries and aimed to answer the following research questions: (1) what combination of fixation methods yields the highest stiffness and the least displacement? (2) Is the combination of a single sacroiliac screw (SI-screw) with a transiliac internal fixator (TIFI) a reasonable alternative to two SI-screws? (3) Is a modified unilateral anterior fixation comparable to a retrograde transpubic screw?
Hypothesis: Minimally invasive fixation techniques provide sufficient biomechanical stability for type C pelvic fractures.
Methods: Thirty synthetic full pelvises were divided into 5 groups, of which 4 groups were assigned a different osteosynthesis method and one was an intact pelvis used as reference (group 1: internal fixator + 2 sacroiliac screws, group 2: internal fixator + transiliac internal fixator + 1 sacroiliac screw, group 3: retrograde transpubic screw + 2 sacroiliac screws, group 4: retrograde transpubic screw + transiliac internal fixator + 1 sacroiliac screw). The pelvises underwent a protocol of cyclic loading between 100 N and 200 N, during which they were subjected to compression loads while the position of the fracture fragments was measured every 30 milliseconds. Displacement and stiffness were calculated for statistical analysis.
Results: The minimally invasive fixation methods investigated in this study all provide sufficient biomechanical stability without one method being superior to the others (p [anterior displacement] = 0.61 and p [posterior displacement] = 0.88). Group 3 was allowed the least displacement (1.8 ± 0.2 mm for anterior and posterior fracture) for the treatment of a C1.3 fracture. The other fixation methods displayed the following dislocations (mm) of the anterior pelvic ring: group 1: 1.9 ± 0.3, group 2: 2.1 ± 0.4, group 4: 2.0 ± 0.5. Posteriorly, the displacements (mm) were the following: group 1: 1.8 ± 0.6, group 2: 1.9 ± 0.2, group 4: 2.0 ± 0.5.
Discussion: The minimally invasive fixation methods investigated in this study all provide sufficient biomechanical stability without one method being superior to the others since differences were not significant regarding anterior and posterior displacements. Even if not significantly, we could reveal that out of all the methods tested the combination of 2 SI-screws with a retrograde transpubic screw (group 3) displayed the least displacement and highest stiffness. These techniques could therefore potentially improve patient's clinical outcome by reducing the surgical invasiveness and procedure time while providing sufficient biomechanical stability.
Level of evidence: III, comparative in vitro study.

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1. Introduction

Pelvic fractures occur with an incidence of approximately 3% and display mortality rates ranging between 10% and 16% [1–3]. Currently, the external pelvic fixator frame or the pelvic C-clamp has become a standard emergency treatment for temporary stabilization in highly unstable pelvic fractures in Europe [1] although complications such as pin tract infection (up to 18%), pin loosening and soft tissue complications persist [3,4]. In case of a pubic ramus fracture, commonly accepted treatment methods include supra-acetabular or iliac wing external fixation, pubic ramus plating or ramus screw fixation [2]. A newly introduced alternative is the subcutaneously applied anterior internal fixator [5]. The bilateral internal fixator consists of three screws at both anterior inferior iliac spines (AIIS) and the pubic tubercle and is described to be stiffer than a standard external fixator [5], eliminating the external pin construct, improving the patients comfort and facilitating his nursing care [4,5].

Treatment options for the posterior pelvic fixation however include external fixation with C-clamp [3], open reduction internal fixation with plates or screws, tension band constructs, transiliac bars, percutaneous sacroiliac screws [6], triangular or lumbo-pelvic stabilization [7,8]. Another option is the transiliac internal fixator (TIFI) [9] with its main indication being unilateral pelvic instabilities that often occur in C-type fractures [10].

Due to the complete disruption of the posterior and anterior pelvic complex, type C fractures represent a highly demanding injury [2] and the definite treatment still remains a widely discussed issue undergoing continuous evolution [1]. Another problem remains the fact that the stabilization of the posterior ring has been studied extensively, while the fixation of the anterior pelvic ring continuous to be rarely investigated [2]. Recently, McLachlin et al. [2] stressed the overall importance of a simultaneous osteosynthesis of the anterior and posterior pelvic ring in order to achieve an early mobilization of the patient and to prevent long-term damage to the pelvis.

Due to the remaining controversy on the superiority of any minimally invasive treatment option for unstable pelvic fractures, this biomechanical study compares different combinations of minimally invasive treatments for unstable C-type pelvic fractures (internal fixator or retrograde transpubic screw for anterior pelvic ring fixation and 2 SI-screws or TIFI + one SI-screw for posterior pelvic ring fixation) and therefore aims to identify the combination offering the best stability with the lowest invasiveness and maximum safety possible based on the following questions:

- what combination of fixation methods yields the highest stiffness and the least displacement?;
- Is the combination of a single sacroiliac screw (SI-screw) with a transiliac internal fixator (TIFI) a reasonable alternative to two SI-screws?;
- Is a modified unilateral anterior fixation comparable to a retrograde transpubic screw?

Wo hypothesized that minimally invasive fixation techniques provide sufficient biomechanical stability for type C pelvic fractures.

2. Material and methods

2.1. Material

Thirty synthetic specimens (model: Full Pelvis 1301, Sawbones™; Pacific Research Laboratories, Vashon, WA, USA) were used in this study.

Table 1
The four osteosynthesis trials.

Group 1	Internal fixator + 2 sacroiliac (SI) screws (Fig. 1A and B)
Group 2	Internal fixator + transiliac internal fixator (TIFI) + 1 sacroiliac screw (Fig. 1B and C)
Group 3	Retrograde transpubic screw + 2 sacroiliac screws (Fig. 1A and D)
Group 4	Retrograde transpubic screw + transiliac internal fixator + 1 sacroiliac screw (Fig. 1C and D)

The equality of all specimens allowed the elimination of potential individual confounding variables, such as anatomical variations or structural differences concerning density or bone quality that could affect the biomechanical outcome when using cadaver pelvises.

In accordance with the AO classification, the C-type fracture investigated in this study can be classified as a C1.3 fracture [11], combining a transalar sacral fracture representing the posterior instability with ipsilateral superior and inferior pubic ramus fractures to represent the anterior instability.

A thin hacksaw blade was used to create the fractures. A metal plate with a width of 2 mm was inserted at the fracture site and was kept in place manually by the surgeon during the performance of each osteosynthesis. This ensured a 2 mm fracture gap in all trials, elevating the level of comparability and standardization.

For osteosynthesis, 4 groups, each consisting of 6 pelvises, were compared (Table 1 and Fig. 1A–D): internal fixator, 80 mm cannulated and fully threaded sacroiliac screws (7,5 mm), TIFI and retrograde transpubic screw (7,5 mm): the modified extended unilateral internal fixator consisted of three pedicle screws (6,5 mm) being connected by a rod (5,5 mm cobalt-chrome). One screw was placed supra-acetabular, whereas the other two were inserted on either side of the pubic symphysis (Fig. 1B). A comparable type of modified internal fixator was used in a recent biomechanical study by Becker et al. [12] using a unilateral modified internal fixator to fix and reduce T-type acetabular fracture with promising results. Parts of the raw data, used for a previous study by Becker et al. [13] were analyzed to calculate displacement of Trial 1. The TIFI was composed of two pedicle screws (6,5 mm), each being inserted 1–2 cm caudal of the right and left posterior superior iliac spine. The screws were then connected by a rod (5,5 mm cobalt-chrome) (Fig. 1C). When using two sacroiliac screws (SI-screws), they were placed into the S1 and S2 vertebrae respectively, whereas when using only one SI-screw, it was placed into S1 (Fig. 1A and C). The retrograde transpubic screw started from the pubic tubercle and ultimately passed through the superior ramus of the pubic bone (Fig. 1D). Also, a reference group consisting of 6 intact specimens representing the intact human pelvis was used.

2.2. Methods

For biomechanical testing, a custom device attached to the sacrum connected the pelvises to an all-electric test instrument (ElectroPuls™ E10000 Linear-Torsion) according to a previous study by Becker et al. [12]. The S1 vertebra was fixed (Fig. 2). The created socket joint allowed free articulation. Torque was not measured, since no force sensor was applied to cables. A dual head prosthesis simulated physiological biomechanical hip loading. A 3D-ultrasound system (Zebris CMS20) measured the movement of each fracture fragment following the loading tests. Cable pulls fixed to the iliac crest simulated the tension banding of the iliotibial tract. The experimental setup is detailed in Fig. 2.

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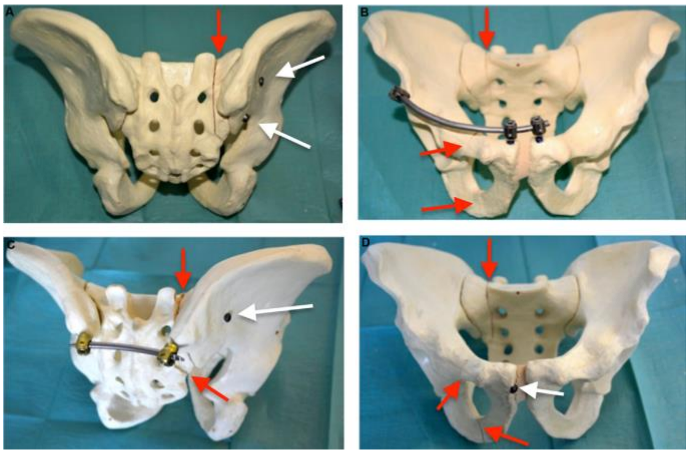

Fig. 1. The four osteosynthesis methods. A. Two sacroiliac screws. B. Modified unilateral internal fixator. C. Transiliac internal fixator (TIFI). D. Retrograde pubic screw. White arrows indicating screw positions and red arrows indicating fracture site.

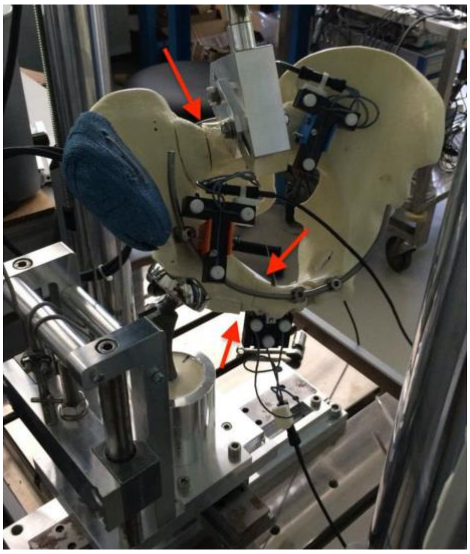

Fig. 2. Experimental setup with a specimen connected to the testing machine and the 3 ultrasound sensors on each fragment. Red arrows indicating the fracture sites. The picture shows a preliminary test of the experimental setup.

2.3. Methods of assessment

To achieve a repeatable simulation, the following 6-step testing protocol according to Becker et al. [13] and McDonald et al. [14] was applied to all trials (Table 2).

The ultrasound system measured the positions of all nine sensors every 30 milliseconds with a resolution of 0,1 mm, allowing the determination of the relative distance between all sensors at all times. Eventually, the maximum relative distance measured in step 3 between each fracture fragment (Table 2) was considered for final analysis. Its calculation was based on the subtraction of the 3D position of all sensors (Fig. 3). We defined the whole construction stiffness as the loading force (N) divided by the maximum distance (mm).

Table 2
6-step protocol for biomechanical testing.

Step 1	Preloading to 200 N to test if the construct is stable and positioned correctly
Step 2	Loading to 150 N for 30 s to establish a baseline for cyclic loading
Step 3	Periodic loading: 25 cycles with a frequency of 0,25 Hz between 100 N and 200 N
Step 4	Loading to 150 N for 30 s back to baseline
Step 5	Maximal loading up to a force of 300 N or until a maximum dislocation of 56 mm (to ensure the tested osteosynthesis is still stable)
Step 6	System back to its original position

2.4. Statistics

An Anova analysis and a Bonferroni adjustment were applied to compare maximum displacement of groups 1 to 4. Afterwards a second Anova was performed in order to compare the four groups to the reference group. A $p < 0{,}05$ was judged as statistically significant with a 95% confidence interval. A non-parametrical test, the Kruskal-Wallis-Test, was added to analyze the sensitivity. Based on current literature [12,13], a sample size of six specimen was chosen. We did not perform a belayed power calculation due to the significance of the results.

3. Results

Comparing our results, all osteosynthesis methods used for the stabilization of the posterior fracture display a similar dislocation to an intact pelvis, whereas anteriorly all surgical treated pelvises showed a slightly higher dislocation (Figs. 4 and 5 and Table 3).

Fixating the posterior fracture with 2 SI-screws (groups 1 and 3) and comparing the different anterior fixation methods of these groups, the retrograde transpubic screw displayed non-significantly less anterior movement (median displacement = 1.8 ± 0.2 mm) than the internal fixator (1.9 ± 0.3 mm) ($p = 0{,}61$).

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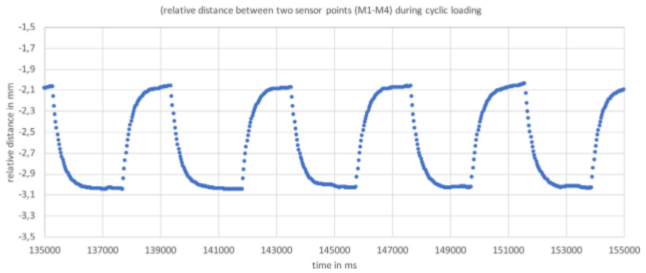

Fig. 3. The evolution of the relative distance during cyclic loading in step 3 over time (ms) (see Table 2).

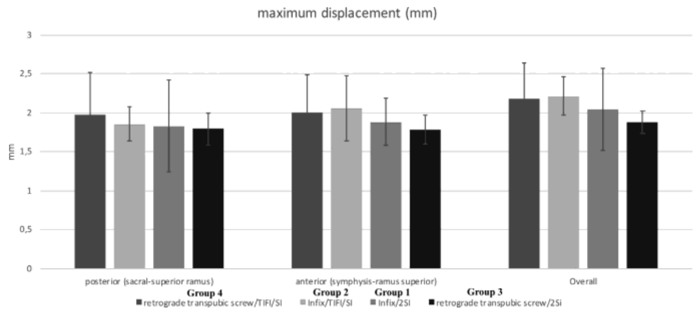

Fig. 4. Maximum displacement of anterior and posterior fracture of groups 1–4 and overall displacement (TIFI: transiliac internal fixator; SI: sacroiliac screw(s); Infix: internal fixator).

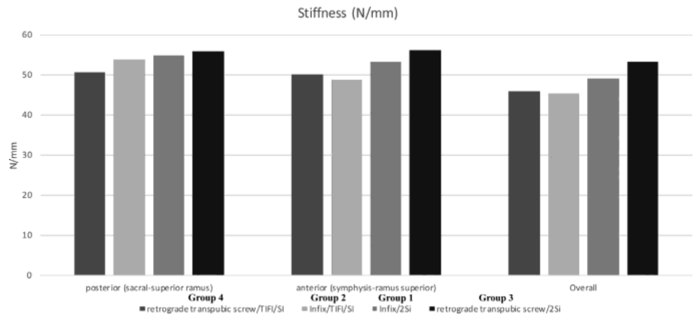

Fig. 5. Stiffness of anterior and posterior fracture of groups 1–4 and overall stiffness (TIFI: transiliac internal fixator; SI: sacroiliac screw(s); Infix: internal fixator).

When implanting 1 SI-screw with a TIFI (groups 2 and 4) and again comparing the anterior movement between the retrograde transpubic screw and the internal fixator, the screw (median displacement = 2.0 ± 0.5 mm) again allowed non-significantly less displacement than the internal fixator (2.1 ± 0.4 mm) (p = 0,61).

Given the anterior fixation with either an internal fixator in group 1 and 2 or a retrograde transpubic screw in groups 3 and 4 and with regard to the posterior displacement, the 2 SI-screws proved to display less displacement with 1.8 ± 0.6 mm in group 1 and 1.8 ± 0.2 mm in group 3 than the combination of a TIFI with 1 SI-screw, that allowed a displacement of 1.8 ± 0.2 mm in group 2 and 2.0 ± 0.5 mm in group 4 (p = 0,88). The overall displacement is calculated as the average between the anterior and posterior fracture (Fig. 4).

Consequently, the combination of 2 SI-screws with a retrograde transpubic screw (group 3) was the minimal-invasive fixation method permitting the least displacement for the treatment of a C1.3 fracture with an overall stiffness of 56.0 N/mm (anteriorly) and 55.9 N/mm (posteriorly) (Fig. 5). Nevertheless, the other osteosynthesis methods displayed to be of comparable stability as differences in displacement and stiffness were found to be non-significant (p [anterior displacement] = 0.61 and p [posterior displacement] = 0.88) see Table 3.

The reference group displayed an anterior mean displacement of 1.4 ± 0,2 mm which was significantly less than group 2 (2.1 ± 0.4 mm) (p = 0,028). Group 1 (p = 0,232), group 3 (p = 0,658) and group 4 (p = 0,056) did not show significant differences to the reference group. The displacement concerning the posterior

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Table 3
Maximum displacement and stiffness of anterior and posterior fractures for the different combinations of minimally invasive techniques.

Treatment group	Maximum displacement (mm)	
	Anterior fracture	Posterior fracture
Group 1: internal fixator + 2 sacroiliac screws	1.9 ± 0.3	1.8 ± 0.6
Group 2: internal fixator + transiliac internal fixator + 1 sacroiliac screw	2.1 ± 0.4	1.9 ± 0.2
Group 3: retrograde transpubic screw + 2 sacroiliac screws	1.8 ± 0.2	1.8 ± 0.2
Group 4: retrograde transpubic screw + transiliac internal fixator + 1 sacroiliac screw	2.0 ± 0.5	2.0 ± 0.5
p-value between group 1–4	0,88	0,61
Group 5: reference	1.4 ± 0.1	2.0 ± 0.4
p-value comparing group 1–4 to reference group	Group 5 to 1: 0,232	0,805
	Group 5 to 2: 0,028	
	Group 5 to 3: 0,658	
	Group 5 to 4: 0,056	

fracture was 2.0 ± 0,4 mm and was not significant compared to all 4 osteosynthesis groups ($p = 0{,}805$).

The non-parametrical Kruskal-Wallis-Test confirmed the results of the Anova showing a non-significant difference for the posterior dislocation ($p = 0{,}732$) and also confirmed the significant difference for the anterior fracture comparing group 2 to the reference group ($p = 0{,}012$).

Concerning the stiffness of the posterior fracture there was no significant difference between all groups and the reference ($p = 0{,}621$). For the anterior stiffness there was no significant difference between the four osteosynthesis groups, however there was a significant difference comparing the reference group to groups 1 ($p = 0{,}030$), 2 ($p = 0{,}030$) and 3 ($p = 0{,}005$).

4. Discussion

C-type pelvic fractures are rare and challenging fractures that often require immediate stabilization [15] in order to achieve anatomic restoration of the pelvis [16,17]. Recently, minimal-invasive treatment approaches have been investigated and found to be equally stable [9,15], yet reducing the risk of common intra- and postoperative problems occurring in open surgery [18,19] due to their minor risk of soft tissue injury, blood loss or neurovascular damage [9]. Various authors have emphasized the superior clinical curative effect of percutaneous sacroiliac screws as an established minimal-invasive method for the treatment of posterior pelvic ring fractures [20,21] due to less damage, bleeding, pain, invasiveness and a quicker recovery compared to ORIF [7,17]. Nevertheless, there is an ongoing controversial issue whether to implant one or two SI-screws [22]. Khaled et al. [22] did not find a correlation between the number of screws implanted and functional outcome, whereas both Yinger et al. [17] and Van Zwienen et al. [23] found a biomechanical superior stability in favor of 2 SI-screws. Van Zwienen et al. [23] furthermore argued that the second SI-screw may inhibit the ilium from rotating around the single SI-screw. On the contrary, van den Bosch et al. [24] claim that the positioning of a lower SI-screw in the second vertebral body is technically more difficult and correlates with a higher risk of nerve injury.

In our biomechanical study we firstly confirmed the possibility to treat type C pelvic fractures in a minimally invasive way, suggesting a high and comparable stability of all osteosynthesis constructions. Yet, we were also able to show that retrograde transpubic screw combined with 2 SI-screws shows the least displacement at the anterior and posterior pelvic ring and the highest stiffness of the fixation methods.

Secondly, we found that a single SI-screw combined with a TIFI is a reasonable and stiff option compared to 2 SI-screws. While we were able to demonstrate the sufficient biomechanical stability of the 2 SI-screws represented by their little displacement and great stiffness, we however also tried to investigate the combination of a single SI-screw in the first sacral vertebrae with a TIFI as an alternative osteosynthesis method to the use of 2 SI-screws, merging the stability of a sacroiliac screw with a decreased risk of nerve injury and screw loosening, especially in osteoporotic bone. The TIFI exerts resistance against horizontal and rotational displacements [25], resulting in a sufficient biomechanical stability along with a minor risk of intraoperative vessel-and nerve injuries [10]. Regarding our results, we identified the implantation of the single SI-screw combined with a TIFI to be reasonable and stiff option as there were comparable results in both displacement and stiffness to the use of 2 SI-screws. Supporting our evidence, Vigdorchik et al. [1] were even able to prove the superiority of 1 SI-screw with a TIFI to 2 SI-screws.

Thirdly, we showed that a modified unilateral internal fixator could be used for anterior fracture fixation with comparable stability to retrograde transpubic screw represented by a high stiffness and small displacement. Our results consequently correspond with a study performed by McLachlin et al. [2] identifying a fully threaded retrograde transpubic screw to sufficiently improve the anterior stability of a pubic ramus fracture. The biomechanical benefit of the cannulated screws has been attributed to their intramedullary fixation and their resistance to rotational forces [26]. Additionally, percutaneously inserted pubic ramus screws are associated with little blood loss and decreased operation time [27]. A disadvantage of this procedure is that it cannot be used easily in displaced pubic ramus fractures [28].

The “standard” internal fixator has already been described to be a considerable option for anterior pelvic disruption in previous studies due to its sufficient biomechanical stability, low complication rate and increased comfort [4,5,25]. However, Vaidya et al. [5] described the lesion of the lateral femoral cutaneous nerve to be a complication unique to the internal fixator due to its anatomical proximity. In our study, we used a modified unilateral internal fixator, that was installed only to the fractured side of the pelvis, combining the previously described biomechanical stability while protecting the contralateral pelvic structures. A previous study by Becker et al. [12] showed good results of a modified unilateral internal fixator in fixing and reducing T-type acetabular fractures.

Finally, it shows that all osteosynthesis methods achieve a similar posterior dislocation compared to the reference group, whereas the anterior fracture dislocates slightly more when surgically treated. The explanation for this phenomenon firstly lays in the artificial models' sacroiliacal joint itself not being as stable as the intact pubic rami. Secondly, for the stabilization of the posterior fracture, two SI-screws or one SI-screw and a TIFI were used, providing not only compression of the fracture fragments but also limiting rotational forces, whereas anteriorly only one screw or a single internal fixator was used for fracture reduction. Thirdly, the greater contact face of the sacral fracture fragments physically generates a higher friction than the smaller anterior contact faces, which consequently results in a higher stability in the posterior fracture after osteosynthesis of the artificial bone models.

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In this study, we used a single leg stance which due to its great shear, bending and rotational forces represents a rather unstable scenario compared to a double leg stance [7,26]. This way we ensured the mechanical forces being applied to the hemi-pelvises only, eliminating potential interference of a double leg stance. Also, the use of identical composite synthetic pelvises eliminates potential confounding variables, however lacks the capability of fully reflecting human anatomy and bone structure. Furthermore, the lack of ligaments, muscles or other soft tissue in synthetic pelvises possibly facilitated the attachment of fixation techniques. Other fixation methods such as plate fixation and open reduction, internal fixation of the sacrum have to be taken into account if open reduction and/or decompression is necessary and if there is no possibility of closed reduction and minimally invasive fixation [29–31]. If all these Minimally invasive fixation techniques provide sufficient biomechanical, in a clinical setting cost and operating time will be a differentiator.

5. Conclusion

We identified various fixation techniques to be biomechanically reasonable options for the treatment of type C1-3 pelvic fractures as demonstrated by their good stability and low displacement. In this study, we revealed that the combination of 2 SI-screws with a retrograde transpubic screw (group 3) displayed the least displacement and highest stiffness out of all methods tested. However, there was no statistical significance found between the 4 osteosynthesis methods investigated, suggesting a comparable stability and therefore a potential favorability for all techniques depending on the clinical situation. In a clinical setting, these techniques could be applied in a minimally invasive way. Yet, further studies are required in order to investigate the feasibility of these techniques in a clinical setting.

Disclosure of interest

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Dr. Woiczinski reports personal fees from Medacta, outside the submitted work.

The other authors declare that they have no competing interest.

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Contribution

Adrian Cavalcanti Kußmaul: study concept, rationale, execution of trials, results interpretation, manuscript writing and data interpretation.

Christian Kammerlander: study concept, manuscript editing and results interpretation.

Christian Zeckey: study setup, data analysis, manuscript writing and results interpretation.

Axel Greiner: study setup and execution of tests, data analysis and results interpretation.

Matthias Woiczinski: help with study setup, data analysis and revision of the manuscript.

Christoph Thorwächter: help with study setup, data analysis and data acquisition.

Clara Gennen: data acquisition, data analysis and draft editing.

Christian Kleber: study concept, study rationale and results interpretation.

Wolfgang Böcker: manuscript editing and results interpretation and methodology.

Christopher A. Becker: study concept, rationale, results interpretation, manuscript writing and data interpretation.

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5.3 Veröffentlichung III

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RESEARCH ARTICLE Open Access

Tape suture for stabilization of incomplete posterior pelvic ring fractures—biomechanical analysis of a new minimally invasive treatment for incomplete lateral compression pelvic ring fractures

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Abstract

Background: Incomplete lateral compression fractures (including AO Type B2.1) are among the most common pelvic ring injuries. Although the treatment of choice remains controversial, sacroiliac (SI) screws are commonly used for the operative treatment of incomplete lateral compression fractures of the pelvic ring. However, the disadvantages of SI screws include the risk of nerve root or blood vessel injury. Recently, tape sutures have been found useful as stabilizing material for the treatment of injuries of the syndesmosis, the rotator cuff and knee ligaments. In this current study, we aimed to test the biomechanical feasibility of tape sutures to stabilize the pelvis in the setting of AO Type B2.1 injury.

Methods: Six human cadaveric pelvises underwent cyclic loading to compare the biomechanical stability of different osteosynthesis methods in a B2.1 fracture model. The methods tested in this experiment were a FiberTape® suture and the currently established SI screw. A 3D ultrasound tracking system was used to measure fracture fragment motion. Linear regression was used to model displacement and stiffness at the posterior and anterior pelvic ring.

Results: At the posterior fracture site, the FiberTape® demonstrated similar displacement (2.2 ± 0.8 mm) and stiffness (52.2 ± 18.0 N/mm) compared to the sacroiliac screw (displacement 2.1 ± 0.6 mm, $P > 0.999$; stiffness 50.8 ± 13.0 N/mm, $P > 0.999$).
Considering the anterior fracture site, the FiberTape® again demonstrated similar displacement (3.8 ± 1.3 mm) and stiffness (29.5 ± 9.0 N/mm) compared to the sacroiliac screw (displacement 2.9 ± 0.8 mm, $P = 0.2196$; stiffness 37.5 ± 11.5 N/mm, $P = 0.0711$).

Conclusion: The newly presented osteosynthesis, the FiberTape®, shows promising results for the stabilization of the posterior pelvic ring in AO Type B2.1 lateral compression fractures compared to a sacroiliac screw osteosynthesis based on its minimal-invasiveness and the statistically similar biomechanical properties.

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Introduction

Fractures of the pelvic ring are frequently seen, especially in polytrauma patients or geriatric patients with poor bone quality [1–3]. Incomplete lateral compression fractures (including AO Type B2.1) are among the most common pelvic ring injuries [4, 5]. The standard treatment of the incomplete lateral compression pelvic ring fracture is controversially discussed, ranging from conservative treatment to surgical care [5, 6]. As a standard concept, the sacroiliac screw (SI screw) fixation is part of the operative care and has shown sufficient biomechanical stability [7–9]. But the disadvantages of this method include nerve root and/or blood vessel damage in case of misalignment of the screw [9, 10]. If two sacroiliac screws are used (S1 and S2), there is an even higher risk of damaging the nerve roots S1/S2 with the second S2-screw [11]. Furthermore, the necessity to compromise the intact sacroiliacal joint in the process of fixing the lateral sacral fracture is questionable. Regarding this problem, a variety of operating methods have been recently developed to stabilize sacral fractures [2, 9, 12, 13].

Recently, tape sutures have proven to be a stabilizing method for syndesmotic injuries in the ankle joint, for injuries to the rotator cuff of the shoulder or for ligamental knee injuries [14–16]. Similar to the recently described transiliac internal fixator (TIFI), which is installed to the posterior superior iliac spine, one could insert a tape suture through this anatomical structure to minimal-invasively stabilize the posterior pelvic ring [12, 13, 17].

The disadvantage of the transiliac internal fixator lays in the possible disturbance of the soft tissue structures dorsal of the posterior superior iliac spine [17]. By using a tape suture one could possibly avoid this issue. Another advantage of a tape suture represents the higher flexibility of the tape compared to the rigidity of a screw. In ankle surgery, a tape suture performs a semi-rigid transfixation of the tibiofibular joint allowing micromotions in movement [18].

In this study, we assume that a tape suture will perform the semi-rigid transfixation of both sacroiliac joints. In addition, when inserting a tape suture in the posterior superior iliac spines, no relevant nerve structure is endangered.

For this reason, we performed a biomechanical analysis on 6 fresh frozen cadaver pelvises to analyze the stability of the tape suture applied to the posterior pelvic ring compared to a sacroiliac screw.

Material and methods

Material

A total of 6 human cadaver pelvises collected between January 2016 and April 2017 were used in this study with the approval of our institution's ethics committee and the approval of the donors' relatives given prior to the experiments. Only intact pelvises without any preexisting damage to the musculoskeletal structure, a tumor, or tuberculosis disease was included in this study. The characteristics of the pelvises are displayed in Table 1.

Methods

Prior to any processing, the bone density of all pelvises was measured with a qCT scan using the fourth and fifth lumbar vertebrae (Table 1).

The pelvises were unfrozen 1 day prior to their experiment. On the day of the experiment, each pelvis was heated in a water bath at roughly 35 °C for 30 min in order to approximate body temperature.

Once heated, the tissue covering the spots needed to install the experiments equipment (Fig. 1a) was dissected; however, the dissection was kept as little as possible to preserve ligamental structures.

After the removal of the tissue, each pelvis was mounted on the testing machine and the 5-step protocol (Table 2) was applied. The first test served as a reference measurement of the intact pelvis (Trial 1: 'reference'). Secondly, an AO type B2.1 fracture was created in accordance with the AO classification, consisting of a partial sacral fracture reaching from the superior margin of the sacrum until the height of the second sacral neuroforamen and of the anterior fracture consisting of an ipsilateral anterior pelvic ring fracture.

Next, the fixation methods were applied with the either tape suture (FiberTape 2 mm, Arthrex, Naples, FL, USA) spanning between both posterior superior iliac spines (Fig. 1b) or the 6.5 mm × 70 mm cannulated, partially threaded sacroiliac screw (DePuy Synthes, Umkirch, Germany) being inserted into the first sacral vertebrae (S1).

For the insertion of the tape suture (FiberTape®), two osseous channels were drilled through both posterior superior iliac spines, beginning from the fracture site using a high speed drill. The drill went through the contralateral posterior superior iliac spine from medial to lateral to achieve an osseous channel in the same direction as on the ipsilateral site. The FiberTape® was then threaded through the bony holes and a metal washer (DogBone®-

Table 1 Characteristics of the specimens

Pelvis	Age (years)	Sex	BMD (mg Ca-Ha/ml)
1	74	Male	104.6
2	72	Male	113.7
3	25	Male	151.7
4	67	Male	63.2
5	60	Male	121.6
6	65	Male	133.7
Mean	60.5 ± 18.1		114.8 ± 30.1
Median	66		117.7

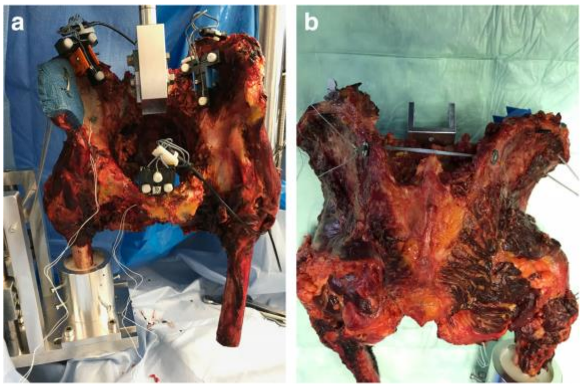

Fig. 1 **a** Positioning of the pelvis onto the testing rig. **b** FiberTape® spanning the posterior superior iliac spines

Button, Arthrex, Naples, FL, USA) first on the contralateral site. Both ends were pulled back through the osseous channel with the tape consequently spanning between both iliac spines. The ipsilateral ends were then threaded through a second DogBone®-Button and manually surgically tied. Consequently, both metal washers were lying on the lateral sides of the osseous channels on each iliac spine (Fig. 1b).

For the S1 screw, the following technique was used. The S1 partially threaded screw was inserted under fluoroscopic control on the fractured site using the S1-corridor above the first neuroforamen, with at first drilling of a Kirschner-wire and secondly inserting the screw using the previously drilled K-wire.

Finally, the pelvises were set up in the testing machine.

Methods of assessment

In this study, we used an all-electric testing machine (Instron ElectroPulsTM E10000 Linear-Torsion, Norwood, MA 02062-2643, USA) and a 3D-ultrasound measuring system (Zebris CMS20, Gilching, Germany) for the recording of all data.

The ultrasound system consisted of 3 sensors that were placed onto the pelvis as seen in Fig. 1 and a transducer that was positioned 50 cm anteriorly to the pelvis. The unilateral embedding of the femur into a metal cylinder containing epoxide resin allowed the simulation of a single leg stance while the superior clamp dissembled a spherical joint.

Table 2 Test protocol

Step 1	Loading up to 150 N
Step 2	Holding at 150 N for 30 s
Step 3	Periodic loading: 20 cycles with a frequency of 0.25 Hz between 150 N and 250 N
Step 4	Holding at 250 N for 135 s
Step 5	System back to its original position of + 28 mm

For the conduction of the experiment, a 5-step protocol was applied according to McDonald et al. [19] (Table 2).

Every 30 ms, the position of all sensors was recorded, allowing the calculation of the relative distances between the sensors at any time. These distances were then used for the statistical analysis.

Statistical analysis

We used linear regression to model the magnitude of displacement between the fracture fragments representing the functionality of the stabilizing techniques used: native pelvis (reference), SI screw, and FiberTape®. Clustered standard errors were calculated using the Huber-White method. Pairwise comparisons were carried out using t tests. The Bonferroni method was used to adjust the P values for multiple comparisons. For all tests, α was set to 0.05. Descriptive statistics are presented as mean ± standard deviation (SD) wherever appropriate.

Results

At the posterior fracture site, the FiberTape® demonstrated similar displacement (2.2 ± 0.8 mm) and stiffness (52.2 ± 18.0 N/mm) compared to the sacroiliac screw (displacement 2.1 ± 0.6 mm, $P > 0.999$; stiffness 50.8 ± 13.0 N/mm, $P > 0.999$) (Table 3) (Fig. 2).

Considering the anterior fracture site, the FiberTape® again demonstrated similar displacement (3.8 ± 1.3 mm) and stiffness (29.5 ± 9.0 N/mm) compared to the sacroiliac screw (displacement 2.9 ± 0.8 mm, $P = 0.2196$; stiffness 37.5 ± 11.5 N/mm, $P = 0.0711$) (Table 3) (Fig. 3).

Table 3 Mean displacement and stiffness measurements for pelvic fractures fixed with either an SI screw or with FiberTape. The *P* value shown is for the difference between both groups

		Reference	FiberTape®	Sacroiliac screw	*P* value
Mean displacement (mm)	Posterior	2.3 ± 0.5	3.2 ± 0.9	3.0 ± 0.5	> 0.999
	Anterior	2.2 ± 0.4	4.5 ± 1.5	3.6 ± 0.6	0.2196
Mean stiffness (N/mm)	Posterior	44.2	31.7	32.8	> 0.999
	Anterior	46.5	24.1	28.9	0.0711

Discussion

The treatment of incomplete posterior pelvic ring fractures (AO type B2.1) can be performed by various conservative and surgical procedures [20–23]. However, conservative therapy shows significantly longer immobility and an increased level of pain [24]. The most frequently surgical method used is percutaneous sacroiliac screw fixation [20]. The advantages are the percutaneous approach with a short operation time and minimal soft tissue injury [20, 25–27]. However, this type of osteosynthesis also has various risks. Due to the complex geometry of the pelvis, a high degree of expertise is required to ensure exact placement of the screw [28]. Osteosynthesis performed with conventional x-ray often show an insufficient representation of anatomical structures, especially in obese patients, in patients with intestinal gas overlay or when positioning a screw in the S2 segment. Thus, screw malposition can be seen in 2 to 68% of patients treated with S1/S2 screw fixation, whereas neurologic symptoms are seen in 0.5 to 7.9% [29, 30]. Methods such as plate osteosynthesis or internal fixation with pedicle screws have a significantly higher morbidity due to the open approach or often lead to irritation of the soft tissue, which can cause problems such as lesions of the skin or pain in the area of the iliac bone [23, 25].

Minimally invasive posterior tension banding with suture tape through the posterior superior iliac spines is a newly introduced method for stabilizing the posterior pelvic ring. This procedure is a minimally invasive fixation method with a sufficient posterior fracture stabilization without implanting any soft tissue disturbing components such as pedicle screw constructs. In addition, the extrasacral position avoids an injury to the sacral nerve roots. Compared to SI screw fixation, tension banding does not compromise the intact SI joint. We assume that this semirigid fixation method also allows physiological mobility in the SI joint, so that removal of osteosynthesis implants is not necessary and there is no danger of stiffening of the joint. Positioning of the drill holes in the posterior superior iliac spine is usually easy to determine from the anatomical landmarks or to visualize in X-rays. This means that no special equipment such as 3D x-ray or navigation system is required to ensure correct positioning of the implants. We think that the radiation exposure and the

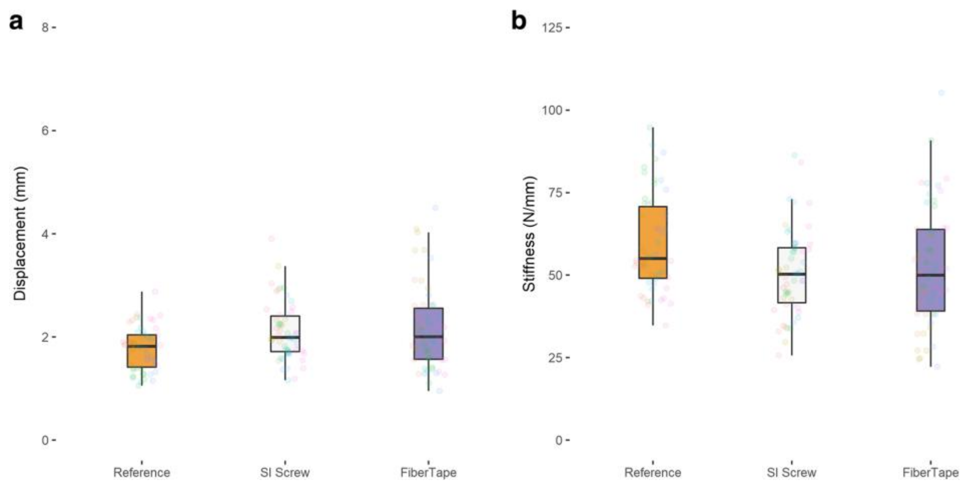

Fig. 2 a, **b** Average displacement and stiffness measurements at the posterior fracture site

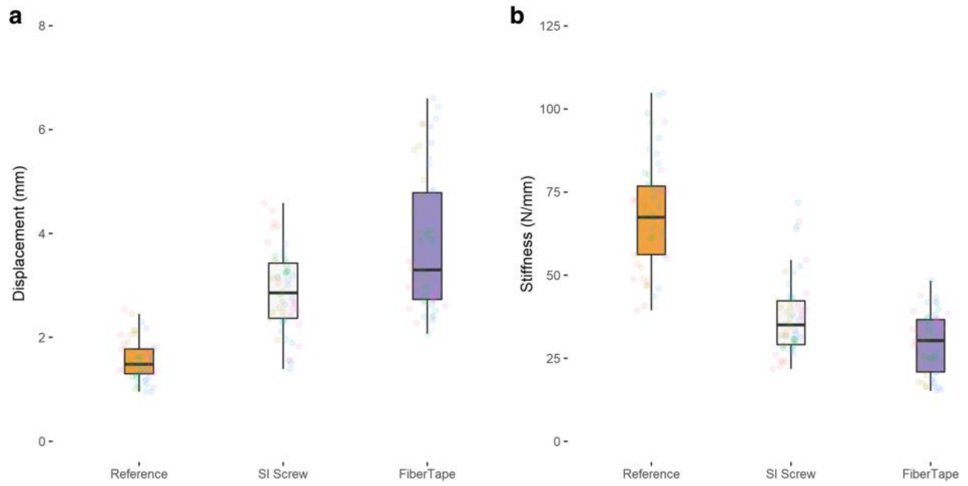

Fig. 3 a, **b** Average displacement and stiffness measurements at the anterior fracture site

surgical demands are also lower in this minimally invasive procedure compared to standard sacroiliac screw fixation.

Our biomechanical results showed no significant difference between screw fixation and minimally invasive posterior pelvic tension banding considering the dislocation of both the anterior and the posterior fracture gap under cyclic loading. Using the FiberTape®, the dislocation of the posterior pelvic ring was 0.2 mm higher (3.2 mm ± 0.9) than with the sacroiliac screw (3.0 mm ± 0.5), however not significantly. Considering the anterior pelvic fracture, the dislocation using the FiberTape® was 0.9 mm higher than the sacroiliac screw fixation, but again not significantly. With a resolution of the ultrasound measuring system of 0.1 mm, we showed that the stabilization of the posterior pelvic ring with a minimally invasive tension banding achieves a comparable stability as a sacroiliac screw. The effect of a higher dislocation of the anterior pelvic fracture as seen in the FiberTape® group could also be seen in conservatively treated pelvic fractures type B 2.1 without any problems in bone healing of the anterior pelvic ring in patients under 65 years [31]. We therefore assume that the slightly increased dislocation at the anterior pelvic ring using tape suture for posterior pelvic ring stabilization is not clinically relevant. The incomplete sacral fracture is good controlled with the extra-sacral implanted tape suture. But we think in higher unstable and dislocated fractures especially at the anterior pelvic ring and complete sacral fractures, the tape suture could not prevent opening of the anterior sacral fracture, as well as the anterior pelvic ring fracture. Thus we, think that our described method does work best in incomplete sacral fractures. Pain control in the sacral area is the most relevant clinical aim in incomplete posterior pelvic ring fracture or insufficiency fractures [32]. In our opinion, a tape suture on patients with incomplete posterior pelvic fracture could be a feasible minimally invasive treatment option for alleviating pain.

In the results presented here, we showed that the stabilization of the posterior pelvic ring was sufficiently achieved by minimally invasive dorsal tension using tape suture.

Conclusion

The newly presented osteosynthesis of the posterior superior iliac spine using FiberTape® shows promising results for the stabilization of the posterior pelvic ring in AO Type B2.1 lateral compression fractures of the pelvis when compared to sacroiliac screw osteosynthesis. Further advantages of the technique presented here are the lack of the necessity of implant removal, lower surgical demands, and lower risk of injury to relevant neural or vascular structures of the patient.

Abbreviations

3D: 3-dimensional; AO: Arbeitsgemeinschaft Osteosynthese, Working Group Osteosynthesis; Fig.: Figure; FöFoLe: Förderprogramm für Forschung und Lehre, support program for research and teaching; GmbH: Gesellschaft mit beschränkter Haftung, private corporation with limited liability; No.: Number; qCT: Quantitative computed tomography; SD: Standard deviation; SI: Sacroiliac; TIFI: Transiliac internal fixator

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Authors' contributions
AK, MW, CB, AG, and WF carried out the experiment. CB wrote the manuscript with support from OP, MR, AG, and ES. CB and AG supervised the project with the help of WB and CK. All authors read and approved the final manuscript.

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Availability of data and materials
The authors confirm that the data supporting the findings of this study are available within the article and its supplementary materials.

Ethics approval and consent to participate
The consent of our ethics committee and the donors' relatives was given before the experiments.

Consent for publication
Consent for publication of the data was obtained from the relatives of the donors before the start of the study.

Competing interests
Markus Regauer reports personal fees from Arthrex, Naples, USA, outside the submitted work. Wolfgang Boecker reports personal fees from Lilly GmbH and from Amgen GmbH, outside the submitted work. The other authors declare that they have no competing interests.

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