



# Impact of resolved early major complications on 2-year follow-up outcome following adult spinal deformity surgery

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## Abstract

**Purpose** Major complications are a concern following ASD surgery. Even when properly managed and resolved, they may still have a relevant impact on HRQL. We aimed to investigate the impact of resolved early major complications on 2-year outcome after ASD surgery.

**Methods** Two groups of consecutive surgical patients were extracted from a prospective multicentre database. Major complication group (MCG) included patients with any major complication, resolved within 6 months after surgery. Patients with further major complications during follow-up were excluded. Control group (CG) included patients with no major complications over the entire follow-up. Analysis of covariance adjusting for preoperative baseline values was used to compare improvements in HRQL measures at 2 years.

**Results** One hundred and seventy-five patients met the inclusion criteria and had complete HRQL data at 2 years (24 MCG, 151 CG). MCG patients were older and had more severe deformity and poorer baseline HRQL. There were 27 resolved major complications at 6 months needing 19 additional surgeries (18 revisions, 1 cholecystectomy). At 2 years, and after adjusting for preoperative data, outcome in MCG patients was as follows: scores were 5.98 (SE 3.03) points higher for the ODI ( $p=0.05$ ), 0.36 (SE 0.13) lower SRS-22 function ( $p=0.01$ ), 4.07 (SE 1.93) lower SF-36 PCS ( $p=0.04$ ), and 0.16 (SE 0.13) lower SRS-22 subtotal ( $p=0.22$ ).

**Conclusion** The results indicate that patients experiencing major complications after ASD surgery have significantly less functional improvement (SRS-22 function, ODI, SF-36 PCS) than their complication-free counterparts, even when complications were considered resolved, and the outcome was measured after an 18-month complication-free period.

## Graphical abstract

These slides can be retrieved under Electronic Supplementary Material.

**Key points**

- Impact of complications on final outcome after surgery should be assessed after a complication-free period allowing for resolution.
- Even when resolved, early major complications had a negative impact on final outcome after a complication-free period.
- Patients with early major complications achieved a significant improvement from baseline, but it was less marked than that of their complication-free counterparts.

	Two-Years	Difference in Score between groups	SE	p	95% CI
ODI		5.98	3.03	0.05	-0.003 11.97
SF-36 PCS		-4.07	1.94	0.04	-7.92 -0.25
SF-36 MCS		-0.97	2.24	0.69	-5.38 3.44
SRS-22 function		-0.33	0.14	0.02	-0.60 -0.05
SRS-22 mental health		-0.09	0.16	0.60	-0.41 0.24
SRS-22 self image		-0.20	0.17	0.24	-0.53 0.13
SRS-22 pain		-0.09	0.19	0.62	-0.46 0.28
SRS-22 subtotal		-0.16	0.13	0.22	-0.42 0.09

**Take Home Messages**

- Patients with major complications considered resolved by 6 months achieved a significant gain from baseline in patient-reported outcome measures at 2 years.
- However, the improvement was lower than that of patients with no complications, suggesting that even after they are resolved, complications can have a negative impact.

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Extended author information available on the last page of the article

**Keywords** Adult spinal deformity · Complications · Outcome

## Introduction

Complications following adult spinal deformity (ASD) surgery are a major concern among patients and caregivers. Broad variations in complication rates have been reported in the related studies (10.5–69.8%) [1–3]. A comprehensive review including data from 93 studies containing 11,692 patients showed an overall mean complication rate of 55% (major perioperative 18.5%, minor perioperative 15.7%, and long-term complications 20.5%) [4]. Complication rates are included in almost every study reporting results after surgery, and the risk of developing complications is a key factor when indicating surgery.

Usually, complications are reported as a complementary outcome measure [5, 2, 6, 7]. Only a few studies have analysed the specific impact major complications have on the final outcome after ASD surgery by assessing patient-reported outcome measures (PROMs) [8, 9]. In addition, the fact that new complications may continue to develop during follow-up, and therefore, prompting further modification in the final PROMs was not specifically taken into account in these reports.

The aim of this study was to determine the impact of resolved early major complications on the final patient outcome after a complication-free period to allow for recovery. We hypothesized that the improvement in PROMs in patients with such complications would be similar to that of patients with no complications after an 18-month complication-free period since resolution of the event.

## Materials and methods

We retrospectively analysed prospectively collected data from ASD patients recruited in six (European) centres from four different countries, recorded in a common, comprehensive ASD database and meeting the following inclusion criteria: age > 18 years and scoliosis > 20° or thoracic kyphosis > 60° or sagittal vertical axis > 5 cm or pelvic tilt > 20°. We included all consecutive, surgically treated patients with PROM data collected at the 2-year follow-up (index surgery between January 2010 and October 2014). Institutional review board approval was obtained from all participating centres, and all patients enrolled gave informed consent for inclusion.

Participating patients were divided into two groups according to the following criteria: (1) major complication group (MCG)—patients experiencing any major complication, resolved within the first 6 months after surgery. Patients who had any further major complications during

follow-up were excluded. And the second is control group (CG)—patients with no major complications over the entire follow-up.

Complications were classified as major or minor following the classification proposed by Glassman [8]. All complications needing revision surgery were considered major. Resolution of a complication was decided by the treating physician. Neurological complications were only considered resolved if the neurological deficit had completely recovered.

## Data collected

The following data from each patient were analysed: (1) demographic data, including age, sex, body mass index (BMI), smoking status, primary spinal diagnosis, prior spine surgery, the presence of at least one comorbidity, and American Society of Anesthesiologists (ASA) score; (2) deformity characteristics, including major curve coronal Cobb angle, coronal balance (C7SVL), sagittal vertical axis (SVA), T2–T12 thoracic kyphosis (TK), L1–S1 lumbar lordosis (LL), global tilt (GT) (defined as the angle formed by the intersection of two lines, one from the centre of C7 to the centre of the sacral endplate, and another from the centre of the sacral endplate to the centre of the femoral heads [10]), pelvic incidence (PI), pelvic tilt (PT), sacral slope (SS), sagittal subluxation, and T1 sagittal tilt; (3) surgical parameters, including total surgical time, estimated blood loss, decompression, number of levels fused, and pelvic fixation; and (4) PROM scores, including the ODI, SF-36, and SRS-22.

Radiological data and PROMs were obtained preoperatively and at 6 and 24 months after the index surgery.

## Statistical analysis

Statistical analysis included descriptive statistics, the Student *t* test, or Wilcoxon test to compare continuous variables when appropriate, and the Chi-square test to compare categorical variables. Analysis of covariance adjusting for the preoperative baseline values was performed to compare the improvement in each HRQL measure between the two groups at 2 years. Analyses were done using SAS 9.3 (SAS Institute Inc., Cary, NC, USA).

## Results

In a total of 402 eligible patients, 175 fulfilled the inclusion criteria and had complete PROM data at 2 years (24 MCG, 151 CG). MCG patients were older, had more severe sagittal deformity (SVA 72.7 mm vs. 21.8 mm), underwent

longer surgeries, and had poorer PROM scores at baseline than controls (Table 1).

There were 27 resolved major complications at 6 months in the 24 patients (8 implant-related complications, 5 deep surgical site infections, 5 medical complications, 2 motor

deficits, 2 proximal junctional kyphosis, and 5 others) (Table 2). Nineteen additional surgeries (18 revision surgeries and 1 cholecystectomy) were performed. Complete follow-up results are summarized in Table 3. Both groups showed a substantial clinical improvement relative to baseline.

At 6 months and after adjusting for preoperative baseline differences in each PROM, there was a smaller gain in function (ODI, SF-36 PCS, and SRS function) and mental health (SF-36 MCS and SRS-22 mental health) in the MCG patients (Table 4) than controls.

At 2 years and after adjusting for baseline data, the MCG ODI score was 5.98 (SE 3.03) points higher ( $p=0.05$ ), SRS-22 function 0.36 (SE 0.13) points lower ( $p=0.01$ ), and SF-36 PCS 4.07 (SE 1.93) points lower ( $p=0.04$ ) than the control scores (Table 4). The initial difference in mental health improvement at 6 months was no longer observed at 2 years.

**Table 1** Baseline characteristics of the study population

	CG mean (SD)	MCG mean (SD)
<b>Baseline characteristics</b>		
Age	48.5 (19.1)	62.3 (16.8)
	CG <i>n</i> (%)	MCG <i>n</i> (%)
Female	118 (78.2%)	13 (54.2%)
Previous Surgery	35 (23.2%)	12 (50%)
ASA1	40 (46.4%)	6 (25%)
ASA2	68 (45.0%)	14 (58.3%)
ASA3	13 (8.6%)	4 (16.7%)
<b>Surgical characteristics</b>		
Estimated Blood Loss	1395.9 (1155.8)	1880.4 (1225.7)
Surgical Time	310.1 (174.2)	364.0 (148.7)
Segments fused	9.92 (4.02)	9.67 (4.10)
	CG <i>n</i> (%)	MCG <i>n</i> (%)
Decompression performed	45 (29.8%)	11 (45.83%)
Fusion to pelvis	44 (29.14%)	13 (54.17%)
3CO	25 (16.6%)	5 (20.8%)
<b>Radiographic parameters</b>		
Major Cobb	41.28 (23.4)	38.78 (21.1)
SVA	21.82 (55.5)	72.69 (69.4)
Global Tilt	21.02 (15.8)	31.0 (17.2)
PI	52.26 (11.1)	54.25 (10.6)
PT	18.89 (10.5)	23.83 (9.7)
SS	33.27 (10.8)	30.42 (10.2)
LL	- 47.56 (21.0)	- 35.32 (18.8)
<b>Patient-reported outcome measures</b>		
ODI	37.69 (20.6)	44.75 (14.1)
SF-36 PCS	36.19 (9.3)	32.98 (6.3)
SF-36 MCS	43.98 (11.4)	42.13 (10.9)
SRS-22—function	3.15 (0.91)	2.95 (0.93)
SRS-22—mental health	3.24 (0.8)	3.18 (0.92)
SRS-22—pain	2.75 (0.98)	2.65 (0.89)
SRS-22—satisfaction	3.0 (1.1)	3.0 (1.0)
SRS-22—self-image	2.53 (0.73)	2.43 (0.63)
SRS-22—subtotal	2.91 (0.7)	2.79 (0.7)

Descriptive results MCG (patients with major complications appeared, treated and resolved within the first six months after surgery without any other major complication in the follow-up) and CG (patients without any postoperative major complication during follow-up)

Global Tilt: angle between the line drawn from the centre of C7 to the centre of the sacral endplate and a line drawn from the centre of the sacral endplate to the centre of the femoral head. From a geometrical point of view, GT equals the sum of the pelvic tilt and the spinal tilt angle

## Discussion

At 2 years after ASD surgery, the clinical status of both groups of patients—those with no major postoperative complications and those with resolved early major complications—had improved significantly from baseline. However, patients with major complications improved to a lesser

**Table 2** Summary of the 27 major complications observed

27 major complications	
Implant related (8)	Set screw dislodgement (2)
	Screw–bone interface loosening (2)
	Rod breakage
	Insufficient implants
	Cross-link dislodgement
	Screw malposition with impingement on a neural structure
Deep surgical site infection (5)	
Medical complications (5)	Lung embolism
	Pneumonia
	Bowel obstruction
	Cholecystitis
	Sepsis
Motor deficit (2)	
Proximal junctional kyphosis (2)	
Epidural haematoma (2)	
Others (3)	Cerebrospinal fluid fistula
	Vertebral body fracture
	Persistent wound seroma

**Table 3** Mean (SD) PROM values at baseline, 6 months, and 2 years

	Preop mean (SD)	6 months mean (SD)	2 years mean (SD)	2-year change from baseline
<b>ODI</b>				
CG	37.69 (20.6)	27.9 (16.7)	23.1 (17.3)	– 14.58
MCG	44.75 (14.1)	39.0(17.1)	32.92 (17.2)	– 11.83
<b>SF-36-MCS</b>				
CG	43.98 (11.4)	48.1 (12.0)	47.27 (11.4)	3.29
MCG	42.13 (10.9)	43.0 (13.6)	45.47 (10.9)	3.34
<b>SF-36-PCS</b>				
CG	36.19 (9.3)	40.5 (8.9)	43.8 (9.9)	7.32
MCG	32.98 (6.3)	35.5 (9.0)	38.49 (10.4)	5.01
<b>SRS-22—function</b>				
CG	3.15 (0.91)	3.32 (0.76)	3.7 (0.9)	0.55
MCG	2.95 (0.93)	3.0 (0.92)	3.28 (1.0)	0.26
<b>SRS-22—mental health</b>				
CG	3.24 (0.8)	3.57 (0.9)	3.63 (0.9)	0.48
MCG	3.18 (0.92)	3.25 (0.8)	3.54 (0.7)	0.52
<b>SRS-22—pain</b>				
CG	2.75 (0.98)	3.47 (0.9)	3.70 (1.0)	0.95
MCG	2.65 (0.89)	3.42 (0.8)	3.54 (0.9)	0.89
<b>SRS-22—satisfaction</b>				
CG	3.0 (1.1)	4.29 (0.8)	4.24 (0.9)	1.24
MCG	3.0 (1.0)	3.6 (0.9)	3.91 (0.9)	0.91
<b>SRS-22—self-image</b>				
CG	2.53 (0.73)	3.59 (0.8)	3.65 (0.8)	1.12
MCG	2.43 (0.63)	3.38 (0.9)	3.45 (0.8)	1.02
<b>SRS-22—subtotal</b>				
CG	2.91 (0.7)	3.49 (0.6)	3.67 (0.7)	0.76
MCG	2.79 (0.7)	3.25 (0.7)	3.45 (0.7)	0.63

*MCG* major complications group (patients with major complications that developed, and were treated and resolved within the first 6 months after surgery with no additional major complications over follow-up), *CG* control group (patients with no major postoperative complications over follow-up)

*ODI* Oswestry Disability Index, *SF-36 PCS* Short Form 36 Physical Component, *SF-36 MCS* Short Form 36 Mental Component, *SRS-22* Scoliosis Research Society-22

degree in terms of function (SRS-22 function, ODI, SF-36 PCS) even though their complications were considered to be resolved, and the final outcome was measured after an 18-month complication-free period.

Some reports have suggested that patients perceive complications to have a greater impact than surgeons do [11, 12]. Therefore, the effect that complications per se have on PROMs should be further evaluated. Glassmann et al. [8] analysed outcome after perioperative complications following ASD surgery and found that major complications had a negative effect on the 1-year SF-12 scores. The impact of minor complications was less relevant [8]. Scheer et al. [9] studied the impact of reoperations and complications on recovery of 149 patients after ASD surgery. A major complication occurred in 26.2% of patients over 2 years, and 28 of 39 complications required surgical treatment (19 of 27 in our sample). Patients with

major complications had poorer ODI, SF-36 PCS, and SRS-22 subtotal scores at final follow-up than those with minor or no complications, although there was a significant improvement from baseline. However, this study did not take into account the time point when complications occurred. It might well have been that complications were still unresolved at final follow-up, or developed late during follow-up or close to the day PROM questionnaires were completed. In fact, the authors suggested that “the closer the complication occurs to when HRQL is reported, the more likely the complication has an effect on HRQL” [9]. Lambat et al. performed a matched-pair analysis using propensity score techniques to assess the impact of complications on outcome after lumbar fusion surgery. In their sample, the percentage of patients reaching a minimum clinically important difference was significantly smaller in the major complication group, although differences in

**Table 4** Difference in scores between the two groups after adjusting for baseline differences using covariance analysis

	Between-group difference in score	SE	<i>p</i> value	95% CI	
Six-month					
ODI	8.14	3.26	0.01	1.69	14.59
SF-36 PCS	− 3.80	1.79	0.03	− 7.34	− 0.26
SF-36 MCS	− 5.09	2.48	0.04	− 9.99	− 0.19
SRS-22—function	− 0.30	0.15	0.04	− 0.60	− 0.01
SRS-22—mental health	− 0.30	0.15	0.05	− 0.61	− 0.01
SRS-22—self-image	− 0.20	0.18	0.25	− 0.55	0.15
SRS-22—pain	− 0.03	0.18	0.89	− 0.39	0.33
SRS-22—subtotal	− 0.21	0.13	0.11	− 0.46	− 0.05
Two-year					
ODI	5.98	3.03	0.05	− 0.003	11.97
SF-36 PCS	− 4.07	1.94	0.04	− 7.92	− 0.05
SF-36 MCS	− 0.97	2.24	0.66	− 5.38	3.44
SRS-22—function	− 0.33	0.14	0.02	− 0.60	− 0.05
SRS-22—mental health	− 0.09	0.16	0.60	− 0.41	− 0.24
SRS-22—self-image	− 0.20	0.17	0.24	− 0.53	0.13
SRS-22—pain	− 0.09	0.19	0.62	− 0.46	0.28
SRS-22—subtotal	− 0.16	0.13	0.22	− 0.42	0.09

ODI Oswestry Disability Index, SF-36 PCS Short Form 36 Physical Component, SF-36 MCS Short Form 36 Mental Component, SRS-22 Scoliosis Research Society-22

the mean ODI scores did not reach statistical significance [13]. None of these studies included a complication-free period in the two patient groups to allow for recovery and to minimize the short-term effects of recent complications on PROMs, as was done in the present study.

Patients with resolved early postoperative complications in our sample scored significantly worse on all the PROM functional measures evaluated (ODI, SF-36 PCS, and SRS-22 function) than their counterparts without complications. The models yielded larger differences than those obtained by comparing the mean values, illustrating the importance of adjusting for baseline values. Even though the complications were considered resolved, and 18 months had passed with no further complications, there was a small but significant difference in the endpoint, HRQL. The impact was quantitatively subtle when considering the absolute score differences between groups, but it was qualitatively relevant after correcting for baseline differences.

The substantial baseline differences between the two groups in our sample could be a potential drawback of the study. An alternative method to minimise the effect of baseline differences would have been to perform a matched-pair analysis [13]. However, strict matching criteria are paramount to obtain reliable results with this method and within the current sample, there were too few available patients to serve as quality controls. Covariance analysis, controlling for the preoperative baseline values of each outcome

measure, was used to minimize the baseline differences in PROM scores.

It could be argued that MCG patients did not achieve greater improvements because of their poorer baseline status, but several recent reports contradict this intuitive idea [14–17]. Smith et al. analysed 206 patients undergoing adult deformity surgery. The older patients in the sample were in a poorer baseline condition and had a significantly greater percentage of complications, but their HRQL outcome was similar to that of their younger counterparts [14]. Two other studies have shown that clinical benefits are similar in patients undergoing primary or revision surgery [15, 16]. An integrated health status (IHS) analysis, using normalized ODI, SF-36, and SRS-22 values, evaluated recovery after ASD surgery, stratifying patients by age and ODI baseline status [17]. Older patients had a more marked improvement and were more likely to reach a minimum clinically important difference. Patients with a poorer baseline ODI score also showed a more marked improvement in IHS in all measures reported except for the SRS-22 appearance and satisfaction domains [17]. In the light of these results, MCG patients, who were older (mean, 62.25 vs. 48.5 years) and had poorer baseline status, would have been expected to achieve even greater improvements than the controls.

Another potential concern regarding the data obtained here is the heterogeneity of the complications analysed: medical complications, surgical site infections, and mechanical complications, among others. One study evaluating the

impact of medical complications after ASD surgery found no significant effect on recovery rates or overall improvement [18]. However, recent reports have suggested that PROM evaluation used in spinal surgery patients may fail to appraise the impact of complications, especially those related to medical conditions that affect the patients' overall health status [19, 20]. These studies reported greater deterioration in the Charlson Comorbidity Index score following major complications, despite gains in spine-related PROMs (ODI) [19, 20]. In our sample, medical complications accounted for only 18.5% of all major complications evaluated. Another study only determined the impact of implant-related and radiological complications at 2-year follow-up [21]. A complication-free period before assessing outcome was not considered. Although both groups achieved a significant improvement, patients with implant-related and radiological complications had lower improvement rates on the SRS-22 and SF-36 [21]. These results are in line with the findings of the present study.

Frailty is another interesting point to be addressed in future studies. In the past few years, there is an increasing amount of literature on the issue, as results show a relevant association between frailty and complications. Recently, a frailty index has been validated for use on the ASD population [22]. Those data were not available while performing the present analysis. In the future, frailty should be taken into account not only as a potential risk factor for presenting complications, but also as a potential drawback for recovery after a given complication.

A relevant lack of improvement in mental health at 1 and 2 years has been reported in relation to the presence of complications and reoperation requirements after ASD surgery [9, 23]. In our sample, a lack of improvement was seen at 6 months, but there were no differences at 2 years (MCS -0.97 points for SF-36, SE 2.24;  $p=0.66$ ), suggesting that resolution of the complications may have led to the expected gain in mental health. The initial lack of improvement may be related to the burden represented by the complication or the fact that additional surgery was needed, but it did not have long-term effects.

At times, it may be difficult to decide when to label a complication as resolved. When proximal junctional kyphosis is successfully treated by an extension of fusion, we could consider the problem resolved. However, the final outcome of an unintended longer fusion may be less favourable than the expected results of the initial procedure without complications. One study has investigated the outcome of patients undergoing reoperations within the first year after ASD surgery [23]. PROMs, measured 1 year after the index surgery, yielded poorer ODI, SRS-22 total, and SF-36 PCS scores in the reoperation group. However, the time of reoperation may have been very close to the 1-year time point when PROMs were collected, and this would have an influence on

the negative results. Another study investigated the 2-year outcome of patients undergoing revision surgery within the first year. There were no significant differences in the mean change in PROMs, although all PROM changes were slightly smaller in the reoperation group [24].

The fact that we found complications do have some effect on PROMs even if they are considered to be resolved and there has been a complication-free period before evaluation reinforces the need for prevention and prediction of complications. Recently, several risk calculators or predictors are being developed for that use [25–27]. Combined knowledge about complications risk and complications impact should enable better patient counselling while indicating surgery.

Despite the baseline differences between the two patient groups evaluated and the heterogeneity of the complications recorded, we found that major complications considered resolved had a significant impact on functional outcome even after an 18-month complication-free period. This finding has implications for patient counselling. Patients should be aware that even if complications can be successfully treated, they may have an unfavourable influence on their 2-year clinical status. Nonetheless, even though a negative impact was observed in the complication group, these patients still experienced a significant improvement from baseline, which suggests that a fear of potentially remediable complications should not necessarily be a reason to refuse surgical treatment.

## Conclusion

Patients with major complications resolved by 6 months after adult spinal deformity surgery attained a significant improvement in the SF-36 and SRS-22 assessments from baseline to 2 years. However, this gain was less marked than that observed in patients without complications. After adjusting for baseline values, the differences in PROM scores between the two groups were statistically significant in all domains evaluating function (ODI, SF-36 PCS, and SRS-22 function).

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## Compliance with ethical standards

**Conflict of interest** SNP and AVC have no conflict of interest. AA, EA, FP, IO, FK and FJSPG have received grants from Depuy Synthes Spine), AA and FP have received grants from Medtronic. FP, IO and FJSPG are consultants for Depuy Synthes Spine, FP is consultant for K2M and IO is Consultant for Medtronic. IO receives royalties from Alpahtech, Clariance and Spineart).

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