Bipolar Fusionless Versus Standard Fusion Surgery in Neuromuscular Scoliosis

A Two-center Comparative Study

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Study Design: Nonrandomized controlled cohort.

Objective: To compare early results between bipolar fusionless construct (BFC) and single posterior fusion (SPF) surgery in neuromuscular scoliosis (NMS).

Background: Surgical treatments for NMS have traditionally been characterized by high complication rates. A mini-invasive BFC was developed to reduce these risks while maintaining adequate curve reduction. There is, however, a current lack of studies comparing clinical and radiologic perioperative outcomes between both techniques.

Methods: All patients surgically treated for NMS with to-pelvis construct between 2011 and 2021 at 2 centers were included and divided into 2 groups according to the surgical technique (BFC or SPF). Gender, age, main deformity region, etiology, preoperative and postoperative main curve magnitude and pelvic obliquity, surgery time, estimated blood loss and transfusion rates, length of hospital stay, the magnitude of main curve and pelvic obliquity correction, and early complications were compared. Quantitative data were compared through ANOVA or Mann-Whitney test. Analysis of qualitative outcomes was performed through Fisher exact test and logistic regressions. Kruskal-Wallis test was used to compare complications between groups.

Results: Eighty-nine NMS patients were included: 48 in the SPF group and 41 in the BFC group. Surgery time (203 vs. 241 min), rate (32 vs. 52%) and severity of complications, unplanned returns to the operating room (15 vs. 39%), estimated blood loss (179 vs. 364 cc), and transfusion rates (27 vs. 73%) were lower in the BFC group ($P<0.05$). There were no significant differences in age, maturity stage, preoperative curve magnitude, preoperative pelvic obliquity and postoperative curve, and pelvic obliquity correction between groups.

Conclusions: BFC may be a safer and less invasive option for NMS surgical treatment, resulting in similar curve corrections while significantly decreasing the number and severity of complications as well as intraoperative blood loss when compared with SPF.

Level of evidence: Level —lll.

Key Words: neuromuscular scoliosis, posterior fusion, bipolar, fusionless, complications, surgery, correction, blood loss

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Neuromuscular scoliosis (NMS) describes a non-congenital spinal deformity on the frontal, sagittal, and transverse planes occurring in patients with an underlying neuromuscular disorder, including but not limited to cerebral palsy, spinal muscular atrophy, and muscular dystrophy.[1,2] The progressing nature of the pathology makes surgical intervention unavoidable in most cases, with single posterior spinal fusion (SPF) being the most common indication.[3]

Pelvic fixation and extensive fusion are often needed for adequate stability and correction of NMS,[4–6] which greatly heighten the risk of major blood loss[7] and surgical site infection.[8,9]

Furthermore, contrary to adolescent idiopathic scoliosis, NMS progresses sooner and faster, resulting in a lower mean age at the time of apex surgery,[10] restricting thoracic and pulmonary development if the surgical fusion of the thoracic spine occurs, further worsening respiratory function in a particularly vulnerable group of patients.[11,12]

Postoperative complication rates are known to be high in NMS surgery, from 4 to 27%.[13,14] However, the exact rate of complications is difficult to assess due to various systems and the accuracy of complication reports.

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Therefore, it seems better to perform comparative studies using an objective scale for complication severity.

Some less invasive constructs exist for NMS treatment to decrease complication rates while maintaining adequate curve correction.[10,15,16] Among them, a 4-rod bipolar fusionless construct (BFC), which was strongly fixed to the upper thoracic spine and to the pelvis, made it possible to avoid final fusion and presented a low rate of mechanical complications (14%) even after 5 years of follow-up.[10,17] There is, however, a current lack of studies comparing clinical and radiologic perioperative outcomes between this technique and SPF for NMS.

The aim of this study is to compare perioperative clinical and radiologic parameters between BFC and SPF of patients treated for NMS at 2 different institutions.

MATERIALS AND METHODS

Patients Selection

All patients surgically treated for NMS with to-pelvis construct from 2011 up to 2021 at 2 different centers, Pediatric Orthopedic Unit, Lenval Hospital, Nice (Fr) (institution 1) and Spine Surgery Unit,University Hospital "Pellegri", Bordeaux,(Fr) (institution 2), were included in this study. Both institutions performed both techniques. The cohort of BFC was prospectively recruited, including learning curve cases too, whereas the control group (SPF) was retrospectively analyzed from medical records.

We recorded gender, age at peak surgery, main deformity region, etiology, preoperative and postoperative main curve magnitude and pelvic obliquity, surgery time, estimated blood loss and transfusion rates, length of hospital stay, the magnitude of main curve and pelvic obliquity correction at last follow-up (minimum 1 y), and any complication that occurred during the first 3 months.

Operative Technique

All surgeries were performed in a prone position with cell saver by orthopedic surgeons with more than 5 years of deformity spine surgery experience. No preoperative halo-traction was used. The operative procedure was carried out following one of the 2 following techniques:

SPF Technique

A standard posterior approach was performed from the upper thoracic spine to the sacrum. Inferior articular facets were resected at all levels. Polyaxial pedicular screws were placed bilaterally at all levels, if possible, with some pedicle-transversal or pedicle-supralaminar claws at upper thoracic levels. Pelvic fixation was achieved by the insertion of 6.5 mm screws into S1 and 6.5 or 7.5 screws into the iliac crest. Two pre-contoured 5.5 or 6 mm titanium rods were connected to the screws using standard connectors (PASS LP, Medicrea Int., Lyon, France). Correction of the deformity was achieved by rod orientation and tightening the nuts into the connectors, according to simultaneous translation on 2 rods or cantilever correction (Fig. 1).[18] Before final tightening, compression or distraction at the lumbo-sacral level was achieved using an L-shaped jaw. A subcutaneous Redon drain was placed for 2 up to 4 days.

BFC Technique

Two types of constructs were used for BFC, either the original technique described by Miladi et al (Fig. 2) with E.Spine implants (Euros, La Ciotat, Fr)[10] or a modified construct with PASS LP implants (Medicrea Int, Lyon, Fr), applying the same principles of bipolar stable fixation (Fig. 3). In both cases, 2 median posterior

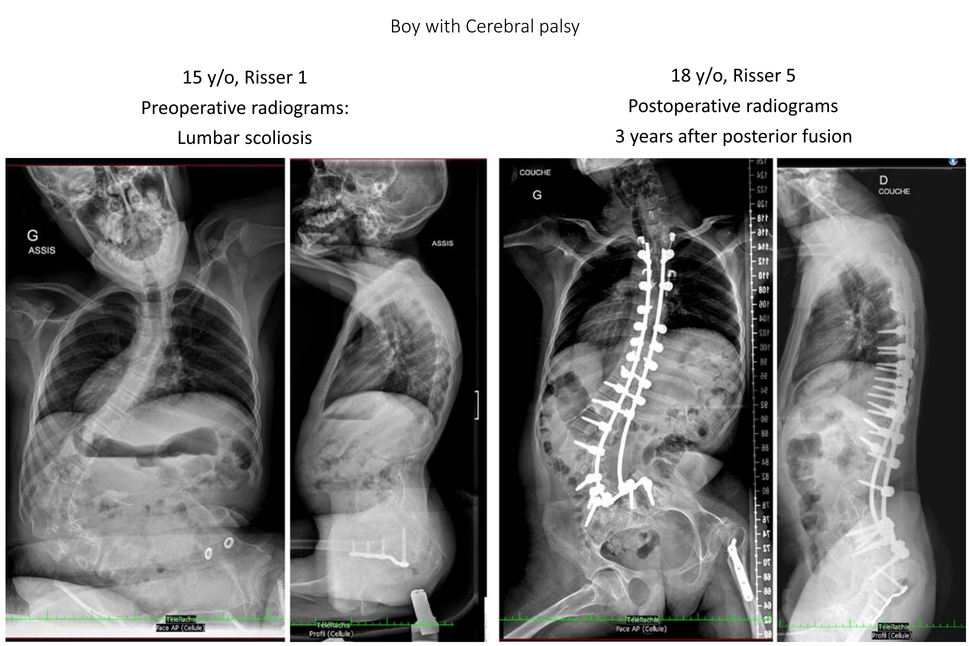

FIGURE 1. Example of posterior fusion. full color online

incisions were made from T2 or T1 to T7 and from L5 or L4 to S1.

For upper thoracic spine fixation, 4 supralaminar and 4 pedicular hooks were implanted according to the original technique, whereas a mix of pedicle-transversal claws and polyaxial pedicular screws were used in the modified technique, with a minimum of 5 and a maximum of 8 points of fixation. Pelvic fixation was achieved by two 7.5 mm cancellous ilio-sacral screws following the original technique (Fig. 2). In the modified technique, 2 iliac screws (6.5 or 7.5 mm) were implanted and up to 6 additional 5.5 mm or 6.5 mm screws into S1 and/or lumbar vertebrae; thus, the sacral and iliac screws were connected by a pre-contoured titanium rod placed in a horizontal position (Fig. 3).

For all patients, 2 pre-contoured titanium rods (either 5.5 or 6 mm) were connected to the pelvic fixation, while another 2 pre-contoured rods connected the vertebral implants of the thoracic spine. These 4 rods were connected 2 to 2 at the lumbar region using side-to-side dominoes. Before final tightening, distraction and compression at the lumbo-sacral level were achieved using an L-shaped jaw. If required, a subcutaneous Redon drain was placed for 2–3 days.

Postoperative Cares

After surgery, all patients were admitted to the intensive care unit for 2–4 days, where physical therapy was initiated, including verticalization, once the patient's condition allowed it. When clinical and laboratory parameters were stable, patients were transferred to the surgical ward, where physical therapy continued. Discharge was decided when acetaminophen and oral tramadol were sufficient to control pain, the respiratory function was similar to the preoperative situation, verticalization was possible, and there was no evidence of complications.

Complications

The number and nature of early complications were noted and assessed utilizing the modified Clavien-Dindo-Sinko Classification (CDSC) of surgical complications and the comprehensive complication index, which have demonstrated good reliability for the evaluation of postoperative complications,[19] including those following pediatric orthopedic surgery.[20] Exclusively for CDSC analysis, autologous blood transfusion was considered a grade 2 complication.

Blood Loss Estimation

Blood loss estimation can be a challenge since blood can be lost into gazes, aspiration, or surgical drapes. For this reason, visual estimation of perioperative blood loss has been demonstrated to be unreliable.[21] Proposed methods to estimate blood loss during surgery include gaze blood saturation[22] and mathematical calculation when a cell saver machine is utilized,[23] the latter being considered more accurate than analog methods even when wash quality is unknown. Unfortunately, the retrospective nature of the control series made blood loss estimation using this formula not possible due to unavailable data. Nonetheless, we confronted cell saver volume as a way of estimating intraoperative blood loss. Therefore, reported blood loss from this study should only be used to compare estimated blood loss within our data and should not be interpreted as an accurate measurement of lost blood volume.

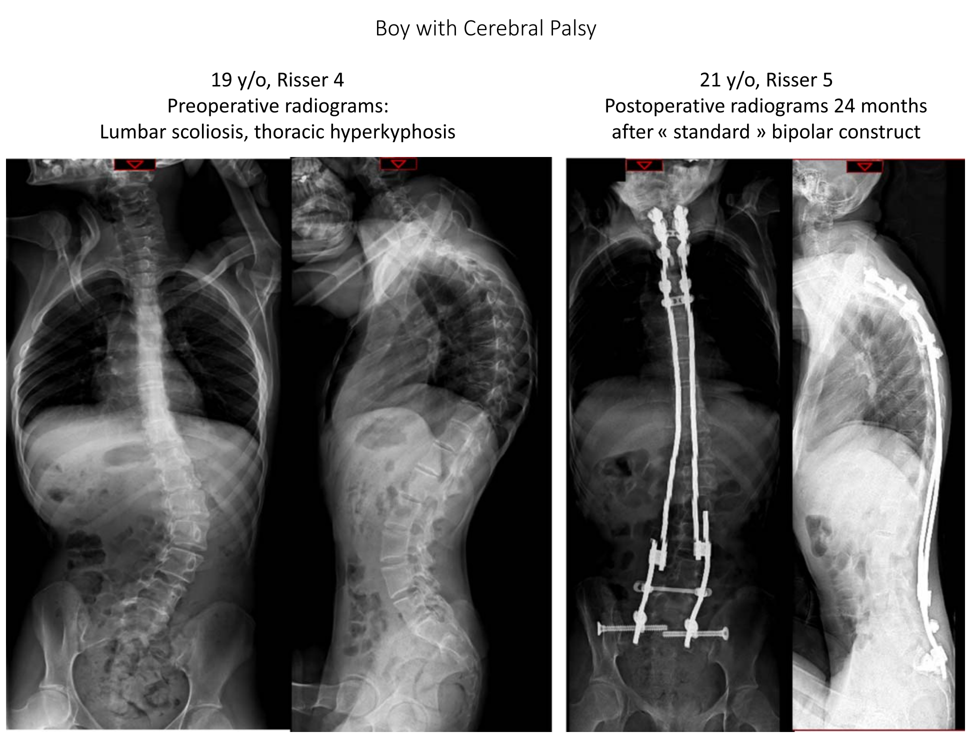

FIGURE 2. Example of "standard" bipolar construct. full color online

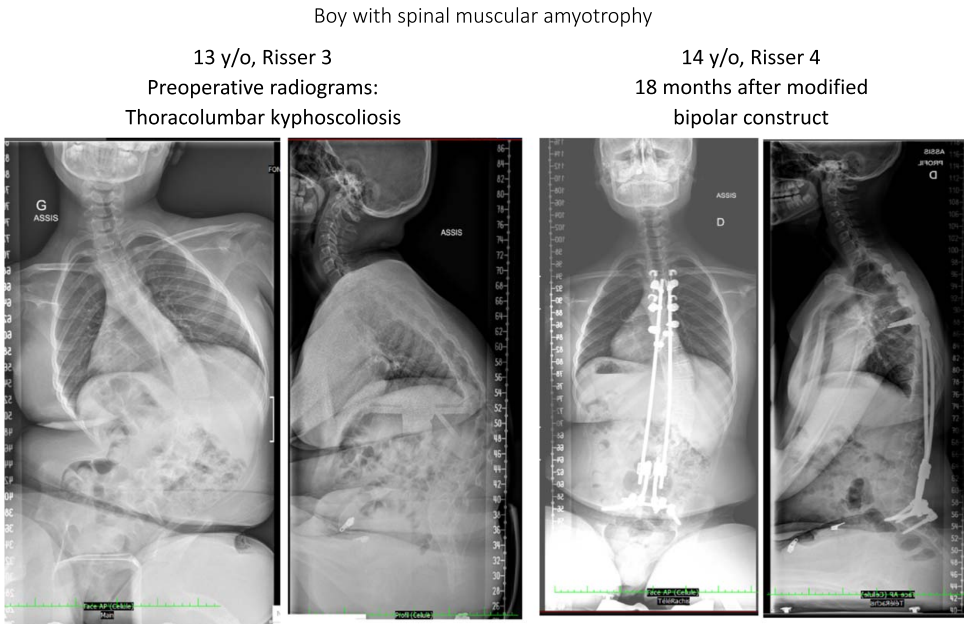

FIGURE 3. Example of the modified bipolar construct. full color online

Radiographic Assessment

All preoperative and last postoperative radiograms were assessed using computerized images by 2 orthopedic surgery residents not involved in the procedures.

The magnitude of the main thoracic or lumbar curve was measured using Cobb's method in full-spine anterior-posterior radiograms employing a dedicated software. Curve correction was expressed in both absolute and percent values.

Pelvic obliquity was measured following the method described by Maloney et al, which has been demonstrated to be the most reliable[24,25] by using a line drawn across the superior aspect of the iliac crests and a second line drawn from the center of T1 to the center of S1. The angle of pelvic obliquity was determined by measuring the angle between the second line and a perpendicular to the first one.

Data Analysis

The patients were divided into 2 groups according to the surgical technique, either BFC or SPF. The data were analyzed using BiostaTGV or XL-STAT software.

TABLE 1. Demographic Data

	SPF (n = 48)	BFC (n = 41)	P
Age at index surgery (y; mean ± SD)	15.8 ± 2.9	14.8 ± 4	0.18
Risser sign ≥ 3 [n (%)]	26 (54)	11 (27)	**0.02**
Sex [n (%) male]	25(52)	17 (41)	0.39
Length of follow-up (y; mean ± SD)	44 ± 25.7	22 ± 18.3	**< 0.0001**
ASA Score 2 or 3 (n for each)	11; 30	18; 23	**0.03**

Bold indicates p < 0.05.
BFC indicates bipolar fusionless construct; SPF, single posterior fusión.

Quantitative data were expressed as the mean ± SD and compared through Student *T*-test, ANOVA or Mann-Whitney test. Binary or qualitative data were presented with Odds Ratios (OR) and compared through Fisher exact test and logistic regressions. A *P* value inferior to 0.05 was considered statistically significant.[26]

Ethics

All procedures performed in this study were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments. All patients and/or parents provided formal written consent. The regional committee for people protection (CPP) approved this study with number 13.003.

RESULTS

Patients Characteristics

We operated on and included 89 NMS patients with to-pelvis constructs: 51 from Institution 1 and 37 from Institution 2. There were no excluded patients and no losses to follow-up. Forty-one patients (17 males, 24 females) were in the BFC group and 48 in the SPF group (25 males, 23 females), with similar gender distribution between groups ($P = 0.39$) (Table 1). The average age at the time of surgery was 14.8 ± 4 years for BFC versus 15.8 ± 2.9 years for SPF ($P = 0.18$). Risser sign was earlier in the BFC group ($P = 0.02$).

The most common etiology was cerebral palsy (n = 52, 58.4%), followed by muscular dystrophy (n = 13, 14.6%). The most common deformity was present at the lumbar spine (37%), followed by the thoracolumbar junction (33.7%).

Groups were similar concerning the severity of the preoperative curve (BFC 70 ± 28° vs. SPF 74 ± 23°, $P = 0.51$) and the initial pelvic obliquity (BFC 16 ± 13° vs. SPF 19 ± 11°, $P = 0.34$) (Table 2).

ASA score was overall 2 or 3. It was higher for the BFC group (OR 2.9, $P = 0.03$). Seven patients from the BFC group had been refused by the anesthetists for SPF due to poor general conditions.

Follow-up was distinctly shorter in the BFC group (22 ± 14 mo vs. 44 ± 26 mo, $P < 0.0001$). The minimum follow-up was 1 year.

At last control, all patients in the SPF group had a Risser sign of 5/5; from the BFC group, 4 still had a Risser sign of 0, 3 had a Risser sign of 1, 4 had a Risser sign of 2, 7 of 3/5, 3 of 4/5, and the others had 5/5 ($P =$ E-7).

Curve and Pelvic Obliquity Correction

Postoperative Cobb's angle of the main curve at the first radiographic exam was similar between the BFC group and the SPF group (38 ± 21° vs. 34 ± 17°, $P = 0.36$) (Table 2).

Similarly, the percentage of coronal curve correction of BFC and SPF groups reached no significant differences (46 ± 29% vs 53 ± 18%, $P = 0.23$). Within the BFC group, it was also similar between patients with the "original" technique and modified technique (44 vs. 51%, $P = 0.9$).

Postoperative pelvic obliquity (8.8 ± 7.9° vs. 8.5 ± 7.1°, $P = 0.82$), and correction rate showed no significant differences between the BFC group and the SPF group (37 ± 33% vs. 37 ± 77%, $P = 0.87$). Within the BFC group, it was also similar between patients with the "original" technique and modified technique (55 vs. 43%, $P = 0.3$).

Surgical and Hospital-stay Data

Operative time was distinctly lower in the BFC group (203 ± 57 vs. 242 ± 54 min, $P = 0.001$) as well as estimated blood loss (179 ± 203 vs. 365 ± 358 mL, $P = 0.005$). The rate of homologous blood transfusion was 27% for BFC versus 73% for SPF ($P < 0.0001$) (Table 3).

TABLE 2. Radiographic Data

	SPF (n = 48)	BFC (n = 41)	*P*
Preoperative curve magnitude (deg; mean ± SD)	74 ± 23	70 ± 28	0.51
Preoperative PO (deg; mean ± SD)	19 ± 11	16 ± 13	0.34
Curve correction (%; mean ± SD)	53 ± 18	46 ± 29	0.23
PO correction (%; mean ± SD)	37 ± 77	37 ± 33	0.87
Preoperative lumbar lordosis (deg; mean ± SD)	50 ± 26	52 ± 22	0.76
Postoperative lumbar lordosis (deg; mean ± SD)	49 ± 17	47 ± 11	0.61
Preoperative thoracic kyphosis (deg; mean ± SD)	59 ± 27	38 ± 27	**0.01**
Postoperative thoracic kyphosis (deg; mean ± SD)	50 ± 18	40 ± 16	0.06

Bold indicates p < 0.05.
BFC indicates bipolar fusionless construct; PO, pelvic obliquity; SPF, single posterior fusión.

The length of hospital stay was 14.2 ± 9.5 days for the BFC group and 20.6 ± 17.6 days for the SPF group ($P = 0.16$).

Complications

A total of 38 (43%) complications were found in this series: 25 from the SPF group and 13 from the BFC group (Odds Ratio, OR = 2.3, $P = 0.04$). The most common complication was wound troubles (n = 11, including surgical site infections), followed by pulmonary complications (n = 8).

According to multivariate analysis, BFC was associated with less complications (OR = 0.046, $P = 0.001$). ASA score was a weak predictor of complications (OR = 2.3, $P = 0.14$), whereas age at peak surgery and preoperative magnitude of the main curve was not related to complications ($P > 0.2$).

CDSC (1 ± 1.2 vs. 2 ± 1.1; $P < 0.001$) and comprehensive complication index (13.3 ± 16.5 vs. 27 ± 17.8; $P < 0.001$) scores showed significantly higher severity of complications in the SPF group.

There were 19 (39.5%) unplanned RORs in the SPF group related to complications, while 6 (14.6%) were present in the BFC group ($P = 0.01$).

There were 5 planned RORs in the BFC group to distract the construct.

DISCUSSION

In this study, we compared the clinical and radiographic outcomes of BFC and SPF for the treatment of NMS. Both severity and rate of early complications are higher for SPF despite higher ASA scores for BFC, whereas coronal corrections were similar between groups. Therefore, the hypothesis of lesser morbidity with similar correction is confirmed for early results.

In a published study by Cai et al[27] comparing the growing rods (GR)[28] technique and SPF for surgical correction of early-onset neurofibromatosis type-1 dystrophic scoliosis, initial curve correction rates were similar between groups (PF 52 ± 15 vs. GR 56 ± 12%; $P = 0.44$), which are slightly higher than our own results. Their reported perioperative complication rate for SPF (3/8, 37%) was significantly lower than ours for SPF group (25/48, 52%), which may be explained by their relatively lower number of levels fused (8 ± 3). The GR group achieved lower operative times (PF 4.4 ± 1.4 vs. GR 3.0 ± 0.4 h; $P = 0.008$), but complication rates were similar between groups (PF 3/8 vs. GR 2/8, $P = 1$). Although lower blood losses were reported in their paper for the GR group, no statistical data appears to be available. Nonetheless, this finding is confirmed by our results.

In a recent retrospective review of a multicenter international database, Li et al[29] analyzed 59 patients with NMS aged 8–11 at index surgery with GR or SPF. Their analysis found 8 times more complications and 9 times more unplanned ROR in the GR group. It must be noted that their GR group's mean age was significantly lower (9 y) compared with our BFC group (14 y), and their GR group underwent a mean of 9 distraction surgeries,

TABLE 3. Surgical and Clinical Data

	SPF (n = 48)	BFC (n = 41)	*P*
Operative time (min; mean ± SD)	242 ± 54	203 ± 57	**0.01**
Length of hospital stay (d; mean ± SD)	20.6 ± 17.6	14.2 ± 9.5	0.16
Estimated blood loss (cc; mean ± SD)	365 ± 358	179 ± 203	**0.005**
Need for homologous transfusion [n (%)]	35 (73)	11 (27)	**< 0.0001**
No. complications [n (%)]	25(52)	13 (32)	**0.04**

Bold indicates p < 0.05.
BFC indicates bipolar fusionless construct; SPF, single posterior fusión.

meaning BFC in patients with lower or no need for construct lengthening may carry a lower risk of complications as shown in our study.

A meta-analysis by Sharma et al,[13] including a total of 15,218 operated NMS patients, demonstrated pulmonary complications to be the most common (23%), followed by implant complications (12%), surgical site infections (11%), neurological complications (3%), and pseudo-arthrosis (2%). In our series, wound troubles were the primary complication, although pulmonary complication rates were in line with their results. No neurological complications or pseudo-arthrosis emerged in our population.

Our study found a similar complication rate compared with the original report from Miladi et al (26%). However, coronal curve correction was lower in our series (46% vs. 63%).[10] This could be related to a lesser experience of the operators of the present study and the inclusion of learning curve cases. Another possible explanation is that the original article reported a nonnegligible rate of preoperative halo-traction, whereas our data did not include any.

A study by Sponseller et al[30] about pelvic fixation and growing rods found a mean correction of the major curve of 47% when using iliac screws, which is in line with our own results, with a total complication rate of 58% and a mechanical complication rate of 28%, which is higher than ours.

Pelvic fixation in our study was achieved following the principles of maximum width introduced by Arlet et al.[10,31] This kind of pelvic fixation is poorly documented in the available literature, and no evidence can be drawn out as to whether the type of pelvic fixation influenced our results. However, our outcomes were similar for the original and modified technique, which suggests that various solid constructs could provide similar efficiency.

Recently published studies by Gaume et al[17,32–34] with up to 10 years of follow-up have demonstrated promising results for the treatment of NMS using BFC techniques: mean curve correction rate of 52%, 5% of mechanical complications, and 22% of surgical site infections. Our results are similar for coronal correction but better for surgical site infections, which could be related to factors unrelated to the surgical technique or to a lesser number of iterative distractions from our study.

Our results support the conclusion of a recent systematic review of the literature,[35] which revealed a higher risk of complications in patients who underwent definitive fusion, further arguing for the solidity of mini-invasive constructs and against the need for posterior fusion. In their review, Ahuja and colleagues showed no differences regarding curve correction between fused and unfused patients, which is in line with our own results.

The BFC allowing further growth of the spine is therefore indicated in immature patients, as confirmed by our own study, allowing early removal of bracing, which has been demonstrated to have a negative impact on the quality of life and treatment satisfaction while not avoiding curve progression.[36,37] Furthermore, the solidity of the BFC makes final spinal fusion unnecessary, preventing further surgical interventions in skeletally mature patients, as demonstrated by long-term studies and recent meta-analyses.[17,33,35]

From our experience, some points are worth highlighting. In the first stages of our experience with BFC, we kept both SPF and BFC for NMC based on age (younger for BFC) and general conditions (better conditions for SPF). After a learning curve and the first clinical results, we stopped performing SPF for NMS. Secondly, since the adoption of BFC, we no longer receive refusals from anesthetists due to the poor general conditions of NMS patients because we do not wait for skeletal maturity but operate on patients as soon as necessary, and the surgery-related stress is significantly lower. Despite similar ages between the groups, skeletal maturity was lower in the BFC group, a sign that we tend to operate on earlier due to the ability to distract the construct if required. Thirdly, the low number of implants requires perfect accuracy in their positioning to limit the risk of mechanical complications.

This study presents some limitations: the retrospective nature of the control group and the short follow-up of the BFC group. In particular, some ROR will probably be required for distracting BFC since skeletal maturity is not fully achieved. Moreover, much longer follow-up is required as the main argument against non-fusion surgery is the long-term risk of hardware failure.

To our knowledge, this is one of the largest studies to date that compares perioperative clinical and radiographic outcomes between BFC and SPF techniques for the treatment of NMS and the only one to report an objective scale for complication severity.

CONCLUSION

BFC may be a safer and less invasive option for all cases of NMS, resulting in similar early curve corrections while significantly decreasing surgical duration, perioperative blood loss, and the number and severity of early complications when compared with SPF. However, for surgical teams wishing to perform both SPF and BFC, the latter could be especially indicated in young, skeletally immature patients with worsening NMS and in fragile patients who cannot bear the surgical stress of SPF.

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