

Technical aspects of surgical correction of spinal deformities in cerebral palsy

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Abstract

Purpose Cerebral palsy (CP) is a disorder arising from a non-progressive lesion in the developing immature brain with an encephalopathy, that results in various levels of motor and sensory dysfunction. Motor disability of these children can be assessed by the Gross Motor Function Classification System in five levels, and depending on their motor functional capability, the most severely affected children fall into levels IV and V. Children in groups IV and V present a full spectrum of musculoskeletal deformities, among which, scoliosis is the most frequently found spinal deformity that most often requires surgical treatment. However, these are procedures that are usually technically demanding, requiring experienced surgical teams and a multidisciplinary approach.

Methods In order to overcome some of the technical pitfalls that may complicate these complex surgical procedures, the authors have gathered together different tips and tricks that may help surgeons performing surgical correction of spinal deformities in CP children.

Conclusion Although for these children surgery is a major undertaking, with the multidisciplinary approach and advances of technology, anaesthesia and optimization of pre- and postoperative care, complications are manageable in most cases, improving not only the outcome of surgery but also the patient's quality of life and satisfaction of parents and caretakers.

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Introduction

Cerebral palsy (CP) is a disorder arising from a nonprogressive lesion in the developing immature brain. It is a static encephalopathy, that results in various levels of dysfunction in motor, sensory, autonomic and central cerebral processes. This process of encephalopathy can be due to different causes and may happen in the pre-natal, natal or post-natal phases of the development of a child. Motor disability of these children can be assessed by the Gross Motor Function Classification System (GMFCS) in five levels depending on their motor functional capability; the most severely affected children fall into levels IV and V. Children in groups IV and V present a full spectrum of musculoskeletal deformities, bony and soft tissue, such as shoulder internal rotation contractures, scoliosis, hip dysplasia, knee and foot deformities as well as many other contractures in multiple extremity segments due to the increased muscle tone. Although the primary condition is in the central nervous system, most of the orthopaedic treatment is focused on preventing or decreasing secondary changes that develop later, through childhood and adolescence.

Scoliosis is the most frequently found spinal deformity in CP and is common in those more severely affected patients, being directly related to the degree of neurological deficit/compromise (approximately 50% incidence in GMFCS grade IV and V). It usually starts between the ages of three to ten years and progresses during adolescent growth. If not treated the deformity becomes guite severe by the end of growth causing different problems, not only postural like difficulties seating, but also more structural problems impacting on pulmonary or gastrointestinal function as well as being the source of discomfort and pain due to pelvic-rib impingement with poor sitting tolerance. In addition to scoliosis some patients develop a significant kyphosis or hyperlordosis that can also create problems with the seating posture, aggravated by the poor muscle head control that these children present and overall decrease in quality of life.

Lonstein and Akbarnia¹ described the two more common types of scoliotic curves in CP patients. Type 1 are single or double major curves, thoracic or lumbar with a levelled pelvis and a balanced spine, usually found in ambulatory children (GMFCS grade II and II). Type 2 are the long lumbar or thoracolumbar C-shaped curves with pelvic obliquity (PO) and an unbalanced spine, commonly found in the more severely affected children (GMFCS grade IV and V). In the sagittal plane hyperlordosis of the lumbar spine and kyphoscoliosis of the thoracic spine are also commonly associated to these two types of deformities in the coronal plane of these children.²

Although nonoperative treatment may be helpful temporarily in some of these children, like those under the age of eight years, it usually has a very limited role in decreasing curve progression in CP.^{3,4} One exception may be those adolescent ambulatory patients with spastic diplegia who develop the idiopathic type of curve (type 1), where bracing may be useful to stop curve aggravation. Despite these few cases where conservative treatment may be indicated, surgery is the only definitive treatment to halt progression of spinal deformities in CP. However, spine surgery in these very disabled children is a risky procedure and there has been controversy on the benefits of these operations as well as no clear data showing the impact on the life expectancy from increasing severity of scoliosis.⁵⁻⁸

The increased risk of surgical complications in these complex patients make decisions regarding treatment challenging. However, with advances in technology, a careful preoperative optimization and postoperative care, surgery does offer a significant improvement in their quality of life.⁹

More recently, in a paper by Jain et al¹⁰ comparing treated and untreated scoliosis patients' qualitative and quantitative health-related quality of life assessments, caregivers reported overall improvement patients' lives after spinal fusion and it was ranked by them as the most beneficial intervention in these children's lives, secondary only to gastrotomy tube insertion.

This article was conceived by the neuromuscular and spine study groups of the European Paediatric Orthopaedic Society (EPOS) based on the presentations of the authors given at the society's 37th annual meeting in Tel Aviv, Israel (5 April 2019) in a two-hour focus session on CP and associated spine deformities. Based on an additional literature review (PubMed, Cochrane) and two decades of surgical experience and functional analysis in the field of neuromuscular spine deformities during growth, the authors highlight the current anatomical and biomechanical understanding, its practical implications for the clinical and radiographic assessment and the surgical strategy when it comes to the decision whether or not to include the pelvis in the fusion.

Indication for surgery and types of procedures

Like in many other pathologies in the spine, the aims of surgical correction in patients with CP include achieving

a balanced spine (standing or sitting), halt curve progression and improve functional quality of life of these boys or girls. However, CP patients are usually complex due to several co-morbidities present that increase the risk for surgery. For this reason, when considering patients as candidates for spinal fusion, we must take into account not only the age of the boy/girl, their medical condition, scoliosis magnitude and flexibility but the desires of families and caretakers knowing that the main objective of surgery is to improve their quality of life. Due to this context, multidisciplinary expert assessment is required for managing these challenging conditions and decision making.

As the CP child with scoliosis grows into adolescence, the magnitude of spinal deformity tends to deteriorate rapidly, becomes more rigid and Pelvic Obliquity (PO) develops once the curve magnitude goes beyond 50°. Those more severely affected, GMFCS grade IV and V, very often achieve curve magnitude of 60° to 90° with significant PO and an unbalanced spine before the end of growth.³⁻¹²

As shown by Thometz and Simon,¹³ curves > 40° tended to progress even after skeletal maturity (1.4° per year), and in particular nonambulators, quadriplegic and thoracolumbar or lumbar curves had the worse prognosis.

For these reasons, early teenagers with CP reaching curves of 40° of Cobb angle should be considered for spinal fusion because waiting will only allow deterioration of the overall patient's condition and make the surgical procedure more aggressive, complex and risky.¹⁴⁻¹⁶

At present most of the surgical procedures to correct these deformities can be done from the posterior approach with several advantages related to the operation and better quality of life as has been shown recently by Jackson et al.¹⁷

Pre-operative spinal assessment

In order to draw the operative plan, curve flexibility must be assessed in both planes (coronal and sagittal). On clinical grounds curve flexibility in the coronal plane can be assessed by the Miller's side bending test (bending test over your knees), which gives you immediately an idea on how stiff the curve is.

The PO can also be assessed clinically to determine if the cause is from the hips or the spine, if it is an intrapelvic, suprapelvic or is of mixed cause. The technique used to determine the cause of PO is to have the patient lie prone with the legs hanging free off the end of the examining couch. Relaxing the hip adductor and abductor muscles with this manoeuvre removes the infrapelvic causes of PO and if the PO does not resolve, then the remaining PO may be from the spinal deformity itself (suprapelvic).¹⁸

However, in order to document and measure the degree of flexibility, you need to take radiographs, performing a

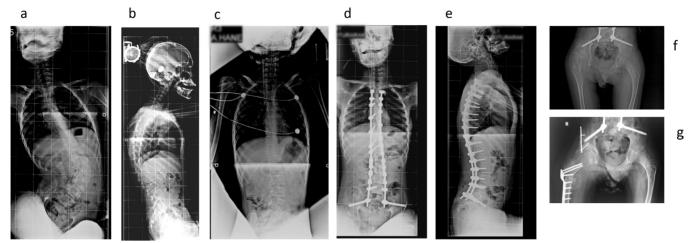


Fig. 1 A 14-year-old male patient with Gross Motor Function Classification System level IV cerebral palsy. He was evaluated for severe spinal deformity and right hip dislocation (**a**, **b**). In the traction film under general anaesthesia (TRUGA), the deformity improved by more than 50% and the pelvis paralleled (**c**). First, posterior instrumentation and fusion combined with multilevel posterior column osteotomies were performed (**d**, **e**). At second stage, femoral shortening varus osteotomy and Pemberton acetabuloplasty were performed for hip dislocation. Six months after hip surgery, both the spine and hip were uneventful (**f**, **g**).

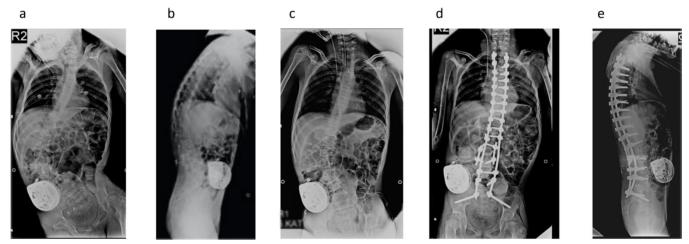


Fig. 2 A 17-year-old male patient with a diagnosis of total body involved spastic cerebral palsy had undergone Intra Thecal Baclofen pump. As deformity progressed, surgical intervention was planned **(a, b)**. Deformity was rigid, and pelvic obliquity could not be reduced to less than 15° on TRUGA radiograph **(c)**. During the posterior instrumentation and fusion, pedicle subtraction osteotomy was performed at L3 level **(d, e)**.

bending film or a traction film in one or in both planes either with the patient awake or under anaesthesia. Both these types of exams are very operator dependent and rely a great deal on the patient's cooperation. For this reason, in patients with CP and scoliosis we prefer to perform the traction films under general anaesthesia (Fig. 1 a–g), prior to the surgical procedure and this way we can better assess not only the curve flexibility but also the degree of PO correction as has been shown by Bekmez et al.¹⁹

Deformities in the sagittal plane should be assessed with radiographs in the lateral position, which sometimes may not be easy. For kyphosis a supine lateral view should be taken with a bolster positioned at the apex of the deformity and for lordosis, the radiograph should be taken with one hip hyperflexed to minimize the lordosis effect.

With this information you should be able to plan your strategy for the operative procedure. You may consider doing it all from the back, posteriorly, and also what type of releases and osteotomies you may require to achieve the best correction, keeping in mind that spine surgery in CP children is not a cosmetic operation. However, in face of a very stiff curve you will have other alternatives that you have to consider; either doing an anterior release before the posterior instrumentation and fusion or doing





Fig. 3 Halo-femoral traction with the head prepared for draping.

a posterior vertebral column resection (PVCR) or other posterior column osteotomies (PCO) and instrumenting all from the back (Fig. 2 a–e).

However, in the presence of a very rigid curve, you may consider using intraoperative traction either using halo-femoral or a distraction rod technique. For the halo femoral traction at the proximal end you will use one of several alternatives to the Mayfield device (MAYFIELD[®] Skull Clamps, Integra LifeSciences, Plainsboro Center, New Jersey), Gardner-Wells tongs (Codman/Symmetry/ Gardner-Wells Traction Tongs from A-Z Orho, Millenium Surgical Instruments, Narberth, Pennsylvania) or halo (Halo traction Device from MediVisuals, Richmond, Virgina) (Fig. 3).

At the distal end you may use a femoral supracondylar Schantz pin on the side of the curve concavity where the iliac is raised (PO > 15°),²⁰ skin traction if you know that the traction applied is not heavy, but if the pelvis is levelled than you may have to use bilateral skin traction not to create undue PO. If you have decided to use an intraoperative distraction rod technique you have to remember that these patients are osteoporotic and, therefore, you need to build a cluster with two or three pedicle screws on the concave side where you will be distracting and by doing so, you will prevent loosening or dislocation of the pedicle screw(s) (Fig. 4). Throughout the procedure, as you perform the posterior releases, you will repeat distraction under the spinal cord monitoring.

With the development of new generations of pedicle screws and different reduction tools and techniques, contemporary instrumentation constructs have challenged the requirement for an anterior approach and whenever possible, stopping the instrumented fusion at L5. Modi et al²¹ have shown that use of posterior-only pedicle screw constructs offers excellent curve correction with a minimal complication rate when compared with the anterior–posterior approaches.¹⁷

So when you enter the operating room prepared to do the traction film you will have to have a plan A and plan B for the procedure, taking into account that not only surgical tools and instrumentations are different but also blood loss and length of the procedure can be quite distinct.

Surgical plan

When you consider instrumented fusion in these children, you must screen all the basic 'safety' principles before embarking on an open major procedure. The multidisciplinary team approach will help you in this task, but from a surgeon's point of view although you have to be concerned with the patient as a whole, you should also focus on the soft-tissue condition over the spine you are going to operate on. You must assess the skin and the underlying muscular layers to see if they are in a good state to cover and protect your instrumentation and if not, how you can optimize this condition. You must remember that there is no skin that will resist prominent screws or rods, mainly at the proximal or distal end of the instrumentation. On the other hand, you must choose the most appropriate instrumentation devices, low profile pedicle screws (poliaxial

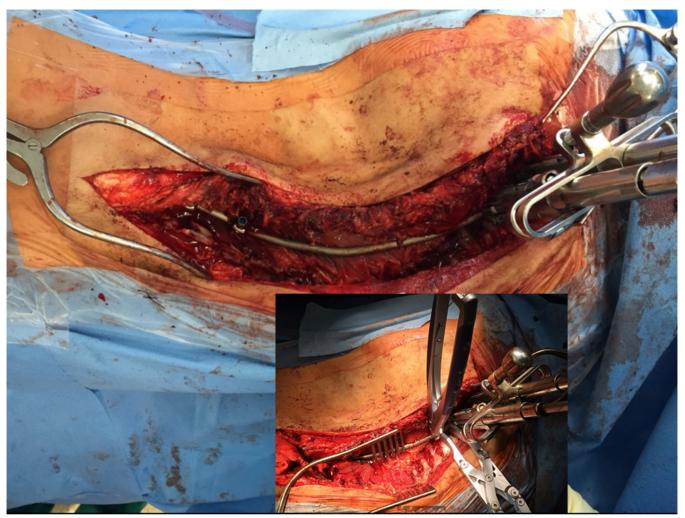


Fig. 4 Distraction rod technique; a cluster with two pedicular screws at the proximal end of the rod.

and monoaxial), sublaminar bands or wires and rods (the use of cobalt-chromium (CoCr) rods increases the correction force) strong enough to resist the lever arm biomechanics of these long instrumentations with poor muscle support.

CP curves (in particular type II) are usually large and extremely rotated. Traditionally, the use of sublaminar wires was recommended although with a limited amount of derotation. However, in osteoporotic spines with a significant degree of rotation, the wires can easily cut out through the laminae. In recent years, the use of sublaminar bands has been an extremely useful device to improve translation, to reduce the incidence of cut out and has become common practice, either alone or in combination with other techniques of segmental fixation (hybrid techniques). Translation can also be performed using reduction screws but beware with the osteoporotic bone. The use of uniplanar screws on the convex side and the direct vertebral rotation manoeuvre will, with the help of these screws, enable effective correction of both rotation and translation upon a good posterior release with large facectomies that are an essential step of the release.

Restoration of the lumbar lordosis is a very relevant target in the surgical plan when correcting these spinal deformities. It is important not only for balancing walking pattern for those that are able to ambulate but also for the sitting balance for the ones who are wheelchair bound. Restoring the best lumbar lordosis for each patient can be achieved by wide facectomies and contouring the rods appropriately with or without the need for PCOs.

Tsirikos et al²² have shown that surgery for these children can not only improve the spinal deformity (68%) but also of the PO (72%) in these complex deformities.

Upper instrumented vertebra (UIV)

As we know upper fixation should extend proximally at least to T3 due to the fact that these children have a very

poor muscular control, poor head control and the deformity is very often kyphotic in the thoracic spine.²³⁻²⁵ This way we may be able to prevent the higher rate of fixation loss (as in the case of sublaminar wiring) or junctional kyphosis^{26,27} that happens at the cephalad end of the instrumentation in these patients (30% to 62%).

For this reason, for thoracic kyphosis T5-T12 where you have to instrument above T3, you should consider other alternative instrumentations like pedicle screws or a hybrid type of construct with hooks or bands.

In order to prevent this proximal junctional kyphosis from happening, care must be taken not to damage the soft tissues at this junctional region and not to correct fully the local cervico-thoracic kyphosis.

For those ambulatory children with Type 1 scoliosis, instrumentation of the UIV should follow the general principles applied for the idiopathic cases.

Lower instrumented vertebra (LIV)

In ambulatory CP patients without PO, there is no indication to extend instrumentation to the pelvis. In these children a mobile lumbosacral junction will help in the sitting and transfer activities and is believed to be essential to adapt angular and rotational movements of the trunk during gait, taking into account that patients require the mobility of the lumbosacral junction to power gait. In these patients, and in a few nonambulatory cases with little or no pelvic tilt (< 15°) and mild spasticity, stopping the arthrodesis at L4-L5 may be the option.²⁸

For the nonambulatory children with significant spasticity, even with mild pelvic tilt, stopping at L4-L5 is a risk due to the recurrence and progression of PO.²⁹

For cases where the apex of the lumbar curve is below L3 and with a pelvic tilt > 15°, fusion should not be stopped at the lower lumbar spine but should be extended to the pelvis in order to achieve a stable balanced sitting posture.

For the ambulatory CP children with type 1 scoliosis, instrumentation of the LIV should follow the standard rules for the idiopathic cases, although these are not suitable for selective fusions. For these reasons, many CP boys and girls with scoliosis can be dealt with in a similar way to adolescent idiopathic scoliosis.³⁰

However, we must be aware that stopping at the lower lumbar spine has multiple advantages; higher fusion rate, lower blood loss, lower infection rate, less implant prominence, shorter procedure in time³¹ and overall is a less aggressive operation.

Fusion to the pelvis

Decision to fuse to the pelvis relies on the patient's ambulatory status and on the degree of PO present. As a general rule extending the fusion to the pelvis should be kept for the nonambulatory children, or the ones with a severe pelvic tilt (> 15°) and these are usually the more severely affected GMFCS IV and V.

However, pelvic fixation is technically challenging in the CP population due to osteopenia that is commonly found and also due to the technical difficulty in getting an appropriate construct for this prominent lumbosacral area with poor soft-tissue cover.

There are several alternatives that you may consider and S1 bicortical screws with S2 Alar-Iliac screws are a good choice. Apart from the screw heads being in the alignment of the two rods, they are well embedded in the wound below the level of the iliac crest and providing a strong fixation (going through three cortices) and occasionally we may have to use double iliac screw fixation either above or below this S2 screw. However, reduction manoeuvres should not be done using these fixation points but with other techniques like supplementary provisional iliac screws and pedicular screws further up in the other end of lumbar or thoracolumbar concavity and an intraoperative distraction rod. For the ones that are not rigid, intraoperative halo-femoral traction (either with the halo, Gardner-Wells tongues or with a Mayfield device) together with a thorough posterior release may suffice the objectives.^{32,33}

For the rigid curves with significant unreducible pelvic tilt, asymmetrical pedicle subtraction osteotomies at the apex of the curvature and joining the two instrumentations with side connectors, the shorter instrumentation usually L4-L5-S1 pelvis and longer construct thoracolumbar, will be another possibility that you may consider.

Although the Luque Galveston Unit rods (*Medtronic* Sofamor-Danek, Memphis, Tennessee) were a very useful tool and a unique device of innovation when they came out, but they are bulky and difficult to match the deep seated L4 and L5 in such a hyperlordotic abnormal thin pelvis.

Another concern at the end of the fusion extending to the pelvis is that pelvis is parallel and well balanced with the spine. As the image intensifier only gives an image of a very restricted area, we do an anteroposterior radiograph on the table to assess the alignment or you may use a sterile T-shaped tool that is placed over the dome of the sacrum. The long arm of this tool should point out to T1, giving you a better view of the alignment achieved (or if it needs more correction).

Although for these cases extending the fusion to the pelvis is the best choice to offer a stable well-balanced sitting posture, we must remember that it is more demanding in terms of technical skills, with increased blood loss, higher pseudarthrosis rate, higher rate of skin breakdown, longer procedure time wise and is overall a more aggressive surgical operation.

Despite all these drawbacks, spine fusion extending to the pelvis provides an excellent deformity correction and



preserves ambulatory function in these patients as shown by Tsirikos et al.³⁴

How to release a stiff rigid curve

In the past, anterior release was part of the strategy to loosen very stiff severe scoliotic curves. However, either in one or in two stages these were very aggressive procedures with a high complication rate, in particular in these weak complex neuromuscular patients. With the advance of the new generations of pedicular screws, spinal cord monitoring and a more widespread use of spinal osteotomies, the indication for anterior release have been decreasing worldwide. Posterior releases and different types of osteotomies,^{35,36} all performed from the posterior approach, have been shown to suffice in reducing very stiff curvatures even in CP patients.^{20,37} However, this posterior release can be optimized by releasing the main apical convexity through the same posterior approach.³⁸ Upon performing Ponte osteotomies at the levels requiring anterior release, the apical intervertebral discs (IVD) are approached from the convex side of the main curve. The lateral annulus on the convex side are then exposed through blunt dissection until the anterior longitudinal ligament (ALL) is reached while 'detaching' and protecting the pleura from the lateral side of the spinal column. This may be somehow difficult due to the drooping of the posterior rib segment and, therefore, the transverse process infra-adjacent to the disc and associated rib head and neck may need resecting. Annulotomies are then performed from the level of base of the pedicle to the anterior aspect of the vertebral bodies, releasing the ALL and the IVD to the end plate (and bone graft added if needed). However, do not forget that by performing this particular step of the procedure you may increase the complication rate, by causing a pneumothorax or a haemothorax on this ipsilateral side of the chest.

In extremely severe and stiff curves, PVCR is also an option that gives good results but with a high risk of major complications, as was shown by Sponseller et al³⁹ in his series of 23 children with neuromuscular scoliosis.

Bekmez et al¹⁹ in 2018 established a protocol based on the correction of the curve with traction films under general anaesthetic. If the pelvis was levelled and there was correction of the deformity > 50%, a Schwab type 1 osteotomy (partial facectomies) was performed,⁴⁰ but if the residual PO is > 15°, then an apical pedicle subtraction (Schwab type 3) osteotomy would be a better choice.

Currently, an adequate posterior release together with excision of the disc and ligaments at the concave/convex apex with posterolateral approach, use of intraoperative traction, single (apical Pedicle Subtraction Osteotomy (PSO)) or multiple level PCOs, combination of poliaxial, monoaxial or reduction screws and sublaminar bands at all levels, CoCr rod preference, has improved significantly the release of these very stiff curves and helped to achieve a balanced spine in these rigid deformities. Remember that many of these children are on antiepileptic medication that induces and aggravates osteoporosis in particular in nonambulatory patients⁴¹ and the more porotic the bone, the better it is to use multipoint fixation either with pedicle screws alone or with a hybrid technique.

Spinal cord monitoring

Among the different types of scoliosis undergoing surgery, congenital and neuromuscular cases have the highest rate of neurologic complications^{42,43} and, therefore, spinal cord monitoring should be used whenever possible as it is considered a standard of care in paediatric spine surgery.

However, as approximately 30% of CP children have a seizure disorder under treatment,⁴⁴ the use of transcranial electrical motor evoked potentials (TcMEPs) during surgery may be a relative contraindication.^{45,46} In these cases, the alternative is to monitor only the somatosensory evoked potential (SSEP) but in approximately 25% of the more severely affected patients not even SSEPs can be monitored at baseline.⁴⁷ These facts show how challenging it can be to obtain reliable baseline potentials to monitor many of our complex spine procedures in these children.

When using TcMEPs, even at reduced intensity stimulus, interpreting changes for alert criteria cannot be based only on the significant reduction (> 80%) of curve amplitude, but the criteria should also include changes in morphology, paradigm and stimulus as pointed out by Nagarajan et al.⁴⁸

Although sometimes difficult, even for GMFCS levels IV and V, the literature shows that the majority of these children can be monitored⁴⁹ and if there is some neurological function to be preserved, either in the form of sphincter continence, movement or protective sensation, we should use all tools available in order to preserve it during surgery (Fig. 5).

Positioning on the operating table

Positioning a CP patient with a spinal deformity on the operating table is not an easy task, because apart from the need to have the abdomen free of compression, these children are usually very thin, with several bony prominences, difficult to align adequately on the frame due to the associated proximal/distal secondary vertebral curves, pelvic tilt and lower limb soft-tissue contractures.

CP children more severely affected (GMFSC IV and V) usually present with their heads slightly anteverted. Due to this reason, when positioning the patient on the table





Fig. 5 Anal sphincter monitoring.

and also when correcting the main curve sagittal profile, this fact should be taken into account. This proximal cervico-thoracic kyphosis should be preserved and you should leave the upper thoracic spine more kyphotic than usual, otherwise the risk of proximal junctional kyphosis increases.

A Jackson operating table (SOMA Technology Inc. from MIZUHO OSI, Union City, California) is an excellent tool for operating on these patients, in particular for those with severe hip and knee contractures. However, due to their body shape and body mass index, it requires extra padding, especially in the iliac crests. The surgeon must check the head and all bony prominences at the beginning and even during surgery, to make sure these highrisk areas are well protected against pressure sores during the surgical procedures while the child is under the surgical sterile drapes. Positioning a patient with hip flexion contractures is an issue, in particular if you have to place these children on traction. This has to be addressed adequately so as not to create undue pelvic anteversion with aggravation of the hyperlordosis, in particular if you do not use an appropriate spine frame on the operating table. Very often parents and caretakers should be warned that these children may require surgery for correction of this deformity at some stage after the spinal surgical procedure.

Complications

The rate of complications for scoliosis surgery in CP patients varies a great deal from 20% to 75%^{20,50} as a result of the diversity of comorbidities that these children with GMFCS types IV and V have. Although pulmonary compli-



cations are the most common, the incidence of postoperative infection is also high (up to 20%)^{51,52} and related to many factors. Total blood loss and the length of the operative procedure have been identified as significant.⁵³⁻⁵⁶ Shrader et al⁵⁷ have also shown that a two-surgeon team approach in surgeries correcting large spine deformities in such patients may lead to a decrease in operative time, hospital length of stay, blood loss and complication rate.

CP patients, like other neuromuscular patients, bleed more than their idiopathic counterparts with scoliosis. Anti-fibrinolytcs agents, in particular tranexamic acid, significantly reduces the intraoperative estimated blood loss associated with posterior spinal fusion with no adverse effects.⁵⁸

Conclusion

Scoliosis in CP children is a common condition that often requires surgical treatment in particular in the more severely affected (GMFCS levels IV and V). Although for these children surgery is a major undertaking, with the multidisciplinary approach and advances of technology, anaesthesia and optimization of pre- and postoperative care, complications are manageable in most cases, improving not only the outcome of surgery but also the patient's quality of life and satisfaction of parents and caretakers.

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JM reports no conflict of interest.

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AUTHOR CONTRIBUTIONS

Both authors have been involved in all aspects of the writing and completion of the manuscript and have read and approved the final version for submission.

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