Eur Spine J (2014) 23:543–549
DOI 10.1007/s00586-013-3048-2

ORIGINAL ARTICLE

Multiaxial high-modularity spinopelvis (HMSP) fixation device in neuromuscular scoliosis: a comparative study

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Received: 15 April 2013 / Revised: 25 September 2013 / Accepted: 25 September 2013 / Published online: 18 December 2013

Abstract
Purpose To compare radiological and clinical results in patients operated for neuromuscular scoliosis with pelvic fixation using high-modularity spinopelvic screw (HMSP) designed by authors.
Methods Of 54 patients with neuromuscular scoliosis, group 1 comprised of 27 patients with conventional pelvic fixation; and group 2 comprised of 27 patients using HMSP. Results were evaluated radiologically and functionally. We compared preoperative and postoperative complications, especially the loosening or breakage of spinopelvis fixation device, failure of fixation, and the change of shadow around the spinopelvis fixation device.
Results There was no difference of correctional power, preoperative average Cobb's angle of each group was 79.8 and 75 to postoperative 30.2 and 28.3 ($P < 0.05$). Pelvic obliquity improved from average 18.3°–8.9° in group I and average 24.3°–12.5° in group II ($P < 0.05$). However, there was no difference between two groups ($P > 0.05$). Average blood loss was 2,698 ml in group 1 and 2,414.8 ml in group 2 ($P > 0.05$). Average operative time was 360 min in group 1 and 332 min in group 2 ($P = 0.30$). There was no difference found between two groups regarding gait and functional evaluation. On the all cases of group 1 and 2, the change of shadow around the spinopelvis fixation device was observed. There was one case of the fracture of spinopelvis fixation device in group I.
Conclusion There was no difference of Cobb's angle and correctional power between the groups using HMSP when compared with the group using standard spinopelvis fixation device. Therefore, HMSP can be used more effectively in case of neuromuscular scoliosis.

Keywords Neuromuscular scoliosis · Pelvic obliquity · Conventional spinopelvic fixation · Multiaxial high-modularity spinopelvic fixation

Electronic supplementary material The online version of this article (doi:10.1007/s00586-013-3048-2) contains supplementary material, which is available to authorized users.

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Introduction

Fixed pelvic obliquity is a frequent feature associated with neuromuscular scoliosis [30]. Several authors recommend pelvic fixation along with scoliosis correction for neuromuscular scoliosis [26]. Methods of pelvic fixation have included the Galveston (L-rod) technique, Dunn–McCarthy (S-rod) technique, transiliac screws, intrasacral screws, iliosacral fixation, and iliac screws [2, 18, 20, 21, 25]. However, pelvic fixation is often related with its inherited complications such as, prominence of implants, pressure sores, and pseudarthrosis [17]. The goals of surgery for neuromuscular scoliosis include safe correction of deformity, solid fusion of fixed levels to make the spine balanced, and provide sitting balance. There is a definite indication for pelvic fixation in neuromuscular scoliosis from the available literature, in which optimal use of instrumentation avoids undue complications associated with pelvic fixation [22].

Phillips et al. [25] noted 59 % complications using iliac screw for pelvic fixation in 50 neuromuscular scoliosis patients. Complications are deep wound infections, and screw-related and non-screw-related problems, which often require reoperation. Emami et al. [11] also prefer using iliac screw for pelvic fixation in spite of a higher rate of painful hardware, which often requires removal, mainly due to stronger purchase and correction, and less pseudarthrosis. With pedicle screws, the literature also describes complications such as neurological injury, vascular injury, loosening of screws, screw pullout, breakage of rod or screw, etc. [7, 8, 10, 12, 13]. Therefore, main aim of any pelvic fixation system is to achieve and maintain the maximum correction in pelvic obliquity and deformity with minimum fixation-related complications [26].

To achieve optimum result and reduce complication related with pelvic fixation, authors have developed a new polyaxial high-modularity spinopelvic screw (HMSP) system along with iliac screw. The purpose of this study was to compare radiological and clinical results in patients with neuromuscular scoliosis operated with pelvic fixation by our new HMSP system versus conventional iliac wing screw fixation.

Materials and methods

Total 54 consecutive patients of neuromuscular scoliosis were included in this study. All patients underwent scoliosis correction using pedicle screw fixation with spinopelvic fixation. None of our patient underwent anterior fixation or any anterior procedure. All patients were operated between 2003 and 2009. Patients were divided in two groups, 27 each. The first group (group I) comprised of 27 patients who were operated between 2003 and 2006 with conventional iliac screw fixation for pelvic obliquity. There were 18 patients with Duchenne muscular dystrophy (DMD) and nine patients with spinal muscular atrophy (SMA): 20 males and 7 females. The average age of the study group was 14.7 ± 4.9 years (range, 8–29 years) and average Cobb angle was 79.8° ± 28.3° (range 40°–150°). Average follow-up was 32.2 ± 9.9 months (range 24–47 months). The second group (group II) included remaining 27 patients operated between 2006 and 2009 with new polyaxial HMSP system for pelvic fixation. There were 22 patients with DMD and five patients with SMA: 22 males and 5 females. The average age of the study group was 14.4 ± 3.3 years (range 10–23 years) and average Cobb angle was 75° ± 28.3° (range 42°–146°). Average follow-up was 32.3 ± 8 months (range 24–51 months).

All patients underwent preoperative, postoperative, and final follow-up whole spine antero-posterior and lateral radiograms to compare the correction. Radiograms were taken in sitting position for all patients as a standard in neuromuscular scoliosis. All were operated by posterior-only approach using pedicle screw fixation. The upper level of fixation was T2–T4 and lower level was L5 or sacrum with pelvis in all patients. If preoperative pelvic obliquity was more than 15°, lower screw was S1; and if pelvic obliquity was less than 15°, lower level stopped at L5. Decisions for pelvic fixation were taken by the senior author (SWS) due to paralytic neuromuscular scoliosis. In group 1, we retrospectively collected data of 27 patients with conventional pelvic fixation system and compared with HMSP connector that was inserted over iliac screw very easily due to multiaxial principle. Details of group 2 data were collected prospectively as a part of this comparative study. Pelvic fixation was achieved by bilateral iliac screw insertion with conventional fixation of the rod to the iliac screw in group 1 (Fig. 1), and with new HMSP connector in group 2 (Fig. 2). HMSP connector was inserted before contouring the rod at the end. The rod was then bent, and final screw–rod construct was achieved. Further correction was performed by rod derotation maneuver with or without in situ bending (Fig. 3). Pelvic obliquity correction was mainly achieved by rod derotation maneuver, and if needed compression was applied between the iliac screw at higher pelvic level and pedicle screws above. Once desired correction achieved, inner nuts were tightened at HMSP connector at both levels, i.e., at iliac screw and the ball socket part over the rod with the help of L-key. Once inner nuts were tightened, whole connector becomes rigid and no further movements were possible.

None of our patients in this study had undergone any other associated procedures such as thoracoplasty, osteotomy or posterior vertebral column resection to achieve the desired level of correction. Pedicle screws were inserted in the thoracic and lumbar level using free-hand technique. All screws were fixed over 6-mm diameter titanium rods bilaterally. Once the correction achieved, posterior fusion was done by local bone grafts from the laminae mixed with the dried frozen allograft. Postoperatively, as a routine, patients were monitored and extubated in the recovery ward by the anesthesiologist.

Coronal angle was measured for the major curve using the Cobb method, while pelvic obliquity was measured as an angle between the line joining the highest points of two iliac crests and the horizontal line. In the sagittal plane, thoracic kyphosis and lumbar lordosis were measured between the maximum tilted vertebrae using the Cobb method. Ambulatory status in each patient was evaluated using the modified Rancho classification [16].

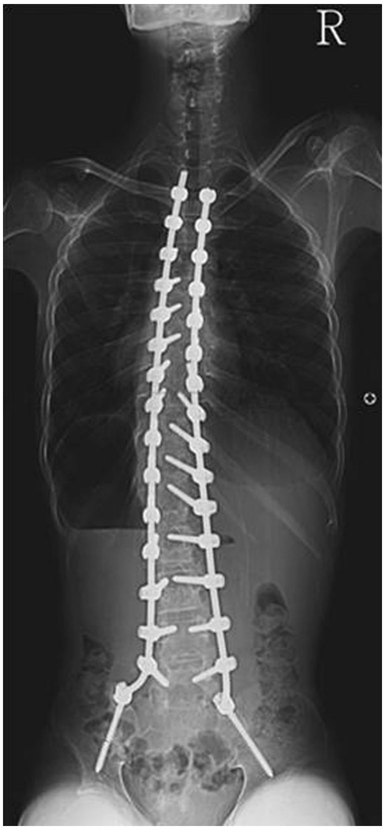

Fig. 1 Figure shows a conventional pelvic fixation with iliac screw where rod has to be bent to fit over the iliac screw. With this system, rod rotation is difficult to achieve for further correction

Postoperatively, the functional status of each patient was evaluated for sitting balance, cosmetic improvement, transportation by relatives, functional freedom of the arm, improvement in nursing care by parents, overall quality of life (bathing, toilet), satisfaction with operation, and, overall respiratory functions according to major, moderate, mild or no improvement as compared to the preoperative functions [6].

We collected all the intraoperative record sheets, and postoperative indoor and follow-up sheets to observe perioperative (till discharge from the hospital including intraoperative) and postoperative (after discharge from the hospital) complications. In this study, we have presented all the complications with specific focus on its possible causes and prevention techniques.

Paired *t* test was used to observe the correction in Cobb angle, pelvic obliquity, thoracic kyphosis and lumbar lordosis between preoperative and postoperative correction, while the same was used to observe the maintenance of the correction between postoperative and final follow-up findings (Fig. 4). In addition, we also observed the postoperative CT scan in all patients to find out any misplacements of the pedicle screws. *P* value less than 0.05 was considered as statistically significant. Complications were discussed in detail with previously reported literature to find out any correlation with the fixation method.

Results

There was no difference of disease, age, and sex between two groups (Table 1). There was significant correction in preoperative average Cobb's angle of each group; 79.8° and 75° to

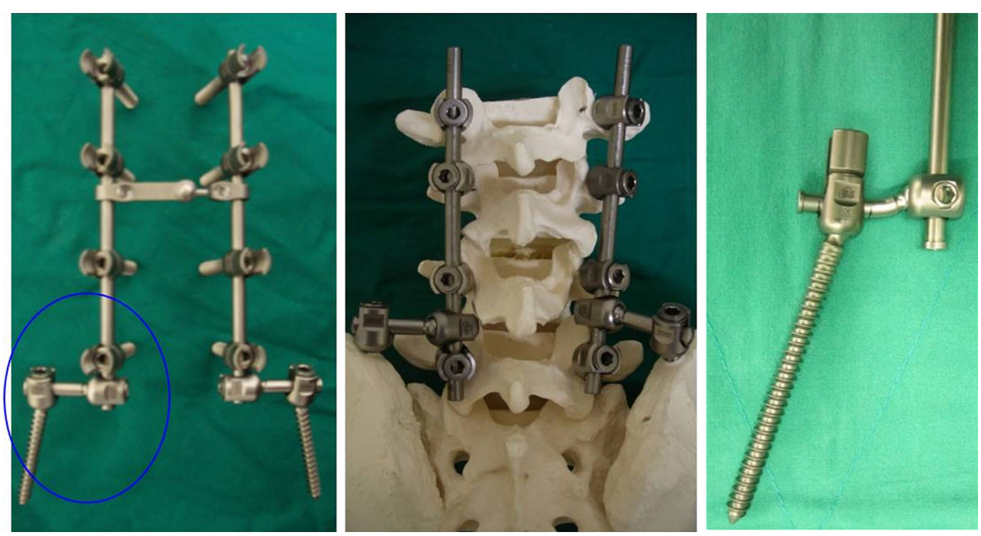

Fig. 2 Picture shows HMSP connector with multiaxial functions with closer look of HMSP connector. Both the ends of HMSP connector can be tightened with simple nut tightener or L-key. First two pictures are older version of HMSP connector, while third picture is new version to make it easier application

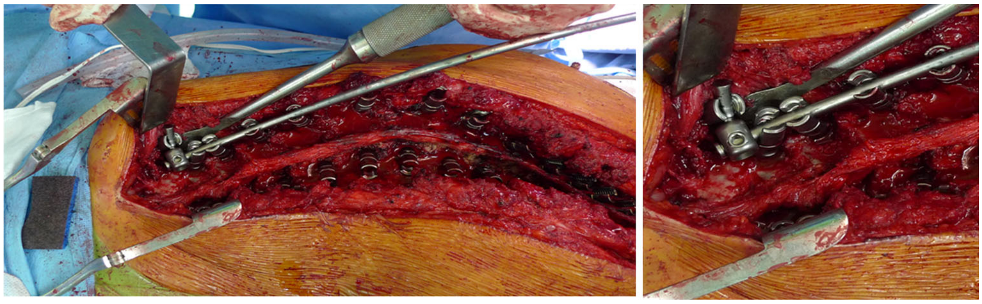

Fig. 3 Operative technique: before contouring the rod, HMSP connector was inserted at the end and connection between the main rod with iliac screw was performed very easily using HMSP connector as shown in the picture. Finally rod screw construct was achieved and rod derotation was applied to achieve desired correction

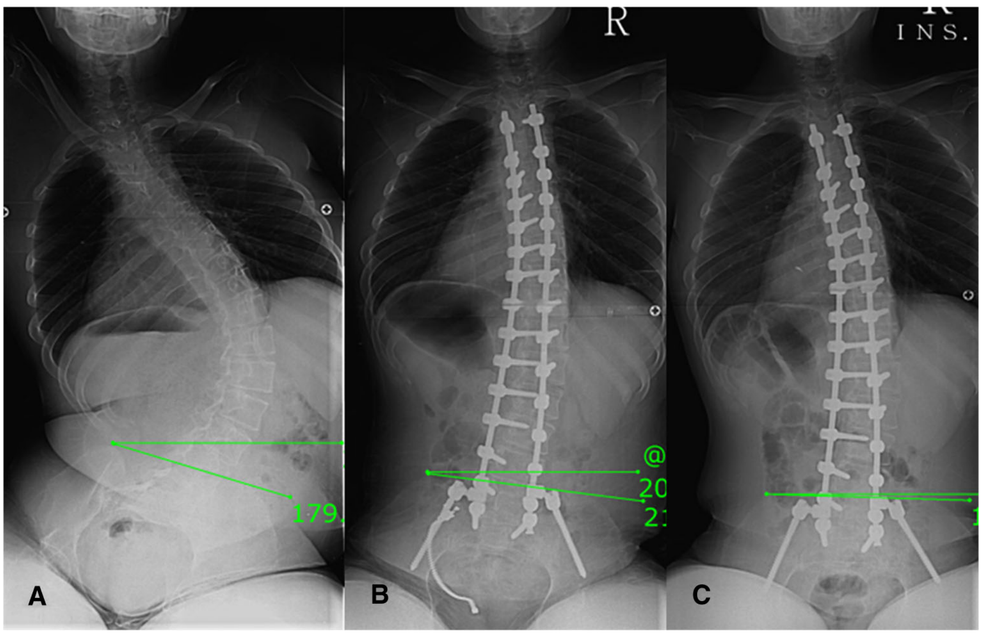

Fig. 4 Radiological picture of a 17-years-old boy with DMD having scoliosis of 87° (**a**). He was operated with pedicle screw fixation with pelvic fixation by HMSP connector. Postoperative X-ray (**b**) showed excellent correction of scoliosis to 21° with improvement in pelvic obliquity from 19° to 5°; which was maintained at final follow-up (**c**)

postoperative 30.2° and 28.3° in group 1 and 2, respectively ($p < 0.05$). There was 63.1 ± 18.4 % correction in group 1 and 64 ± 10.4 % correction in group 2 was achieved. All the corrections were maintained at the final follow-up in both groups as shown in the table. There was a significant improvement in pelvic obliquity in both groups; from preoperative 18.3° to postoperative 8.9° (52.9 ± 27.9 % correction) in group 1 and preoperative 24.3° to postoperative 12.5° (48.8 ± 32.6 % correction) in group 2. Correction in pelvic obliquity was maintained at the final follow-up. There was no difference between two groups ($P > 0.05$) in terms of correction in pelvic obliquity in both groups. Improvement or change in thoracic kyphosis and lumbar lordosis was also not different between both groups (Table 1).

The average amount of blood loss was 2,698 ml in group I and 2,414.8 ml in group II. Although there was decrease in blood loss in group II, there was no statistical difference. The average operation time was 360 min in group 1 and 332 min in group 2. However, there was no statistical difference ($P = 0.30$). Evaluating gait and functional outcome, there was no difference between two groups in preoperative ($\chi^2 = 0.507$) and postoperative ($\chi^2 = 0.571$) functions (Table 2). There was one case of the breakage of rod at spinopelvis fixation device in group I which was removed without any further sequel. However, there was no such complication or loosening of fixation in group II.

Discussion

Paralytic neuromuscular scoliosis is often associated with pelvic obliquity which makes difficult to sit. Literatures

Table 1 Patient demographics

Details	Group 1		Group 2		*P* value
	Value	Range	Value	Range	
Total patients (*n*)	27		27		
Male:female	20:07		22:05		0.429
Average age (years)	14.7 ± 4.9	8–29	14.4 ± 3.3	10–23	0.82
Average F-U (months)	32.2 ± 9.2	24–47	32.3 ± 8	24–51	0.854
Average flexibility (°)	21.2 ± 8.9	9–42	26.9 ± 18	5–60	0.147
Average Cobb angle (°)					
Pre op	79.8 ± 28.3	40–150	75 ± 28.3	42–146	0.525
Post op	30.2 ± 19.1	4–65	28.3 ± 18	11–82	0.709
Final F-U	31.9 ± 19	5–68	29 ± 18.9	13–84	0.568
Average pelvic obliquity (°)					
Pre op	18.3 ± 7.0	4–30	24.3 ± 17.3	1–69	0.101
Post op	8.9 ± 6.7	1–24	11.3 ± 9	1–34	0.279
Final F-U	11.2 ± 7.2	0–28	12 ± 10.9	0–41	0.734
Average thoracic kyphosis (°)					
Pre op	27.6 ± 32.5	(−)20–84	29.4 ± 41.4	(−)42–136	0.864
Post op	19.9 ± 9.5	5–42	22.6 ± 13.2	4–52	0.403
Final F-U	18.2 ± 9.8	5–40	22.5 ± 12.1	1–48	0.175
Average lumbar lordosis (°)					
Pre op	15.6 ± 44.8	81–(−)72	16.9 ± 34.2	77–(−)77	0.903
Post op	(−)22.4 ± 7.9	(−)8–(−)35	(−)24.3 ± 9.4	(−)11–(−)42	0.266
Final F-U	(−)20.9 ± 9.5	(−)5–(−)38	(−)22.1 ± 11	(−)9–(−)44	0.404

Table 2 Functional gait evaluation of patients in both groups by modified Rancho classification

Functional status	Group I		Group II	
	Preoperative (*n*)	Postoperative (*n*)	Preoperative (*n*)	Postoperative (*n*)
Class 1 (independently ambulating)	0	0	0	0
Class 2 (ambulatory with support/aids)	0	1	0	2
Class 3 (sitting without support)	0	21	1	20
Class 4 (sitting with support)	7	4	5	4
Class 5 (confined to bed)	20	1	21	1

recommend pelvic fixation in such cases [2, 18, 20, 21, 25]. Iliac screw for pelvic fixation is now most often recommended and has promising results [24, 25]. Conventional fixation of rod to the iliac screw needs rod to be contoured till pelvis for fixation. It often becomes difficult and takes more time for the construct and possible complications related with the rod impingement. To overcome such complications various types of connectors are also in use. Authors also have developed a new multiaxial high-modularity spinopelvis (HMSP) system for pelvic fixation which proved to be equally effective and convenient to construct the spinopelvic fixation. In addition once desired correction is achieved by rod derotation and compression maneuver, it just requires two nuts to be tightened at both ends of the HMSP connector with the help of simple L-key, and it makes a rigid construct. This study showed similar clinical and radiological results with both conventional and new HMSP system in total 54 paralytic neuromuscular scoliosis patients with minimum follow-up of 2 years.

The goal of surgery was a stable maximally-corrected spine above a level pelvis, providing freedom from bracing with improved function and comfort [23]. Luque segmental instrumentation was chosen as the treatment of choice in the literature since it was an established technique providing secure fixation with minimum morbidity [5, 9, 14, 19]. Although the quality of bone in patients with DMD or SMA is often poor, the laminae are sufficiently robust to support sublaminar wires in such patients which is the reason often given for the sublaminar wiring. The duration of surgery should be kept to a minimum; pedicle screw fixation at multiple levels requires fluoroscopic control and would prolong the operating time considerably [5]. However, in our study we used free-hand technique for the insertion of pedicle screw which eliminated the prolonged exposure of radiation and the long duration of surgery. Recently, posterior segmental fixation (in particular pedicle screw fixation) was found to be superior to distraction spondylodesis with Harrington rod instrumentation, since it gives better preservation of correction, less rod failure, and does not require postoperative bracing [15, 23, 28]. Anterior release and/or instrumentation and fusion in DMD and SMA are not advised [3]. Our study shows that using all pedicle screw construct, we achieved an overall correction of 63 and 64 % in the coronal plane and 52 and 49 % in pelvic obliquity in group 1 and 2, respectively, which was maintained at the final follow-up. Blood loss is another important consideration in DMD. Piazzolla et al. [26] also noted increased EBL during surgery in neuromuscular scoliosis using Cotrel-Dubousset instrumentation. Decortication of the laminae was not carried out in the series of 27 patients presented by Bentley et al. [5] mainly to prevent excessive blood loss and to shorten the duration of operation. Bellen et al. [4] also reported that fusion without decortications did not affect the outcome, and reported that improved stabilization encourages fusion, and it is, therefore, apparent that the near-rigid Luque technique suffices. However, these patients lost some slight correction during the first year [4, 5]. Using all pedicle screw construct in our study group, we were able to decorticate the laminae for fusion, and maintained the corrections in both coronal as well as sagittal plane at final follow-up in both groups. We also removed spinous processes to obtain more bone grafts for the fusion. In addition due to pedicle screws we were able to decorticate laminae as much as possible in the lumbar spine. And inferior facetectomy was done in the thoracic spine before inserting the pedicle screws to achieve mobility. Remaining portion of laminae was also decorticated in the thoracic spine for the fusion.

There are various techniques for pelvic fixation such as the Galveston system, S-rod fixation, sacral screws, iliosacral fixation, the STIF technique, iliac fixation, etc., which show good results [2, 18, 20, 21, 25]. Pelvic fixation, however, is a challenge to most surgeons because it carries a high rate of implant-related complications. As pelvic fixation has a high complication rate, there are various papers reporting the different methods. Allen and Ferguson popularized their Galveston method for pelvic fixation which has a high rate of complications including 'wind shield wiper sign', pressure sores, etc. [1, 2]. On the other hand, the literature shows evidence that finishing the fixation at the lumbar spine corrects and maintains pelvic obliquity as well as Cobb's angle very well [29]. Sengupta et al. [27] using hybrid constructs with pedicle screws for fixation of lumbar spine till L5, found that they were able to achieve adequate correction and maintenance in patients with pelvic obliquity of <15° without instrumentation of the pelvis. Hahn et al. [15] reported 65 % correction rate of pelvic tilt and good maintenance by use of pedicle screws fixation for the entire spine and iliac screws fixation of the pelvis in all patients irrespective of their preoperative pelvic obliquity. Peelle et al. [24] suggested that the method of iliac screws has similar results as compared to the Galveston system and fewer complications; therefore, we used iliac screw fixation in our study. Phillips et al. [25] reported that use of two screws in each iliac wing provides stronger purchase than one screw in each iliac wing; however, we used one screw in each iliac wing and achieved good purchase. Miladi et al. [21] reported a long-term study in neuromuscular scoliosis patients with iliosacral fixation. They noted that pelvic fixation becomes easier with a connector between the rod and iliac screw. We have used a similar type of HMSP connector for pelvic fixation which was not difficult to assemble. The added advantage of our HMSP connector is that it is high modularity with multiaxial in function, so that we can assemble it before screw–rod fixation. Once pelvic fixation is achieved without any difficulty, rest of the construct is also easy to construct due to multiaxial nature of HMSP connector which helps in accommodating the curve. And once final construct is made, with HMSP connector (by keeping it loose) we can perform rod derotation and in situ bending maneuver to achieve desired correction. Final tightening with L-key should be done once desired correction in pelvic obliquity achieved with further compression maneuver between the iliac screw and the pedicle screw. We feel that less operation time and EBL in group 2 (although was statistically not different than group 1) was due to HMSP connector which made pelvic fixation very quick and convenient. In addition, on the gait evaluation and functional evaluation, there was no difference between two groups. On the all cases of group I and II, the change of shading around the spinopelvis fixation device was observed. There was one case of the fracture of spinopelvis fixation device in group I. However, there was no fracture case in group II.

In conclusion, our paper showed similar clinical and radiological results with conventional and HMSP-based pelvic fixation in patients with paralytic neuromuscular scoliosis. However, due to its high modularity and multiaxial functions which makes it very convenient to use, we feel that new HMSP-based pelvic fixation system would be as effective option as the traditional iliac screw fixation for pelvic fixation especially in neuromuscular scoliosis.

Conflict of interest None.

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