Health-Related Quality of Life Outcomes of Instrumented Circumferential Spinal Fusion for Pediatric Spondylolisthesis: A Comparison With Age and Sex Matched Healthy Controls

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Health-Related Quality of Life Outcomes of Instrumented Circumferential Spinal Fusion for Pediatric Spondylolisthesis. A comparison with age and gender matched healthy controls

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Introduction

Spondylolisthesis is one of the most common causes of low back pain and radicular symptoms in the adolescent population[1,2]. It is divided in low-grade and high-grade spondylolisthesis according to Meyerding classification: a vertebral slip on a sagittal lumbar radiograph less than 50% (Meyerding I-II) is low-grade and a slip over 50% (Meyerding III-V) is high-grade[3,4]. Low-grade spondylolisthesis is treated with pain medication, restriction of sports and operated only if there is persistent pain after conservative treatment[5-8]. In pediatric high-grade spondylolisthesis, an operative treatment with a short posterolateral fusion has been suggested due to the risk of slip progression and higher degree of symptoms[8-11]. Instrumented reduction seems to improve fusion rate as compared with in situ fusion[12], although the long-term health-related quality of life has been better with circumferential in situ fusion than with reduction[13].

Previous smaller studies have suggested improvement in the health-related quality of life (HRQOL) after spinal fusion in children with spondylolisthesis[14,15], but guidance is limited in children as the largest series included also young adults[16]. The latter multicenter study showed improvement in the HRQOL in all the areas of SRS-22 questionnaire after the surgery in majority of patients, especially in the high-grade spondylolisthesis patients.

In this study we aimed to examine whether the HRQOL improves in children after operative treatment for spondylolisthesis using an instrumented reduction and circumferential spinal fusion. We also wanted to compare the HRQOL in these children with age and gender matched healthy controls and whether there is a difference in the HRQOL between operatively treated low-grade and high-grade spondylolisthesis patients. The hypothesis was that the HRQOL improves after surgery, is better in low-grade spondylolisthesis patients compared to high-grade spondylolisthesis patients and is at similar level in these patients as compared to the healthy controls.

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Materials and methods

Patients

Twenty-six consecutive patients aged between 10 through 18 years with operatively treated spondylolisthesis were prospectively included from May 2009 to November 2017 in this study. All of the patients had pedicle screw instrumentation with intercorporeal fusion using TLIF cage or autologous structural bone graft. Neural elements were widely decompressed for nerve roots (L5, S1) and cauda equinae. Reduction of the vertebra was performed in all patients expect for the one with spondyloptosis (slip 100%) who underwent transsacral instrumentation and bone grafting in situ. Patients with low-grade spondylolisthesis had pedicle screws inserted into L5 and S1 to reduce the spondylolisthesis and patients with high-grade spondylolisthesis underwent instrumentation from L4 to S1 with iliac or S2AI screws[17-20]. Transforaminal lumbar intercorporeal fusion cage was inserted in addition to standard posterolateral spinal arthrodesis. All patients were operated by a single orthopedic spine surgeon (IH) and had a minimum 2-year follow-up.

Outcome parameters

Clinical and radiographic was collected prospectively preoperatively, at 6 months, and at two year follow-up. The HRQOL was analyzed using Scoliosis Research Society-24 (SRS-24) outcome questionnaire[21]. The follow-up time in all patients was a minimum of 2 years (mean 3.3 years, range 2 to 10 years). Perioperative data as in operation time, blood loss, and levels of instrumentation was collected. Radiographic outcome was assessed from a standing radiographs of the spine. Standing spinal radiographs were taken prior to operation, 6 months and 2 years after the operation. Of these radiographs the percentage slip of the vertebra, lumbosacral angle, pelvic incidence, pelvic tilt, sacral slope, and lumbar lordosis (T12-S1) were measured as radiographic parameters[22]. The high-grade spondylolisthesis patients were divided into balanced and unbalanced groups[23,24]. For follow-

up visits, the status of the instrumentation was evaluated (intact, broken screws or rods, signs of loosening). A routine CT scan was not obtained to evaluate spinal union at the final follow-up.

Healthy controls

Healthy controls were obtained from our previous population based study in which healthy adolescents and adults were asked to fill out a modified version of the original SRS health-related quality of life questionnaire (SRS-24)[21]: the SRS-22r questionnaire[25,26]. In this study 272 healthy controls were selected from a population register and were invited to complete and return the SRS-22r questionnaire between January 2012 and December 2015. Two controls from this cohort were matched with each patient for age (+/- 2 years) and gender. Age matching was done with the age of the surgically treated patients in their last follow-up.

Scoliosis Research Society Outcome Questionnaire

The SRS-24 is the original disease specific questionnaire developed by the Scoliosis Research Society[21]. It originally measured and evaluated the HRQOL in operatively treated patients with adolescent idiopathic scoliosis. However, it has been broadly accepted and used to evaluate the HRQOL in patients treated operatively for other spinal problems as well, including pediatric lumbar spondylolisthesis[27-29]. The SRS-24 questionnaire consists of 24 questions concerning 7 domains: pain, general self-image, function from back condition, general level of activity, postoperative self-image, postoperative function, and satisfaction. Every question is scored from one to five and the maximum score of this questionnaire is 120. The higher the score, the better the outcome. The questions from 16 to 24 concerns the treatment and can therefore be filled out post treatment only.

SRS-22r is an improved version of the SRS-24 questionnaire. Its questions are either exactly the same or close to the original SRS-24 questionnaire questions. In our study the control group members had filled SRS-22r questionnaire. Because the control group were healthy individuals without any treatment, only questions 1 to 15 from the original SRS-24 (preoperative domains) were used and compared with the similar questions of the SRS-22r (questions 1, 2, 4, 5, 6, 8, 9, 11, 12, 14, 15, 17, 18, 19, 20 from the SRS-22r). The domains were formed as follows: pain

(SRS-24: 1, 2, 3, 6, 8, 11; SRS-22r: 1, 2, 4, 8, 11, 14), general self-image (SRS-24: 5, 14, 15; SRS-22r: 6, 19, 20), general function (SRS-24: 7, 12, 13; SRS-22r: 9, 15, 18), and general activity (SRS-24: 4, 9, 10; SRS-22r: 5, 12, 17)[30,31]. There are eight exactly the same questions with exactly similar options in the SRS-24 and the SRS-22r and these questions were also compared across the groups (SRS-24: 1, 2, 3, 4, 5, 6, 7, 8; SRS-22r: 1, 2, 4, 5, 6, 8, 9, 11).

Statistical analysis

Statistical comparisons of radiographic parameters were performed with unpaired t tests. Linear mixed models for repeated measures analysis were used to study the variation of SRS domains over time. We log transformed the mirror transforms of the domain scores prior to analysis in order to prevent left skew in the residuals of those models. We applied the Kruskal-Wallis test on the original domain scores to compare patients with controls. The p-values in pairwise comparisons were adjusted for time. Significance level was at <0.05.

Ethical Committee approval

Ethical committee approval was obtained from local ethical boards. For the spondylolisthesis patients ethical committee did not request informed consent as they underwent clinically standardized treatment protocol without additional examinations. Written informed consent was acquired from the normative population and if needed from their guardians.

Results

A total of 26 consecutive adolescents (mean [SD] age at the time of surgery 14.7 years [± 1.9 years]) who underwent operative treatment for spondylolisthesis were included in this study (Table 1). Eleven (42%) of the patients had low-grade and 15 (58%) had a high-grade slip. One of the high-grade spondylolisthesis was spondyloptosis (slip 100%, Meyerding V). The indication for surgery was either a low-grade slip with ongoing symptoms after a year of conservative treatment or a high-grade spondylolisthesis. Conservative treatment consisted of restriction of sports, pain medication and in some cases brace treatment to relief the pain. Associated pain scoliosis was seen in two (18%) patients with a low-grade spondylolisthesis and in 10

(67%) patients with a high-grade spondylolisthesis (Table 2). In these patients the lumbar scoliosis resolved after spinal fusion for spondylolisthesis. Therefore, we assumed this deformity to be part of the deformity itself or the pain component of the spondylolisthesis. Additionally, idiopathic scoliosis was found in 3 (27%) patients in the low-grade spondylolisthesis group and six (40%) patients in the high-grade spondylolisthesis group. Two patients with a high-grade spondylolisthesis had earlier undergone spinal arthrodesis for adolescent idiopathic scoliosis.

Seventeen (65%) of the patients were asymptomatic at the end of the follow-up and did not develop any complications.

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Radiographic outcome

The mean preoperative slip in the low-grade patients was 25% (± 13%) and 67% (± 15%) in the high-grade patients (Table 2). After instrumented reduction the mean slips were 6% (± 7%) and 21% (±25%), respectively. Similarly, the lumbosacral angle remained at 10° degrees pre- and postoperatively in the low-grade group, but improved from 14° (±11°) to 10° (±6°) degrees in the high-grade group. Unbalanced pelvis occurred preoperatively in eight (53%) of the high-grade patients and in seven (47%) at two-year follow-up (N.S.). An example of patient's radiographs prior and after the operation are seen in **Figures 1 A, B and 2 A,B.**

Complications

Three (12%) patients had a cerebrospinal fluid leak during surgery, which was noted and closed during the primary operation without further events. None of the patients developed a persistent neurologic deficit, but five (19%) patients had radicular pain at least occasionally postoperatively during the follow-up time. Two (8%) of these patients presented with chronic postsurgical pain persisting 2 years. Seven (27%) of the patients had reoperations for any reason during the follow-up time. Three (12%) of the patients (one with low-grade and two with high-grade slip) developed a pseudoarthrosis, two of them have undergone a revision procedure, one of them twice (5 years and

8 years after the primary operation). One (4%) patient developed spondylolisthesis at the level above the index procedure (L4-5) necessitating fusion over this level eight months after the primary operation. Four (15%) patients had mechanical discomfort from the iliac screws and they were later removed. In one of these four patients a persistent postoperative cerebrospinal spinal fluid leakage required a re-revision to seal the leak. There were no deep surgical site infections.

Quality of life and SRS scores in surgically treated spondylolisthesis patients

Twenty-two (85%) patients completed the SRS-24 questionnaire preoperatively and twenty-three (88%) patients filled the same questionnaire two years after the surgery. The SRS-24 pain and activity domains improved significantly from preoperative to 2-year follow-up ($p \leq 0.007$ for both) (Table 3). With the exception of postoperative function and satisfaction, the scores of the SRS-24 questionnaire were higher for high-grade spondylolisthesis patients than for low-grade spondylolisthesis patients, but only the difference in the self-image domain was significant ($p=0.008$, results not shown).

Comparison of Quality of life and SRS scores in operatively treated spondylolisthesis patients and controls

The SRS scores in pain, self-image and function domains and the total SRS score were significantly lower in the surgically treated spondylolisthesis patients at their 2-year follow-up visit than in the age and gender matched controls ($p<0.05$ for all comparisons, table 4). The spondylolisthesis patients reached controls only in the activity domain during the 2-year follow-up time. When low-grade and high-grade spondylolisthesis patients where separately compared to controls it was noted that the low-grade spondylolisthesis patients had statistically significantly lower scores in pain ($p=0.002$), self-image ($p=0.027$) and function ($p<0.001$) domains. The high-grade spondylolisthesis patients had statistically significantly lower scores in the pain ($p=0.020$) and the function ($p<0.001$) domains (table 5).

Discussion

To the best of our knowledge, this is the first prospective study comparing the HRQOL of the operatively treated spondylolisthesis patients with age and gender matched controls. Our study shows that the HRQOL improves in pain and activity domains in spondylolisthesis patients after surgery but reaches equal level compared to healthy controls only in the activity domain. Surprisingly, the low-grade spondylolisthesis patients had lower values in all the domains expect for the activity of the SRS questionnaire than the healthy controls, whereas the high-grade spondylolisthesis patients had lower values only in the pain and function domains.

Comparison with previous data

In previous studies, the HRQOL has improved after surgical treatment for pediatric spondylolisthesis[14-16]. Bourassa-Moreau et al[15] published a study 2013 where they measured HRQOL of the conservatively treated and the surgically treated high-grade spondylolisthesis patients during 2-year follow-up. In their study there where 23 patients in the surgically treated group and only 5 patients in the conservatively treated group. The decision of the surgical treatment was not standardized but left for the treating surgeon. The age of the patients was between 10 and 20 years at initial presentation. In their study the HRQOL improved in all the domains of SRS-22 for the surgically treated high-grade spondylolisthesis patients and stayed the same in the conservatively treated high-grade spondylolisthesis patients. They did not compare the HRQOL in conservatively vs surgically treated patients. Tsirikos et al[14] examined fusion rates and the HRQOL of the low-grade spondylolisthesis patients who failed the conservative treatment and went through in situ posterolateral arthrodesis without instrumentation. In their study all 36 adolescent patients (aged between 9.8 to 17.3 years) had spinal fusion but the pars interarticularis fracture (spondylolysis) persisted at least in one side in most of the patients. In their study the HRQOL improved statistically significantly in all the domains of the SRS questionnaire following surgery.

In a prospective multicenter study done by Bourassa-Moreau et al[16] the HRQOL of the surgically treated spondylolisthesis patients improved in all the domains of the SRS-22 questionnaire 2 years after the surgery compared to the SRS-22 prior the surgery. In their study young adults were included to the study cohort, as the age limit was between 10 and 25 years at surgery. When comparing separately low-grade and high-grade spondylolisthesis patients, the pain and function domains of the low-grade spondylolisthesis patients improved after surgery whereas in high-grade spondylolisthesis patients all of the domains improved statistically significantly after surgical treatment for spondylolisthesis. In their study indication for surgery and technique of the surgical intervention were left to the decision of the surgeon. In a long-term study patients fused in situ for high-grade spondylolisthesis had a similar pain and mental health SRS scores as compared with healthy controls, while self-image and function scores were significantly lower, but the difference in means was small[32]. In the current study the pain and activity domains improved from preoperative to 2-year follow-up in the surgically treated adolescents. Despite improvement, the SRS total score, pain, self-image, and function domains remained at significantly lower level at the end of follow-up than in controls.

Seven (27%) of the patients underwent re-operation during follow-up. Two of these were due to non-union, one had junctional issue necessitating extension of instrumentation, and four patients required removal of symptomatic iliac screws. In an evidence-based review of spondylolisthesis, Longo et al.[12] observed pseudoarthrosis in 5.5% of 165 patients undergoing reduction as compared with 17.8% of 101 undergoing fusion in situ. The risk of non-union (12%) in the current series after instrumented reduction and circumferential spinal fusion was higher than in this review. Iliac screw augmentation of S1 pedicle screws has improved the fusion rate of high-grade spondylolisthesis[20]. In accordance with our study, however, a large number of their patients (53%) also required symptomatic iliac screw removal.

Carreon et al[33] have defined the minimum clinically important difference (MCID) for the SRS-22r questionnaire for appearance/self-image, activity and pain domains after surgical correction of adolescent idiopathic scoliosis. In this study the MCID for the pain domain was 0.20, 0.08 for the activity domain, and 0.98 for the appearance domain. There are no similar definitions to surgically treated children with spondylolisthesis. In our study the improvement was 0.68 in the pain, 0.19 in the self-image, and 0.89 scores in the activity domain. Improvements in the pain and activity domains are significantly above the MCID levels as defined for operatively treated scoliosis patients and it can be assumed that the changes in these domains are over the minimum clinically important difference also in the spondylolisthesis patients. In our previous study adolescents operated for **adolescent idiopathic scoliosis (AIS)** had similar scores of the SRS-24 domains except for the function domain at five-year follow-up compared to age and gender matched controls[28]. We hypothesize that pain may have more pronounced effect on health-related quality of life than pure spinal deformity does.

Limitations and strengths

Children needing surgical treatment for spondylolisthesis are relatively rare even in an academic pediatric spine unit. Thus, the number of surgically treated patients was relatively small. One limitation of this study was the somewhat different questionnaires used (the SRS-24 and SRS-22r). However, we chose to keep the same original SRS-24 questionnaire in the surgical treatment group in order to provide data from preoperative to minimum 2 years follow-up. We used the 15 most similar preoperative questions from the SRS-24 and SRS-22r to provide comparable questionnaires, including 8 questions that were exactly the same. With these questions we formed the pain, activity, self-image, and function domains of SRS-24. The strengths of this study include a comparison with an age and gender matched healthy control group consisting of two matched controls to each surgically treated spondylolisthesis patient. This is a prospective, consecutive cohort study, where the indications for surgery were clear. All the patients were operated using a similar surgical

technique by a single orthopedic spine surgeon. The follow-up time was a minimum of two years. The SRS-24 questionnaire used in this study is standardized, validated and widely used.

Conclusions

In conclusion, the SRS-24 scores in pain and activity domains improved statistically significantly after the surgery for spondylolisthesis during 2-year follow-up time. However the scores in pain, self-image and function domains were significantly lower as compared to age and sex matched healthy controls.

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Table 1. Clinical characteristics

Variable	**Spondylolisthesis patients (n=26)**	**Healthy controls (n=52)**
Age at 2-year FU (y)	16.7 ± 1.94	17.6 ± 3.8
Gender (male)	23% (6/26)	23% (12/52)
FU time (y)	3.3 ± 1.75	
Amount of slip		
• low grade (0-50%)	42% (11/26)	
• high grade (51-100%)	58% (15/26)	
Levels fused		
• L5-S1	46% (12/26)	
• L4-S1	54% (14/26)	
Blood loss (mL)	391 ± 185	
Operative time (hr)	3.8 ± 1.3	

* FU = follow-up

Scores are mean values and SD

Table 2. Radiographic parameters of the study groups

Radiographic parameters	Low-grade (n=11)	High-grade (n=15)	p value
Slip (%)			
• preoperative	25% ± 13%	67% ± 15%	<0.001
• 2-yr FU	6% ± 7%	21% ± 25% *	0.041
Lumbosacral angle			
• preoperative	10° ± 8°	14° ± 11°	0.322
• 2-yr FU	10° ± 8°	10° ± 6°	0.884
Pelvic tilt			
• preoperative	18° ± 9°	30° ± 8°	0.004
• 2-yr FU	20° ± 5°	26° ± 8°	0.044
Sacral slope			
• preoperative	44° ± 12°	46° ± 8°	0.628
• 2-yr FU	40° ± 13°	46° ± 6°	0.164
Unbalanced pelvis			
• preoperative	N/A	57% (8/14)	
• postoperative	N/A	47% (7/15)	
Pelvic incidence	60° ± 10°	72° ± 10°	0.007

* in the high-grade group one patient had spondyloptosis (100% slip) and no reduction of the slip was performed in the operation

Scores are mean values and SD

Table 3. The changes in SRS-24 outcome questionnaire.

SRS Domain	**preoperative (N= 22)**	**6 months follow-up (N=20)**	**2-year follow-up (N=23)**	**p value**
Total	3.59 ± 0.61	3.82 ± 0.52	3.86 ± 0.68	0.059*
Pain	3.27 ± 0.93	4.24 ± 0.89	3.92 ±1.03	0.007*
Self-image	4.03 ± 0.63	4.11 ± 0.39	4.28 ± 0.57	0.052*
Function	3.85 ± 0.50	3.96 ± 0.52	4.10 ± 0.46	0.065*
Activity	3.53 ± 1.06	3.81 ± 1.18	4.22 ± 1.25	0.001*
Postop self-image	N/A	3.18 ± 0.57	3.26 ± 0.67	0.627**
postop function	N/A	2.42 ± 1.17	3.00 ± 1.41	0.072**
satisfaction	N/A	4.02 ± 0.60	3.91 ± 0.56	0.260**

* 2-year follow-up scores compared to preoperative scores

** 2-year follow-up scores compared to 6 months follow-up scores

Scores are mean values and SD

Table 4. Comparison of SRS outcomes between surgically treated patients and age and gender matched controls

SRS Domain	**2-year follow-up (n=23)**	**Healthy controls (n= 52)**	**p value**
Total*	4.10 ± 0.76	4.73 ± 0.33	<0.0001
Pain**	3.97 ± 1.02	4.76 ± 0.45	<0.001
Self-image	4.28 ± 0.57	4.57 ± 0.50	0.018
Function	4.09 ± 0.46	4.91 ± 0.19	<0.0001
Activity	4.22 ± 1.25	4.66 ± 0.46	0.482
Total of 8 same questions	4.03 ± 0.89	4.67 ± 0.41	<0.001

* 2-year follow-up SRS scores excluding the questions regarding postoperative state

** the postoperative pain question is excluded

Scores are mean values and SD

Table 5. Comparison between SRS domains in the low-grade vs high-grade slips and healthy controls

SRS Domain	**Low-grade 2-year follow-up (n=10)**	**Healthy controls (n= 52)**	**p value***	**High-grade 2-year follow-up (n=13)**	**p value****
Total ˆ	3.81 ± 0.95	4.73 ± 0.33	<0.001	4.33 ± 0.51	0.002
Painˆˆ	3.68 ± 1.25	4.76 ± 0.45	0.002	4.19 ± 0.79	0.020
Self-image	4.13 ± 0.55	4.57 ± 0.50	0.027	4.38 ± 0.59	0.457
Function	3.88 ± 0.62	4.91 ± 0.19	<0.0001	4.26 ± 0.20	<0.0001
Activity	3.67 ± 1.54	4.66 ± 0.46	0.150	4.64 ± 0.81	0.816
Total of 8 same question	3.74 ± 1.05	4.67 ± 0.41	0.009	4.26 ± 0.69	0.067

ˆ 2-year follow-up SRS scores excluding the questions regarding postoperative state

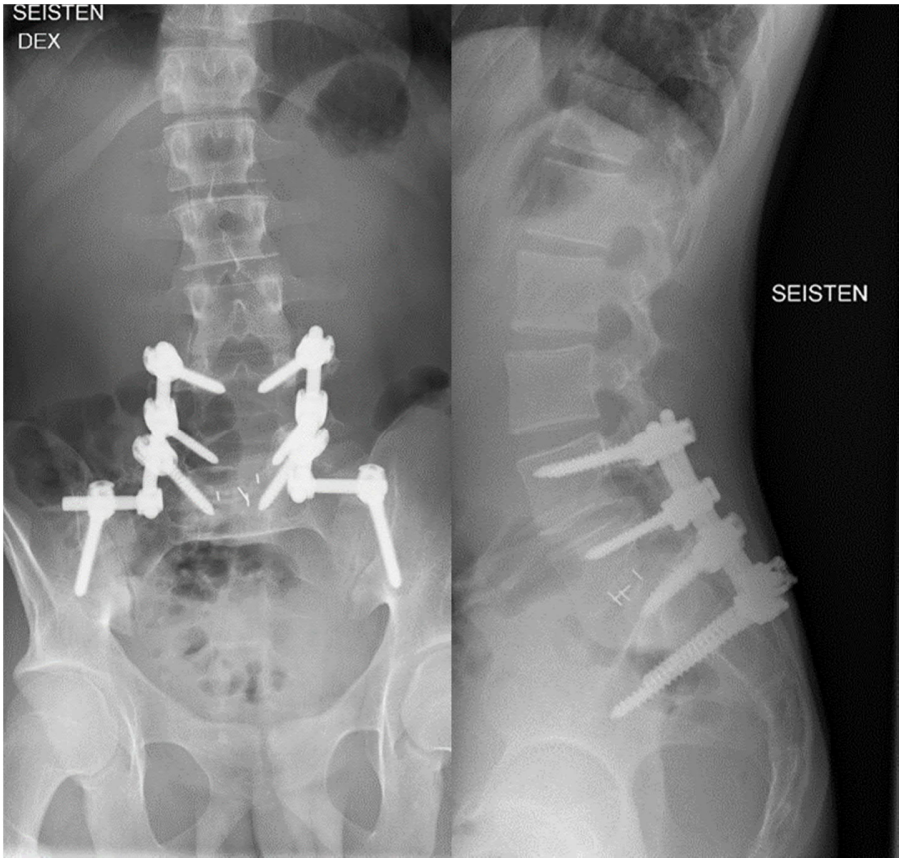
ˆˆ The postoperative pain question is excluded

*low-grade srs-24 2-year follow-up vs healthy controls srs-22

** high-grade srs-24 2-year follow-up vs healthy controls srs-22

Scores are mean values and SD

Figures 1-A and 1-B. A fifteen-year-old boy with a high-grade spondylolisthesis (slip 58%). Fig. 1-A Posteroanterior and lateral (Fig. 1-B) standing lumbar spine radiograph



Figures 2-A and 2-B. The same patient as in the Figure 1 two years after L5 and S1 nerve root decompression and circumferential spinal fusion with instrumented reduction from L4 to S1 with iliac screws