Aus der
Klinik für Orthopädie und Unfallchirurgie
des Universitätsklinikums Düsseldorf
(Direktor: Univ.-Prof. Dr. med. Joachim Windolf)

„Untersuchungen zur Therapie von idiopathischen Skoliosen“

Kumulative Habilitationsschrift zur Erlangung der Venia Legendi
für das Fach Orthopädie und Unfallchirurgie
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vorgelegt von

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2. Abkürzungsverzeichnis

Abb.:	Abbildung
AIS:	Idiopathische Skoliose bei Adolescenten
cGy/cm^2:	Centigray pro Quadratcentimeter
CT:	Computertomographie
DFP:	Dosis-Flächen-Produkt
DLP:	Dosis-Längen-Produkt
DTC:	Dynamische Thorakale Compliance
ED:	Effektive Dosis
EOS:	Early-Onset Skoliose
et al.:	Et alii
mGy/cm:	Milligray pro cm
ml/mbar:	Milliliter pro Millibar
mm:	Millimeter
mSv:	Millisievert
mSv/Gy·cm2:	Millisievert pro Gray mal Quadratcentimeter
mSv/mGy·cm:	Millisievert pro Milligray mal Centimeter
p.a.:	Strahlengang von posterior nach anterior
PI:	Pelvic Incidence
PT:	Pelvic Tilt
SS:	Sacral Slope
TIS:	Thoraxinsuffizienzsyndrom
TLSO:	Thoraco-Lumbo-Sacral Orthoses
VEPTR:	Vertical Expandable Prosthetic Titanium Rib
3D:	Dreidimensional

3. Zusammenfassung

Idiopathische Skoliosen sind definiert als eine dreidimensionale Deformität der Wirbelsäule mit einem in der Frontalebene gemessenen Cobb-Winkel von mehr als 10 Grad. Zur Prävalenz gibt es bisher keine eindeutigen Daten, da die einzelnen Studien mit unterschiedlichen Diagnosekriterien und Altersstufen durchgeführt wurden. Deswegen analysierten wir die vorhandenen Daten in einem Review. Am häufigsten tritt die idiopathische Skoliose bei Adoleszenten auf mit einer Prävalenz von 0,47 bis 5,2 Prozent, wobei diese Häufigkeit von vielen Faktoren beeinflusst wird. Ältere Kinder haben häufiger eine Skoliose als jüngere und Mädchen haben häufiger eine Skoliose als Jungs. Insbesondere schwere Kurven mit einem Cobb-Winkel von mehr als 40 Grad treten etwa sieben Mal häufiger bei Mädchen auf als bei Jungs.

Die Behandlung von idiopathischen Skoliosen richtet sich nach dem Cobb-Winkel. Ab 20 Grad ist eine Korsettbehandlung empfohlen, um eine weitere Progredienz zu verhindern. Das Korsett wird nach internationalem Konsens für mindestens 18 Stunden pro Tag verordnet. Es ist bekannt, dass die Progredienz der Skoliose negativ mit der Tragezeit des Korsetts korreliert, jedoch korreliert die Compliance mit der Korsettbehandlung negativ mit der verordneten Tragezeit. Die meist jugendlichen Patienten haben häufig psychologische Probleme, wenn sie das Korsett im Umgang mit ihren Altersgenossen (vor allem in der Schule) tragen müssen. Aus diesem Grund untersuchten wir, ob eine Tragezeit von 12 bis 16 Stunden pro Tag ein schlechteres Outcome zeigt als eine Tragezeit von mehr als 16 Stunden pro Tag. Die reduzierte Tragezeit würde den jugendlichen Patienten erlauben, das Korsett für die Zeit in der Schule abzulegen. Es zeigte sich kein signifikanter Unterschied in der Progredienz der Skoliose zwischen den beiden Gruppen: Die kürzere verordnete Tragezeit führt mutmaßlich zu einer höheren Compliance mit der Korsettbehandlung und dadurch nicht zu einem schlechteren Outcome als eine Verordnung von einer längeren Tragezeit pro Tag.

Wenn der Cobb-Winkel 40 Grad oder mehr erreicht, wird eine operative Behandlung der Skoliose empfohlen, um eine lebenslange Progredienz und damit auch eine zunehmende Einschränkung der Lungenfunktion zu verhindern. Insbesondere dann, wenn die Skoliose vor dem 10. Lebensjahr auftritt, kann eine schwere Form der Lungenfunktionsstörung, ein Thoraxinsuffizienzsyndrom, entstehen. Deswegen wird eine früh auftretende schwere Skoliose schon im Kindesalter operativ mittels mitwachsender, verlängerbarer Implantate versorgt. Eine dieser Techniken ist die Implantation von VEPTR-Stäben, welche teilweise oder ganz auf den Rippen verankert werden und über die Rippen einen korrigierenden Druck entgegen der Deformität der

Wirbelsäule ausüben. Mit dieser Technik wird eine Vergrößerung des Lungenvolumens erreicht, jedoch wird theoretisch durch die operationsbedingten Narben auf dem Thorax und die Titanstäbe auf den Rippen die pulmonale Compliance beeinträchtigt. Wir untersuchten daher die pulmonale Compliance unserer Patienten im Verlauf des Wachstums und verglichen deren Entwicklung mit der einer gesunden Kontrollgruppe: Wir konnten zeigen, dass sich die pulmonale Compliance der VEPTR-Patienten ab der Operation mit einer identischen Rate vergrößerte, wie die der Kontrollgruppe. Jedoch hatten die VEPTR-Patienten zu Beginn der Behandlung bereits eine deutlich geringere pulmonale Compliance als die Kontrollgruppe und holten diesen Unterschied im Laufe der Behandlung nicht mehr ein. Aus diesen Ergebnissen leitet sich die Empfehlung ab, möglichst früh mit der Behandlung zu beginnen, um einen Unterschied zum altersentsprechenden Befund gar nicht erst entstehen zu lassen.

Nach Abschluss des Wachstums sind keine mitwachsenden Systeme mehr indiziert. Es wird bei schweren Skoliosen eine Aufrichtung der Wirbelsäule in Verbindung mit einer Fusion der betroffenen Segmente durchgeführt. Heute werden mehr als 90 Prozent dieser Eingriffe von dorsal mit einem Pedikelschrauben-Stab-System durchgeführt.
Die Pedikelschrauben können mit verschiedenen Techniken implantiert werden: Die navigierte Technik führt zu einer höheren Präzision bei der Platzierung der Schrauben. Jedoch gibt es einige Studien, welche eine höhere Strahlenbelastung für den Patienten mit der navigierten Technik im Vergleich zur konventionellen fluoroskopischen Technik beschreiben.
Da diese Vorstudien mit heterogenen Patientengruppen und Indikationen sowie hauptsächlich mit kurzstreckigen Versorgungen und mit zusätzlicher Implantation von intervertebralen Cages durchgeführt wurden, ohne zwischen der Strahlenbelastung für den Patienten und für das Operationsteam zu unterscheiden, untersuchten wir zunächst die Strahlenbelastung für Patienten und für das Operationsteam bei multisegmentalen Versorgungen mit reinen Schrauben-Stab-Systemen von dorsal. Dabei zeigte sich, dass die Strahlenbelastung mit der navigierten Technik im Vergleich zur konventionellen fluoroskopischen Technik für Patienten um mehr als 40 Prozent, und für das Operationsteam um mehr als 80 Prozent gesenkt werden konnte.

In einer weiteren Arbeit untersuchten wir die Strahlenbelastung für den Patienten bei der Versorgung von idiopathischen Skoliosen.
Es zeigt sich, dass die navigierte Technik zu weniger Strahlenbelastung für den Patienten führt, als die konventionelle fluoroskopische Technik.

Weiterhin verglichen wir die Navigation auf Grundlage eines präoperativen Computertomographie-Scans mit derjenigen auf Grundlage eines intraoperativen 3D-Scans. Wir konnten zeigen, dass die Technik mit intraoperativem 3D-Scan zu deutlich weniger Strahlenbelastung führt, als die auf einem präoperativem Computertomographie-Scan basierende Technik.

4. Literaturangaben zugrundeliegender Publikationen

Arbeit 1

Epidemiology of adolescent idiopathic scoliosis.

Konieczny MR, Senyurt H, Krauspe R.

J Child Orthop. 2013 Feb;7(1):3-9. doi: 10.1007/s11832-012-0457-4. Epub 2012 Dec 11. Review. PubMed PMID: 24432052; PubMed Central PMCID: PMC3566258.

Impact Factor 1,296

Arbeit 2

Time in brace: where are the limits and how can we improve compliance and reduce negative psychosocial impact in patients with scoliosis? A retrospective analysis.

Konieczny MR, Hieronymus P, Krauspe R.

Spine J. 2017 Nov;17(11):1658-1664.

doi: 10.1016/j.spinee.2017.05.010. Epub 2017 Aug 15. PubMed PMID: 28821442.

Impact Factor 3,196

Arbeit 3

Vertical expandable prosthetic titanium ribs (VEPTR) in early-onset scoliosis: impact on thoracic compliance and sagittal balance.

Konieczny MR, Ehrlich AK, Krauspe R.

J Child Orthop. 2017;11(1):42-48.

doi: 10.1302/1863-2548-11-160222

Impact Factor 1,296

Arbeit 4

Navigation Versus Fluoroscopy in Multilevel MIS Pedicle Screw Insertion: Separate Analysis of Exposure to Radiation of the Surgeon and of the Patients.

Konieczny MR (1), Krauspe R.

Clin Spine Surg. 2019 Jun;32(5): E258-E265. doi: 10.1097/BSD.0000000000000807.

Impact Factor 1,726

Arbeit 5

Effective dose of radiation per screw in surgery of adolescent idiopathic scoliosis: Matched pair analysis of 293 pedicle screws inserted in three different techniques.

Konieczny MR, Boos J., Steuwe A., Schleich C., Prost M., Krauspe R.

J Child Orthop Accepted 03.11.2020

Impact Factor 1,075

5. Einführung

Eine Skoliose ist eine dreidimensionale Deformität der Wirbelsäule (Abb.1), die in den meisten Fällen während des Wachstums entsteht und progredient verläuft. Der Schweregrad der Skoliose wird in einer Wirbelsäulenganzaufnahme in posterior-anteriorem Strahlengang mit dem Cobb-Winkel bestimmt (Abb. 2).

Abbildung 1: 3D-Rekonstruktion aus einer Computertomografie der Wirbelsäule einer Patientin mit einer Skoliose

Quelle: Mit freundlicher Genehmigung von Prof. Dr. med. G. Antoch, Direktor des Institutes für Diagnostische und Interventionelle Radiologie

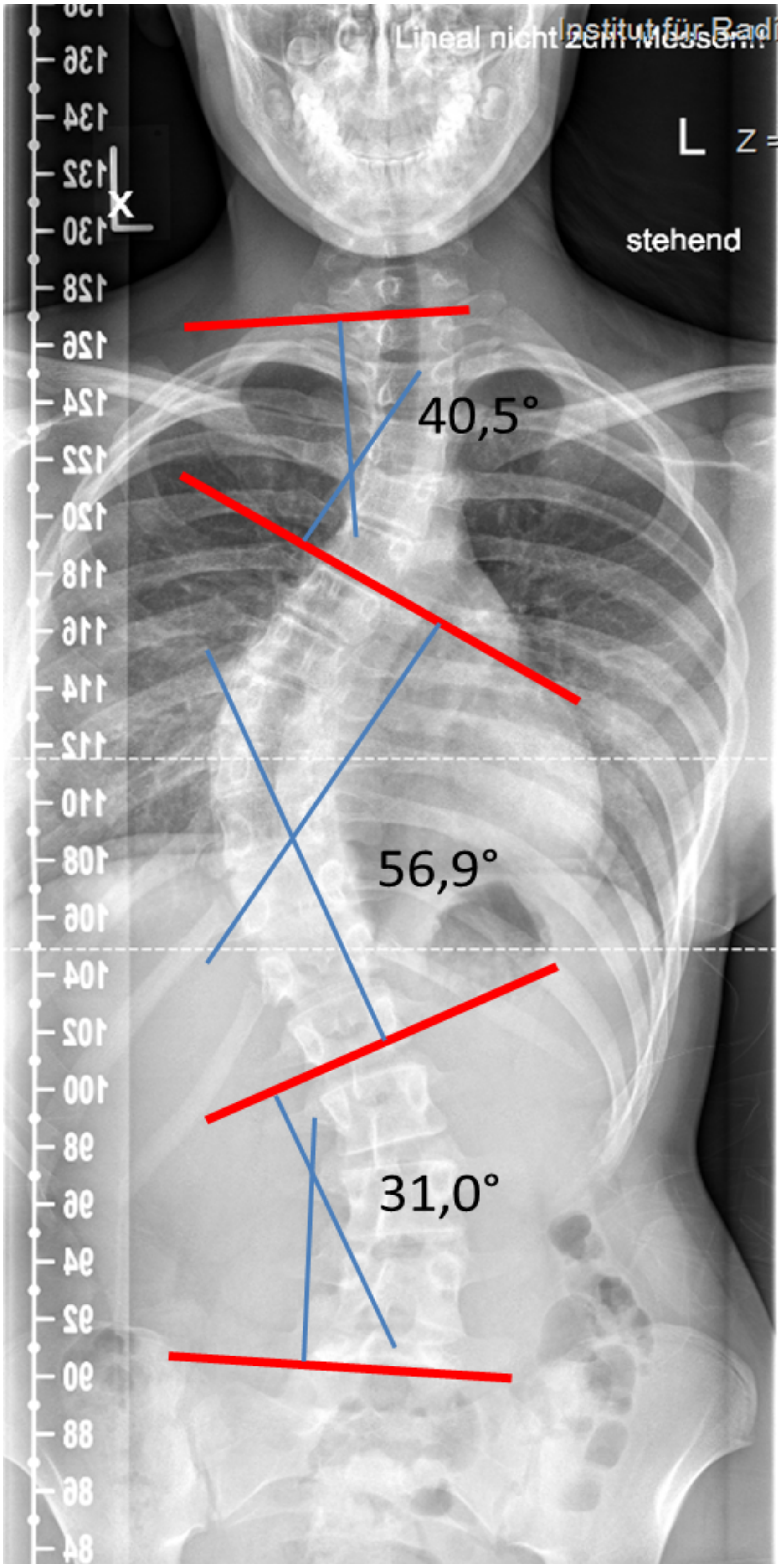

Abbildung 2: P.a.-Röntgenaufnahme einer Wirbelsäule mit Messung der Cobb-Winkel

Quelle: Mit freundlicher Genehmigung von Prof. Dr. med. G. Antoch, Direktor des Institutes für Diagnostische und Interventionelle Radiologie

Die Genese der Skoliose kann kongenital durch Fehlbildungen von Wirbelkörpern, neuromyopathisch durch eine Erkrankung des Nervensystems oder der Muskulatur, mesenchymal etwa bei einem Ehlers-Danlos-Syndrom, traumatisch oder metabolisch sein. Wenn die zuvor aufgeführten, nicht idiopathischen Genesen für eine Skoliose ausgeschlossen sind, liegt eine idiopathische Skoliose vor.

Über 90 Prozent der Skoliosen sind idiopathisch. Die Ursache von idiopathischen Skoliosen ist nicht geklärt. Es werden genetische Faktoren diskutiert, da bei etwa 97 Prozent der Patienten noch ein weiteres Familienmitglied eine Skoliose hat. Jedoch konnte noch kein Genlocus identifiziert werden, der für die Entwicklung einer Skoliose verantwortlich ist [1,2,3]. Es wird weiterhin vermutet, dass noch andere Faktoren einen Einfluss auf die Genese von idiopathischen Skoliosen haben, jedoch gibt es bisher keine eindeutigen Beweise dafür: Grivas et al. [4] berichtet etwa über eine negative Korrelation des Alters der Mutter bei der Geburt des Kindes mit der der Prävalenz von Skoliosen. Jedoch wurden in diese Studie auch Kurven von weniger als 10 Grad eingeschlossen (per Definition [5] liegt in diesem Fall keine Skoliose vor). Zudem war das Ergebnis nur für Jungen signifikant, nicht aber für Mädchen. In Arbeit 2 untersuchten wir daher unter anderem weitere Faktoren auf einen möglichen Einfluss auf die Prävalenz sowie auf die Progression einer Skoliose.

Zur Prävalenz von idiopathischen Skoliosen gibt es nur Daten aus Arbeiten mit unterschiedlichen Einschlusskriterien und Altersgruppen. So wurden etwa in einigen Arbeiten Patienten mit Cobb-Winkeln von weniger als 10 Grad untersucht und in anderen nur Mädchen oder nur Kinder im Alter von 9 bis 14 Jahren. Es wird in diesen Arbeiten eine Abhängigkeit der Prävalenz vom Alter der Kinder, dem Geschlecht und dem Schweregrad der Skoliose beschrieben [6-12]. Wichtig ist die Unterscheidung nach dem Lebensalter bei Auftreten der Skoliose. Bei Beginn der Skoliose vor dem 10. Lebensjahr liegt eine Early-Onset Skoliose vor, vom 10. bis zum 18. Lebensjahr eine Adolescentenskoliose [5].

Early-Onset Skoliosen weisen eine erhöhte Mortalitätsrate im Kindesalter auf [13]. Dies liegt vor allem an der Entwicklung eines Thoraxinsuffizienzsyndroms durch die Deformierung des knöchernen Thorax: Tritt die Deformierung vor dem 10. Lebensjahr auf, wird die Lungenentwicklung nachhaltig gestört und kann bis zur Unfähigkeit der suffizienten Oxygenierung führen [14].

Patienten mit einer idiopathischen Adolescentenskoliose zeigen im Gegensatz zu Early-Onset Skoliosen keine erhöhte Mortalitätsrate und haben dieselbe Lebenserwartung wie gesunde Vergleichsgruppen. Allerdings zeigen sich bei Patienten, die bei Wachstumsabschluss einen Winkelgrad der Skoliose von mehr als 40 Grad aufweisen, deutlich vermehrte Rückenschmerzen

und Ateminsuffizienzen im Vergleich zu Patienten mit geringerem Schweregrad der Skoliose. Bei Wachstumsabschluss sinkt bei milden Skoliosen die Progressionsrate der Skoliose auf 0 Grad pro Jahr. Bei einem Winkelgrad von mehr als 40 Grad zeigt sich eine lebenslange Progressionsrate von 0,5 Grad bis 1 Grad pro Jahr und es wird im Verlauf Kurzatmigkeit nachgewiesen. Werden 90 Grad und mehr erreicht, sind pulmonale Restriktion und pulmonal arterielle Hypertonie die Folgen [15-18].
Das Ziel der Therapie ist es, eine Progression der Skoliose zu verhindern und bei Winkelgraden über 40 Grad zusätzlich die Korrektur der Deformität mit Wiederherstellung der frontalen und sagittalen Balance zu erreichen.

5.1 Konservative Therapie mit Korsett

Bis etwa 20 Grad Cobb-Winkel wird eine Skoliose im Wachstumsalter mittels Krankengymnastik behandelt, indem derotierende Übungen, Atemübungen und Symmetrietraining durchgeführt werden. Bei Erreichen von mindestens 20 Grad oder bei Zunahme der Skoliose um mindestens 5 Grad in einer Kontrolle wird zusätzlich zur Krankengymnastik eine Korsettbehandlung empfohlen [19,20]. Als Korsett werden „Thoraco-Lumbo-Sacral Orthoses“ (TLSO) verordnet, in Europa am häufigsten die TLSO vom Typ „Cheneau“ [21], welche auch in unserer Klinik verordnet wird (Abb. 3). Nach stereotaktischer Oberflächenvermessung oder Gipsabdruck wird das Korsett entsprechend der Körperform des Patienten so erstellt, dass ein korrigierender, derotierender Druck auf den Scheitelpunkt der Skoliose ausgeübt wird. Nach sechs bis zwölf Wochen Tragedauer wird ein Röntgenbild mit getragenem Korsett erstellt.

Abbildung 3: Cheneau Korsett

Quelle: Dr. med. M. Konieczny

Wenn die Skoliose durch das Korsett um weniger als 20 Prozent korrigiert wird, muss es nachgebessert werden. Mit einer konsequent durchgeführten Korsetttherapie kann eine Progression der Skoliose effektiv verhindert werden [22,23] (Abb.4).

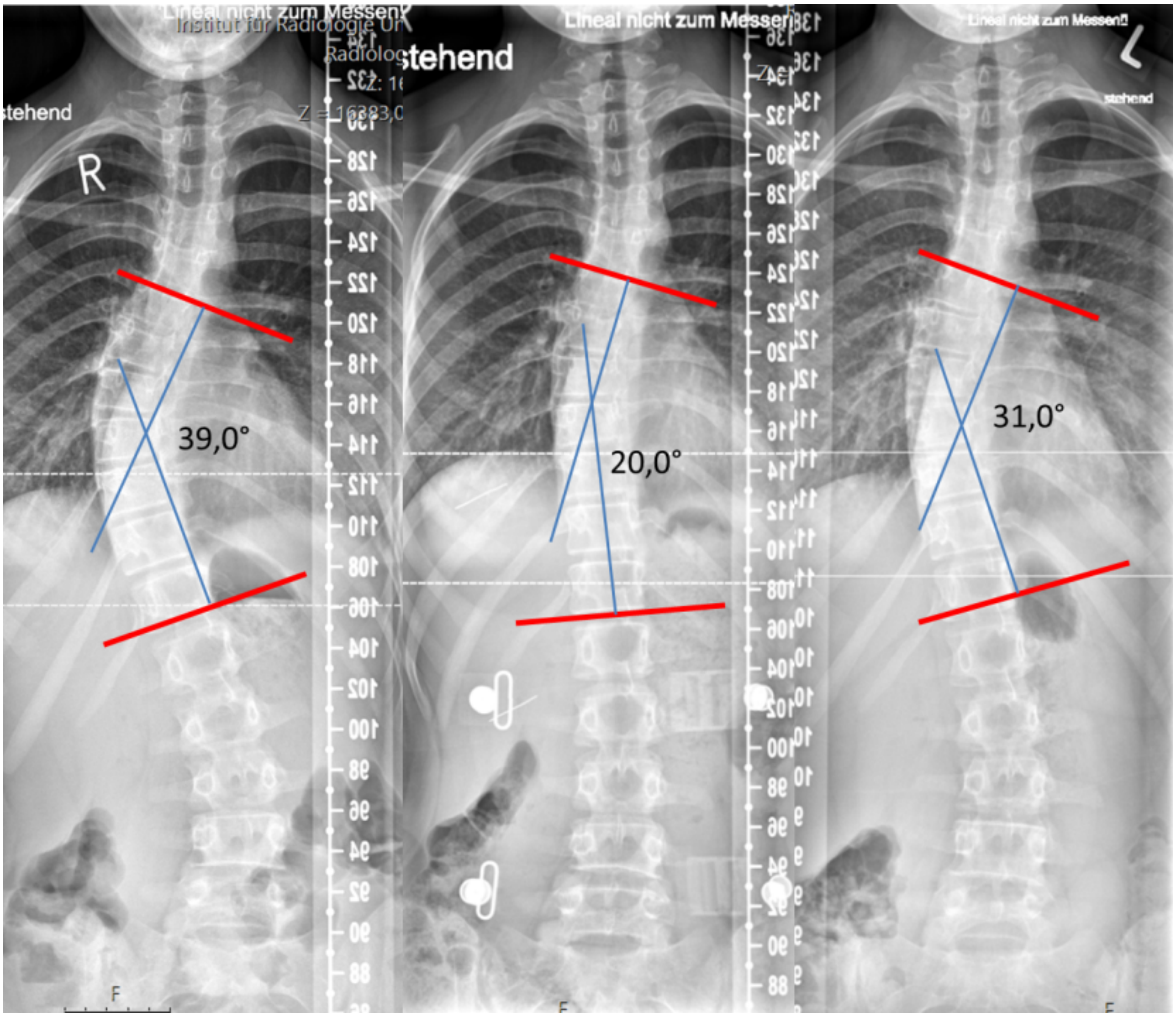

Abbildung 4: Verlauf einer Korsetttherapie: Initial 39 Grad Cobb, Korrektur im Korsett auf 20 Grad, nach Wachstumsabschluss 31 Grad

Quelle: Mit freundlicher Genehmigung von Prof. Dr. med. G. Antoch, Direktor des Institutes für Diagnostische und Interventionelle Radiologie

Es gibt jedoch keine eindeutigen Daten darüber, wie viele Stunden pro Tag das Korsett getragen werden muss, um effektiv zu sein, da sich die einzelnen Arbeitsgruppen gegenseitig widersprechen und jeweils andere Zeiten empfehlen [23-26]. Die aktuellsten Leitlinien sind nur von geringer Evidenz und wurden in einem Delphi-Prozess entwickelt. Es wird eine Tragezeit von mindestens 18 Stunden pro Tag empfohlen [19].

Es ist bekannt, dass die tägliche Tragezeit des Korsetts in Stunden negativ mit der Progressionsrate der Skoliose korreliert [23,24]. Es ist aber auch gesichert, dass die Compliance mit der Korsettbehandlung geringer ist, je länger die verordnete tägliche Tragzeit ist, und dass eine höhere Compliance zu einer niedrigeren Progressionsrate der Skoliose führt [24,27]. Weiterhin ist bekannt, dass die tägliche Tragezeit des Korsetts positiv mit Depressivität bei den Patienten korreliert [28]. Es wird in aktuellen Arbeiten eine Compliance mit der Korsetttherapie von 27 bis 47 Prozent berichtet [24,27]. Gerade im Umgang mit ihren Altersgenossen in der Schule leiden viele Patienten unter der Korsetttherapie. Wenn eine Tragezeit des Korsetts von 12 bis 16 Stunden pro Tag genauso effektiv in der Verhinderung der Progression der Skoliose wäre wie eine Tragezeit von mehr als 16 Stunden pro Tag, könnten die Patienten das Korsett für die Schulzeit ablegen. Dies könnte theoretisch die Compliance mit der Korsettbehandlung erhöhen, so dass die Patienten mit einer Verordnung, welche die Zeit in der Schule ausschließt, das Korsett effektiv mindestens genauso viele Stunden pro Tag tragen, wie die Patienten mit einer Verordnung von 18 Stunden oder mehr pro Tag.

5.2 Operative Therapie

5.2.1 Operative Therapie mit noch vorhandener großer Wachstumsreserve

Eine progressive hochgradige Early-Onset Skoliose (EOS) kann zu einem Thoraxinsuffizienzsyndrom (TIS) führen [14]. Dieses ist definiert als eine durch den knöchernen Thorax bedingte Unfähigkeit, eine normale Atmung und ein normales Lungenwachstum zu ermöglichen. Das TIS ist durch klinische Zeichen der respiratorischen Insuffizienz sowie dem Verlust der Beweglichkeit des knöchernen Thorax gekennzeichnet [29]. Um ein TIS zu verhindern, muss bei einer hochgradigen EOS schon vor Wachstumsabschluss eine operative Versorgung durchgeführt werden. Anders als nach Abschluss des Wachstums, kann in diesen Fällen keine definitive Fusion der Wirbelsäule durchgeführt werden. Es tritt sonst eine Deformierung durch das Restwachstum auf, so dass die Wirbelsäule und damit das Volumen des Thorax nicht mehr ausreichend wachsen würde. Es wurden deshalb mitwachsende Systeme entwickelt, von denen die „growing rods“ [30] und die „Vertical Expandable Prostetic Titanium Ribs“ (VEPTR) [14,29] die bekanntesten sind. Die VEPTR-Technik wurde zunächst nur in Fällen eingesetzt, in denen eine Skoliose durch eine Deformität des Thorax entstand: Bei Synostosen von zwei oder mehr Rippen entwickelt sich eine zur Synostose der Rippen hin konkave Skoliose (Abb. 5). Die

VEPTR-Implantate werden von Rippe zu Rippe (gegebenenfalls auch von Rippe zum Ileum) eingebracht, nachdem die Rippensynostose osteotomiert wurde, und drückt die konkave Seite über den Hebel der Rippen in Richtung in einer Korrektur der Deformität (Abb. 6).

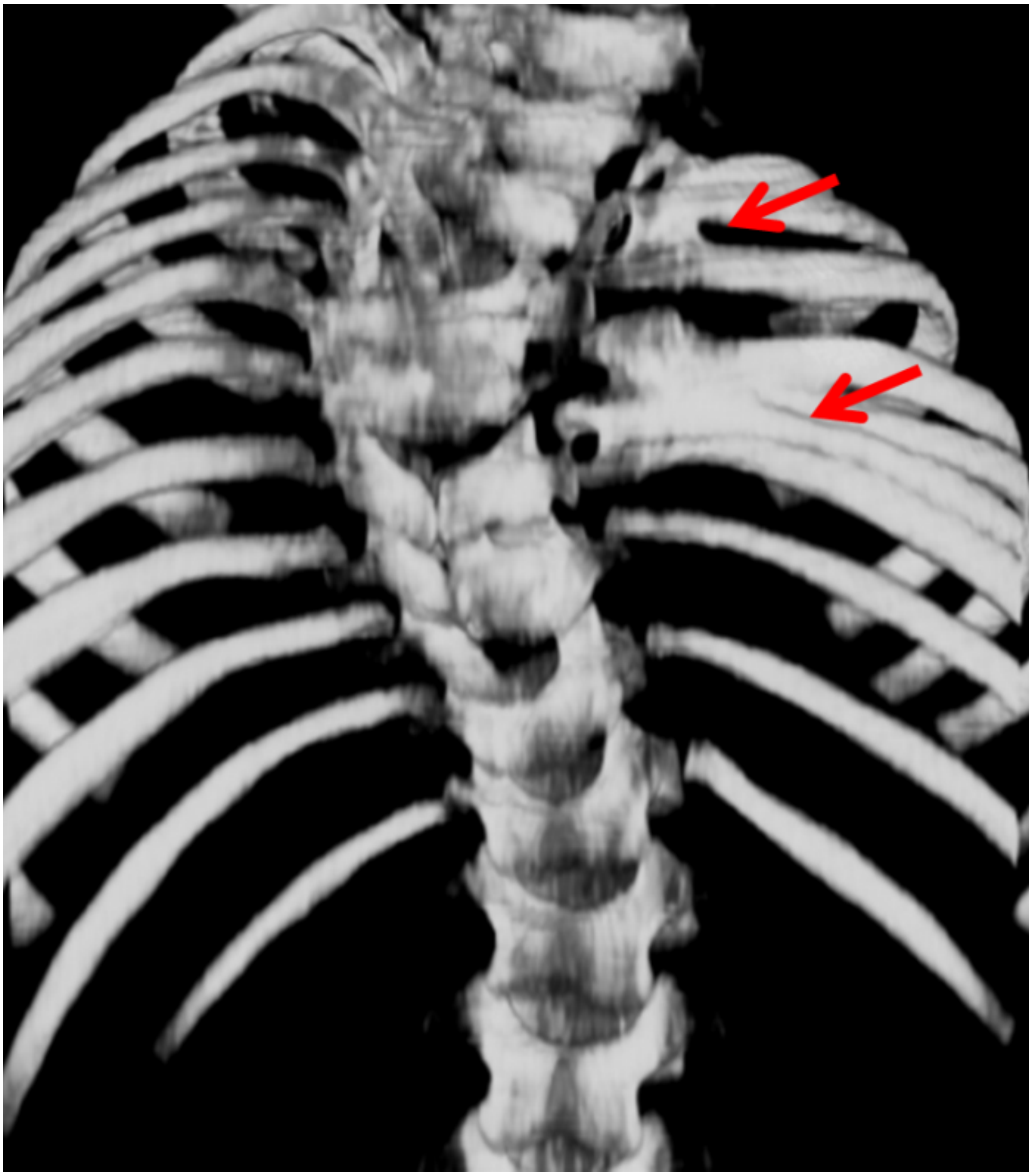

Abbildung 5: 3D-Rekonstruktion einer Computertomographie des Thorax einer Patientin mit Rippensynosthosen (Pfeile)

Quelle: Mit freundlicher Genehmigung von Prof. Dr. med. G. Antoch, Direktor des Institutes für Diagnostische und Interventionelle Radiologie

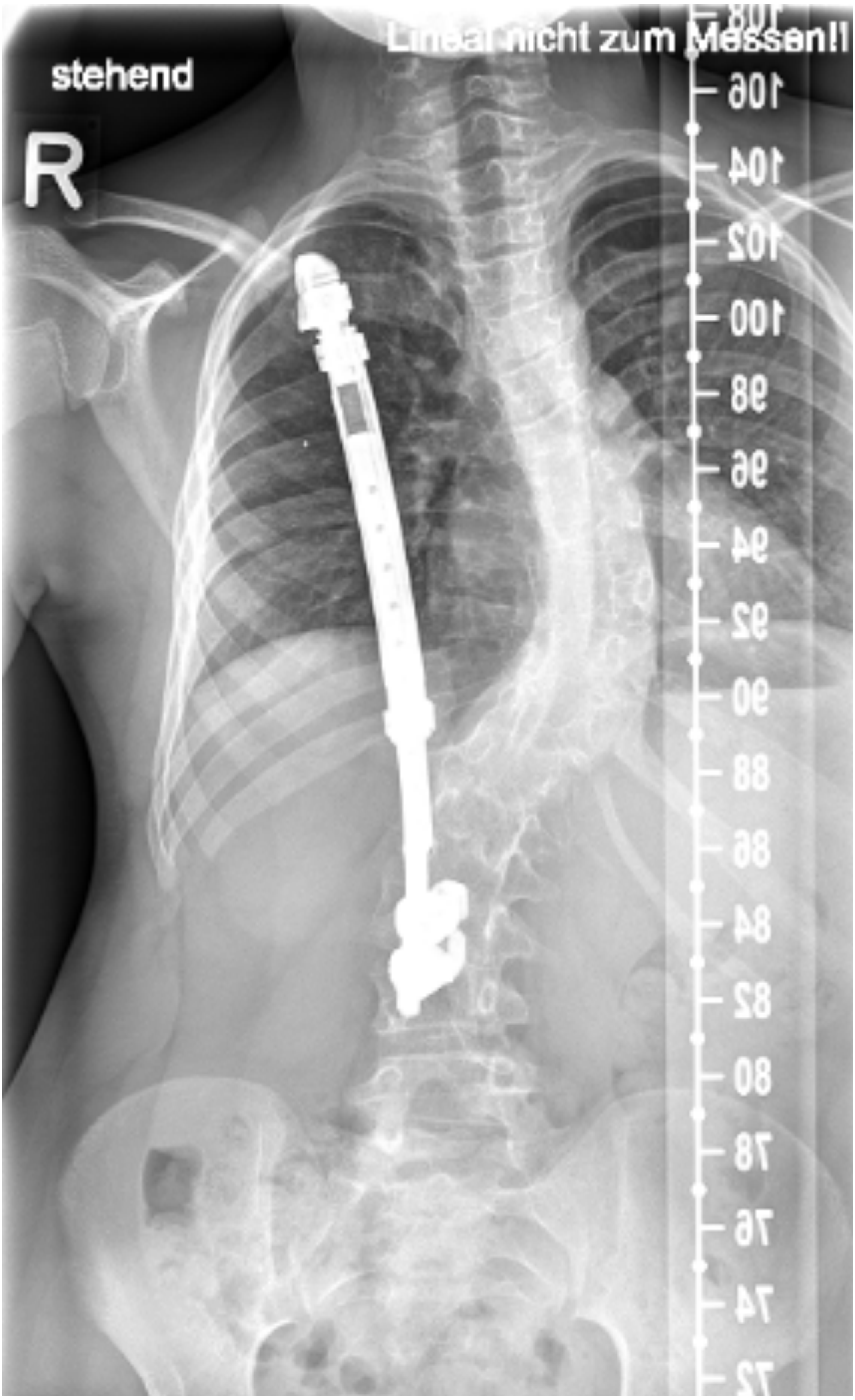

Abbildung 6: Patientin mit thoraxbedingter Skoliose und VEPTR-Patientin mit Rippensynosthosen

Quelle: Mit freundlicher Genehmigung von Prof. Dr. med. G. Antoch, Direktor des Institutes für Diagnostische und Interventionelle Radiologie

Durch diese Operation mit Osteotomie der Rippensynostose wird umgehend das Lungenvolumen vergrößert [31]. Der Effekt der Titanstäbe und der Vernarbung auf dem knöchernen Thorax auf die thorakale Compliance wurde noch nicht untersucht. Nach einer Osteotomie von zuvor zusammengewachsenen Rippen, wird die thorakale Compliance theoretisch zumindest nicht schlechter durch das Implantieren der VEPTR-Implantate.
Die VEPTR-Systeme werden aktuell auch für nicht durch thorakale Fehlbildungen bedingte Skoliosen verwendet, um den durch „growing rods" beschriebenen Nachteil der ungewollten Fusion von Wirbelsäulensegmenten zu vermeiden: „Growing rods" werden von Wirbelkörper zu Wirbelköper verspannt, über Verankerung an Laminae oder Pedikeln (Abb. 7). Der Kontakt der Implantate mit der Wirbelsäule führt dazu, dass an diesen Stellen ungewollte knöcherne Verbindungen zwischen Wirbelkörpern entstehen, sodass am Ende der Behandlung – am Ende des Wachstums – selbst nach einer Metallentfernung eine Versteifung des betroffenen Abschnitts der Wirbelsäule vorliegt [30]. Über die Verankerung der VEPTR-Implantate fern der Wirbelsäule, an den Rippen, erhoffte man sich eine Vermeidung dieser ungewollten Fusionen [32]. Es konnte jedoch sowohl in unserem Patientengut als auch in einer anderen Arbeitsgruppe gezeigt werden, dass auch bei der Behandlung mittels VEPTR ungewollte Fusionen der erkrankten Wirbelsäulenabschnitte auftreten [33].
Zusätzlich zur Auswirkung der Implantation von VEPTR auf die thorakale Compliance wurde auch deren Auswirkung auf die sagittale Balance der Wirbelsäule noch nicht untersucht. Die statischen („pelvic incidence") und dynamischen („pelvic tilt" und „sacral slope") Parameter des Beckens (Abb. 8), die für die sagittale Balance der Wirbelsäule essentiell sind, entwickeln sich während des Wachstums: Die „pelvic incidence" nimmt während des Wachstums stetig zu. Nach Abschluss des Wachstums bleibt die „pelvic incidence" lebenslang unverändert [34]. Theoretisch könnte diese Entwicklung durch das Einbringen von Implantaten, welche die Wirbelsäule verspannen und das Wachstum lenken sollen, beeinflusst werden.

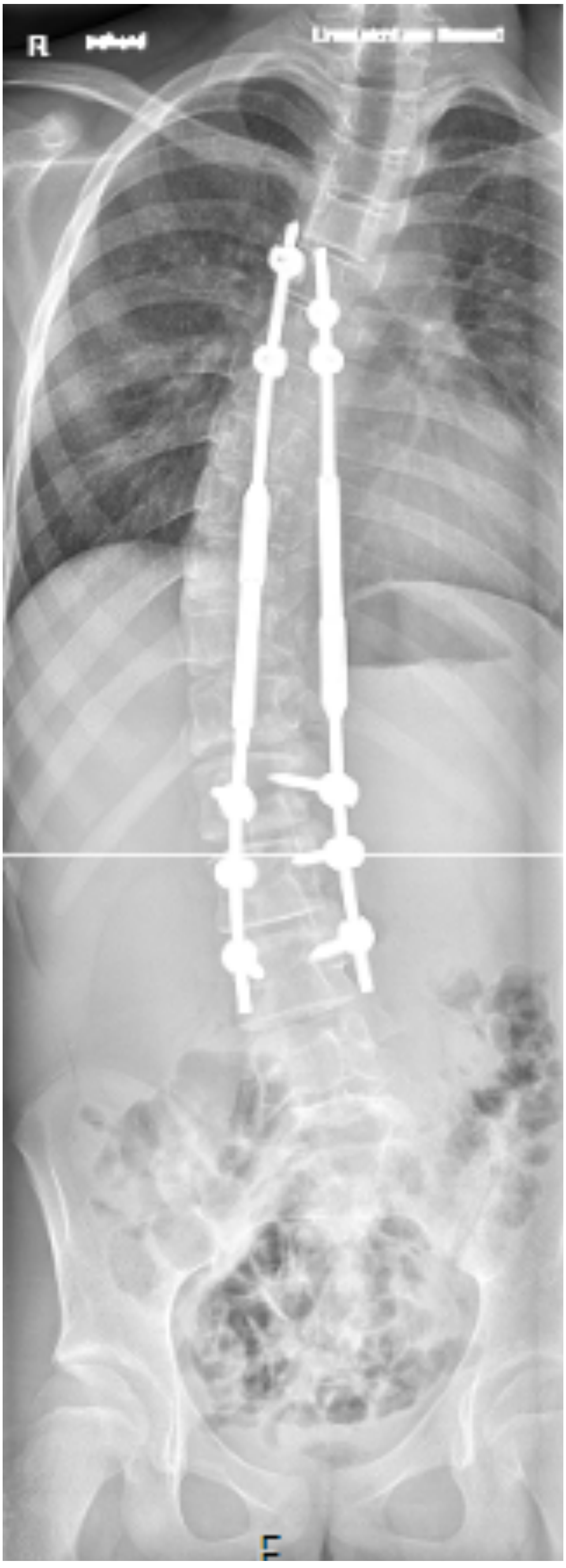

Abbildung 7: Wirbelsäulenganzaufnahme einer Wirbelsäule nach Implantation von „growing rods“

Quelle: Mit freundlicher Genehmigung von Prof. Dr. med. G. Antoch, Direktor des Institutes für Diagnostische und Interventionelle Radiologie

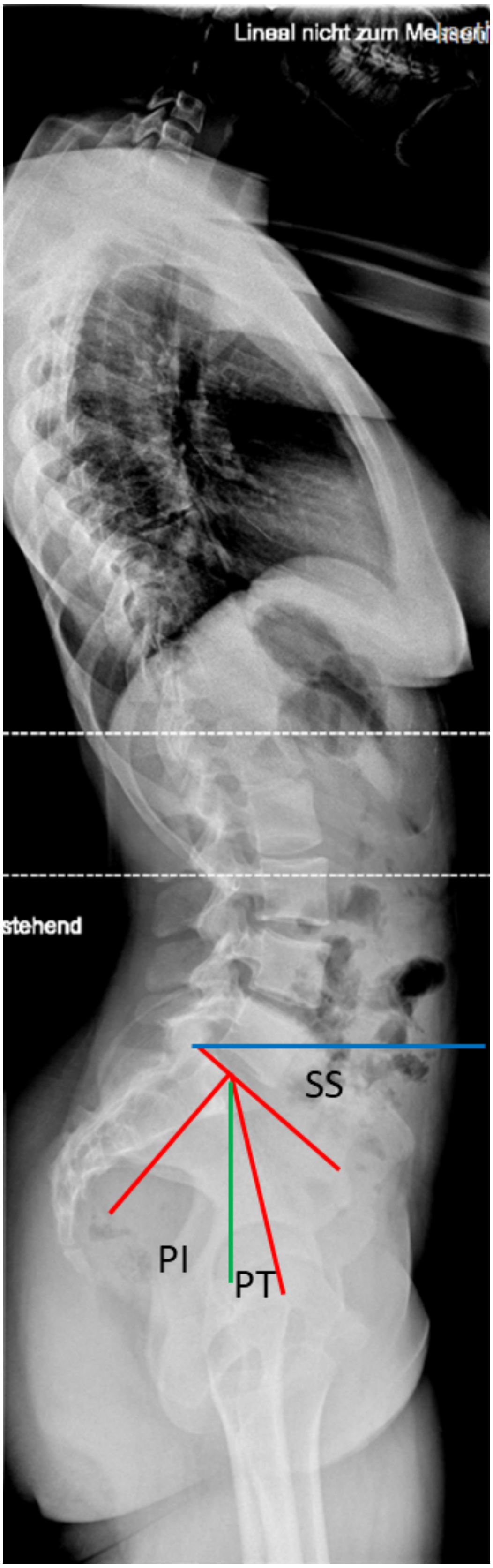

Abbildung 8: Beckenparameter der sagittalen Balance: PI („pelvic incidence"), PT („pelvic tilt"), SS („sacral slope")

Quelle: Mit freundlicher Genehmigung von Prof. Dr. med. G. Antoch, Direktor des Institutes für Diagnostische und Interventionelle Radiologie

5.2.2 Operative Therapie nach Abschluss des Wachstums

Wenn nach Abschluss des Wachstums eine hochgradige Skoliose operativ versorgt wird, ist das Verwenden von Wachstumsstäben nicht mehr notwendig und das Vermeiden einer Fusion der betroffenen Wirbelsäulenabschnitte ist nicht mehr möglich. Bei der operativen Versorgung muss das frontale und sagittale Profil der Patienten wiederhergestellt werden, die Lungenfunktion soll erhalten werden und ein zufriedenstellendes kosmetisches Ergebnis soll für den Patienten erreicht werden.

Es gibt verschiedene Techniken für die Wiederaufrichtung und Fusion einer Skoliose. Die Versorgung kann unter anderem von ventral, von dorsal, sowie von dorsal und ventral durchgeführt werden.

Seit der Entwicklung und Einführung von Pedikelschrauben-Stab-Systemen (Abb. 9), die von dorsal eingebracht werden, werden die anderen Verfahren immer seltener durchgeführt.

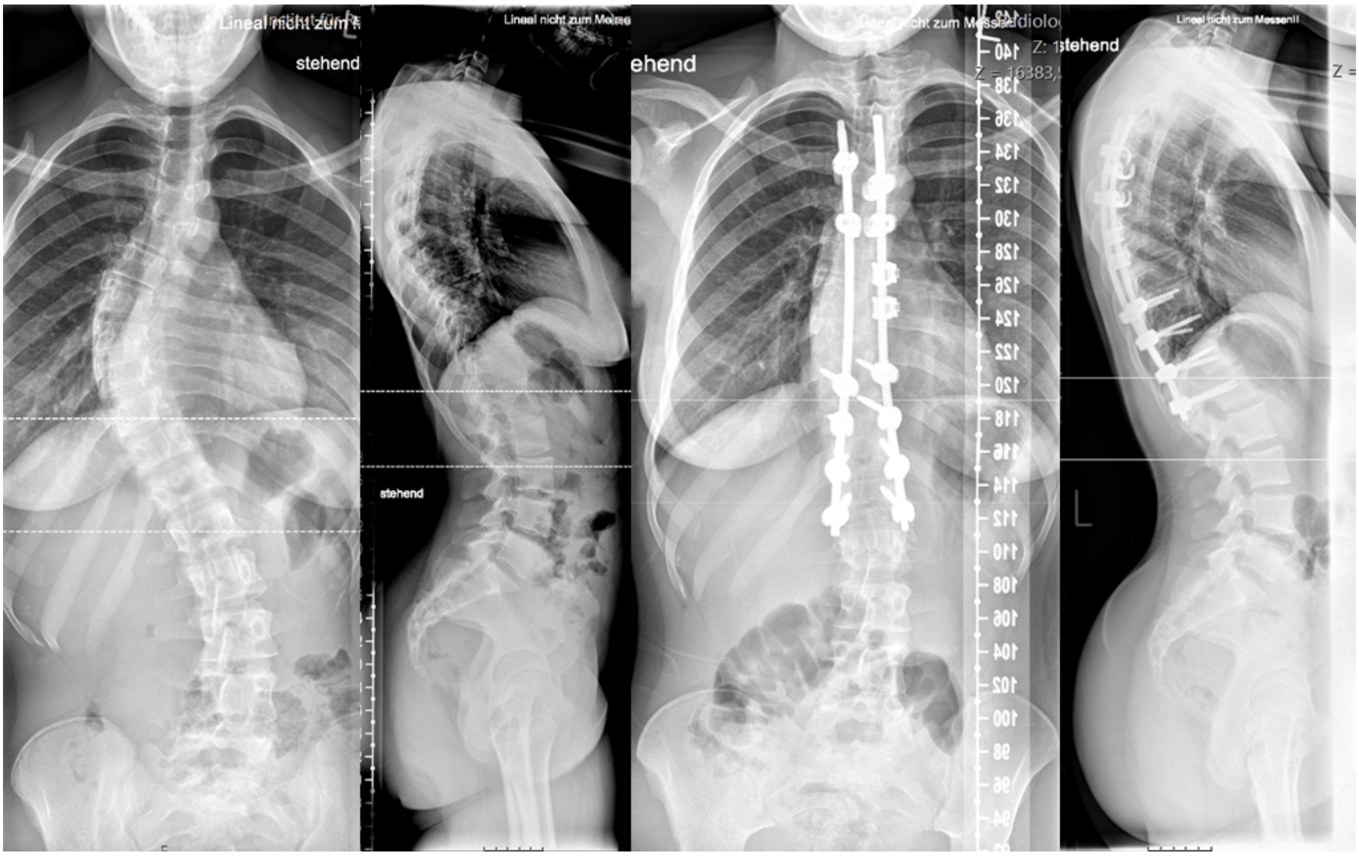

Abbildung 9: Wirbelsäulenganzaufnahme in zwei Ebenen einer Wirbelsäule vor und nach Versorgung mit einem Pedikelschrauben-Stab-System

Quelle: Mit freundlicher Genehmigung von Prof. Dr. med. G. Antoch, Direktor des Institutes für Diagnostische und Interventionelle Radiologie

Technisch kann man über dieses System die Wirbelsäule sehr gut in allen drei Ebenen korrigieren. Inzwischen werden in den Vereinigten Staaten von Amerika mehr als 90 Prozent aller Skoliosen von dorsal mittels Pedikelschrauben-Stab-Systemen operativ versorgt [35].

Die Implantation von Pedikelschrauben kann mit verschiedenen Techniken erfolgen. Am meisten verbreitet ist die konventionelle Implantationstechnik unter fluoroskopischer Kontrolle, gefolgt von der navigierten Technik.
Bei Verwenden der fluoroskopischen Technik wird von einer Fehllagerate der Pedikelschrauben von etwa 30 Prozent berichtet. Beim Verwenden von Navigationstechnik ist die berichtete Rate an Fehllagen um 50 Prozent geringer als bei der fluoroskopischen Technik. Werden Pedikelschrauben in der thorakalen Wirbelsäule implantiert, ist die berichtete Fehllagerate fünffach erhöht im Vergleich zur Implantation in der lumbalen Wirbelsäule. Bei der Implantation von Pedikelschrauben bei Patienten mit einer Skoliose ist die Fehllagerate erhöht im Vergleich zur Implantation bei Patienten ohne Skoliose [36-38]. Wenn eine Pedikelschraube von der idealen Position im Pedikel mehr als 2mm nach medial in den Spinalkanal abweicht, sind neurologische Komplikationen zu erwarten [39]. Wegen dieser Daten wissen wir, dass eine höhere Präzision der Pedikelschrauben gerade bei der operativen Versorgung von Patienten mit einer Skoliose die Patientensicherheit signifikant erhöht. Die Verwendung der Navigation bei der operativen Versorgung von Skoliosen hat somit deutliche Vorteile bezüglich der Präzision gegenüber der konventionellen fluoroskopischen Technik.

Die Auswirkung der navigierten Technik auf die Strahlenbelastung für das Operationsteam wurde noch nicht eindeutig untersucht. Rampersaud et al. [40] zeigten, dass die Strahlenbelastung für Wirbelsäulenchirurgen um ein Zwölffaches höher ist als für alle anderen muskuloskelettalen Chirurgen, weswegen das Thema gerade bei den in der Regel langstreckigen Instrumentierungen bei der Versorgung von Skoliosen eine hohe Relevanz hat. Es gibt nur wenige Untersuchungen, die die Strahlenbelastung für das Operationsteam explizit analysieren, und diese schlossen hauptsächlich monosegmentale Versorgungen und Operationen mit Einbringen von intervertebralen Cages ein [41,42].
Zu der Strahlenbelastung für den Patienten gibt es Arbeiten, die berichten, dass die navigierte Technik zu einer höheren Strahlenbelastung für den Patienten führt als die konventionelle fluoroskopische Technik [42-46]. Dies wäre insbesondere bei der Versorgung von pädiatrischen Patienten inakzeptabel: Wir wissen, dass die Inzidenz von Brustkrebs mit der Strahlendosis korreliert, der ein Mensch im Laufe seines Lebens ausgesetzt ist. Dies ist der Grund, aus dem

Patientinnen mit einer Skoliose signifikant häufiger an Brustkrebs erkranken als die Normalbevölkerung [47].
Die Studien, welche eine erhöhte Strahlenbelastung für die Patienten bei der navigierten Technik zeigten, untersuchten Patienten, die mittels kurzstreckigen Fusionen, heterogenen Indikationen, in minimalinvasiver und in offener Technik versorgt wurden, mit und ohne interkorporellen Cage [42-46].
Eine Untersuchung zur Strahlenbelastung der navigierten im Vergleich zur konventionellen fluoroskopischen Technik bei der Versorgung von Deformitäten der Wirbelsäule gab es bisher noch nicht. Die Hypothese, dass die Strahlenbelastung durch die navigierte Technik auch bei der Versorgung von Skoliosen gesenkt werden kann, ist naheliegend, da die Implantation von Pedikelschrauben in deformierte Wirbelköper anspruchsvoller ist als in nicht deformierte.
Navigiert werden kann mit dem Bilddatensatz einer präoperativ erstellten Computertomographie, oder mit intraoperativ mittels 3D-Scan erstellten Bilddatensätzen. Welche Navigationstechnik die geringere Strahlenbelastung für den Patienten verursacht, ist noch nicht bekannt. Vorherige Arbeiten erhoben Datensätze in nicht vergleichbaren Einheiten [48], was an der unterschiedlichen Registrierung der Strahlendosis bei der Computertomographie und dem 3D-Scan, welcher mit einem Bildwandler im Operationssaal durchgeführt wird, liegt. Der Computertomographie-Scan registriert das Dosis-Längen-Produkt in mGy/cm, der 3D-Bildwandler registriert das Dosis-Flächen-Produkt in cGy/cm2. Die jeweilige Dosis muss somit mit speziellen Konversionsfaktoren in mSv (Effektivdosis) umgerechnet werden, um die verschiedenen Techniken miteinander vergleichbar zu machen. Basierend auf den Daten von Suzuki [49] und Huda [50] müssen die Konversionsfaktoren sowohl an das verwendete Gerät als auch an die gescannte Region angepasst werden.

6. Eigene Untersuchungen

6.1 Epidemiologie von idiopathischen Skoliosen

Es gibt nur wenige epidemiologische Untersuchungen zur Prävalenz von Skoliosen. Die vorhandenen Untersuchungen haben zudem substantielle Schwächen, da sie unterschiedliche Definitionen für Skoliosen, Studienprotokolle und Altersgruppen einbezogen [6-12]. In Arbeit 1 analysierten wir daher mit einem Review die bisher veröffentlichten epidemiologischen Primärdaten.

Es zeigte sich eine gesamte Prävalenz für idiopathische Skoliosen von 0,47 bis 5,2 Prozent. Wir fanden deutliche Unterschiede in der Prävalenz je nach Alter und Geschlecht der Patienten sowie je nach Schweregrad der Skoliose.

Kinder unter zehn Jahren zeigten die niedrigste Prävalenz mit weniger als ein Prozent, Kinder von 10 bis 14 Jahren zeigten eine Prävalenz von 1 bis 6,5 Prozent, Kinder die älter waren als 14 Jahre zeigten eine Prävalenz von bis zu 11,1 Prozent.

Auch der Schweregrad der Skoliose zeigte einen deutlichen Einfluss auf die Prävalenz von Skoliosen. Skoliosen mit einem Cobb-Winkel von bis zu 20 Grad zeigten eine Prävalenz von 1,5 bis drei Prozent, Skoliosen mit einem Cobb-Winkel von mehr als 20 Grad und bis zu 40 Grad zeigten eine Prävalenz von 0,2 bis 0,5 Prozent. Skoliosen mit einem Cobb-Winkel von mehr als 40 Grad zeigten die niedrigste Prävalenz mit 0,04 bis 0,3 Prozent.

Bei der Analyse der Unterschiede zwischen den Geschlechtern zeigte sich, dass die schweren Kurven häufiger bei Mädchen auftraten als bei Jungs. Patienten mit Cobb-Winkeln von mehr als 40 Grad waren etwa siebenmal häufiger Mädchen als Jungs. Das Verhältnis von Mädchen zu Jungs reduzierte sich bei Patienten mit Cobb-Winkeln von 20 bis 40 Grad auf etwa 4 zu 1, und bei Cobb-Winkeln unter 20 Grad auf etwa 1,4 zu 1.

Weiterhin zeigte sich eine unterschiedliche Häufigkeit für verschiedene Kurventypen. Thorakale Kurven waren mit etwa 48 Prozent am häufigsten, gefolgt von thorakolumbalen oder lumbalen Kurven mit etwa 40 Prozent. Nur etwa 10 Prozent aller Patienten mit einer idiopathischen Skoliose zeigten eine Doppelkurve mit entweder zwei thorakalen oder einer thorakalen und einer lumbalen Kurve.

Aufgrund der zu Beginn dieses Kapitels beschriebenen Ausgangslage dient diese Arbeit sehr häufig als Referenz für die Prävalenz von Skoliosen und wurde bisher 281 Mal in diesem Zusammenhang zitiert.

6.2 Konservative Therapie mit Korsett

International wird auf Grundlage von geringer Evidenz eine Tragezeit des Korsetts von mindestens 18 Stunden pro Tag verschrieben [20], weil bekannt ist, dass die Anzahl der Stunden, die das Korsett pro Tag getragen wird, negativ mit der Progressionsrate der Skoliose korreliert [23,24]. Wie viele Stunden pro Tag das Korsett mindestens getragen werden muss, um effektiv zu sein, ist nicht bekannt. Die jugendlichen Patienten zeigen mehr Depressivität, je länger sie das Korsett tragen müssen, und die Compliance mit der Korsetttherapie ist geringer, je höher die verordnete Tragezeit ist [24,27,28].

In Arbeit 1 untersuchten wir, ob eine Tragezeit des Korsetts von 12 bis 16 Stunden pro Tag ein schlechteres Outcome zeigt, als eine Tragezeit des Korsetts von mehr als 16 Stunden pro Tag. Mit bis zu 16 Stunden verordneter Tragezeit pro Tag müssten die Jugendlichen das Korsett nicht in der Schule tragen und könnten die psychologische Belastung durch das Korsett erheblich reduzieren.

Wir identifizierten in Arbeit 1 in einer retrospektiven Untersuchung zunächst alle Patienten, die sich zwischen dem 01.10.2010 und dem 31.06.2013 wegen einer idiopathischen Skoliose in unserer Skoliose-Sprechstunde vorstellten. Patienten mit einem Cobb-Winkel von mindestens 20 Grad und noch starker Wachstumsreserve (Risser-Stadium höchstens 3 [51] (Abb.10), höchstens ein Jahr nach der Menarche), die bis zum Ende einer verordneten Korsettbehandlung und für mindestens zwei Jahre nachuntersucht wurden, schlossen wir in die Studie ein.

Patienten mit inkompletten Bilddatensätzen wurden ausgeschlossen. Aus den Röntgenbildern erhoben wir die Cobb-Winkel und das Risser-Stadium, an klinischen Daten wurden der Status der Menarche, der Beginn und das Ende der Korsettbehandlung sowie die tägliche Tragezeit des Korsetts aufgezeichnet.

Weiterhin erhoben wir die Anzahl der Stunden von sportlichen Aktivitäten des Patienten pro Woche, die Anzahl der Stunden an krankengymnastischen Eigenübungen pro Woche, das Körpergewicht des Patienten, den Bildungsstatus der Eltern, die Art der Schultasche (Tragen auf einer oder zwei Schultern), den Bildungsstatus des Patienten und den Raucherstatus der Eltern. Bei der ersten Vorstellung wurde eine Wirbelsäulen-Ganzaufnahme in posterior-anteriorem Strahlengang durchgeführt und die Cobb-Winkel bestimmt (Abb. 2). Jedes Korsett wurde auf Effektivität geprüft: Nach sechs Wochen Tragezeit wurde mit getragenem Korsett eine weitere Wirbelsäulen-Ganzaufnahme in posterior-anteriorem Strahlengang durchgeführt.

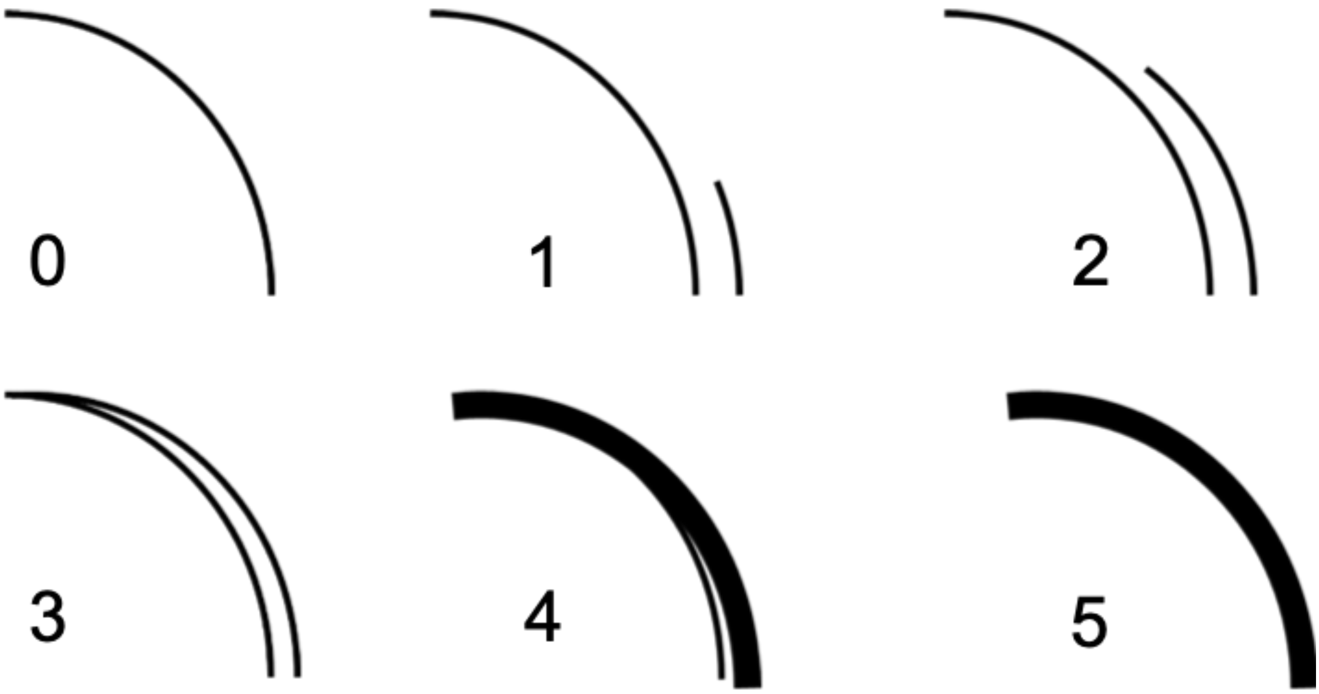

Abbildung 10: Risser-Stadium. Das Schema zeigt den linken Beckenkamm von vorne. Die beiden Linien zeigen den knöchernen kranialen Rand des Beckenkamms und die zunächst knorpelig angelegte Beckenkammapophyse, welche langsam verknöchert. Die Verknöcherung der Beckenkammapophyse schreitet von medial nach lateral voran und verschmilzt im Stadium 5 mit dem Beckenkamm. Der Grad der Verknöcherung der Beckenkammapophyse von Stadium 0 bis 5 ist ein Indikator für die Skelettreife. Bei Stadium 5 ist das Wachstum abgeschlossen.

Quelle: Dr. med. M. Konieczny

Wenn sich der Cobb-Winkel in dieser Aufnahme nicht um mindestens 20 Prozent reduziert hat als in der Aufnahme ohne Korsett, wurde es nachgebessert, bis die adäquate Besserung erreicht wurde. Im Anschluss wurden alle sechs Monate Kontroll-Röntgenuntersuchungen ohne Korsett durchgeführt, bis das Wachstum der Patienten abgeschlossen war (Risser-Stadium mindestens 4).

Von 601 Patienten, die sich in unserer Skoliose-Sprechstunde vorstellten, wurden nach Anwenden von Ein- und Ausschlusskriterien 72 in die Studie eingeschlossen: Neunzig Prozent der Patienten hatten eine idiopathische Skoliose, von diesen Patienten wies etwa ein Drittel einen Cobb-Winkel von mehr als 20 Grad auf. Von den verbliebenen 178 Patienten hatten 85 noch ein ausreichendes zu erwartendes Restwachstum. Dreizehn dieser Patienten hatten unvollständige Bilddatensätze.

Um zu ermitteln, wie viele Stunden täglich die Patienten das Korsett getragen haben, wurden bei jeder Wiedervorstellung (alle sechs Monate) zunächst der Patient und dann beide Eltern befragt. Es wurden jeweils drei Fragen gestellt:

1. Wurde das Korsett die ganze Nacht getragen? „Ja“ wurde als acht Stunden Korsett-Tragezeit gewertet, „Nein“ als null Stunden Korsett-Tragezeit.
2. Wurde das Korsett in der Schule getragen und dort nicht abgenommen? „Ja“ wurde als acht Stunden Korsett-Tragezeit gewertet, „Nein“ als null Stunden Korsett-Tragezeit.
3. Wie viele Stunden pro Tag (null bis acht zur Auswahl) wurde das Korsett täglich nach der Schule und vor Beginn der Nachtruhe getragen? Der Durchschnittswert der Woche vor der jeweiligen Untersuchung wurde erfragt.

Die niedrigste angegebene Stundenzahl von einem der drei Befragten (Patient, Mutter, Vater) wurde als Antwort eingetragen. Die Stunden aus Fragen 1. bis 3. wurden addiert.
Die Alternative zu dieser Befragung sind Wärmesensoren, die in das Korsett eingelassen sind und aufzeichnen, wann das Korsett getragen wurde und wann nicht. Dafür müssten allerdings mindestens die Eltern darüber aufgeklärt werden, dass kontinuierlich Daten von ihrem Kind erhoben werden, was zu einem Bias in der Korsett-Tragezeit der Studiengruppe im Vergleich zu den Patienten außerhalb der Studie (ohne Sensoren) führen könnte. Das von uns verwendete System ist zuverlässig dazu in der Lage, die Patienten in eine der drei Gruppen (unter 12 Stunden pro Tag, 12 bis16 Stunden pro Tag, mehr als 16 Stunden pro Tag) einzuteilen: Fragen 1. und 2. sind simpel mit „ja“ oder „nein“ zu beantworten. Wenn die Kinder das Korsett nicht in der gesamten Nacht tragen, neigen sie dazu, dieses sehr früh in der Nacht abzulegen. Deswegen wurde ein „nein“ stets als null Stunden Tragezeit in der Nacht gewertet. Ein „nein“ bei Frage 2. wurde ebenfalls als null Stunden Tragezeit gewertet: Die Jugendlichen, welche ihr Korsett nicht in der Schule tragen, tun dies vor allem aus psychologischen Gründen nicht. Daher ziehen diese das Korsett während der Schulzeit entweder gar nicht erst an oder legen es sehr früh ab. Frage 3. ist durch die Befragung von Patienten und von beiden Eltern abgesichert. Weiterhin würde eine falsche Angabe bei dieser Frage eher nicht dazu führen, dass ein Patient zu Unrecht in die zweite anstatt in die dritte Gruppe (oder umgekehrt) einsortiert würde.
Die drei Gruppen wurden zunächst mit einem Kruskall-Wallis-Test in Bezug auf unterschiedliche Progressionsraten der Skoliose analysiert. Dieser zeigte, dass es innerhalb der drei Gruppen signifikante Unterschiede zueinander gab in Bezug auf die Progressionsrate der Skoliose. Anschließend wurden die zweite (Korsett 12 bis16 Stunden pro Tag) und dritte Gruppe (Korsett mehr als 16 Stunden pro Tag) mit einem Man-Whitney-U-Test bezüglich der Progressionsrate der Skoliose miteinander verglichen. Es zeigte sich kein signifikanter Unterschied zwischen den Gruppen.

Die Anzahl der Stunden, in welchen die Patienten wöchentlich Sport trieben, der Body-Mass-Index der Patienten, das Alter der Patienten bei Einsetzen der Menarche, die Anzahl der Stunden, in welchen die Patienten wöchentlich selbständig Übungen der Physiotherapie durchführten, die Art der Schultasche, der Bildungsstatus der Eltern, und der Bildungsstatus der Patienten hatten keinen Einfluss auf Inzidenz oder Progression der Skoliose.
Der Anteil an Rauchern war unter den Eltern von den untersuchten Patienten mit einer Skoliose signifikant höher als im Durchschnitt der Bevölkerung [52].

6.3 Operative Therapie

6.3.1 Operative Therapie mit noch vorhandener großer Wachstumsreserve

Wenn eine Skoliose vor dem 10. Lebensjahr beginnt, besteht die Gefahr, dass sich ein Thoraxinsuffizienzsyndrom bildet. Deswegen wird regelhaft schon vor Wachstumsabschluss eine operative Korrektur der Deformität mittels mitwachsender Systeme durchgeführt.
Eines dieser Systeme sind die VEPTR, welche von Rippe zu Rippe oder von Rippe zum Ileum, also am knöchernen Thorax, angebracht werden (Abb. 6). Das Lungenvolumen wird bei der Implantation von VEPTR zwar vergrößert, theoretisch wirken sich jedoch die Titanimplantate und die durch die Operation entstehenden Narben negativ auf die thorakale Compliance aus.
Um dies zu untersuchen, schlossen wir in Arbeit 3 retrospektiv 21 konsekutive Patienten mit einem mittleren Alter von 5,3 Jahren bei der ersten Operation ein, die wegen einer idiopathischen Early-Onset Skoliose mit VEPTR versorgt wurden. Patienten zwischen einem und zehn Jahren mit einem Cobb-Winkel von mehr als 40 Grad oder einem "rib vertebra angle" von mindestens 20 Grad wurden eingeschlossen, da dies die Patienten sind, die ein hohes Risiko haben, ein Thoraxinsuffizienzsyndrom zu entwickeln [53]. Patienten mit präoperativ bestehender Rippensynostose wurden ausgeschlossen. Nach der Implantation von VEPTR mit Korrektur der Deformität wurden alle sechs Monate Verlängerungsoperationen durchgeführt. Die Patienten wurden im Mittel 60,7 Monate nachuntersucht. Festgehalten wurden der Cobb-Winkel vor und nach der ersten Operation sowie nach dem letzten Follow-up. Das Gewicht wurde vor jeder Operation und die dynamische thorakale Compliance (DTC) direkt vor jeder Operation festgehalten, zehn Minuten nach endotrachealer Intubation. Die Veränderung der DTC im Wachstum ist abhängig von Alter und Gewicht der Patienten [54,55], weswegen wir die Veränderung der DTC (ml/mbar) von der ersten Operation bis zur letzten in Relation zum Körpergewicht in Kilogramm erfassten.

Wir untersuchten zusätzlich eine Kontrollgruppe von 16 Patienten mit einem mittleren Alter von 5,3 Jahren, die aus anderen Gründen (weder wirbelsäulen- noch thoraxbedingt) mehr als einmal operiert wurden und erfassten auch hier Alter, Gewicht und DTC vor jeder Operation. Diese Patienten wurden im Mittel 55,4 Monate nachuntersucht.
In der VEPTR-Gruppe wurde kein Patient von der Rippe bis zum Ileum instrumentiert. Wir schlossen daher noch eine weitere Kontrollgruppe von acht Patienten ein, die eine Instrumentierung bis zum Ilium erhielten, und verglichen die Entwicklung der Beckenparameter der sagittalen Balance im Wachstum der beiden Gruppen miteinander.
Die Auswertung der DTC der VEPTR- und der Kontrollgruppe zeigte, dass die DTC der Kontrollgruppe initial und am Ende der Nachuntersuchungszeit signifikant höher war als die der VEPTR-Gruppe. Der Anstieg der DTC in Relation zum Körpergewicht zeigte jedoch keinen signifikanten Unterschied zwischen den Gruppen (Abb. 11).
Die Entwicklung der Parameter der sagittalen Balance zeigten keinen signifikanten Unterschied zwischen den Gruppen mit und ohne Instrumentation bis zum Ilium.
Für „growing rods“ wird eine Komplikationsrate, vor allem Wundheilungsstörungen und Implantatlockerungen, von 42 bis 58 Prozent berichtet [56,57]. In unserer Gruppe der Patienten, die mittels VEPTR versorgt wurden, zeigte sich eine Komplikationsrate von 33 Prozent.

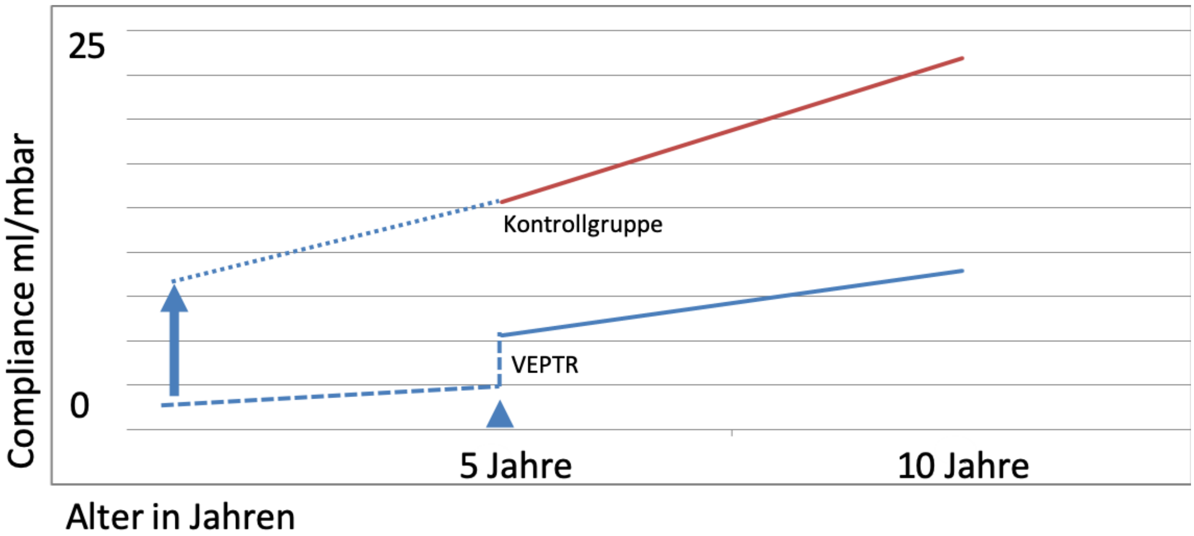

Abbildung 11: Die blaue Linie zeigt die Entwicklung der pulmonalen Compliance bei Patienten mit einer Early-Onset Skoliose, wenn im Alter von fünf Jahren ein VEPTR implantiert wird. Theoretisch könnte diese Entwicklung bei einem früheren Beginn der Behandlung näher an das Niveau der gesunden Kontrollgruppe gebracht werden (rote Linie).

Quelle: Modifiziert nach: Vertical expandable prosthetic titanium ribs (VEPTR) in early-onset scoliosis: impact on thoracic compliance and sagittal balance. Konieczny MR, Ehrlich AK, Krauspe R. J Child Orthop. 2017;11(1):42-48. doi: 10.1302/1863-2548-11-160222

6.3.2 Operative Therapie nach Abschluss des Wachstums

Wenn nach Abschluss des Wachstums eine Skoliose mit einem Cobb-Winkel von mehr als 40 Grad besteht, wird eine operative Versorgung erwogen. Mehr als 90 Prozent dieser Versorgungen werden von posterior mit einem Pedikelschrauben-Stab-System durchgeführt [35]. Die Pedikelschrauben können unter fluoroskopischer Kontrolle oder mit verschiedenen Navigationstechniken eingebracht werden. Es ist aktuell noch nicht bekannt, welche Technik bei der Versorgung von Skoliosen zu weniger Strahlenbelastung für den Patienten führt.

In Arbeit 4 analysierten wir die Strahlenbelastung pro implantierter Schraube für den Operateur und für den Patienten getrennt voneinander. Zusätzlich wurde die Präzision der Schraubenplatzierung analysiert. Nach einer Power Analyse schlossen wir 205 konsekutiv implantierte Pedikelschrauben ein und werteten retrospektiv die erhobenen Daten aus.
In unserer Klinik wurden Patienten mit einer instabilen pathologischen Fraktur bei einer Metastase im Bereich der Wirbelsäule minimalinvasiv versorgt. Patienten, die zusätzlich zur dorsalen Stabilisierung mit einem Pedikelschrauben-Stab-System eine dorsale Dekompression benötigten, wurden mittels navigierter Technik versorgt, da der Dornfortsatz zur Platzierung der für die Navigation notwendigen Referenzklemme ohnehin freigelegt wurde. Die Patienten, die keine zusätzliche Dekompression benötigten, wurden mittels konventioneller fluoroskopischer Technik versorgt. Es wurden nur Patienten eingeschlossen, bei denen mehr als ein Segment versorgt wurde. Alle Patienten erhielten postoperativ zur Planung der Bestrahlung der Metastase eine Computertomographie der operierten Segmente der Wirbelsäule. Wir werteten die Strahlendosis für den Patienten und für das Operationsteam getrennt voneinander aus, zudem wurde die Präzision der Schraubenlage beurteilt. Für die Navigation wurden Bilder verwendet, die mittels intraoperativem 3D-Scan erstellt wurden.
Bei 22 Patienten wurden 118 Pedikelschrauben in navigierter und 87 Pedikelschrauben in konventioneller fluoroskopischer Technik implantiert.
Im Vergleich zur konventionellen fluoroskopischen Technik wurde bei der navigierten Technik das Operationsteam nur 19,9 Prozent der Strahlendosis ausgesetzt, und die Patienten nur 58,7 Prozent der Strahlendosis. Der Unterschied war jeweils signifikant. Bezüglich der Präzision der Schraubenplatzierung fanden wir keinen signifikanten Unterschied. Es zeigten 2,3 Prozent der Schrauben in der fluoroskopischen Technik und 1,7 Prozent der Schrauben in der navigierten Technik eine Fehllage. Die einzige höhergradige Schraubenfehllage wurde in der fluoroskopischen Technik diagnostiziert.

In Arbeit 5 schlossen wir prospektiv zehn adoleszente Patienten mit einer idiopathischen Skoliose in unsere Untersuchung (erste Gruppe) ein, die mit navigierter Technik auf Grundlage eines präoperativen Computertomographie-Scans der betroffenen Wirbelkörper operativ versorgt wurden. Anschließend schlossen wir im Rahmen einer Matched-Pair-Vergleichsanalyse für den ersten der zehn Patienten aus der ersten Gruppe zwei Patienten mit einer idiopathischen Skoliose ein, die denselben Lenke Typ [58] der Skoliose hatte und bei welchem dieselben Segmente operativ versorgt wurden.

Tabelle 1: Lenke Klassifikation

Kurven-typ	Beschreibung	Hochthorakal	Thorakal	Thorakolumbal/ Lumbal
1	Thorakal	Nicht strukturell	Strukturell (Haupt-kurve)	Nicht strukturell
2	Thorakal doppel-bogig	Strukturell	Strukturell (Haupt-kurve)	Nicht strukturell
3	Zwei strukturelle Kurven	Nicht strukturell	Strukturell (Haupt-kurve)	Strukturell
4	Drei strukturelle Kurven	Strukturell	Strukturell (Haupt-kurve)	Strukturell (Haupt-kurve)
5	Thorakolumbal/ lumbal	Nicht strukturell	Nicht strukturell	Strukturell (Haupt-kurve)
6	Thorakolumbal/ lumbal mit thora-kaler Hauptkurve	Nicht strukturell	Strukturell	Strukturell (Haupt-kurve)

Die Klassifikation nach Lenke [51] beschreibt sechs Haupttypen der Skoliose. Die Typen werden danach unterschieden, wie viele strukturelle Kurven vorliegen und in welchem Abschnitt der Wirbelsäule sich die Hauptkurve befindet. Die Patientin in Abbildung Nr. 9 weist etwa eine Lenke Typ 1 Kurve auf: Die Hauptkurve ist thorakal, weitere strukturelle Kurven liegen nicht vor.

Quelle: Dr. med. M. Konieczny

Einer der zwei Patienten wurde mit der navigierten Technik auf Grundlage eines intraoperativen 3D-Scans operativ versorgt (zweite Gruppe). Der zweite Patient wurde mit der fluoroskopischen Technik ohne Navigation operativ versorgt (dritte Gruppe). Dieses Vorgehen wurde für die übrigen neun Patienten aus der ersten Gruppe wiederholt, sodass jeweils zehn Patienten in jede der drei Gruppen eingeschlossen wurden.
Die Patienten wurden bezüglich der Strahlungszeit und -dosis pro implantierter Pedikelschraube miteinander verglichen.

Für die erste Gruppe wurde die Dosis der Strahlung, die durch den präoperativen Computertomographie-Scan verursacht wurde, mit der Strahlungsdosis addiert, die intraoperativ durch den Bildwandler entstand. Für die zweite Gruppe wurde die intraoperativ entstandene Strahlungsdosis des 3D-Bildwandlers erfasst.
Um die Strahlendosis der beiden Verfahren miteinander vergleichen zu können, musste die im Computertomographie-Scan als DLP und im 3D-Bildwandlers als DFP erfasste Strahlungsdosis jeweils in die effektive Dosis (ED in mSv) umgerechnet werden.
Auf der Grundlage der Arbeiten von Huda et al. und Suzuki et al. [59,60] wurden Konversionsfaktoren errechnet: Der Faktor für CT-Untersuchungen betrug in der thorakalen Wirbelsäule 0.0204 mSv/mGy·cm und in der lumbalen Wirbelsäule 0.0163 mSv/mGy·cm. Für den 3D-Bildwandler betrug der Faktor für die thorakale Wirbelsäule 0.19 mSv/Gy·cm2 und für die lumbale Wirbelsäule 0.21 mSv/Gy·cm2.
In der dritten Gruppe wurden verschiedene Bildwandler für die fluoroskopische Technik benutzt. Deswegen wurde hier nicht die effektive Dosis mit den anderen Verfahren verglichen, sondern die Durchleuchtungszeit. Für den präoperativen Computertomographie-Scan gibt es keine vergleichbare Durchleuchtungszeit, weswegen wir die Zeit der intraoperativen Durchleuchtung von der zweiten mit der von der dritten Gruppe verglichen.
In den drei Gruppen wurden insgesamt 293 Pedikelschrauben implantiert.
Die Strahlendosis für die Patienten aus der ersten Gruppe (CT-basierte Navigation) pro implantierter Pedikelschraube war signifikant (um 97,5 Prozent) höher als die in der zweiten Gruppe (Navigation basierend auf intraoperativem 3D-Bildwandler).
Die Durchleuchtungszeit in der dritten Gruppe (fluoroskopische Technik ohne Navigation) war signifikant (um 56 Prozent) länger als die in der zweiten Gruppe.

7. Schlussfolgerungen

Idiopathische Skoliosen zeigen eine Prävalenz von etwa fünf Prozent, wobei diese bei älteren Kindern häufiger ist als bei jüngeren, und bei Mädchen häufiger als bei Jungs. Die schweren Kurven kommen etwa zehnmal häufiger vor als leichte Kurven.
Für die konservative Therapie von Skoliosen mit einem Korsett konnte gezeigt werden, dass diese für die meist jugendlichen Patienten verträglicher gestaltet werden kann. Eine Tragezeit von 12 bis 16 Stunden pro Tag zeigte keine höhere Progressionsrate als eine Tragezeit von mehr als 16 Stunden pro Tag. Dies ermöglicht den Patienten, das Korsett während der Schulzeit abzulegen. Insgesamt könnte so die Compliance mit der Korsetttherapie verbessert werden, so

dass die Patienten das Korsett außerhalb der Schulzeit konsequent tragen. Weiterhin könnten psychologische Probleme durch die Korsetttherapie verhindert oder vermindert werden.
In den von uns erhobenen epidemiologischen Daten zeigte sich, dass die Eltern von Kindern mit einer Skoliose häufiger Raucher sind als der Durchschnitt der Bevölkerung. Das Rauchen der Eltern kann nun noch genauer im Hinblick auf Ursachen für Skoliosen untersucht werden.
Bei der operativen Therapie zeigte sich für Early-Onset Skoliosen, dass die operative Versorgung möglichst frühzeitig durchgeführt werden sollte: Patienten mit einer Early-Onset Skoliose haben nach der Versorgung mit einem VEPTR-Implantat im Verlauf des Wachstums die gleiche Steigerung der pulmonalen Compliance wie eine gesunde Kontrollgruppe, holen jedoch nicht den Unterschied zu der Kontrollgruppe auf, der zu Beginn der Behandlung besteht. Die Behandlung sollte deswegen so früh wie möglich beginnen, damit der Unterschied zum Normalbefund möglichst gering ausfällt.
Nach Wachstumsabschluss erfolgt die operative Versorgung von schweren Skoliosen zwar standardisiert, jedoch sind unterschiedliche Techniken der Implantation von Pedikelschrauben möglich. Die konventionelle fluoroskopische Technik führt dabei zu einer signifikant höheren Strahlenbelastung für den Patienten und für das Operationsteam als die navigierte Technik. Unter den navigierten Techniken führt die Navigation auf Grundlage von intraoperativ mit einem 3D-Bildwandler erstellten Bildern zu signifikant weniger Strahlenbelastung für den Patienten als die Navigation auf Grundlage eines präoperativ erstellten Computertomographie-Scan. Mit der Navigationstechnik ist wegen der hohen Präzision, die bei der Implantation von Pedikelschrauben erreicht werden kann, auch postoperativ kein Computertomographie-Scan zur Kontrolle der Schraubenlage notwendig.
Die Verwendung der navigierten Technik auf Grundlage von intraoperativen, durch einen 3D-Bildwandler erstellten Bildern wird daher laut vorliegenden Daten zur Dosis-Wirkungsbeziehung zu einer geringeren Rate an malignen Erkrankungen bei den operierten Patienten führen als bei Verwendung der anderen untersuchten Techniken.

8. Ausblick

Patienten mit einer schweren Skoliose, die noch ein relevantes Restwachstum haben, werden noch immer traditionell mit VEPTR-Implantaten versorgt. Diese Technik zeigt jedoch, ähnlich wie die „growing rod“-Technik, eine hohe Komplikationsrate, welche vor allem durch implantatassoziierte Infektionen getriggert ist. Die hohe Infektionsrate ist durch die häufigen, halbjährlichen Folgeoperationen zur Verlängerung der Implantate begründet. Weil sich des Weiteren bei VEPTR-Implantaten der zunächst postulierte Vorteil der niedrigeren Rate an ungewünschten Spontanfusionen unter anderem in unserer Arbeit nicht bestätigt hat, sind andere Techniken notwendig. Wir wenden daher seit Ende 2018 das „vertebral body tethering“ an. Dieses ist ein wachstumslenkendes Verfahren: Durch Implantation von Schrauben von ventral auf der konvexen Seite der Kurve, welche mit flexiblen Bändern miteinander verbunden sind, wird das Wachstum auf der konvexen Seite der Wirbelsäule gebremst. Folglich richtet sich die Wirbelsäule im Laufe des folgenden Wachstums auf und eine dreidimensionale Korrektur kann erreicht werden, ohne die betroffenen Wirbelkörper miteinander fusionieren zu müssen. Das Vermeiden einer Versteifung der betroffenen Wirbelsäulensegmente hat theoretisch substantielle Vorteile für die Patienten, etwa im Hinblick auf das Verhindern der Degeneration von angrenzenden Wirbelsäulensegmenten und einer uneingeschränkten Sportfähigkeit durch das wachstumslenkende Verfahren. Die ersten Ergebnisse des neuen Verfahrens sind sehr vielversprechend, müssen jedoch genau analysiert werden. In einem aktuellen Forschungsprojekt vergleichen wir das „vertebral body tethering“ mit etablierteren Verfahren, die eine Fusion der betroffenen Wirbelkörper bedingen, im Hinblick auf Effektivität, Langzeitergebnisse und Komplikationsraten. Wir sind dabei die aktuell einzige Einrichtung weltweit, die dieses Verfahren in navigierter Technik durchführt. Die theoretischen Vorteile durch eine geringere Strahlenbelastung des Operationsteams und des Patienten werden ebenfalls wissenschaftlich aufgearbeitet.

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11. Eidesstattliche Erklärung

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Eidesstattliche Erklärung

Hiermit erkläre ich, Dr. med. Markus Konieczny, geboren am 07.02.1979 in Recklinghausen, an Eides statt, dass:

- Die von mir vorgelegte schriftliche Habilitationsleistung eigenständig und nur unter Verwendung der angegebenen Hilfsmittel und Quellen angefertigt wurde;
- Bei den wissenschaftlichen Untersuchungen, die Gegenstand der von mir vorgelegten schriftlichen Habilitationsleistung sind, ethische Grundsätze und die Grundsätze und Empfehlungen zur Sicherung guter wissenschaftlicher Praxis berücksichtigt wurden;
- An keiner anderen Hochschule ein Habilitationsverfahren von mir eingeleitet oder erfolglos beendet wurde.

Düsseldorf, 14.12.2020

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Dienstag
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Gelenkchirurgie / Sporttraumatologie
Kindertraumatologie

Mittwoch
Handsprechstunde
Kinder- / Neuroorthopädie
Skoliosesprechstunde

Donnerstag
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TRAUMAZENTRUM

12. Zugrunde liegende Forschungsarbeiten

12.1 Arbeit 1

Mit freundlicher Genehmigung des Springer Verlags.

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CURRENT CONCEPT REVIEW

Epidemiology of adolescent idiopathic scoliosis

Markus Rafael Konieczny · Hüsseyin Senyurt · Rüdiger Krauspe

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Abstract Adolescent idiopathic scoliosis is a common disease with an overall prevalence of 0.47–5.2 % in the current literature. The female to male ratio ranges from 1.5:1 to 3:1 and increases substantially with increasing age. In particular, the prevalence of curves with higher Cobb angles is substantially higher in girls than in boys: The female to male ratio rises from 1.4:1 in curves from 10° to 20° up to 7.2:1 in curves >40°. Curve pattern and prevalence of scoliosis is not only influenced by gender, but also by genetic factors and age of onset. These data obtained from school screening programs have to be interpreted with caution, since methods and cohorts of the different studies are not comparable as age groups of the cohorts and diagnostic criteria differ substantially. We do need data from studies with clear standards of diagnostic criteria and study protocols that are comparable to each other.

Keywords Epidemiology · Adolescent idiopathic scoliosis · Prevalence · Scoliosis · School screening

Introduction

The term "scoliosis" derives from the ancient Greek word "skolios" (curved, crooked) and was first established by Galen (130–201 AD).

Scoliosis is the most common spinal disorder in children and adolescents. A scoliosis is characterized by a side-to-side curvature of the spine >10°, usually combined with a rotation of the vertebrae and most often a reduced kyphosis in thoracic curves [1].

Scoliosis patients are classified in different types according to age of onset, etiology, severity and type of curve. Each type shows different characteristics as rate of curve progression, degree and pattern of the three-dimensional deformity. High rate of curve progression and early onset of scoliosis are negative predictive parameters for a poor outcome in idiopathic scoliosis like a thoracic insufficiency syndrome [2].

The two major groups of scoliosis are idiopathic scoliosis and non-idiopathic scoliosis. The diagnosis of an idiopathic scoliosis is made if a non-idiopathic one has been excluded.

Non-idiopathic scoliosis is classified into the following subgroups:

Congenital scoliosis:

Congenital scoliosis is caused by malformation of vertebrae like hemivertebra, unilateral bar or block vertebra (Fig. 1). It may not be clinically evident at birth but develops until adolescence [3]. Genes that are associated with vertebral malformation have been identified in several studies [4–6], and similar defects have been induced in animal models by hypoxia or toxic agents [7, 8].

Neuromuscular scoliosis:

Neuromuscular scoliosis is caused by insufficiency of active (muscular) stabilizers of the spine, like in cerebral palsy, spinal muscular atrophy, spina bifida, muscular dystrophies or spinal cord injuries.

Surgical treatment of neuromuscular scoliosis is associated with the highest rate of complications compared to other types of scoliosis [9].

Mesenchymal scoliosis:

Mesenchymal scoliosis is caused by insufficiency of passive stabilizers of the spine, like in Marfan's syndrome,

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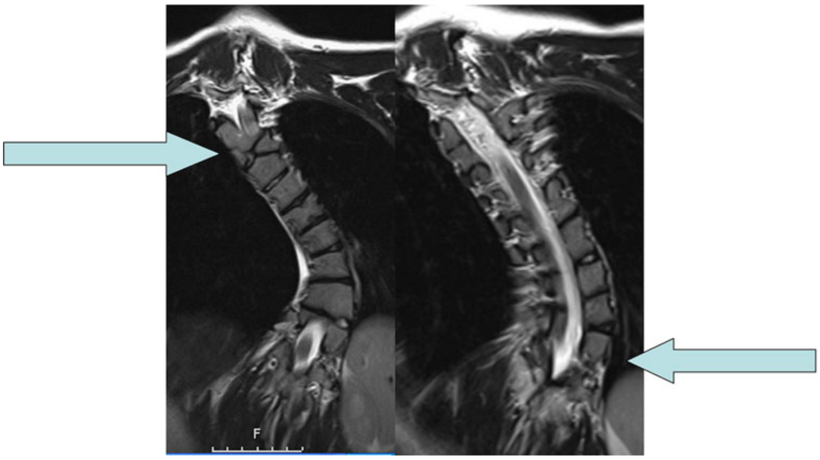

Fig. 1 MRI of the spine of a patient with a congenital scoliosis. The *arrows* indicate malformations of vertebra (hemivertebra, butterfly vertebra)

mucopolysaccharidosis, osteogenesis imperfecta, inflammatory diseases or postoperative after thoracic surgery (open heart surgery).

Idiopathic scoliosis is classified into the following subgroups:

Infantile scoliosis:

Infantile scoliosis develops at the age of 0–3 years and shows a prevalence of 1 %. Mau and McMaster [10, 11] report about a radical decrease in number of infantile scoliosis in The 1980s, probably related to the recommendation of prone position for the infants. McMaster and Diedrich [11, 12] describe that, in contrast to adolescent idiopathic scoliosis (AIS), there is a regression of scoliosis in more than half of the cases. Mehta [13] described the rib–vertebra angle difference and identified that an angle difference of more than 20° indicates a poor prognosis and rapid progression.

Juvenile scoliosis:

Juvenile scoliosis develops at the age of 4–10 years and comprises 10–15 % of all idiopathic scoliosis in children [14], untreated curves may cause serious cardiopulmonary complications, and curves of 30° and more tend to progress, 95 % of these patients need a surgical procedure [14].

Adolescent scoliosis:

Adolescent scoliosis develops at the age of 11–18 years and accounts for approximately 90 % of cases of idiopathic scoliosis in children (Fig. 2).

Adult scoliosis (de novo scoliosis in adults):

Scoliosis has a prevalence of more than 8 % in adults over the age of 25 and rises up 68 % in the age of over 60 years, caused by degenerative changes in the aging spine [15, 16].

In this article we present an overview on reported data on epidemiology of AIS with special attention to prevalence and rate of curve progression according to race, age of onset, gender, and severity of scoliosis.

Prevalence of AIS

Overall prevalence

There are not many studies that provide data of high relevance regarding prevalence of AIS. Several studies that do provide such data have substantial weaknesses like varying definitions of scoliosis, study protocols, and age-groups, missing standards for comparison and inclusion of curves $<10°$, although international consensus is given that per definition scoliosis is a deformity $\geq 10°$.

The study of Kamtsiuris [17] was conducted in Germany by the Robert Koch Institute (RKI). 17,641 children (8,656 girls, 8,995 boys) were interviewed and examined for chronicle diseases, children from 0 to 17 years participated.

The study of Suh [18] was conducted in Korea. 1,134,890 children participated (584,554 boys and 550,336 girls). Two age groups were investigated: 10–12 years and 13–14 years.

The study of Nery [19] was conducted in Brasil. 1,340 children participated (684 boys, 656 girls). Mean age was 12.7 years.

The study of Daruwalla [20] was conducted in Singapore. 110,744 children were examined (60,167 girls, 50,577 boys). Three age groups were investigated: 6–7,

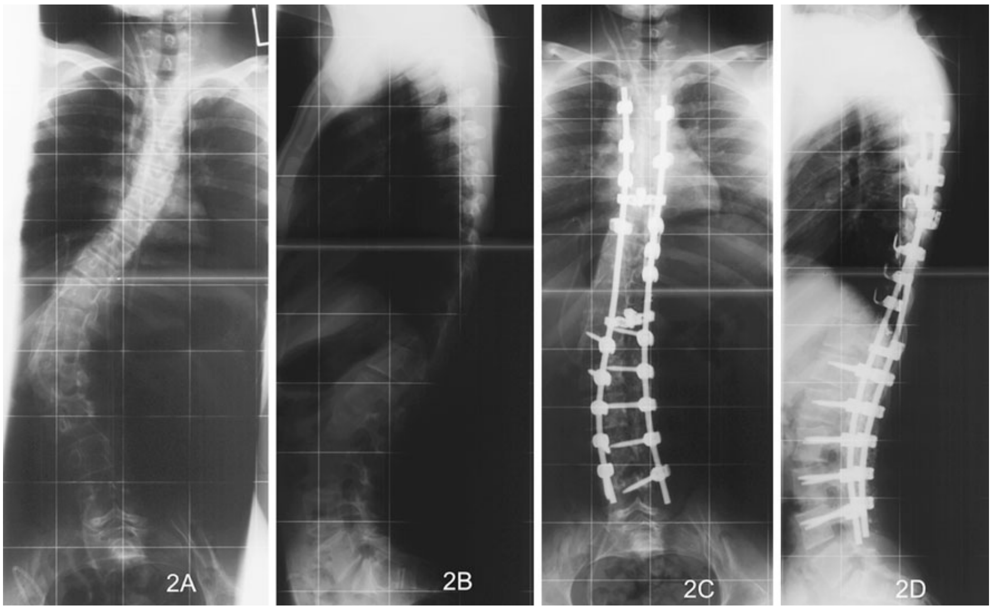

Fig. 2 16-year-old female patient with an adolescent idiopathic scoliosis. **a**, **b** Preoperative Cobb angle 50°, **c**, **d** Postoperative Cobb angle 10°

11–12 and 16–17 years (only girls were investigated in the last group).

Twenty years later Wong [21] conducted another study in Singapore and investigated 72,699 children (37,141 girls and 35,558 boys).

The study of Cilli [22] was conducted in Turkey. 3,175 children participated (1,538 girls, 1,637 boys). Children from 10 to 15 years were enrolled.

The study of Soucacos [23] was conducted in Greece. 82,901 children participated (41,939 boys and 40,962 girls). Children from 9 to 14 years were enrolled.

Data from these studies indicate a prevalence of 0.47–5.2 % for AIS. (Table 1).

Comparing these results prevalence to the prevalence of measles (7.4 %) and mumps (4.0 %) [17], it is obvious that AIS is a common disease in children (we have to consider that the actual prevalence of measles and mumps in Germany is substantially diminished by vaccination).

Prevalence according to "race"/genetic factors

Genetic factors do influence the incidence [24] and progression [25] of scoliosis. 97 % of AIS patients are related to other family members with AIS [26], in Prader–Willi syndrome patients, scoliosis is found up to 40 % [27]. The influence of genetic factors in scoliosis is also apparent in epidemiologic studies:

Kamtsiuris et al. [17] found a higher prevalence of scoliosis in German children (5.5 %) than among immigrant children (3.5 %). That difference in prevalence can be attributed to genetic factors and not to malnutrition or other factors like a lower social status, because children of families of a high or middle social status had a higher prevalence (6.2 % high status, 5.6 % middle status) than children of a lower social status (3.5 %).

Ratahi et al. [28] described that AIS is more frequent in Europeans than in Polynesians, and that scoliosis secondary to syringomyelia is more frequent in Polynesians than in Europeans.

A study that investigated pupils in Singapore [20] found a higher prevalence for Chinese girls than for Malay and Indian girls.

Carter [15] described a higher prevalence of scoliosis in the Afroamerican population (9.7 %) than in the Caucasian population (8.1 %). As he investigated the adult population, his findings are of a lower relevance for AIS.

Prevalence according to age

Daruwalla [20] found a higher prevalence for adolescents than for young children: 0.12 % in the 6–7 years-group, 1.0 % in the 11–12 years group and 3.12 % in the 16–17 years group (only girls investigated in the latter group). Cilli [22] did not find any significant relationship

Table 1 Detailed data of school screening studies [17–23]

Study	Country	Children	Girls	Boys	Age (years)	Prevalence combined (%)	Prevalence girls %	Prevalence boys %
Kamtsiuris [17]	Germany	17,641	8,656	8,995	0–17	5.2	6.0	4.4
							11–13 years:8.3	11–13 years: 5.0
							14–17 years:13.5	14–17 years:9.0
Daruwalla [20]	Singapore	110,744	60,167	50,577	6–7	1.0	6–7 years: 0.15	6–7 years: 0.10
					11–12		11–12 years: 1.67	11–12 years: 0.44
					16–17		16–17 years:3.12	16–17 years: not tested
Wong [21]	Singapore	72,699	37,141	35,558	6–7	0.59	6–7 years: 0.05	6–7 years: 0.02
					9–10		9–10 years: 0.24	9–10 years: 0.15
					11–12		11–12 years: 1.37	11–12 years: 0.21
					13–14		13–14 years: 2.22	13–14 years: 0.66
Nery [19]	Brasil	1,340	684	656	10–14	1.4	1.98	0.87
Suh [18]	Korea	1,134,890	550,336	584,554	10–12	3.26	4.65	1.97
					13–14			
Cilli [22]	Turkey	3,175	1,538	1,637	10–15	0.47	0.65	0.31
Soucacos [23]	Greece	82,901	40,962	41,939	9–14	1.7	2.6	0.9

of the curvature with age groups, but they investigated only children from 10 to 15 years. In Germany Kamtsiuris [17] found a prevalence of 6.5 % in the age of 11–13 years and a prevalence of 11.1 % in the age of 14–17 years.

These data indicate a higher prevalence of scoliosis in patients older than 15 years (after puberty).

Prevalence according to gender

Kamtsiuris [17] found a prevalence ratio of 1.5:1, with slight increase with age (Table 1). Daruwalla [20] found a prevalence ratio female to male of 2:1, rising up to 3:1 in the age of 11–12 years. Cilli [22] and Nery [19] found a prevalence ratio of 2:1 without differentiation of different age groups. These data indicate an overall prevalence ratio of 2:1 female to male with an increase with age.

Gender and severity:

Prevalence does not seem to be the only character of scoliosis that is influenced by gender: Several studies [18, 20, 29–31] report about higher Cobb angels in girls than in boys (Table 2), indicating that scoliosis in girls progresses to a higher grade of severity. For patients with a Cobb angle of more than 30° the prevalence ratio gets as high as 10:1 [23, 32–37]. The prevalence of severe scoliosis is much higher for girls than for boys; however, Weijun [38] reports a higher prevalence of atypical curve types in boys with Cobb angles of more than 20° than in girls, and a higher risk of progression in the main thoracic right convex curve.

The overall prevalence of different grades of severity is given in table 2.

Table 2 Prevalence and female to male ratio of different Cobb angles [18, 20, 29, 30]

Cobb angle of curve	Prevalence (%)	Female:male ratio
11°–20°	1.5–3	1.4:1
21°–40°	0.2–0.5	2.8–5.4:1
>40°	0.04–0.3	7.2:1

Table 3 Prevalence of different curve types according to gender [18]

Curve type	Thoracic	Thoracolumbar/ lumbar	Double	Double thoracic
Prevalence boys %	44.06	49.55	4.26	2.14
Prevalence girls %	49.10	36.09	11.10	3.71

Curve types

Overall prevalence of different curve types:

Thoracic curves are the most common (48 %), followed by thoracolumbar/lumbar curves (40 %). Double curves (9 %) and double thoracic curves (3 %) are less common [18]. 80 % of all children have thoracic or thoracolumbar/ lumbar curves [18].

Curve type according to gender:

Boys have a higher proportion of thoracolumbar/lumbar curves, girls have a higher prevalence of thoracic and double curves [18] (Table 3).

Curve type according to age:

Infantile scoliosis (0–3 years) has a much higher prevalence of left sided curves (56–88 %) than adolescent scoliosis [39–41]; in juvenile idiopathic scoliosis the left and right sides curves are evenly divided [42, 43]. Janssen [44] investigated the reason for that distribution of curve types: he found a pattern of pre-existent vertebral rotation in the normal spine that depends on age. In the infantile age, rotation is predominantly to the left, in the adolescent age it is to the right, and in the juvenile age there is no predominant rotation to either side. These results [44] match the curve direction of scoliosis in infantile, juvenile and adolescent scoliosis.

Discussion

Present data show an overall prevalence of AIS of 0.47–5.2 %. The prevalence and severity of scoliosis is higher in girls than in boys. All data were obtained by school screening, and yet school screening is the most effective method for creating epidemiological data of adolescent scoliosis. However, school screening programs have many limitations which have been well described by Fong et al. [45]: The overall positive predictive value for detecting curves $\geq 10°$ and $\geq 20°$ were low, indicating that school screening has not been conducted effectively, and they showed a high heterogeneity of study designs across all screening programmes [45]. They also investigated the effectiveness of the Adams forward-bending test [46] and concluded that it was very low! If additional tests like angle of trunk rotation or Moiré topography were used, the effectiveness of screening could be improved, but so far no test could produce substantial benefit with a sufficient level of evidence [45].

Main individual limitations of the screening studies we cited:

Kamtsiuris [17] provided very good epidemiologic data, but they did not provide exact criteria of diagnosis of scoliosis. It also remains unclear who established the diagnosis of scoliosis: General practitioner or orthopedic surgeon.

Cilli [22] and Nery [19] only investigated children in the age range of 10–15 years, excluding important other age groups.

The lower prevalence of scoliosis in the study of Cilli [22] could be related to the age group investigated: They enrolled children from 10 to 15 years, whereas Daruwalla [20] showed that the highest prevalence of scoliosis is in girls that are older than 15 years. Kamtsiuris [17] also found highest prevalence in children of 14–17 years. Daruwalla [20] did only investigate age groups (6–7, 11–12 and 16–17 years) and they only enrolled females in the group of 16–17 years, and Suh [18] investigated only two age groups (10–12 and 13–14 years). Wong [21] also enrolled only children from 9 to 14 years and included curves $<10°$. The other epidemiologic studies mentioned above also did not explicitly exclude curves $<10°$.

Soucacos [23] conducted a very good study in Greece, describing his exact parameters for diagnosis of scoliosis. All listed epidemiologic studies used the Adams forward-bending test [46] for primary screening and performed radiologic diagnostics only when this test was positive, but Soucacos [23] was the only one who explicitly had the school screening tests performed by orthopedic surgeons, and not by nurses or other non-academic medical staff, diminishing the bias of his results.

However, the limitation of his study is again the investigated age group (9–14 years), excluding older adolescent children.

Investigation of comparable age groups is difficult because of differences in culture and school systems in the individual countries. In Singapore, for example, in the age group of 16–17 years there are only girls at school because the boys have to attend military service at that age [20].

Another bias mentioned in nearly all epidemiologic studies is that they do not consider the psychological impact of scoliosis on children, although it has been described extensively in current literature [47–49]. Young girls particularly, but also boys, that have deformities might feel embarrassed when being examined in school. When these children fall “ill” because of this embarrassment or beg their parents to refuse the examination and miss the school screening, a substantial bias is the consequence. Only one study [23] deals with that important potential bias and describes how the children are prepared psychologically for the examination and how fears and anxieties are dealt with.

Conclusion

Idiopathic adolescent scoliosis is a common disease with a prevalence of 0.47–5.2 %. Prevalence and curve severity are higher for girls than for boys, and the female to male ratio increases with increasing age of the children.

The current epidemiologic data have to be interpreted with caution since methods and cohorts of the existing studies are not comparable.

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12.2 Arbeit 2

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Clinical Study

Time in brace: where are the limits and how can we improve compliance and reduce negative psychosocial impact in patients with scoliosis? A retrospective analysis

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Abstract

BACKGROUND: Brace treatment for adolescent idiopathic scoliosis (AIS) is generally prescribed for 18–23 hours per day, but the minimal time of brace wear per day to stop progression of AIS is still unclear. Compliance of patients with AIS with brace treatment is reported to be between 27% and 47% of the prescribed time, brace wear especially at school is often described as embarrassing by adolescent patients. It has been reported that a higher rate of compliance leads to a significantly lower rate of curve progression. Theoretically, prescribing brace treatment 16 hours instead of 23 hours per day (patients are allowed to attend school free of their brace) could lead to a higher rate of compliance, and subsequently reduce progression rate of patients with AIS.

PURPOSE: To investigate if brace treatment 16 hours per day is noninferior to >16 hours with regard to curve progression, and if other clinical and demographic factors that might influence incidence and progression (apart from time of brace wear) of AIS can be identified.

STUDY DESIGN: In a retrospective study, we investigated patients with AIS who had been admitted to our outpatient clinic and enrolled them in one of three groups: group 1 brace <12 hours per day, group 2 brace 12–16 hours per day, and group 3 brace >16 hours per day.

PATIENT SAMPLE: Seventy-two patients met our inclusion criteria and were enrolled in our study, 61 female and 11 male patients. Twenty-eight were allocated in group 1, 13 in group 2, and 25 in group 3.

OUTCOME MEASURES: Progression of Cobb angle with regard to brace wear per day was the main outcome measure.

METHODS: Skeletally immature patients who presented from October 2010 to June 2013 with an AIS and a Cobb angle >20° were enrolled in our study and have been prescribed a Chêneau orthesis. Demographic parameters, progression of Cobb angle, and time of brace wear have been recorded. Groups 1, 2, and 3 of brace wear were analyzed for differences.

RESULTS: The overall difference between the groups referring to increase of Cobb angle was significant ($p<.05$). Further analysis of groups 2 and 3 showed that the difference between these groups was not significant ($p>.05$).

Apart from time of brace wear, no other factor showed any influence on curve progression.

Smoking status of parents of our patients was significantly more often positive than in the general local population ($p>.05$).

CONCLUSIONS: Twelve to 16 hours of brace wear per day did not lead to a higher progression rate of AIS compared with more than 16 hours in our study group.

FDA device/drug status: Not applicable.

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Our analysis showed that smoking status of parents possibly contributes to the risk of developing AIS; however, we did not find an impact on progression of scoliosis.

Keywords: Adolescent idiopathic scoliosis; Brace treatment; Conservative treatment; Epidemiology; Scoliosis; Time of brace wear

Introduction

There are several rather similar treatment algorithms for adolescent idiopathic scoliosis (AIS) [1,2], the majority recommending observation for low grade, brace treatment for moderate grade when growth is still expected, and surgery for patients with severe scoliosis (surgery widely recommended when Cobb angle >45°).

Negrini et al. [1] recently recommend brace wear 23 hours per day and at least 18 hours per day for patients with moderate AIS (Cobb 20°±5°), but the recommendation was not based on data of high evidence. The SOSORT guidelines [1] have been developed in a Delphi procedure.

On the other hand, compliance of brace treatment is reported to be between 27% and 47% of the prescribed time. Compliance with brace treatment was lower the longer the patients had to wear the brace [3,4]. Katz et al. [4] reported that a higher rate of compliance leads to a significantly lower rate of curve progression.

Misterska et al. [5] reported a positive correlation between time of brace application per day and depressiveness in patients with scoliosis. No correlation has been found between any psychological symptoms and months of brace treatment, age on initiation of treatment, and severity of the scoliosis.

We do also know that wearing the brace at school during the interaction with their peer group is often described as embarrassing by adolescent patients. Prescribing the brace 23 hours per day leads to this embarrassment.

With regard to these data, time of brace wearing per day of 16 hours, thus not being obliged to wear the brace at school, theoretically might improve compliance with brace treatment (what could lead to a lower progression rate [4]) and reduces risk of depression with longer time in brace per day and negative self-esteem while interacting with their peer group.

The aim of our study is to investigate if brace treatment 16 hours per day leads to a similar progression rate of scoliosis compared with brace treatment >16 hours per day in a retrospective analysis of a selected group of patients.

We further analyzed other clinical and demographic factors that might influence incidence and progression (apart from time of brace wear) of AIS.

Methods

In a retrospective study, we analyzed data of all patients who were admitted to our scoliosis clinic from October 1, 2010 to June 31, 2013.

We enrolled all patients who were diagnosed with AIS, initially presented to our unit with a Cobb angle [6] of at least 20°, a Risser level ≤3 [7], and in women ≤1 year after menarche and have been followed up until the end of brace treatment.

We excluded all patients with incomplete radiological data.

From the data we retrieved demographic parameters, Cobb angle, modality of treatment, sports activities, frequency of self-administered physiotherapeutic exercises, educational level of the patients and parents, smoking status of parents, patients' weight, and hours per day of brace wear.

All patients have been prescribed 23 hours of brace wear per day; a Chêneau orthesis was prescribed [8] (Fig. 1).

Effectiveness of prescribed brace was tested by posteroanterior radiograph taken with brace on after 6–8 weeks of brace wear (Figs. 2 and 3). If the Cobb angle did not improve by at least 20% compared with the last posteroanterior radiography before brace treatment, the brace was adjusted accordingly until an improvement by 20% is achieved. Clinical and radiological assessment has been performed in 6-month intervals.

During these assessments, the patients and the parents reported the time they wore their brace per day; at first, the patient and then both parents have been asked the same three questions:

(1) Has the brace been worn during the whole night? A "Yes" has been noted as 8 hours of brace wear (average for school kids), a "No" as 0 hours of brace wear.
(2) Has the brace been worn and not been taken off in school? A "Yes" has been noted as 8 hours of brace wear (according to local school schedules), a "No" as 0 hours of brace wear.
(3) How many hours per day (0–8) has the brace been worn after school and before the night? The average time of the week preceding the examination has been recorded.

The hours of brace wear of answers 1–3 have been added, and the lowest reported time of brace wear (either by parents or by the patient) has been recorded.

Descriptive data are presented by mean and standard error (StE).

Data have been analyzed by SPSS Statistics 23 (IBM, Armonk, New York, USA). Kolmogorov-Smirnov test was used to test for normal distribution.

Apart from maternal age at child's birth, smoking status of parents, and patients' age at menarche, all other parameters did not show normal distribution.

Fig. 1. Ten-year-old girl, Chêneau orthesis.
In that age, compliance with brace wear may still be supported by childish colors and pictures on the brace. That usually does not work anymore on adolescents.

A two-sided *t* test has been used to analyze the effects of maternal age at child's birth and smoking status of parents by comparing the two parameters with data of the country's general population [9,10].

Hours of brace wear per day have been split into three groups: group 1 <12 hours per day, group 2 12–16 hours per day, and group 3 >16 hours per day.

A Kruskal-Wallis test has been performed, and the subgroups of special interest (2 and 3) have been analyzed by a one-sided Mann-Whitney *U* test to show if there is a difference between these groups referring to increase of Cobb angle.

The study has been conducted according to the revised declaration of Helsinki and was approved by the institutional review board.

Results

We analyzed data of 601 patients who were admitted to our scoliosis clinic. Ninety percent of them presented with an AIS; one-third of these patients had a Cobb angle of 20° or more. Of the remaining 178 patients, 85 were skeletally immature and 13 patients have been lost to follow-up. Seventy-two patients were enrolled in the study. Sixty-one (86%) were female and 11 (15%) were male.

Mean age at menarche was 12.3 years (StE 0.2). Mean time between diagnosis and admission to our scoliosis clinic was 8.3 months (StE 1.9).

Mean follow-up was 52.8 months (StE 2.5).

Mean Cobb angle on admission to our scoliosis clinic was 35.9° (StE 1.5°); mean Cobb angle at last follow-up was 42.8° (StE 1.8°). Mean progression of Cobb angle during treatment was 6.9° (StE 1.3°) (Table 1).

Table 1
Results summary

	Number of patients	Percent
Risser <3, menarche <1 year ago	47	64.4
Risser 3, menarche 1 year ago	9	12.3
Undetermined	16	21.9

Mean hours of sports per week outside school were 2.0 hours (StE 0.3 hours).

Mean body mass index (BMI) was 20.96 (StE 0.38).

Epidemiologic data

Mean age of mother at child's birth was 28.9 years (StE 0.6 years).

In 49% (28 of 57 patients) of all patients, at least one parent smoked.

In 43.9% (25 of 57 patients), there was a positive family history for scoliosis. In eight patients (14%), 1 parent was affected; in six patients (11%), both parents were affected. In 11 patients (19%), a sibling or second-degree relatives were affected by scoliosis.

Twenty-two of 57 (39%) patients' parents did not have any educational degree, nine (16%) had an academic degree, and 26 (46%) successfully completed a vocational training.

Five of 57 patients (9%) were vegetarians; all other patients did not report any diets or specialties in nutritional habits.

Forty-two of 57 (74%) patients did not perform swim training as a baby, 13 (23%) did.

Thirty-one of 56 (55%) patients did wear their school bag on one shoulder, 25 (44%) on both shoulders.

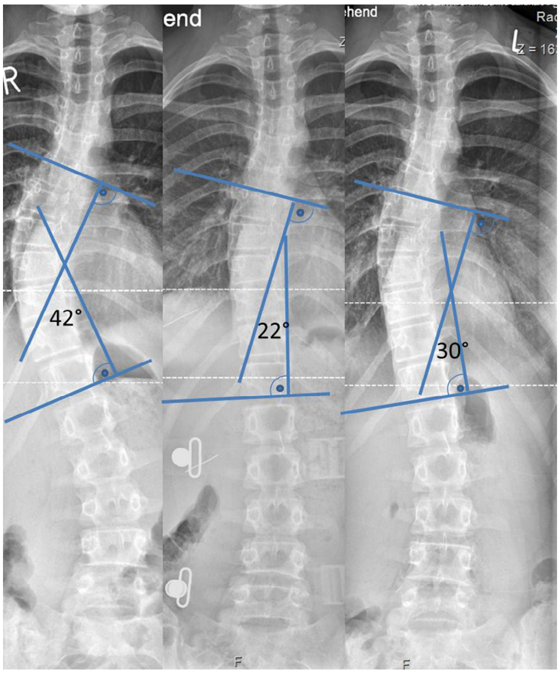

Fig. 2. Twelve-year-old girl, 1 year after menarche, Risser 1. First admission with an adolescent idiopathic scoliosis (Left). No progression of curve and even slight improvement during treatment with brace (Right). Effectiveness of brace is proven by radiography (Middle).
(Left) 12 years, first admission, posteroanterior radiography of the whole spine, right convex, Cobb 42°.
(Middle) 12 years, 6 weeks after onset of brace treatment (Chêneau orthesis), posteroanterior radiography of the whole spine, significant improvement of curve by orthesis.
(Right) 13 years, 1 year after first admission, posteroanterior radiography of the whole spine, right convex, Cobb 30°.

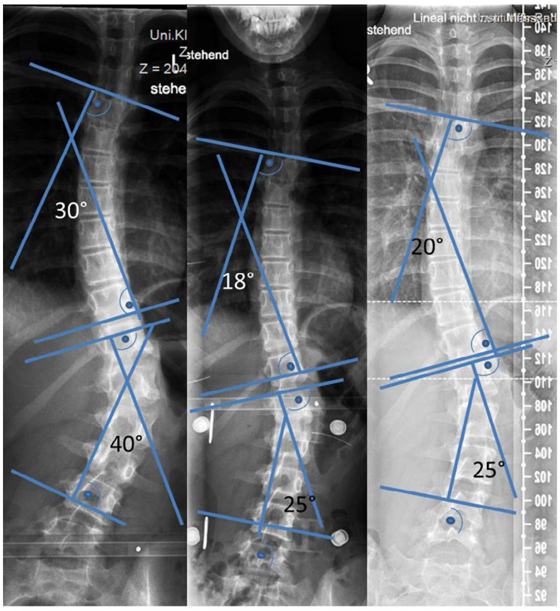

Fig. 3. Fourteen-year-old girl at first admission. Risser 1, 1 year after menarche. Efficacy of orthesis (Chêneau) proven by radiography (Middle). No progression of curve and even slight improvement during treatment with brace (Right).
(Left) 14 years, first admission, posteroanterior radiography of the whole spine; Cobb 1, 30° right convex; Cobb 2, 40° left convex.
(Middle) 14 years, 6 weeks after onset of brace treatment (Chêneau orthesis), posteroanterior radiography of the whole spine, significant improvement of curve by orthesis
(Right) 16 years, 2 years after first admission, posteroanterior radiography of the whole spine, right convex; Cobb 1, 20° right convex; Cobb 2, 25° left convex.

Thirty of 51 (53%) patients visited a high school, 16 (28%) a secondary school, and five (9%) a middle school.

Statistical testing

Time of brace wear

The Kruskal-Wallis test between group 1, group 2, and group 3 showed that the difference between the groups in regard to increase of Cobb angle was significant ($p<.05$) (Table 2).

A one-sided Man-Whitney *U* test was performed for groups 2 and 3. The difference between these groups was not significant ($p>.05$). Statistical power of this testing was 0.99 [11,12], effect size 2°.

Table 2
Time of brace wear

Group	Patients with progression of Cobb angle by 5° or more
1 (<12 h per day)	18/28 (64.3%)
2 (12–16 h per day)	6/13 (46.2%)
3 (>16 h per day)	8/25 (32.0%)

Hours of sports per week outside of the school

We divided our patients in two groups: group 1, less than 1 hour of sports per week (18 of 62 patients, 29%); and group 2, at least 1 hour of sports per week (44 of 62 patients, 71%). We performed a one-sided Mann-Whitney *U* test. The difference between these groups with regard to increase of Cobb angle was not significant ($p>.05$).

BMI

We tested BMI at skeletal maturity and increase of Cobb angle for correlation (Pearson). We did not find a significant correlation between these groups ($p=.193$).

Age at menarche

Mean age at menarche did show a correlation neither with the initial Cobb angle nor with progression of Cobb angle ($p>.05$).

Other factors

We performed a binary logistic regression analysis (stepwise, backward) to test if there is an influence on increase of Cobb angle (increase of Cobb angle by 5° or more was tested as dichotomous outcome variable). We included hours of self-training per week, educational level of parents, family history of scoliosis, nutritional behavior, type of school bag, and educational level of the patients.

None of these factors were included in the final equation.

Discussion

Brace effectiveness is proven [13,14], and hours of brace wear correlates negatively with the progression rate of AIS [4,14]. However, there is still no consensus concerning how many hours per day the brace should be worn to prevent progression [4,14,15,16].

Actual guidelines [1] recommend 23 hours of brace wear per day; on the other hand, it has been reported that compliance was lower the longer brace wear was prescribed, that a higher degree of compliance leads to a lower degree of progression [3,4], and that time of bracing per day and depressiveness of patients are positively correlated [5].

If wearing the brace always but not in school (16 h/d) would be as effective as wearing the brace 23 hours per day, adolescent patients would show an improved compliance with brace treatment.

Here, we report on statistically significant differences between the three groups of brace wear time (<12 hours, 12–16 hours, and >16 hours per day), but we did not find a statistically significant difference in the progression of AIS between patients who wore the brace 12–16 hours per day and patients who wore the brace more than 16 hours per day.

Only 15 of 66 patients (22.73%) wore the brace more than 20 hours per day, although all patients have been prescribed 23 hours of brace wear per day.

These results may hint toward a noninferiority of prescribing brace wear of 16 hours per day versus more than 16 hours per day and would enable our patients to attend school without brace.

The low rate of compliance in our patients—according to other reported rates [3,4]—could be noticeably improved if patients were allowed to attend school without their brace. Subsequently, a higher rate of compliance could lead to a lower rate of progression of AIS. Prescribing brace 16 hours per day could theoretically lead to an overall longer time of brace wear in adolescent patients with scoliosis by improving acceptance of the treatment.

The results of this study now justify an interventional study (prescribing 16 hours instead of 23 hours per day of brace wear).

Additionally we analyzed etiologic factors of AIS in our group of patients.

Etiology for AIS seems to be related to multiple factors, most of them still unknown.

We know that genetic parameters [17,18] may be involved in induction of AIS; other parameters are still not fully investigated.

Grivas et al. [19] reported a negative correlation of maternal age at birth and prevalence of scoliosis, but major weaknesses have to be recognized: curves of 5° were included, the effect was significant only in boys, not in girls.

Age at menarche seems to be related to prevalence and severity of scoliosis [20]. Tanchev et al. [21] and Meyer et al. [22] reported that joint laxity and a late menarche combined with regular gymnastics lead to a significantly higher prevalence of scoliosis. Girls with a late menarche are reported to have a higher rate of joint laxity than normal controls, and girls with a joint laxity who perform regular gymnastics show a higher rate of scoliosis than normal controls [21]. However, Kenanidis et al. [23] did not find any differences between athletes and nonathletes in rate of scoliosis, but did not regard severity of scoliosis or influence of skeletal maturity.

The parents of our patients did not show any statistically significant differences with pertaining to maternal age at patient's birth, indicating that the incidence of scoliosis is not related to this factor. Data of the "Gender Report" [9] show that mean age of mother at child's birth in Germany was 28.8 years in the year 2000. In a two-sided one-sample *t* test, we found no significant difference in our group ($p>.05$).

This analysis supports the representativeness of our group of patients.

Age at menarche was not correlated with severity or progression of scoliosis. This lack of correlation, which is in contrast to the reported data of Mao et al., Tanchev et al., and Meyer et al. [20–22], may be caused by the low mean of hours of sports per week (2.03 hours), knowing that increased joint laxity (more frequently found in girls with late menarche) combined with sports-related increased strains on the spine leads to scoliosis. Because there were only a few children who practiced high-level sports activities in our group of patients, no causal evidence could be retrieved.

The factors hours of sports per week, hours of self-training per week, body weight in kilogram, educational level of parents, family history of scoliosis, nutritional behavior, type of school bag, and educational level of the patient did not show any statistically significant influence on progression of scoliosis.

Smoking status of our patients' parents showed a statistically significant difference to the reported rate of smokers in Germany. Data of the "Statistisches Bundesamt" show that probability of being a smoker was 0.38 in the general population in 1999 [10]; in our group of patients' parents, it was 0.49. In a two-sided *t* test, the difference was significant ($p<.05$).

Smoking of parents may lead to a higher rate of scoliosis in children, a factor that should be further investigated. However, smoking status of patients did not show an impact on progression of scoliosis in our analysis.

Ylikoski [24] reported that the initial Cobb angle showed a positive correlation with the progression rate of scoliosis in his study. Mean Cobb angle of our group of patients was 35.9°, which explains the high rate of progression (mean of 6.9°). This explains the data of our patients enrolled in our study who showed Cobb angles close to 40°.

The flaws of our study are that heat sensors were not used to investigate the exact time of brace wear more objectively, and the low number of patients.

Heat sensors would provide more exact data, but although we cannot fully deny a possible bias on brace wear per day, we established a system that should validly depict the time of brace wear:

We asked the patients and then their parents (both parents) and recorded the lowest reported time of brace wear repeatedly every 6 months and simplified the assessment of brace wear:

The two "yes or no" questions (Nos. 1 and 2) have been answered without any difficulty and without any mean of "smoothing" the answer. The third question could add between 0 and 8 hours to the time of brace wear per day.

Possible biases:

Question No. 1: If a patient did not wear the brace the whole night but took it off during the night after going to bed with the brace, we would underestimate the time of brace wear. However, if brace wear during the night is not tolerated, the kids tend to take the brace off early during the night (to be able to sleep at all) and not at the end of the night. Thus, recording 0 hours when the brace has not been worn the whole night seems accurate.

Question No. 2: School kids who do not wear the brace usually reject the brace because of psychological reasons (mocking by peers, low self-esteem, perceived deterioration of self-appearance [5]) and not because of discomfort. If they admit not wearing the brace the whole time at school, an estimated time of brace wear of 0 hours in school seems to be correct because the psychological reasons to take the brace off are present during the whole time at school.

Question No. 3: Usually the parents are present during that time of the day and monitor the patient with regard to brace wear. However, if the answer should not be true, the consequences would be acceptable because the bias would, with a high probability, not be enough to lift a patient from group 2 to group 3 or vice versa.

Applying strict inclusion and exclusion criteria will repeatedly lead to lower numbers of patients; on the other hand, we achieved a high statistical power comparing groups 2 and 3 of brace wear: the power was 0.88 (1 – ß err) [11,12].

Conclusions

Twelve to 16 hours of brace wear per day did not lead to a higher progression rate of AIS compared with more than 16 hours in our study group.

Our analysis shows that smoking status of parents possibly contributes to the risk for developing AIS; however, we did not find an impact on progression of scoliosis.

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12.3 Arbeit 3

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Original Clinical Article

JOURNAL OF CHILDREN'S ORTHOPAEDICS

Vertical expandable prosthetic titanium ribs (VEPTR) in early-onset scoliosis: impact on thoracic compliance and sagittal balance

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Abstract

Background Theoretically, dynamic thoracic compliance (DTC) should be reduced by vertical expandable prosthetic titanium ribs (VEPTR) since titanium rods, scar tissue and ossifications increase stiffness of the rib cage. The effect of VEPTR on thoracic compliance has not yet been elucidated. The impact of VEPTR on the development of sagittal balance has not been fully investigated.

Patients and Methods In a retrospective study, we investigated 21 consecutive children who were treated by VEPTR from 2004 to 2011 and three control groups. We compared the development of thoracic compliance during growth to Nr1. Development of sagittal balance during growth was compared to Nr2 and to Nr3 (which has been instrumented from ileum to rib). Mean follow-up was 60.67 months (standard error of the mean (SE 4.77).

Results The difference of change of DTC during growth of VEPTR group *versus* a control group was not significant ($p < 0.05$). However, initial DTC and DTC at last follow-up of VEPTR group were lower than DTC of the control group. The difference was significant ($p < 0.05$). Mean correction of Cobb angle after the first operation was 16.41° (SE 3.01). Until last follow-up, we saw a loss of correction of 8.23° (SE 3.22). The differences between the development of parameters of sagittal balance during growth between the VEPTR group, control group 2 and control group 3 were not significant ($p > 0.05$).

Conclusions VEPTR treatment should start as early as possible since VEPTR seems to lead to an increased rate of DTC that is similar to healthy controls. Sagittal balance showed a similar development as in healthy children.

Keywords: early-onset scoliosis; VEPTR; thoracic compliance; sagittal balance; ala hooks; growing spine

Introduction

Early onset scoliosis (EOS) bears the risk of rapid progression and may lead to thoracic insufficiency syndrome (TIS) if left untreated.[1] TIS is defined as the inability of the thorax to support normal respiration and/or lung growth and is diagnosed by clinical signs of respiratory insufficiency and loss of chest wall mobility.[2]

The correction of spinal deformity by vertical expandable prosthetic titanium ribs (VEPTR) and the impact of VEPTR on thoracic volume, space available for lung (SAL) and forced vital capacity (FVC) are positive and documented in several reports.[3-6]

What has not yet been elucidated is the effect of VEPTR on thoracic compliance: VEPTR implantation causes thoracic scar tissue, the longitudinally implanted titanium rods produce additional stiffness of the thoracic wall and unintended bone fusions of the ribs.[7,8] These constrictive mechanisms on the thoracic mobility may reduce thoracic compliance which forces infants to use more energy for respiration.

VEPTR was primarily applied with thoracostomy in patients with thoracic malformation that induced scoliosis.[3,4] With VEPTR instrumentation osteotomies of rib synostosis were performed and thoracic compliance theoretically improved because the bony elements of the thorax became less rigid. Implantation of stiffening VEPTR may dilute or even counter that effect. It is reported that thoracic volume was increased acutely (Fig. 1).[4] The effect on thoracic compliance is not reported.

Since the growing rod technique[9] (instrumentation spine to spine, ileum to spine) may cause spontaneous spinal fusion. Also, the use of VEPTR in patients without thoracic induced scoliosis[10] by instrumentation from rib to rib, ileum to rib or spine to rib (Fig. 2) was established because it was thought to avoid spinal fusion. Recent

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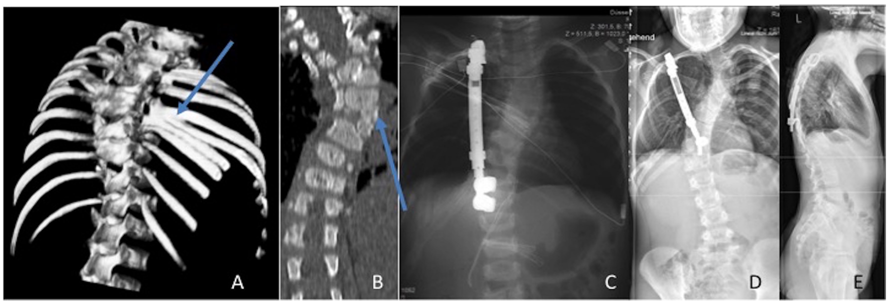

Fig. 1 A female child with congenital scoliosis combined with rib synostosis. Treatment with vertical expandable prosthetic titanium ribs (VEPTR) was started at the age of 2.5 years. The child was not enrolled in the study. (**A**) Pre-operative CT scan, 3D reconstruction. Arrow points at rib synostosis. (**B**) Pre-operative CT scan, coronal plane reconstruction. Arrow points at hemivertebra. (**C**) Post-operative posteroanterior (PA) radiograph of the spine. At the age of 2.5 years, VEPTR was implanted with osteotomy of rib synostosis. (**D**) PA radiograph of the spine at the age of 11 years after multiple elongation procedures. Frontal balance acceptable. (**E**) Sagittal radiograph of the spine at the age of 11 years. Sagittal balance acceptable.

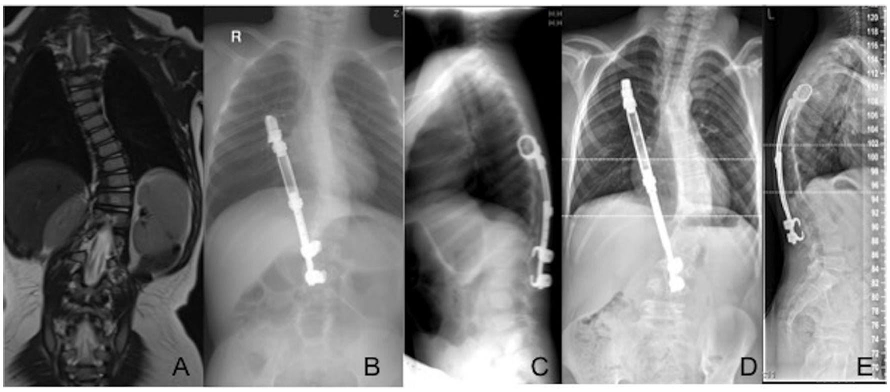

Fig. 2 A male child with idiopathic EOS. Treatment with vertical expandable prosthetic titanium ribs (VEPTR) was started at the age of 3.5 years. (**A**) MRI of whole spine, coronal plane reconstruction. (**B**) Post-operative whole spine posteroanterior (PA) radiograph at the age of 3.5 years. Frontal balance acceptable. (**C**) Post-operative whole spine sagittal radiograph at the age of 3.5 years. Sagittal balance acceptable. (**D**) Whole spine PA radiograph at the age of ten years. No change in frontal balance. (**E**) Whole spine sagittal radiograph at the age of 3.5 years. No change in sagittal balance.

reports contradict this theory by stating that VEPTR regularly causes spontaneous spinal fusion.[8]

Thus, the theoretical advantage of avoiding spontaneous spinal fusion by correcting spinal deformity with VEPTR instrumentation, rather than with growing rods, is in doubt.[8]

A disadvantage of VEPTR instrumentation may be the impact on thoracic compliance. To investigate the effect of an intervention, it has to be compared to natural history.

The aim of our study was to investigate the impact of scoliosis on thoracic compliance and also to analyse the quality of deformity correction in the coronial plane and the impact of VEPTR on sagittal balance (sagittal plane) since this procedure is applied by a growing number of institutions.

Patients and methods

In a retrospective study, 21 consecutive children (treatment group) who were treated by VEPTR technology between January 2004 and July 2011 were analysed. The mean age at initial surgery was 5.26 years (standard error (SE) 0.68).

Our inclusion criteria were children aged one to ten years with a rib–vertebra angle difference ≥ 20°,[1] a Cobb angle ≥ 40° or a progression of the Cobb angle of ≥ 5° in six months. We excluded patients with pre-operative rib synostosis. After initial surgery, these patients had elongation procedures every six months. Follow-up was 60.67 months (SE 4.77).

Data for analysis were clinical characteristics, complications, initial Cobb angle and Cobb angle before and after surgery for elongation, weight before each surgical procedure and dynamic thoracic compliance (DTC) directly before each surgical procedure, ten minutes after orotracheal intubation in supine position and always with the same respirator (Primus Draeger). We did not use muscle relaxation for our patients.

Compliance

We measured the dynamic total compliance, not the static compliance. Dynamic total compliance is the combined compliance for the lung and chest wall (C total dyn = dV/dP). Since Sharp et al[11] and Zapletal, Paul and Samanek[12] found that the change of compliance in lung development is dependent on weight and age, compliance was standardised in relation to weight in kilograms. The difference between initial and last compliance in mL/mbar was related to the difference between initial and last weight in kilograms.

A control group of 16 consecutive patients who had more than two operations for other reasons (non-spinal, non-chest) were analysed.

Age, diagnosis and compliance before each surgery (ten min after orotracheal intubation in the supine position and always with the same respirator as in the scoliosis group) were recorded. Diagnoses that led to first operation were clubfoot (six patients), hip dislocation (four patients), cartilaginous exostosis (two patients) and slipped capital femoral epiphysis (four patients).

The mean age of the control group was 5.3 years (SE 0.94). We performed a mean of 3.4 (SE 0.42) operations in these patients. The mean follow-up was 55.4 months (SE 7.0).

We excluded patients with neurologic or anatomic impairment of pulmonary function.

Sagittal balance

We compared the change of sagittal balance to a control group of five patients that received more than one standard radiograph of the spine and in whom spine and hip disease were excluded. Reasons for the radiograph were blunt traumata. The mean age of the control group was 6.1 years (SE 2.3). The mean follow-up was 32.4 months (SE 14.2).

For additional analysis of any effect of ala hooks (ilium to rib) on sagittal balance compared with spine to rib instrumentation, we also measured a control group of eight patients who received an instrumentation from ileum to rib (the VEPTR group did not include any patients with ala hooks). The mean age at initial surgery was 8.78 years (SE 0.91).

Statistical methods

Statistical analysis was performed with SPSS 22 (IBM). Kolmogorov–Smirnov test was performed and showed normal distribution for compliance, Cobb angle, weight and parameters of sagittal balance. An ANOVA was performed for parameters of sagittal balance; Student's t-test for unrelated variables was performed for the other parameters. Results were regarded as statistically significant if $p < 0.05$. Descriptive data are given as mean and standard error of the mean (SE).

Results

Thoracic compliance

In a one-sided t-test, the difference between the initial compliance of the VEPTR group *versus* the control group and the difference of the compliance at last follow-up (LFU) of the VEPTR group *versus* the control group was significant ($p < 0.05$).

Initial and last measured compliance of the VEPTR group was lower compared with the initial and last measured compliance of the control group (Table 1).

The difference of the change of the compliance in relation to weight gain during growth in the VEPTR group *versus* the control group was not significant ($p > 0.05$).

The result is illustrated in Figure 3: pre-operative (Pre) and post-operative (POP) compliance of the VEPTR group is lower than that of normal controls, but the slope of improvement matched that of normal controls.

Differences in age and follow-up period between both groups were not significant ($p > 0.05$).

Sagittal balance

Apart from initial pelvic incidence (PI), pelvic tilt (PT) and sacral slope (SS) ($p < 0.05$), we did not find any statistical significant differences between the development of

Table 1. Thoracic dynamic compliance

Group	Initial compliance (mL/mbar)	Compliance last follow-up (mL/mbar)	Compliance change ((ml/mbar)/kg)	Initial weight (kg)	Weight last follow-up (kg)
VEPTR	10.64 (SE 0.92)	17.94 (SE 1.34)	0.425 (SE 0.102)	16.66 (SE 1.40)	32.48 (SE 12.38)
Control group	15.06 (SE 2.42)	23.99 (SE 2.91)	0.482 (SE 0.275)	24.84 (SE 4.45)	42.69 (SE 6.85)

VEPTR, vertical expandable prosthetic titanium ribs; SE, standard error

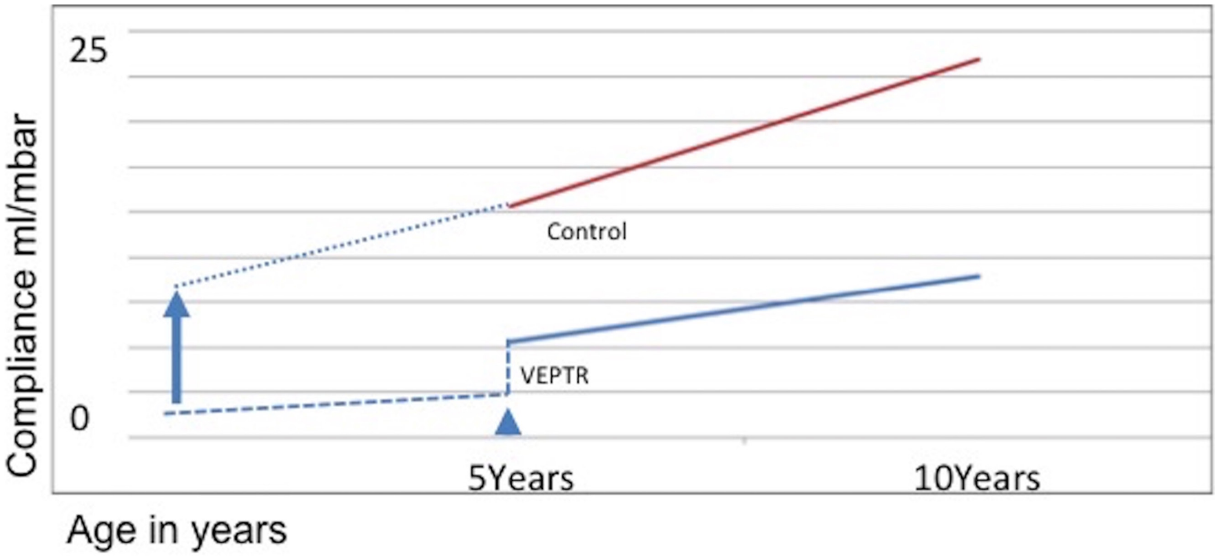

Fig. 3 Development of thoracic compliance during growth. The vertical expandable prosthetic titanium ribs (VEPTR) group showed a lower thoracic compliance than the control group at the beginning of treatment and at the end of treatment. Increase rate of thoracic compliance during growth did not show any statistically significant differences. Assuming that treatment would begin earlier, the same increase rate of thoracic compliance during growth could lead to a 'normal' thoracic compliance at the end of treatment. The arrow head indicates start of treatment (mean age in this study). The dotted line at the left of the arrow head indicates assumed thoracic compliance before treatment. The arrow indicates the theoretical start of treatment as early as possible. The dotted line right to the head of the arrow indicates theoretical thoracic compliance of patients whose treatment started as early as possible.
VEPTR, thoracic compliance of VEPTR group; Control, thoracic compliance of healthy control group.

parameters of sagittal balance during growth between the VEPTR group, the group who received ala hooks and the healthy control group: SS Pre-POP difference, PT POP to PT Pre-POP difference, PI POP to PI Pre-POP difference, SS at LFU, PT at LFU, PI at LFU, SS POP – SS LFU difference, PT POP – LFU difference, PI POP –LFU difference ($p > 0.05$). Table 2 shows the descriptive data.

Correction of frontal Cobb angle

In the VEPTR group, we saw a mean correction of Cobb angle after the first operation of 16.41° (SE 3.01). We saw a loss of correction of 8.23° (SE 3.22) at LFU. Data are shown in Tables 3 and 4.

Complications

Complications were recorded in seven patients in the VEPTR group.

Five patients sustained mechanical complications: three rib–anchor dislocations, one lamina hook dislocation and two rod breakages.

Three patients sustained soft-tissue complications from implant-related ulcers. Two patients could be managed by local revision and one patient received defect repair by a local musculocutaneous flap. All complications could be managed without further recurrent complications.

Discussion

Thoracic compliance

Other study groups reported that thoracic volume, SAL and FVC increased with the same rate as in healthy children after surgery with VEPTR.[3-6]

Thoracic volume and space available for lungs are static parameters and measurement of FVC is dependent on the interaction with the patient who has to be cooperative and very motivated for the required tests. For patients with a mean age of five years it seems very difficult to obtain valid results.

We measured DTC by applying a method that does not depend on the co-operation or motivation of the patient (who was under general anaesthesia) and therefore investigated valid dynamic parameters over a period of 60.67 months (SE 4.77).

We measured dynamic and not static compliance in our patients since it was more accessible for this study. Popow and Simbruner[13] stated that dynamic and static compliance are strictly correlated to each other, so the choice of either parameter did not cause any bias.

A group of untreated patients with EOS would have been the ideal control group to compare the intervention (VEPTR implantation) with natural history, but not treating EOS patients who are admitted to our unit is not an

Table 2. Parameters of sagittal balance of vertical expandable prosthetic titanium ribs (VEPTR) group, control group sagittal balance and control group ala hook

		Mean	SE
SS Pre	VEPTR	34.500	2.2479
	Control group sagittal balance	.	.
	Control group ala hook	21.957	2.3816
	All	29.879	2.1635
SS POP	VEPTR	37.611	1.7935
	Control group sagittal balance	28.680	3.3750
	Control group ala hook	24.013	2.3553
	All	32.661	1.6853
SS Pre-POP	VEPTR	1.67	4.647
	Control group sagittal balance	.	.
	Control group ala hook	-0.67	2.275
	All	0.89	3.146
PT Pre	VEPTR	11.250	3.1211
	Control group sagittal balance	.	.
	Control group ala hook	14.486	4.1925
	All	12.760	2.5098
PT POP	VEPTR	9.947	1.4599
	Control group sagittal balance	14.180	2.5510
	Control group ala hook	13.488	3.7730
	All	11.494	1.3356
PT Pre-POP	VEPTR	9.67	10.418
	Control group sagittal balance	.	.
	Control group ala hook	0.75	1.921
	All	6.10	6.253
PI Pre	VEPTR	47.111	3.5215
	Control group sagittal balance	.	.
	Control group ala hook	36.443	3.8554
	All	42.444	2.8616
PI POP	VEPTR	48.579	2.3337
	Control group sagittal balance	42.860	2.8807
	Control group ala hook	38.750	2.1960
	All	45.228	1.7026
PI Pre-POP	VEPTR	3.73	6.454
	Control group sagittal balance	.	.
	Control group ala hook	0.08	1.410
	All	2.44	4.154
SS LFU	VEPTR	34.238	1.9197
	Control group sagittal balance	30.240	1.8933
	Control group ala hook	.	.
	All	33.469	1.6096
PT LFU	VEPTR	11.800	1.9810
	Control group sagittal balance	15.325	3.3325
	Control group ala hook	.	.
	All	12.388	1.7372
PI LFU	VEPTR	44.350	2.4955
	Control group sagittal balance	43.925	2.6329
	Control group ala hook	.	.
	All	44.279	2.1069
SS POP-LFU	VEPTR	2.222	2.0025
	Control group sagittal balance	–1.560	4.3528
	Control group ala hook	.	.
	All	1.400	1.8124
PT POP-LFU	VEPTR	0.333	1.8078
	Control group sagittal balance	10.800	18.6007
	Control group ala hook	.	.
	All	2.609	4.0619
PI POP-LFU	VEPTR	5.1111	2.82483
	Control group sagittal balance	0.5250	4.14415
	Control group ala hook	.	.
	All	4.2773	2.42493

SE, standard error; SS, sacral slope; PT, pelvic tilt; PI, pelvic incidence; Pre, pre-operative; POP, post-operative; Pre-POP, difference between the pre-operative angle and the post-operative angle; LFU, last follow-up (angle measured at last follow-up); POP-LFU, difference between the angle after the last operation and angle at last follow-up

Table 3 Cobb angles of the vertical expandable prosthetic titanium ribs (VEPTR) group

	Mean Cobb angle (°)	SE
Cobb angle difference Pre-POP	16.41	3.01
Cobb angle difference POP-LFU	–8.23	3.22
Cobb angle Pre	54.68	3.82
Cobb angle POP	40.49	2.89
Cobb angle LFU	51.50	4.25

SE, standard error; Pre, pre-operative; POP, post-operative; Pre-POP, difference between the pre-operative angle and the post-operative angle; LFU, last follow-up (angle measured at last follow-up); POP-LFU, difference between the angle after the last operation and angle at last follow-up

Table 4. Cobb angles of ala hook group

	Mean Cobb angle (°)	SE
Cobb angle difference Pre-POP	–7.52	4.82
Cobb angle Pre	53.78	4.48
Cobb angle POP	60.06	6.29

SE, standard error; Pre, pre-operative; POP, post-operative; Pre-POP, difference between the pre-operative angle and the post-operative angle

option. This is why we chose a control group of healthy patients. The aim of our treatment is to enable our patients to have functional capacities as close to normal as possible and our results show how far we get by applying VEPTR.

Scar tissue, titanium rods and unintended ossifications at the ribs (which are reported to occur in 50% of EOS patients with VEPTR)[7] theoretically increase stiffness of the thoracic wall. Despite that, in our group of patients who were treated with VEPTR, we found an increase of dynamic compliance during growth in the same rate as in healthy controls, thus VEPTR seems to support children with EOS in developing their compliance as positively as healthy controls. Possible reasons for VEPTR allowing the total compliance to increase even when scar tissue and the titanium rods and ossifications theoretically counter that effect may be the mechanics of VEPTR. The pressure force vector of the VEPTR clamps is oriented cranially in the cranial clamp and caudally in the caudal clamp, resulting in forces that do not counter expansion of the thoracic wall.

We performed an additional analysis and compared the subgroups of patients with unilateral (7/21 patients) and bilateral (14/21) VEPTR implantation. In a two-sided t-test, the difference between the groups was not significant ($p < 0.05$), which further supports the finding that the rib cage with VEPTR shows a similar improvement of thoracic compliance during growth than those without.

On the other hand, in our control group, there was a higher level of lung compliance than in the scoliosis group before the first surgical procedure and this difference remained until the end of follow-up.

In our study, patients with EOS showed a lower initial thoracic compliance compared with healthy children that would subsequently deteriorate without treatment and may have ended up in a TIS.[2] By surgically correcting these children, we could prevent deterioration of thoracic compliance. Also, an increase of total compliance similar to that of a healthy control group could be shown but without catching up to the higher level of the controls. A similar effect was described for thoracic volume, SAL and FVC in recent studies.[3-6] The reason may be that pulmonary development is strongly influenced by thoracic volume and structure in a very young age[1,2,14-16] and we do not operate on our patients before the age of one to two years. In patients without rib synostosis, thoracic compliance is impaired by reduced thoracic height (cranio-caudally) and spinal rotation.[2] Having shown a similar increase in compliance after the initial procedure, we should consider treating our patients as early as possible and try to achieve the highest degree of initial correction of the spinal deformity as possible to support pulmonary development (Fig. 3).

Coronal balance and complications

In our study, the initial correction of Cobb angle by VEPTR instrumentation was 16.41° (Tables 3 and 4). The complication rate was 33% (7/21). Elsebai et al[17] reported an initial correction of 21° and a complication rate of 42% with the growing rod technique with a lower mean time of follow-up (four years *vs* five years). Bess et al reported a complication rate of 58%.[18] Comparing both techniques, VEPTR shows an acceptable correction of the deformity with a slightly lower rate of complications.

Sagittal balance

Mac-Thiong et al[19] reported a change in PT and PI during growth in healthy children. We did not observe a significant difference in these parameters between the VEPTR group and the control group, which may indicate that 'VEPTR patients' show a development of their sagittal balance which is comparable with healthy children. Initial pelvic parameters of sagittal balance were different in the ala hook group compared with the VEPTR group. Since these parameters (PI) seem to be a 'spinal fingerprint', a different result in each patient was to be expected.

The main limitation of our study is the low number of patients and the fact that we could not analyse the C7 plumb line as full spinal radiographs were not available in our control group.

However, we did analyse a control group for every parameter of main interest (DTC, impact of VEPTR on sagittal balance, impact of ala hooks on sagittal balance) and our control group for thoracic compliance did not show a significant difference in age and time of follow-up compared with our VEPTR group, which reduces the bias. Mac-Thiong et al[19] reported a change in PT and PI during growth in healthy children, which is why we concentrated on these parameters and the bias caused by the missing C7 plumb line is reduced.

VEPTR seems to lead to an increased rate of DTC that is similar to healthy controls, but the difference could only be stabilised and not be reduced in patients with a mean age of 5.26 years. Therefore, VEPTR treatment should be initiated as early as possible. Sagittal balance showed a similar development compared to healthy children.

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COMPLIANCE WITH ETHICAL STANDARDS

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No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

ETHICAL STATEMENT

The study was conducted in accordance with the ethical standards of the institutional research committee and with the 1964 Declaration of Helsinki and its later amendments. For this type of study formal consent is not required.

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12.4 Arbeit 4

Wolters Kluwer genehmigte dieses „final peer-reviewed“ Manuskript.

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Clinical Spine Surgery

Navigation versus Fluoroscopy in multilevel MIS pedicle screw insertion: Separate analysis of exposure to radiation of surgeon and of patients

--Manuscript Draft--

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Article Type:	Primary Research (Unsolicited)
Keywords:	pedicle screw; minimally invasive surgery; navigation; radiation; breaching; posterior stabilization; complications; metastatic lesions of the spine
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Abstract:	Study Design Retrospective radiographic analysis of consecutive patients Objective To analyze exposure to radiation of surgeon and - separately - of patients in minimally invasive surgery (MIS) of multilevel posterior stabilization by pedicle screw insertion guided by navigation (PIN) versus pedicle screw insertion guided by fluoroscopy (PIF). Summary of Background Data Spine surgeons are exposed to a 12-fold higher dose of radiation than other non-spinal musculoskeletal surgeons and PIF in MIS leads to a 2-fold higher dose of radiation than in open surgery. PIN might reduce dose of radiation for surgeon and patient especially in multilevel MIS surgery. To the best of our knowledge there is only rare data of short-segment fusions that does not focus on exposure to radiation of surgeons. Methods After power analysis we included 205 consecutive screws (22 patients). We monitored dose of radiation (recorded separately for patient and surgeon), accuracy of screw placement, time of operation and approach related complications. Results In PIN only 58.7% of Dose Area Product (DAP) (cGy x cm2) per screw of PIF was determined for patients (p<0.01). Surgeon was only exposed to 19.9 % of radiation per screw in PIN compared to dosage in PIF (p<0.01). Four of 205 screws (2.0%) were classified as being incorrect positioned: Two of 87 screws (2.3%) in PIF and 2/118 screws (1.7%) in PIN (p>0.05). We did not observe any wound infections. Conclusions. PIN in MIS is a safe procedure and does, compared to PIF, lead to significant reduction of radiation dose for patients and - even more - for spine surgeons.

Fluoroscopy versus Navigation in multilevel MIS: Exposure to radiation of surgeon and patient and accuracy of pedicle screw placement

Introduction:

Spine surgeons are exposed to up to 12-fold higher dose rates of radiation than other nonspinal musculoskeletal surgeons [1] and it is reported that pedicle screw insertion (PSI) guided by fluoroscopy (PSIF) in minimally invasive surgery (MIS) leads to a 2-fold higher dose of radiation compared to pedicle screw insertion in open surgery [2]. Techniques to reduce dose of radiation without reduction of accuracy of PSI, especially in MIS, are therefore needed: Accuracy of pedicle screw insertion guided by navigation (PSIN) in open technique has been reported to be superior to pedicle screw insertion guided by fluoroscopy (PSIF) [3] and theoretically percutaneous pedicle screw insertion (PPSI) guided by navigation (PIN) could lead to a lower dose of radiation for spine surgeons than PPSI guided by fluoroscopy (PIF). However overall dose of radiation in PSIN is reported to be significantly higher than in PSIF [2] for open surgery and data on PIN in MIS, especially for multilevel surgery, are still not sufficient:

Kaminski et al. [2] did not find any difference in overall dose of radiation between PIN versus PIF in MIS, but he did not report on the impact of MIS on exposure to radiation of the surgeon. In his study he included patients with a median number of 4 screws (monosegmental fusions) and did not investigate the accuracy of screw placement. Several reports show a higher breaching rate in PIF versus PIN in PPSI but these studies only investigated mono – or bisegmental fusions and did not report on radiation [4,5,6].

Grelat et al. [7] investigated the time the surgeon’s eyes were exposed to radiation during MIS PIF versus PIN. He reported an exposure of 0 minutes of radiation during PIN surgery vs 3.72 minutes (mean) in PIF surgery. However he reported exclusively on monosegmental fusions and of only 24 screws.

Kim et al. [8] reported on exposure to radiation by PIN versus PIF and found less exposure to radiation for surgeons in PIF. However he investigated exclusively monosegmental fixations combined with a TLIF (thus he did not record radiation per screw but radiation for implantation of four screws and a TLIF) and only on PIN based on 2D fluoroscopy. Yang et al. [9] reported on overall time of radiation and accuracy of screw placement in PIN versus PIF and found less time of radiation in PIN than in PIF. However he reported on only 4.9 screws per patient, navigation based on 2D fluoroscopy and he did not report on exposure to radiation of the surgeon.

Further concerns with regard to PIN have also not been fully investigated: Placement of reference (needed for navigation) to instrumented area leads to a higher accuracy of screw placement [10], however this may lead to a higher rate of infections because of a slightly more invasive approach due to placement of reference to spinous process. Surgery of metastatic lesions of the spine (MLS) leads to a higher rate of infections than that of non-neoplastic lesions [11,12] and more invasive procedures lead to a higher rate of infections [11]. If PIN would not lead to a higher rate of infections than PIF in MLS, it could be regarded as a safe procedure with regard to approach related complications.

To the best of our knowledge there is no published data of impact of navigation on MIS in multilevel fixations with separate investigation of dose of radiation for patient and surgeon, the accuracy of screw placement and whether navigation in MIS leads to a higher rate of approach related complications due to placement of reference in patients with a malignant neoplastic disease.

Methods

Patients

This is a retrospective analysis of prospectively collected data on consecutive patients who were treated by MIS multi-level spondylodesis by a pedicle screw rod construct to stabilize a metastatic lesion of the spine (MLS) from 10.2015 to 12.2017. All patients received radiation treatment for oncologic reasons 3-4 weeks after the surgery and therefore a postoperative CT scan for planning of the radiotherapy.

Dose of radiation (recorded separately for the patient and for the surgeon), accuracy of screw placement, time of operation, clinical parameters and complications have been monitored. Since we investigated postoperative radiologic parameters and perioperative wound infections [11,12] follow up for all patients was set at a minimum of 3 months.

The CT scans have been evaluated independently with regard to accuracy of pedicle screw placement by two orthopedic surgeons and by the radiologic department of our institution. If assessment of a screw differed between the three investigators the worst assessment (largest distance of pedicle screw to ideal position) was included in the study. Accuracy of screw placement has been assessed according to the scoring system of Neo et al. [13](Table 1) and by the system of Upendra et al. [14] (Table 2). Screw was regarded as "incorrect positioned" if it was type II or type III according to Upendra et al. [14].

Inclusion criteria

Patients with a MLS who were classified as "unstable" according to the SINS criteria [15], had an expected time of survival of more than 6 months and had to be treated by instrumented fixation of more than one segment were included in the study (Figure 1).

Patients who needed a decompression due to a metastatic spinal cord compression (MESCC) received MIS PIN based on intraoperative 3D scan (exposure for decompression was used to place reference clamp), patients who did not need decompression received MIS by PIF.

Exclusion criteria

We excluded patients with a polyneuropathy or those who had previous spine surgeries in their medical history.

Surgical technique

Systems

Intraoperative imaging was performed with Siemens Arcadis Orbic 3D (intraoperative Cone beam scanner) in all procedures (PIF and PIN).

The Navigation System "Kick" (© Brainlab, Munich, Germany) was applied in PIN. Reference clamp for spinous process was applied and attached to the region which was scanned [10].

The MIS Pedicle Screw Rod – System VIPER (©Depuy Synthes, Germany) was used in all patients

PIF

PPSI has been performed under fluoroscopic guidance (pa and lateral view) (Figure 2).

Pa and lateral radiography of the whole construct were taken at the end of the procedure.

PIN

The pedicles of all levels to be instrumented and of the level to be decompressed (according to preoperative planning) have been marked by pa radiography. The first step was a limited posterior approach to the level to be decompressed (exposure of left and right lamina and spineous process of affected level). The reference clamp (carbone clamp, © Brainlab) has been fixed to the spinous process of the affected level. The surgeon then left the operation theater and a 3 D scan of 2 or 3 vertebra was performed (Arcadis Orbic 3D, ©Siemens, Berlin, Germany). The surgeon then reentered the operation theater. Subsequently pedicle screws were implanted by MIS approach (percutaneously), guided by Navigation (Kick, © Brainlab) (Figure 3). The same procedure was performed for the levels below the affected level. After that the rods were inserted in MIS technique. Afterwards decompression of the spinal cord was performed at the preoperatively identified levels. No additional fluoroscopy was needed for decompression since pedicels of the area to be decompressed had been identified for PPSI and could be used as landmarks.

Pa and lateral radiographs of the whole construct were taken at the end of the procedure.

Assessment of radiation

Dose Area Product (DAP) has been retrieved from the automatically recorded protocol of the Arcadis Orbic 3D (©Siemens) for all patients. Time of fluoroscopy of one 3D scan (used for navigation) was 60 seconds. We separately recorded DAP (cGy x cm^2) with the surgeon in the operation theater (exposed to radiation) and with the surgeon not in the operation theater (not exposed to radiation) while the 3D scan was performed.

Statistics

Statistical analysis has been made with SPSS 24 (©IBM, Armonk, USA). Descriptive data are reported as mean and standard error of mean (StE).

Kolmogorov Smirnov Test was applied to test parameters for normal distribution. Since the tested parameters did not show normal distribution, we applied Man-Whitney U tests for DAP and OP time per screw and Chi Square tests for independence for accuracy of screw placement. Power analysis was performed with G-Power 3.1.6 (© Franz Faul, Edgar Erdfelder, Albert-Georg Lang) [16,17] and a minimum number of 80 screws for each group was determined to achieve an effect size of 0.5 or greater for analysis of exposure to radiation of surgeon. Bonferroni adjustment was performed to compensate for multiple testing.

Results

We enrolled 205 screws (22 consecutive patients) in our analysis: 118 screws (12 patients) have been inserted guided by navigation (PIN), 87 (10 patients) guided by fluoroscopy (PIF).

Eighty-one screws have been inserted in thoracic vertebrae (39.5%), 124 (60.5%) in lumbar vertebrae. Details are reported in Table 3.

Type of malignancy was multiple myeloma in 11 patients, breast cancer in 4 patients, and 7 patients presented with other malignancies (carcinoma of the lung, of the penis and of the uterus).

We did not find any significant differences between patients operated by PIN and PIF with regard to age, number of screws, number of segments, days in hospital and BMI (Table 4) ($p>0.05$).

Radiation (Table 5)

Exposure to radiation of the surgeon: If the surgeon used navigation he was only exposed to 19.9 % (13.3 cGy x cm2 versus 66.8 cGy x cm2) of the radiation compared to the dosage when fluoroscopy technique was applied. The difference was significant ($p<0.01$) with an effect size of 0.72 and a statistical power of 1.0 (high statistical power). [16,17]

Overall radiation (for the patient): In the navigated technique only 58.7% (39.2 cGy x cm2 versus 66.8 cGy x cm2) of the DAP of the fluoroscopy technique was determined.

The difference was statistically significant ($p<0.01$) with an effect size of 0.25 and a statistical power of 0.41 (medium statistical power). [16,17]

An analysis of subgroups by spinal region (thoracic screws versus lumbar screws) showed the same results ($p<0.01$).

Time of operation per screw (Table 6)

Time of operation per screw (time of operation/number of screws) was 22.3 (StE 0.7) min for PIF and 26.2 (StE 0.4) min for PIN. The difference was significant ($p<0.01$) with an effect size of 0.31 and a statistical power of 0.57 (medium statistical power). [16,17]

Accuracy of screw positioning (Tables 1 and 2)

Four of 205 screws (2.0%) were classified as being incorrect positioned (accuracy of 98%). Two of 85 screws (2.3%) in PIF and 2/118 screws (1.7%) in PIN. One (0.5%) grievous placement (according to upendra et al. [14]) where the screw was placed outside the pedicle with full diameter was found in PIF, none (0%) in PIN. The difference was not significant (p>0.05) with an effect size of 0.8 (high effect size). [16,17]

None of the 4 screws were clinically symptomatic; none of the screws were revised although revision was offered to the patient in whom the screw was placed outside the pedicle by full diameter. The patient refused revision surgery (presently 16 months post OP).

Complications

We did not observe any wound infections or neurologic impairments. 1 patient (66 years, BMI 37) developed pleura effusions 1 week after the operative procedure, treated conservatively, one patient (47 years, BMI 28) developed a pulmonary embolism 4 weeks after the operative procedure during chemotherapy of her breast cancer.

Discussion

Radiation

During Surgery by PIN the surgeon was exposed to 80.1 % less radiation than during PIF (Table 5)! This result is even more appreciable if the subtleties of the different techniques are analyzed:

During PIN most of the radiographs are taken when the surgeon is not in the operation theater, and for all other radiographs (the remaining 19.9%) the surgeon can step back from the C – Arm (major reduction of dose of radiation due to the inverse – square law) or even step behind a shield.

During PIF most of the radiographs are taken during insertion of the pedicle screws while the surgeon is standing directly beside the C – Arm, which further and substantially increases the dose of radiation for the surgeon in

PIF compared to PIN. The body of the surgeon may be protected by led, but eyes, hands and other parts of the body are usually unprotected.

In our study the patients were exposed to 41.3% less radiation per screw insertion in PIN compared to PIF, the difference was significant. These results are in contrast to the report of Kaminski et al. [2] who recorded a higher dose of radiation for the patient in PIN than in PIF. This discrepancy may be explained by the following facts: Kaminski et al. [2] reported on open surgeries. In open surgery the surgeon relies on anatomical landmarks for the insertion of pedicle screws and takes radiographs to control the trajectory of his screw. In MIS the “data” of the anatomical landmarks are missing and the surgeon has to compensate the missing data by taking more radiographs which may lead to the two-fold higher dose of radiation in MIS compared to open surgery [2].

Accuracy and Breaching

Neo et al. [13] (Table 1) classifies all screws that are not 100% in the pedicle as breaching. However, for clinical reasons the definition which was established by Upendra et al. [14] (Table 2) is more expedient, especially for thoracic screws (Figures 4,5): If the screw is contained within the pedicle rib unit (in – out – in screws), position is regarded as “acceptable” and equivalent to a screw that does not breach the wall of the pedicle (Figures 6,7). This is why we report our results according to both classifications and regarded a screw as “incorrect positioned” if it was type II or type III according to Upendra et al. [14].

Breaching is reported to be up to 5 fold higher in PIF than in PIN [18]. The difference was not significant in our study.

Rate of screw accuracy is reported to be significantly higher in PIN than in PIF in thoracic pedicle screws compared to lumbar pedicle screws [18,19]. Nineteen of 87 (21.8%) screws in PIF were inserted in thoracic pedicles, compared to sixty-two of 118 (52.5%) screws in PIN. That may explain the non-significant difference of accuracy of screw placement in our cohort.

Weaknesses of this study

We did not record the DAP for every screw separately but divided the DAP of the patient by the number of screws which were inserted. However, since radiation has exclusively been applied for pedicle screw insertion (no radiation needed for decompression, no implantation of intervertebral cages) the DAP per screw which has been calculated can be considered as a valid parameter. Rate of breaching can also be considered as a valid parameter since every screw has been evaluated separately based on a CT scan performed for oncologic radiotherapy.

The parameter “time of operation per inserted screw” is of a lower validity.
The difference, which we found between PIN (32.9 min) and PIF (26.6 min) (Table 6) is biased by the additional decompression, which had been performed in PIN: If no decompression had been performed there could have been no difference or a much smaller difference of operation time per screw between PIN and PIF. Therefore, we do not think that our results strongly support the assumption that PIN takes longer than PIF.

We investigated only 22 patients. However, we analyzed 205 screws and achieved medium to high statistical power.

Conclusion:

MIS Pedicle screw insertion guided by navigation (PIN) is a safe procedure with regard to accuracy of screw placement and approach related rate of complications. PIN in MIS does, compared to pedicle screw insertion guided by fluoroscopy, lead to a significant reduction of radiation dose for the patient and – even more – for the spine surgeon who is usually constantly exposed to radiation. Therefore, we do recommend preferring PIN over PIF for MIS spine surgery.

Conflict of interest:
We did not receive any funding for this study, the authors state that there is no conflict of interest.

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Figure Legends

1. Painful Osteolysis of L3 in a patient with multiple myeloma, stabilized by posterior spondylodesis in MIS technique from L1 to L5. Patient presented with significantly reduced bone density.
   - A Sagittal reconstruction of a CT scan of the lumbar spine. Osteolysis > 50% of vertebral body, slight comminution of endplates, lytic lesion of anterior wall, superior endplate and inferior endplate: Vertebroplasty was rejected by patient due to possible leakage of cement.
   - B Lateral postoperative radiograph of lumbar spine
   - C Posteroanterior postoperative radiograph of lumbar spine

2. MIS insertion of pedicle screw guided by fluoroscopy (PIF)
   - A Posteroanterior (pa) intraoperative radiograph: Tip of the jamshidi needle at the entry point of the lumbar pedicle.
   - B Posteroanterior intraoperative radiograph: Jamshidi needle is advanced centrally in the pedicle, controlled by posteroanterior radiograph.
   - C Posteroanterior intraoperative radiograph: Advancement stops when tip of jamshidi needle reaches medial wall of pedicle.
   - D Lateral intraoperative radiograph: Jamshidi needle is advanced if it is still in pedicle (controlled in pa – view as in 2. B) and has reached posterior wall of vertebral body.

3. Intraoperative photograph of pedicle screw insertion guided by navigation:
   Patient in prone position, patient's head left of surgeon. Surgeon (right handed) at left side of patient, camera caudal and left of the patient. Screen caudal and right of the patient.

4. Intraoperative screenshot from navigation screen, screen shown in Figure 3: Planning of screw insertion in the right pedicle of a thoracic vertebra. Arrows point at possible breaching if screw is inserted in the pedicle.
   - A Axial view. Arrow points at the medial wall of the right pedicle.
   - B Sagittal view.

C Probe's eye view: Cross section perpendicular to the line from A and B at a distance from 0, 5, 10 and 15mm from the tip of the straight probe. The circle has a diameter of 3.5mm. Arrows point at the medial wall of the pedicle.

5. Intraoperative screenshot from navigation screen, screen shown in Figure 3. Same vertebra as in Figure 4: Entry point chosen slightly lateral from ideal entry point to the pedicle, within the pedicle rib unit. Screw length and diameter is planned, no breaching of the medial wall of the pedicle.

A Axial view. Arrow points at the costovertebral joint.

B Diameter and length of screw is planned.

C Sagittal view

D Probe's eye view: Cross section perpendicular to the line from A and C at a distance from 0, 5, 10 and 15mm from the tip of the straight probe. The circle has a diameter of 4.5mm. Arrows point at the costovertebral joint, dotted arrow points at the medial wall of the pedicle.

6. Intraoperative screenshot from navigation screen, screen shown in Figure 3: Planning of screw insertion in a thoracic vertebra. Screw insertion in the right pedicle not possible. Screw insertion within the pedicle rib unit is planned.

A Axial view. Arrow points at the costovertebral joint.

B Sagittal view

C Probe's eye view: Cross section perpendicular to the line from A and B at a distance from 0, 5, 10 and 15mm from the tip of the straight probe. The circle has a diameter of 4.5mm.

7. Intraoperative screenshot from navigation screen, screen shown in Figure 3, same vertebra as in Figure 6. Monitoring of screw insertion within the pedicle rib unit.

A Axial view. Arrow points at the costovertebral joint.

B Sagittal view

C Probe's eye view: Cross section perpendicular to the line from A and B at a distance from 0, 5, 10 and 15mm from the tip of the screw. The circle has a diameter of 4.5mm.

7. Table Legends

8.

9. **Table 1:** Classification of Neo et al.

10. Assessment of accuracy of screw placement as described by Neo et al. [13]

11. All screws that are not 100% in the pedicle are classified as breached.

12. PIF screws: Pedicle screw insertion guided by fluoroscopy

13. PIN screws: Pedicle screw insertion guided by navigation

14.

15. **Table 2:** Classification of Upendra et al.

16. Assessment of accuracy of screw placement as described by Upendra et al. [14]

17. For clinical reasons the definition of Upendra et al. [14] is more expedient than that of Neo et al [13], especially for thoracic screws: If screw is contained within the pedicle rib unit (in – out – in screw) the position is regarded as “acceptable” and equivalent to a screw that does not breach the wall of the pedicle. If screw breaches medial pedicle wall by more than 2mm, placement is classified as “unacceptable”. If screw breaches medial pedicle wall by more than 4mm or compromises blood vessels, it is classified as “grievous placement”.

18. PIF screws: Pedicle screw insertion guided by fluoroscopy

19. PIN screws: Pedicle screw insertion guided by navigation

20.

21.

22. **Table 3:** Spinal region of screw

23. PIF screws: Pedicle screw insertion guided by fluoroscopy

24. PIN screws: Pedicle screw insertion guided by navigation

25.

26.

27. **Table 4:** Descriptive Data of all patients

28. Nr: Number

29. BMI: Body Mass Index

30.

31.

32. **Table 5:** Dose Area Product per screw

33. PIF screws: Pedicle screw insertion guided by fluoroscopy
34. PIN screws: Pedicle screw insertion guided by navigation
35. DAP: Dose area product (cGy x cm2)
36.
37.
38. **Table 6:** OP time per screw:
39. PIF screws: Pedicle screw insertion guided by fluoroscopy
40. PIN screws: Pedicle screw insertion guided by navigation

Figure 1

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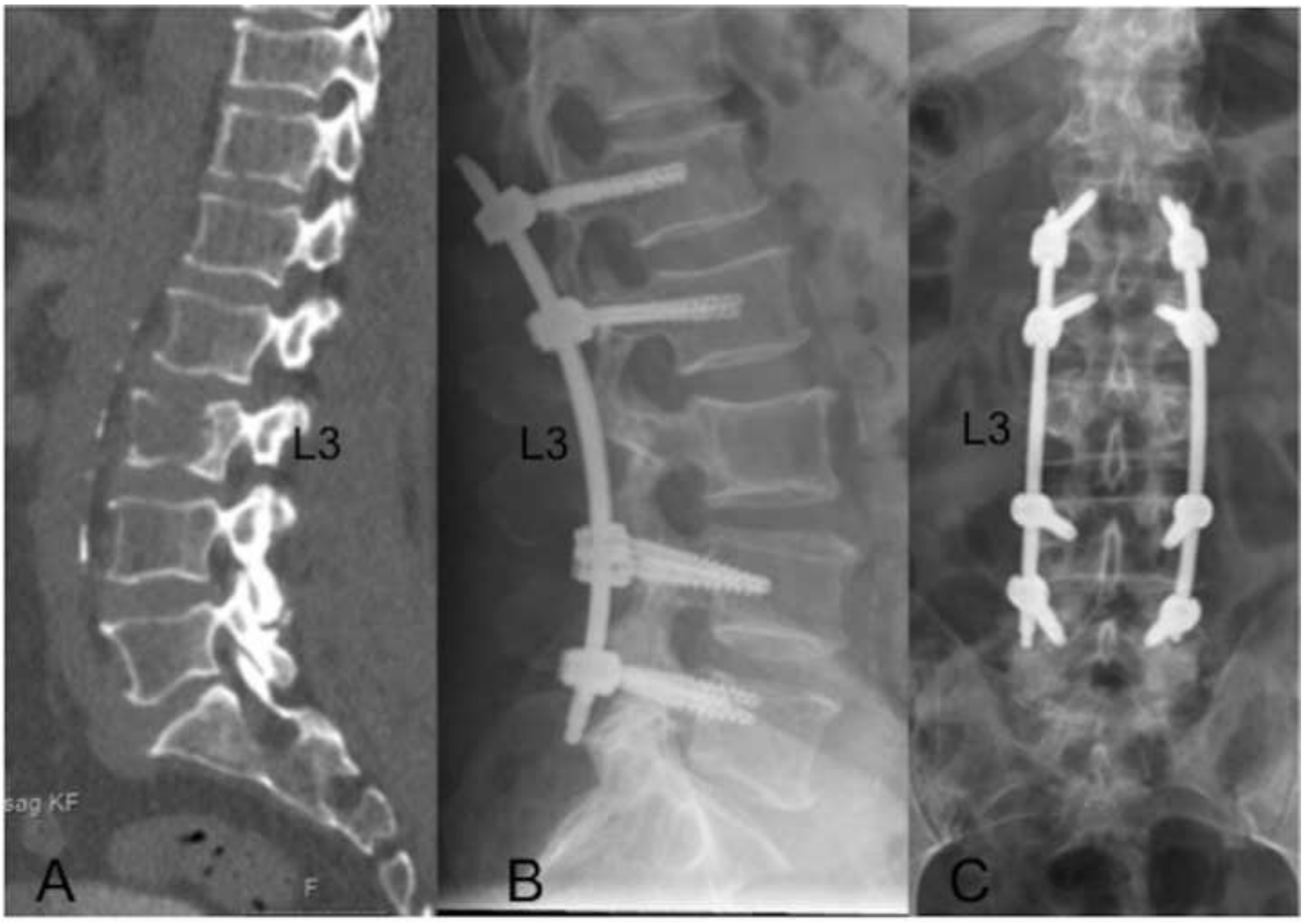

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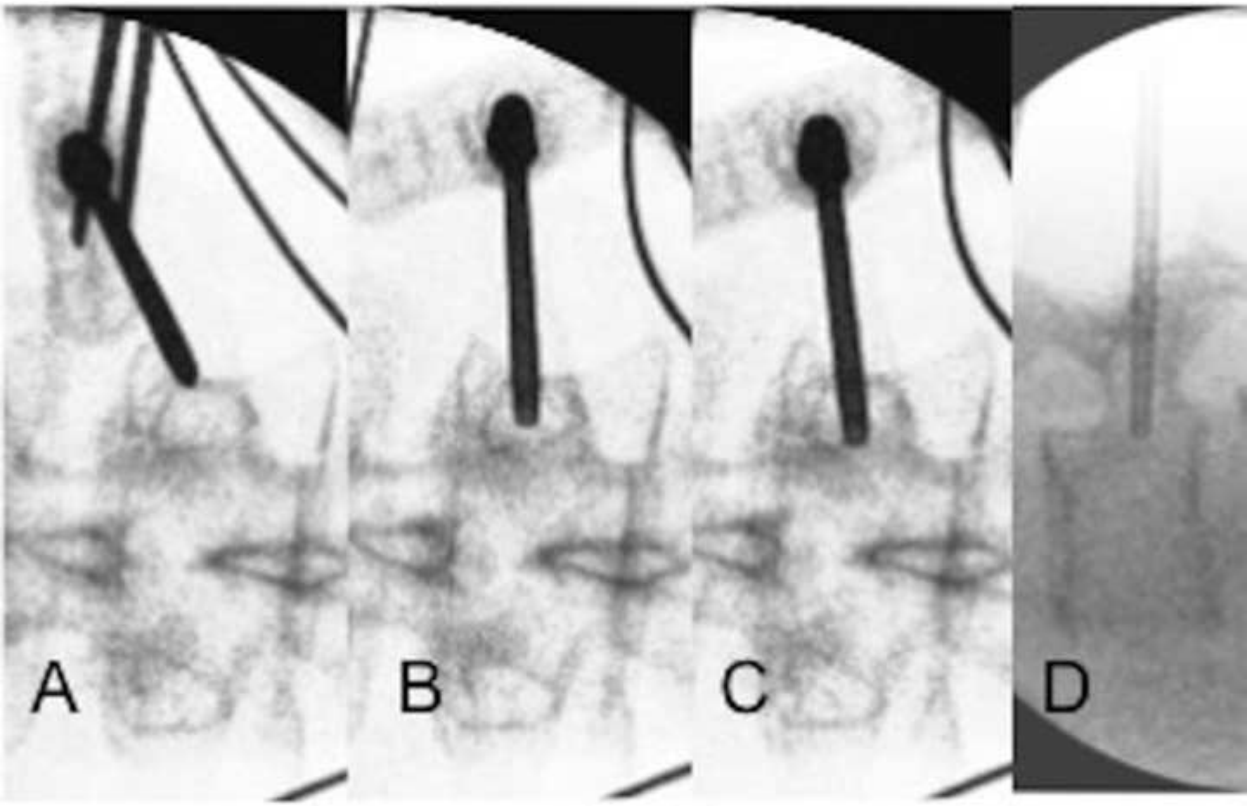
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Figure 3

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Figure 4

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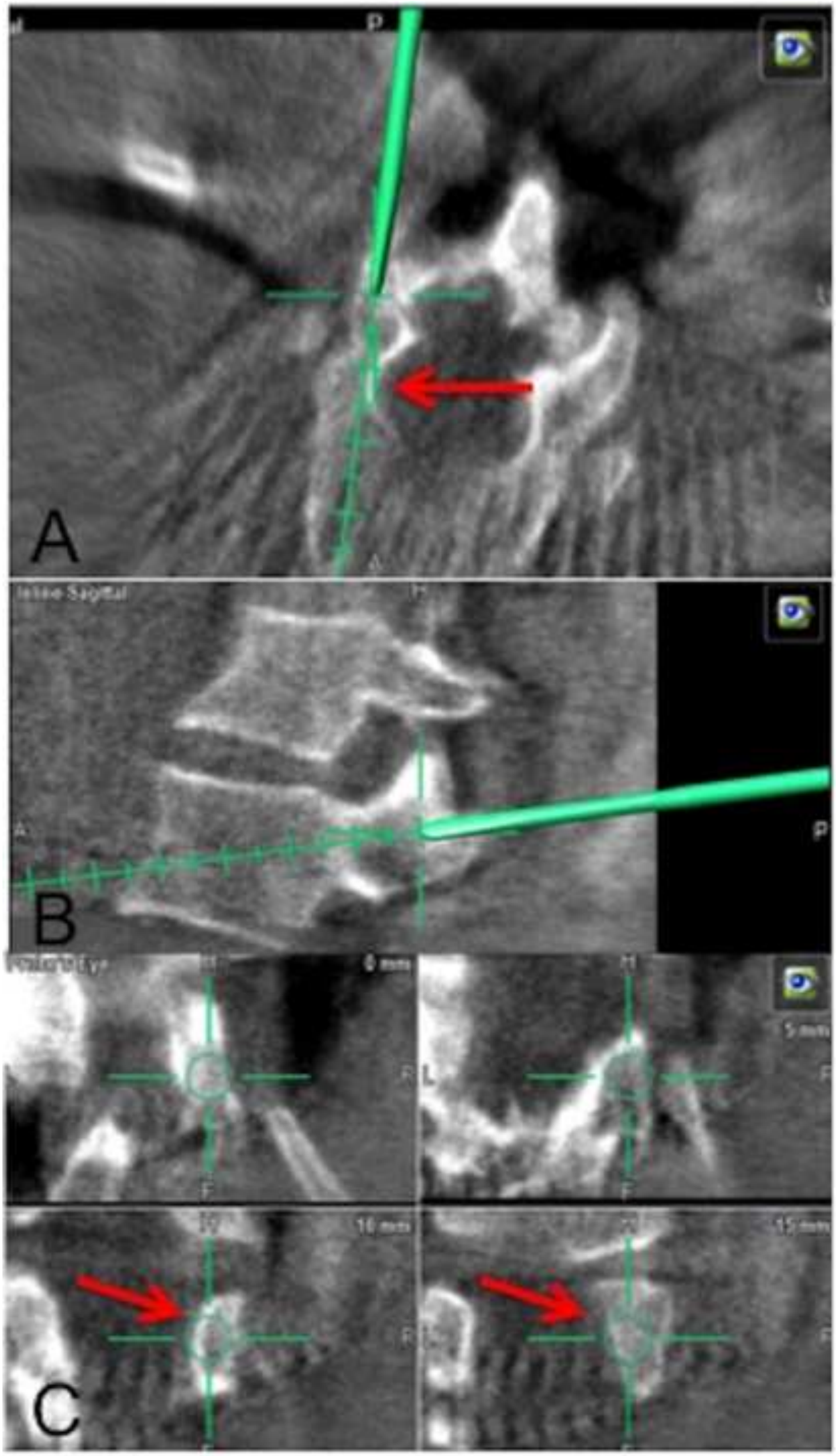

Figure 5

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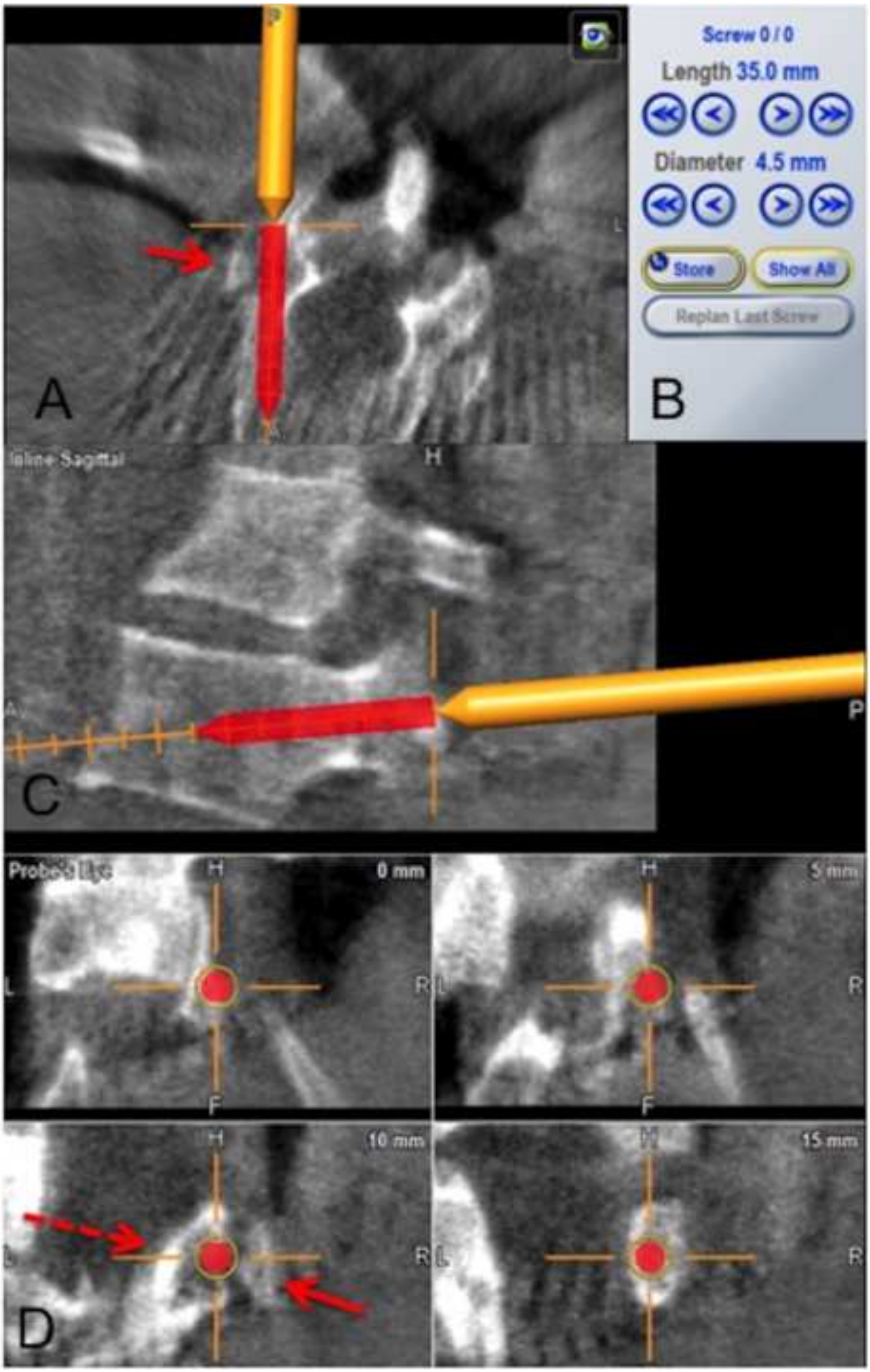

Figure 6

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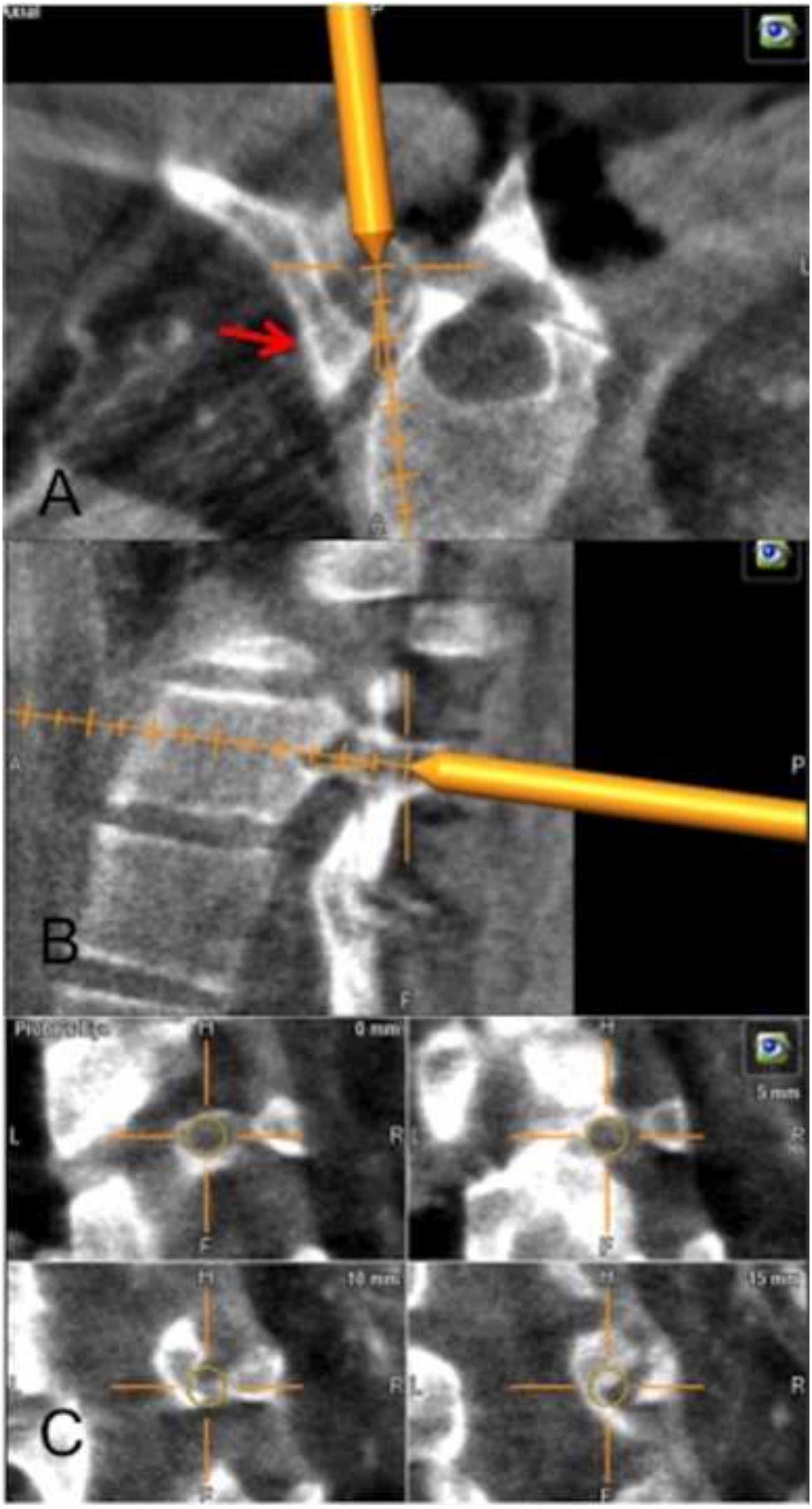

Figure 7

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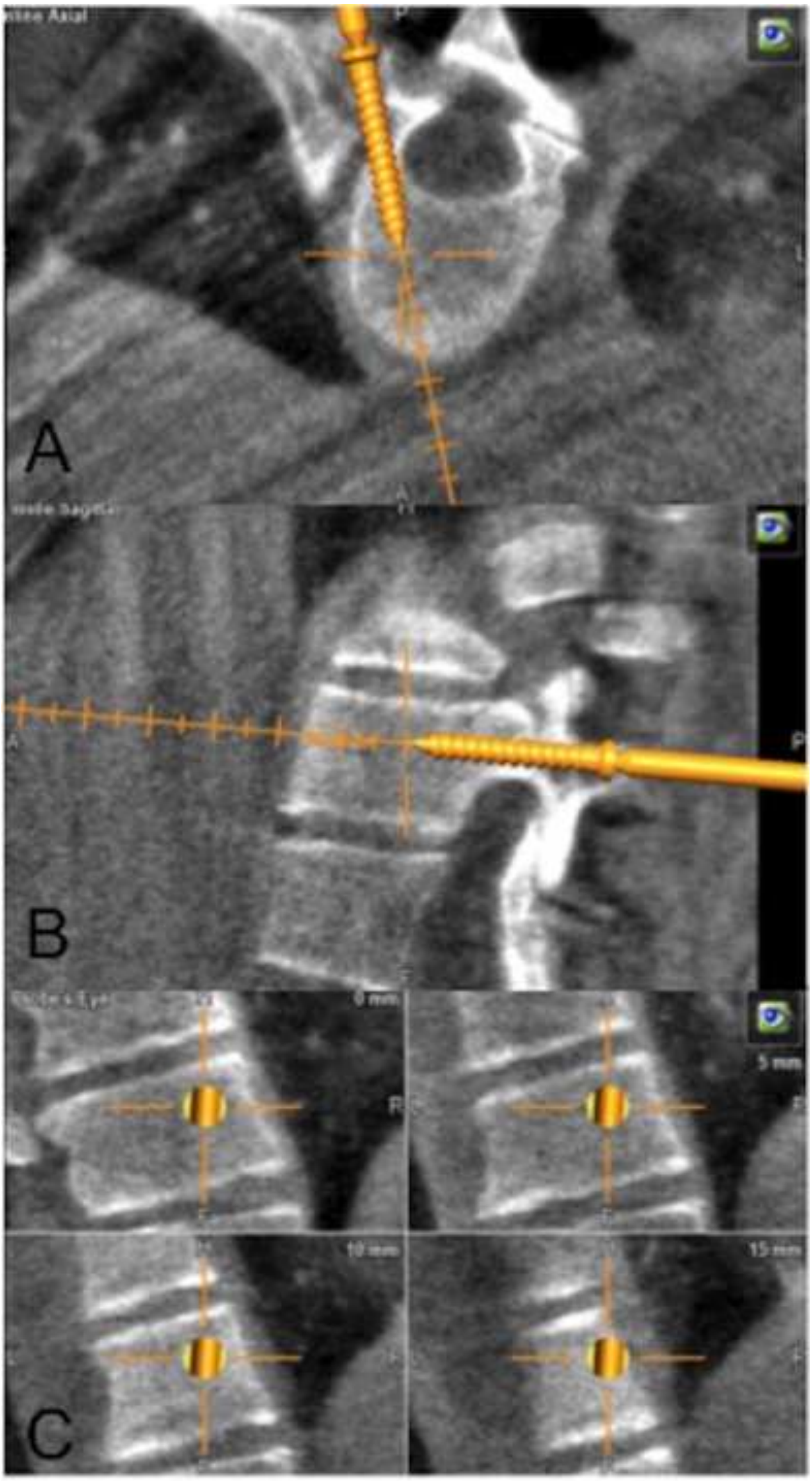

Table 1

Table 1: Accuracy of screw placement (Neo et al.)

	All screws	PIF	PIN
Grade 0 no pedicle perforation	195 (95,1%)	82 (94,3%)	101 (95,3%)
Grade 1 <2mm threads outside the pedicle	6 (2.9%)	3 (3,4%)	3 (2,8%)
Grade 2 2-4mm of core screw diameter outside pedicle	3 (1.4%)	1 (1.1%)	2 (1,9%)
Grade 3 entire screw outside the pedicle	1 (0.5%)	1 (1.1%)	0 (0%)

Table 2

Table 2: Accuracy of screw placement (Upendra et al.)

	All screws	PIF	PIN
Type I acceptable placement	201 (98,0%)	85 (97,7%)	116 (98,3%)
Type II unacceptable placement	3 (1.4%)	1 (1.1%)	2 (1,7%)
Type III grievous placements	1 (0.5%)	1 (1.1%)	0 (0%)

Chi Square tests for independence: $p>0.05$

Table 3

Table 3: Spinal region of screw

	Thoracic	Lumbar
All screws	66 (42%)	91 (58%)
PIF screws	10 (16.1%)	52 (83.9%)
PIN screws	56 (58.9%)	39 (41.1%)

Table 4

Table 4: Descriptive Data of all patients

	Age	Nr of Segments	Nr of Screws	BMI
All patients	63,9 (3,1)	4.8 (0,3)	9.3 (0,5)	26,9 (5,3)
Fluoroscopy group	58,3 (3,7)	4.3 (0,4)	8.5 (0,5)	29,6 (8,0)
Navigation group	68,5 (4,4)	5.2 (0,4)	10,0 (0,8)	26,2 (1,4)
Man Whitney U Test	p>0.05	p>0.05	p>0.05	p>0.05

Table 5

Table 5: Dose Area Product per screw

	DAP(cGy x cm^2) patient	**DAP(cGy x cm^2) surgeon**
All screws	50,9 (3.0)	42.9 (3,5)
PIF screws	66,8 (6,6)	**66,8** (6,6)
PIN screws	39,2 (1.3)	**13,3** (0,8)
Man Whitney U Test	P<0.01	P<0.01

Table 6

Table 6: OP time per screw

	Time (min)
All screws	24,5 (0.4)
PIF screws	22,3 (0,7)
PIN screws	26,2 (0,4)
Man Whitney U Test	P<0.01

12.5 Arbeit 5

Mit freundlicher Genehmigung von Bone & Joint Publishing.

Original Clinical Article

JOURNAL OF CHILDREN'S ORTHOPAEDICS

Effective dose of radiation per screw in surgery of adolescent idiopathic scoliosis: matched pair analysis of 293 pedicle screws inserted using three different techniques

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Abstract

Purpose Reports on heterogenous groups of patients have indicated that pedicle screw insertion guided by navigation (PIN) leads to, for the patient, higher doses of radiation compared with pedicle screw insertion guided by fluoroscopy (PIF). This would be a major concern, especially in paediatric deformity correction.

Methods After a power analysis (aiming at > 0.8) 293 pedicle screws which were inserted in patients with adolescent idiopathic scoliosis were analyzed by comparing effective dose and fluoroscopy time per screw for three different techniques. Groups 2 and 3 were matched to Group 1 by Lenke type of scoliosis. Group 1 were prospectively enrolled consecutive patients that have been operated on by PIN with image acquisition by preoperative CT scan (CTS) Group 2 were consecutive retrospectively matched patients who have been operated on by PIN with image acquisition by an intraoperative 3D scan (3DS). Group 3 were consecutive retrospectively matched patients who have been operated on by PIF.

Results Mean dose of radiation per screw was 1.0 mSv (SD 0.8) per screw in CTS patients, 0.025 mSv (SD 0.001) per screw in 3DS patients and 0.781 mSv (SD 0.12) per screw in PIF patients. The difference was significant ($p < 0.0001$).

Conclusion When we compared different techniques of navigation, navigation by image acquisition with CTS showed a significantly higher (by 97.5%) dose of radiation per screw for the patient than navigation by image acquisition by a 3DS. Navigation by 3DS showed significantly lower effective dose per screw for the adolescent patients than the fluoroscopic technique.

Level of Evidence: II

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Keywords: adolescent idiopathic scoliosis; navigation; computer-assisted surgery; effective dose; pedicle screws

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Introduction

Pedicle screw insertion guided by navigation (PIN) has been reported to be superior to pedicle screw insertion guided by fluoroscopy (PIF) with regard to accuracy of pedicle screw insertion. Especially in thoracic vertebrae, where the accuracy of PIN is reported to be up to five times higher than that of PIF.[1-5] Additionally, PIN has been reported to significantly reduce exposure of the surgical team to radiation,[6-8] which is highly relevant, especially for high-volume deformity surgeons.

On the other hand, there are reports of higher overall doses, for the patient, of radiation with PIN *versus* PIF[7,9-12] which is a major concern especially in the surgery of paediatric deformities. Doody et al[13] reported that the incidence of breast cancer correlates with dose of radiation and is significantly higher in scoliosis patients than in the normal population.

However, the former reports which state higher doses of radiation in PIN compared with PIF[7,9-12] investigated mainly short segment fusions and enrolled patients with heterogenous indications for surgery, heterogenous surgical levels and heterogenous techniques including minimally invasive surgery (MIS) and standard open surgery, with and without interbody spacers. To the best of our knowledge, there is no data available comparing the dose of radiation of PIN *versus* PIF in instrumented posterior fusion of spinal deformities.

PIN can be performed by different techniques of image acquisition, among them intraoperative 3D scan (3DS) and preoperative CT scan (CTS). We do not know which technique allows for lower exposure to radiation; former investigations recorded radiation exposure in non-comparable units (mGy, mGy*cm, cGy*cm², mSv/pt, nSv/pt and others) and compared heterogenous groups of patients[11] which did not lead to sufficient data to compare dose of radiation after 3DS with that of CTS. Furthermore, there are no reports that compare these different techniques of image acquisition for navigation with regard to dose of radiation in surgery of spinal deformities. The complexity of the calculation of dose of radiation to compare 3DS and CTS may be one reason why there are no reports on this comparison:

For CTS the dose of radiation that results from the CTS has to be added to the dose of radiation that results from intraoperative fluoroscopic images by C-arm which are performed to control the position of the inserted screws and the result of the deformity correction. This addition is a complex calculation since radiation exposure of CT scans is recorded as dose-length-product (DLP, mGy*cm) and radiation exposure of fluoroscopy is recorded as dose-area-product (DAP, cGy*cm²).

For 3DS the DAP that results from the 3DS has to be added to the DAP that results from intraoperative fluoroscopic images by C-arm which are performed to control the position of the inserted screws and the result of the deformity correction.

Since the parameters DAP and DLP cannot be compared (cGy*cm² *versus* mGy*cm), they both have to be converted to the effective dose in mSv to allow for comparison of dose of radiation of 3DS with dose of radiation of CTS.

Radiation exposure and conversion factors from DAP or DLP to effective dose are hardware- and body mass index (BMI)-dependent. Therefore, conversion factors have to be adapted to the exposed region (thoracic or lumbar spine), as other investigators have described.[14,15]

There is no report that compares the overall dose of radiation (intra- and preoperative) for the patient by navigation with image acquisition by CTS to the dose of radiation of navigation by image acquisition with a 3DS in spinal deformity surgery.

In this study, we investigated which technique of navigation (image acquisition by CTS or image acquisition by 3DS) exposes adolescent patients undergoing surgical correction of idiopathic scoliosis to higher doses of radiation during the insertion of pedicle screws. Furthermore, we tested the hypothesis that PIN leads to lower doses of radiation for the patient than PIF in patients with idiopathic scoliosis.

Patients and methods

We conducted matched pair analysis of consecutive patients. Sample size was determined by a prior power analysis based on a former investigation;[6] 293 screws were analyzed.

Group A: prospective data collection

We prospectively collected data of ten consecutive patients with adolescent idiopathic scoliosis (AIS) that were operated on in a 12-month period by posterior stabilization with a pedicle screw rod construct and PIN with image acquisition by CTS of the relevant spinal segments (group A). Lenke type of scoliosis,[16] number of screws implanted, level of implantation of screw and time of operation were recorded.

Groups B and C: retrospective data collection

We retrospectively included ten consecutive matched patients who were operated on by PIN with image acquisition by 3DS (group B) and ten consecutive matched patients who were operated on by PIF (intraoperative fluoroscopy without navigation) (group C).

Matching procedure

After inclusion of the ten prospective CTS patients (group A), we identified all patients with AIS that were operated on by posterior stabilization with a pedicle screw rod construct in our institution by diagnostic code. Matching patients were allocated, backwards in order of date of surgery, to CTS patients. The first CTS patient that was operated on was matched with the latest patients (one 3DS and one PIF) of the retrospective database that showed identical Lenke type of scoliosis and fused segments. The matching process was conducted accordingly for the remaining nine CTS patients. Patients with incomplete sets of data, previous spinal surgery, BMI > 25 and spinal anomalies were excluded.

All patients operated on by CTS and 3DS were operated on by the first author (MRK), whilst the patients operated on by PIF were operated on by three different surgeons. All surgeons had at least eight years of experience in surgical correction of spinal deformity.

Imaging and technique of pedicle screw insertion: pre-operative CT (group A)

Preoperative CT scans were acquired with a Somatom Definition Flash CT-scanner (Siemens Healthineers, Forchheim, Germany). The scan range included the thoracic and lumbar spine. Scans were performed at a tube potential of either 100 kV_p or 120 kV_p.

Imaging and technique of pedicle screw insertion: navigation (group A and B)

For CTS and 3DS the same C-arm (Arcadis; Siemens Healthineers, Forchheim, Germany) was used in all cases for intraoperative fluoroscopy, which was exclusively applied to control the position of the pedicle screws and the correction of the deformity in CTS patients and additionally for 3D scan in 3DS patients.

The Navigation System 'Kick' (Brainlab, Munich, Germany) was applied in CTS and 3DS. Reference clamp for spinous process was applied and attached to the segment which was instrumented. Preparation of pedicle and insertion of pedicle screws was performed with navigation. In 3DS the operative team left the operating room during fluoroscopy acquisitions.

Imaging and technique of pedicle screw insertion: fluoroscopy (group C)

For PIF a different C-arm (a flat panel detector, Exposcop 8000; Ziehm Imaging, Nürnberg, Germany) was used. Fluoroscopy was exclusively applied for insertion of the pedicle screws and to control the correction of the deformity. Hence, the operative team did not leave the operating room during these fluoroscopic acquisitions. The pedicle screws were inserted similarly to the technique described by Kim et al.[17] Entry points were exposed and identified, then a cortical breach of approximately 5 mm depth was created. Subsequently, a slightly curved gear shift was used to probe the pedicle. It was pointed laterally at first. When the posterior border of the vertebral body should have been reached, according to the inserted length of the probe, it was taken out, the pedicle was palpated to exclude a soft-tissue breach, and reinserted pointing medially. An anteroposterior fluoroscopic control was then made to ensure correct positioning of the probe before it was inserted into the vertebral body. Following this, the entire created canal was palpated to exclude a soft-tissue breach. After screw insertion fluoroscopic control was performed in two planes (anteroposterior and lateral), three to four segments at the same time were checked.

Instrumentation: navigation (groups A and B)

The 3DS and CTS patients were operated on using the same technique. Caudally three to four segments were instrumented by pedicle screws, and the upper instrumented vertebra (UIV) and the vertebra below the UIP (UIV + 1) were instrumented by pedicle hooks. The other vertebra were instrumented by (lamina -) tapes.

Instrumentation: fluoroscopy (group C)

In PIF patients pedicle screws were used in all instrumented vertebra.

Monitoring of the dose of exposure to radiation and calculation of the effective dose

The doses of exposure to radiation were recorded automatically by the different devices (CT scanner or flat panel detectors) and were monitored for all patients.

For group A, the dose of exposure to radiation was recorded by adding the dose of exposure to radiation of the preoperative CT to that of the intraoperative fluoroscopy. The dose of exposure to radiation of group A was compared with the dose of exposure to radiation of groups B and C.

For this purpose, the overall dose of radiation (addition of pre- and intraoperative dose of radiation) that patients operated on by navigation were exposed to was converted to the effective dose (mSv).

3DS

No direct conversion factor was available for the system used in our study (Arcadis). In spite of similarities in the hardware, a direct application of the conversion factors used by Suzuki et al[14] was not possible, since the tube potential for their phantom acquisitions was considerably lower (72 kV_p to 79 kV_p, depending on phantom size). For each patient's image acquisition, the effective dose was calculated by multiplication of the examination's DAP with the thus determined BMI-specific conversion factor. The conversion factors are 0.19 $mSv/Gy{\cdot}cm^2$ for the thoracic spine and 0.21 $mSv/Gy{\cdot}cm^2$ for the lumbar spine.

PIF

Effective dose was calculated in the same technique as for 3DS.

Since a different C-arm (Exposcop 8000) (which might have led to different doses of radiation for comparable images) was used for PIF patients, we additionally compared time of fluoroscopy of these patients with time of fluoroscopy of 3DS patients to enhance the validity of the results.

CTS

For CT examinations, the International Commission on Radiological Protection (ICRP)103 conversion factors from DLP to effective dose for scans of thoracic and lumbar spine were taken from the recent publication by Huda et al.[18] The conversion factors are 0.0204 mSv/mGy·cm for the thoracic spine (chest region) and 0.0163 mSv/mGy·cm for the lumbar spine (abdominal region).

Effective dose of 3DS and CTS matched patients was compared.

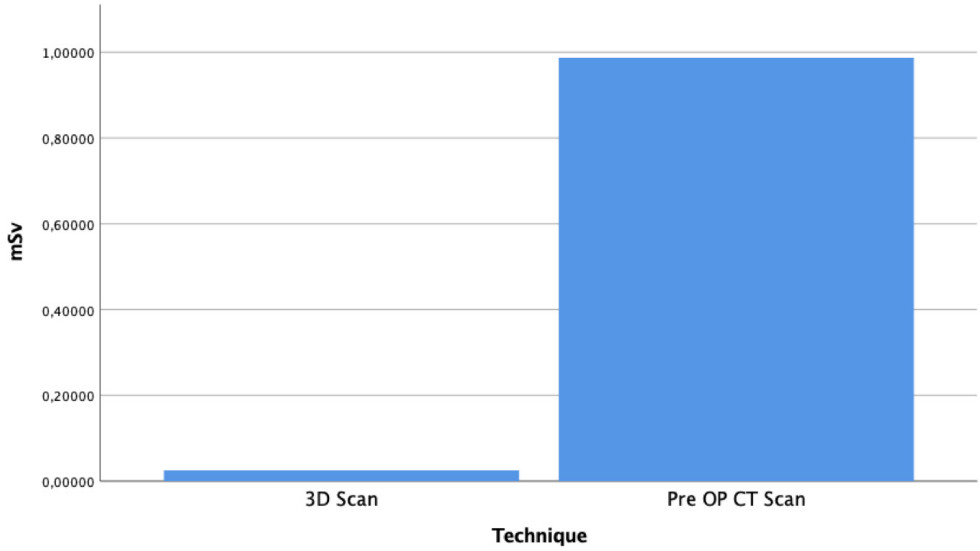

Fig. 1 Effective dose of radiation of pedicle screw insertion guided by navigation. Image acquisition by intraoperative 3D scan *versus* image acquisition by preoperative CT scan.

Statistical analysis

In a matched pair analysis, we investigated if PIN (3DS) was different in CTS, 3DS and PIF with regard to overall dose of exposure to radiation (for the patient). Since dose and time of exposure to radiation did not show normal distribution in a Kolmogorow-Smirnow test, we performed Mann-Whitney U Tests. We first determined which technique of navigation (3DS or CTS) led to the lowest dose of exposure to radiation per screw and then compared this technique with PIF.

Power analysis was performed by G-Power (Heinrich Heine University, Institute for industrial and cognitive psychology, Düsseldorf, Germany)[19,20] based on results of former reports.[6] To achieve a high statistical power (> 0.8) at least 80 screws per group were needed.

Since cancer induction and radiation induced hereditary effects are stochastic effects, there is no 'minimal clinically important difference'; we, therefore, reported the statistical power of our tests.

Statistical analysis was performed by SPSS 25 (IBM, Armonk, New York). Descriptive data are reported as mean and SEM.

Results

Patient cohort

The mean age of the CTS patients was 15.9 years (SEM 0.9) (group A); 16.0 years (SEM 1.6) for 3DS patients (group B); and 15.6 years (SEM 0.8) for PIF patients (group C).

Lenke type was 1A in three pairs, 1B in three pairs, 1C in one pair, 2A in one pair, 2B in one pair and 5C in one pair.

In CTS patients, 81 screws were inserted (8.1 screws per patient), 81 screws in 3DS patients (8.1 screws per patient) and 131 in PIF patients (13.1 screws per patient).

Dose of exposure to radiation

Mean dose of exposure to radiation per screw was 1.0 mSv (SEM 0.8) per screw in CTS patients; 0.025 mSv (SEM 0.001) per screw in 3DS patients; and 0.78.1 mSv (SEM 0.12) per screw in PIF patients (Fig. 1).

The difference between CTS and 3DS was significant ($p < 0.0001$) with a high statistical power (0.95).

The difference between 3DS and PIF was significant ($p < 0.001$) with a high statistical power (0.80).

Fluoroscopy time

Mean fluoroscopy time per screw was 15.0 seconds (SEM 0.8) in all patients; 13.5 seconds (SEM 0.3) per screw in 3DS patients; and 24.1 seconds (SEM 1.4) per screw in PIF patients (Fig. 2).

The difference between 3DS and PIF was significant ($p < 0.0001$) with a high statistical power (0.80).

Complications

In the PIF group three malpositioned screws had to be revised within one week of surgery, two due to neurological deficits and one due to radicular pain. No other

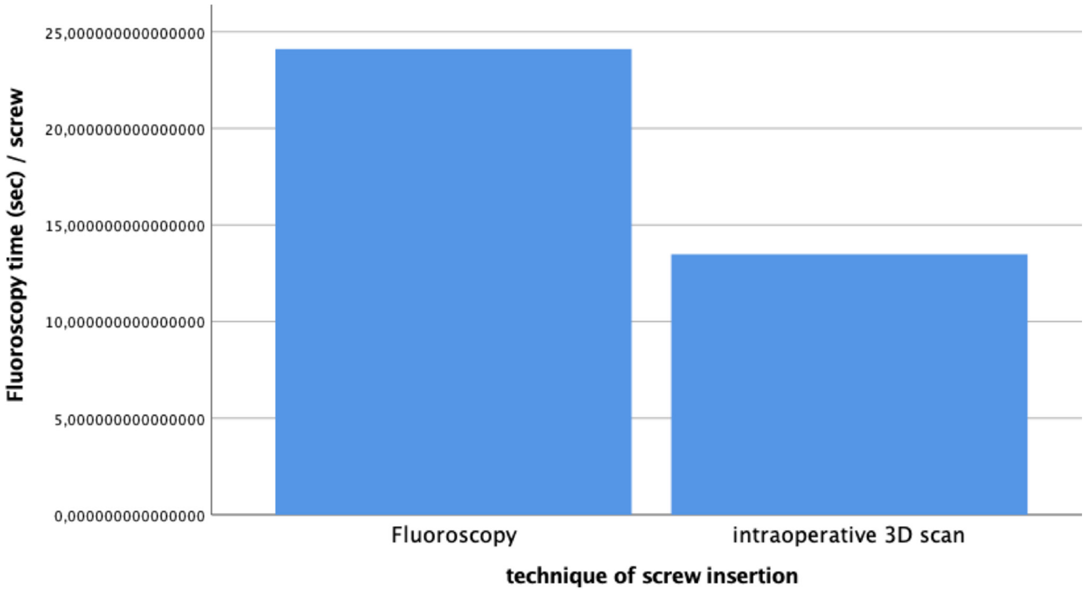

Fig. 2 Effective dose of radiation of pedicle screw insertion guided by fluoroscopy *versus* pedicle screw insertion guided by navigation and image acquisition by intraoperative 3D scan.

complications and no anomalies in the neuromonitoring occurred in all other patients of the three groups.

Discussion

Doody et al[13] showed that cumulative effective dose of standard radiographs, performed for diagnosis and follow-up of scoliosis, correlates with incidence of breast cancer in scoliosis patients. Since PIF and PIN lead to relevant and possible cancer inducing effective doses,[6,21] we should not only focus on the reduction of effective dose by optimizing technique and frequency of standard radiographs for diagnosis and follow-up of scoliosis, but on procedure-related effective dose too. We conducted this investigation to analyze which technique, PIF, 3DS or CTS, leads to the lowest effective dose for the patient. An alternative to PIF (the fluoroscopic technique) is the free hand technique, where the pedicles are felt by probes and ball-tipped guides without radiographic control. Radiation is only applied after the instrumentation to control the screw positions. Usually several levels are controlled simultaneously. This technique leads to a lower effective dose for the patient and for the surgical team than the fluoroscopic technique and also a lower effective dose for the patient than the navigated technique and, if the surgical team leaves the room for the control radiographs, the same reduction of effective dose for the surgical team.

However, Vaccaro et al[1] reported a breaching rate of 40% in the free hand technique. Insertion of PIF shows a breaching rate of 2% to 30% and insertion of PIN shows a breaching rate of 2% to 15%.[2-6] A breaching rate of 0% cannot be achieved by either technique.

Experienced and skilled surgeons might have a lower breaching rate in the free hand technique than less experienced surgeons in the navigated technique. However, statistically, according to available data, the navigated technique shows the lowest breaching rate.

Whether a lower breaching rate justifies a higher procedure-related effective dose cannot be determined. In our opinion it cannot be decided if a higher risk of postoperative pain, neurological deficits and possible revision surgery is 'outweighed' by the stochastical risk for cancer by a higher effective dose or vice versa. However, if PIF or PIN are applied, reduction of the procedure-related effective dose as much as possible is essential.

This investigation showed the lowest effective dose in 3DS. CTS showed a higher effective dose than 3DS and PIF.

There was a reduction of dose of exposure to radiation and fluoroscopy time by 56% (13.5 seconds navigation by 3DS *versus* 24.1 seconds without navigation) when navigation by 3DS was applied compared with the fluoroscopic technique.

There are reports of higher overall doses of radiation by PIN *versus* PIF[7,9-11] in heterogeneous groups of patients.

However, in a previous investigation,[6] we could show that in patients without deformity operated on using a MIS technique without interbody fusion, dose of exposure to radiation of patients was reduced by 41% and for surgeons by 81%.

This result can further be explained by the more difficult insertion of pedicle screws in deformed vertebrae compared with vertebrae without deformity. A former report states that rate of screw accuracy is significantly higher in PIN than in PIF in scoliosis surgery.[22] Depicting a pedicle in the correct plane by fluoroscopy is more challenging in patients with deformity than in patients without deformity and may take more fluoroscopy time.

This part of the study, the comparison of PIF with 3DS, has several possible biases. A different C-arm was used in the retrospective group of PIF patients, thus the comparison of dose of radiation of PIF with 3DS is of lower validity. Less modern image intensifiers might produce images of lesser quality which necessitates more than one image to clarify the position of the implant. However, the fluoroscopy time of 13.5 seconds per screw in 3DS patients *versus* 24.1 seconds per screw in PIF patients seems to indicate that the 3DS technique needed less radiation than the PIF technique.

Furthermore, the PIF patients were operated on by three different surgeons. This might have led to a bias. However, all three surgeons were experienced (at least eight years of experience in deformity surgery) and applied the same technique of pedicle screw insertion in the same institution. Additionally, in PIF all segments were instrumented by pedicle screws, whereas in 3DS and CTS, to reduce effective dose, hooks and tapes were applied for cranial segments, i.e. only one or two 3D scans had to be performed (3DS) or not all segments had to be included in the CTS. This is a possible bias since more challenging pedicles might have been instrumented in PIF than in 3DS and CTS. However, effective dose per screw in 3DS and CTS is the same for all types of pedicles since image acquisition does not dependent on form and shape of the instrumented pedicle, and thus this bias may not be crucial.

These possible biases may render the results of the comparison between the effective dose of PIF with 3DS less valid than the results of the comparison between 3DS and CTS, even if the analysis achieved a high statistical power. In spinal segments with a lower degree of deformity the difference in effective dose between PIF and 3DS might be lower than in spinal segments with a higher degree of deformity. However, the mean effective dose of all spinal segments of PIF was significantly higher than the mean effective dose in 3DS (which is not dependent on degree of deformity), with a high statistical power.

We also compared navigation by CTS with navigation by 3DS. Hecht et al[3] showed that there is no significant difference in accuracy of pedicle screw placement between CT-based navigation and 3D scan-based navigation, which is why we did not analyze accuracy of screw placement. CTS led to a 97.5% higher dose of exposure to radiation (1.0 mSv per screw in CTS *versus* 0.025 mSv per screw in 3DS) than 3DS. This might be due to the larger field of view in a CT scan compared with a 3DS and to the higher resolution of the CT scan compared with a 3DS. The 3D scan can be performed with a lower resolution than the CTS because the registration of the intraoperative images can be performed automatically (a reference clamp is placed before the 3D scan; after the scan the reference is already registered in relation to the images). The CTSs have to be registered intraoperatively by a matching process that requires a higher resolution.

The substantial advantage of CTS is that the CTS allows for meticulous preoperative planning, which is known to reduce the rate of wrong level surgery.[23] However, the results of this study suggest that a CTS before a surgical correction of a pediatric deformity should not be performed, especially since Miglioretti et al[21] showed that an effective dose of > 20 mSv was delivered in 6% to 14% of all spine CTs and that 270 to 800 spine CTs lead to one case of solid cancer.

For 3DS and CTS, the entirety of the operative team was not exposed to radiation since they could leave the operating room during fluoroscopic acquisitions. This seems even more valuable in the light of the report of Rampersaud et al[24] which states that spine surgeons are exposed to up to 12-fold higher dose rates of radiation than other non-spinal musculoskeletal surgeons.

With the fluoroscopic technique the surgical team could, theoretically, also leave the room for each fluoroscopic control, but it would be more often than in the 3DS technique. The plane of the fluoroscopic control often needs to be adjusted, in both planes, to gain acceptable visibility of the pedicle, so the surgeon may need to reenter the room more than once to guide the adjustment. This procedure (leaving and reentering the room) takes time and disturbs the flow of the surgery.

If the surgical team stayed in the room and stepped behind a lead panel, the surgical team must, according to the federal office for radiation protection, still wear lead due to scattered radiation, although eyes and hands would still be unprotected. Even if the resulting procedure-related effective dose to the surgical team would be very low, it would not be 0. The surgeon and the other members of the surgical team might choose to take this risk of exposing themselves to a minimal amount of scattered radiation.

Conclusion

When we compared different techniques of navigation, navigation by image acquisition with CTS of the levels to be instrumented showed a significantly higher (by 97.5%) dose of radiation per screw for the patient than navigation by image acquisition by a 3DS. Navigation by 3DS in posterior instrumented fusion of idiopathic scoliosis showed a significantly lower dose of radiation and fluoroscopy time (by > 50%) per screw for the adolescent patients than the fluoroscopic technique.

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COMPLIANCE WITH ETHICAL STANDARDS

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OA LICENCE TEXT

ETHICAL STATEMENT

Ethical approval: This study was approved by the local ethics committee (registry number 2018-316-RetroDEuA) and was conducted according to the revised declaration of Helsinki.

Informed consent: Informed consent was obtained from all individual prospectively included participants in the study.

ICMJE CONFLICT OF INTEREST STATEMENT

MRK reports personal fees from Globus Medical, outside the submitted work.

RK reports personal fees from Corin, Nuvasive and Medacta, outside the submitted work.

The other authors declare no conflict of interest relevant to this work.

AUTHOR CONTRIBUTIONS

MRK: Conception and design, Administrative support, Provision of study materials or patients, Data analysis and interpretation, Manuscript writing, Final approval of manuscript.

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AS: Manuscript writing, Final approval of manuscript.

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