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Dynamic posterior stabilization for degenerative lumbar spine disease: a large consecutive case series with long term follow-up by additional postal survey

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Abstract

Introduction

Dynamic stabilization of the degenerated spine was invented to overcome the negative side effects of fusion surgery like adjacent segment degeneration. Amongst various different implants DSS® is a pedicle based dynamic device for stabilizing the spine and preserving motion. Nearly no clinical data of the implant have been reported so far. The current analysis presents results from a single spine surgeon who has been using DSS® for the past 5 years and recorded all treatment and outcome data in the international Spine Tango registry.

Materials/ Methods

From the prospectively documented overall patient pool 436 cases treated with DSS® could be identified. The analysis was enhanced with a mailing of COMI patient questionnaires for generating longer term follow-ups up to 4 years.

Results

387 patients (189 male, 198 female; mean age 67.3 years) with degenerative lumbar spinal disease including degenerative spondylolisthesis (6.1%) could be evaluated. The type of degeneration was mainly spinal stenosis (89.9%). After a mean follow-up of 1.94 years the COMI score and NRS back and leg pain improved significantly and to a clinically relevant extent. The postoperative trend analysis could not determine a relevant deterioration of these outcomes until 4 years postoperative. 10 patients were revised (2.6%) and the implant was removed, in most cases a fusion was performed. Another 5 cases (1.3%) had an extension of the dynamic stabilization system to the adjacent level. 84.2% of patients rated that the surgery had helped a lot or had helped.

Discussion

The results of this large consecutive series with a follow-up up to 4 years could demonstrate a good and stable clinical outcome after posterior dynamic stabilization with DSS®. For degenerative diseases of the lumbar spine this treatment seems to be a valid alternative to fusion surgery.

Keywords: dynamic stabilization; degenerative spine disease; Spine Tango

Introduction

A multitude of fusion techniques of the lumbar spine exist, and fusion per se is still considered as the gold standard therapy for many degenerative conditions [1]. Nevertheless, in the long term spondylodesis may lead to accelerated degeneration of the adjacent segments. Biomechanical changes like increased mobility, increased facet loading and increased intradiscal pressure in these segments could play a primary role in the development of adjacent segment disease [2]. To minimize the risk of adjacent segment degeneration an interest arose in alternative motion preserving techniques which restore the intersegmental stability and motion in a controlled way. Throughout the years different devices have been developed for achieving a dynamic stabilization: nucleus replacements, total disc replacements (TDR), interspinous spacers and pedicle screw based posterior dynamic stabilization systems [3].

Several of these pedicle screw based dynamic stabilization devices are available. As a consequence of the different biomechanical properties, indications used in clinical studies vary, and no obvious consensus exists. Charles et al. considered moderate disc degeneration in combination with mild facet arthrosis, mild spondylolisthesis without instability, dynamic spinal stenosis, or topping off a multilevel fusion as indications with a high probability of success [4].

The DSS® device (Paradigm Spine, LCC, New York, NY, USA) was developed according to a biomechanical evaluation of the optimal stiffness parameters for a dynamic pedicle screw based stabilization device [5]. DSS® testing on cadaver specimens showed a 54% reduction in segmental flexion, 39% in extension, 45% in lateral bending, and 7% in axial rotation [5]. In a biomechanical evaluation of DSS® using a circumferential dynamic stabilization application in combination with a TDR, the stabilizing effect could be verified. DSS® limited all degrees of freedom [6].

Only very limited clinical data of this device are available so far. Our aim was to report the 4-year results of a large single surgeon case series of patients treated with DSS® for degenerative conditions of the lumbar spine.

Materials and Methods

This prospectively and consecutively documented case series of patients with degenerative lumbar spinal disease treated with a dynamic pedicle screw based stabilization system (DSS®, Paradigm Spine, NY, USA) at the Orthopedic Center xxx, xxx, was extended with a postal survey of the Core Outcome Measures Index (COMI Back) [7]. The responsible institutional review board did not request an additional ethical approval for this study but accepted the positive vote for data collection within the xxx arm of the Spine Tango registry of the ethics committee of the University hospital xxx (No. 09-182), where the xxx Spine Tango server module is located . Spine Tango is a voluntary registry under the auspices of Eurospine, the Spine Society of Europe, hosted at the Institute for Evaluative Research in Medicine at the University of Bern in Switzerland. Physician based primary and follow-up data on surgical and conservative spinal treatments are collected. The COMI Back and Neck are the official patient based outcome instruments of Spine Tango. They are short, self-administered outcome instruments consisting of seven questions to assess the following five dimensions: pain, back-related function, symptom-specific well-being, general quality of life and disability (social and work)[7]. Two numerical rating scales (NRS 0-10 points) are used to assess back and leg pain, and all

other items result in a sum score between 10 (worst) and 0 (best) function. Likert scale based patient satisfaction with the medical care and their perception of the effectiveness of treatment are captured in the follow-up section of the COMI.

The search of the first author's Spine Tango data for patients with sole motion preserving posterior dynamic stabilization of the lumbar and lumbo-sacral spine without additional fusion or rigid stabilization produced 436 patients treated with the DSS® device between 11/2009 and 10/2013. To all 436 patients a COMI questionnaire was sent by mail to receive additional (longer term) follow-up information. 307 patients returned the COMI questionnaire, 5 patients had died, 11 had moved in the meantime, 3 patients were not able to answer the questions due to other conditions, and 110 patients did not respond.

For the outcome analysis only patients with a pre- and at least 1 postoperative COMI questionnaire were included who suffered from a degenerative disease of the lumbar spine including degenerative spondylolisthesis. Three hundred and eighty-seven patients (189 male and 198 female) with a mean age of 67.3 years (SD 9.8; range 36-90) met the criteria. The most frequent indication for dynamic stabilization was a degenerative, secondary stenosis of the lumbar spine (89.9%). Due to the risk of subsequent instability requiring re-operation, simple decompression surgery was deemed insufficient in these cases. In 21 cases (5.4%) a disc herniation was documented, in 24 cases (6.2%) a degenerative spondylolisthesis grade I, and adjacent segment degeneration and degenerative disc disease were specified in 2 patients each (0.5 % each). None of the patients had an additional spinal pathology. Forty-one patients (10.6%) had undergone 1 previous surgery, 7 patients (1.8%) 2 previous surgeries. For 28 patients (7.2%) the previous surgery was at the same level. In 84.5% a monosegmental DSS surgery was performed and in 15.5% the surgery covered 2 or 3 segments. The segment L4/5 was predominantly affected (71.6%) followed by L3/4 (19.9%). Segments L2/3 and L5/S1 were only treated in 4.1% each and the segment L1/2 in 0.3% of the cases.

The clinical outcome was measured with the Core Outcome Measures Index (COMI) back questionnaire, assessing back and leg pain on a 0-10 numerical rating scale (NRS). The instrument also documents five domains (pain, back-related function, symptom-specific well-being, general quality of life and disability (social and work)), based on which a COMI score (0-10) is calculated. Follow-up COMIs also include a question on reintervention: ''Since the operation in our hospital, have you had any further operation(s) on your lumbar spine in our or in other hospitals?'' with three possible answers: ''no'', ''yes, but at a different level of the spine'', ''yes, at the same index level of the spine''. The surgeon based follow-up form was used for recording the overall outcome and complications from the surgeons` point of view.

Statistical analyses

The Wilcoxon signed rank test was used for pre- to postoperative comparisons of continuous variables like COMI score and NRS for back and leg pain. The analysis of the postoperative outcome trend was performed with repeated measures mixed models, calculating one-sided pairwise comparisons of non-inferiority between the one-year and each subsequent follow-up at 2, 3 and 4 years after surgery. Tukey`s correction was used to adjust for repeated testing. We declared non-inferiority if the upper 90% confidence limit for the difference in the means lied below a clinically defined change of two points, representing a relevant loss of treatment effect. This minimal clinically

relevant change of two points was chosen for all three outcomes, COMI score and NRS leg and back pain [8, 9]. Statistical analyses were performed using the software package SAS 9.4 (SAS Institute Inc, Cary, NC) with an alpha=0.05.

Results

Since the COMI postal survey could only gain additional patient based information, different sub-groups with different follow-up intervals were available for surgeon and patient based outcomes. 299 surgeon based follow-ups were documented within the Spine Tango database (follow-up rate of 76.5%) with a mean follow-up time of 9 months (range 27 days - 4.2 years). The overall outcome rating by the surgeon was good in 98.0 % and excellent in 2.0% of the cases.

For the COMI the mean follow-up interval for the last available form was 1.9 years (SD 1.4y range 9 days - 4.4 years). The COMI score improved significantly from a preoperative mean of 8.1 (SD 1.5 range 2.7-10) to a mean of 4.7 (SD 2.8 range 0-10) points at the last available follow-up ($p<0.0001$). The NRS back and leg pain improved significantly from preoperative mean 6.2 (SD 2.7 range 0-10) and 7.1 (SD 2.4 range 0-10) points to postoperative mean 3.5 (SD 2.8 range 0-10) and 3.5 (SD 3.0 range 0-10) points, respectively (each $p<0.0001$).

The model means and standard errors of the mean of the COMI score and the NRS back and leg pain of all available data at the different follow-up intervals are displayed in figure 1; table 1 shows the corresponding values. For all measured outcomes, COMI score and NRS back and leg pain, no clinically relevant deterioration could be observed from year 1 to all later follow-ups. Table 2 shows that the pairwise comparisons confirmed non-inferiority of post-operative outcome assessments until the end of the observation period.

The question on how much the operation had helped the patient`s back problem was answered with “helped a lot” in 45.5 %, “helped” in 38.8%, “helped only little” in 11.6% of the cases , “didn´t help” in 3.6% and “made things worse” in 2 patients (0.5%).

During the analysis it became obvious that patients with multiple follow-ups displayed a worse postoperative course of pain and function compared to those with a single follow-up form. Hence we stratified the COMI score and NRS pain results by the number of available COMI questionnaires per patient and displayed them in figures 2-4; the corresponding values are shown in table 3.

During hospitalization (median length of stay 11 days, range 3-43 days) the following surgical complications were documented: 2 malpositionings of the implant (0.5%), 13 dura lesions (3.4%), 3 (superficial) wound infections (0.8%) and 1 hematoma (0.3%). During the follow-up period 1 additional superficial wound infection was documented after 6 weeks and for 23 patients (5.9%) a second surgery was documented. Eight patients had a second surgery at the cervical spine, in 5 cases the dynamic stabilization was extended. In 10 patients (2.6%) a revision surgery was performed: in 3 patients the DSS implant was removed and a two-level fusion was performed; in 2 cases an instability needed to be revised; 2 cases were decompressed due to neurocompression - 1 with implant removal and the other with dynamic restabilization; 1 case with implant failure was fused; 1 implant removal was performed and 1 patient developed multisegmental degeneration which required fusion over multiple levels.

Discussion

This large consecutive series of 391 patients could demonstrate good and stable mid-term clinical outcome after dynamic stabilization with the DSS® system in patients with degenerative disease of the lumbar spine. Back and leg pain alleviation as well as functional improvement were significant, clinically relevant and stable over a follow-up interval of about 4 years. Nearly 85% of patients rated the surgery as very helpful or helpful. 2.6% of patients were revised.

There are only sparse clinical data available of the DSS® implant. Bertagnoli [10] evaluated the safety and efficacy of the DSS® system in a prospective consecutive study of 94 patients. 43 patients of this series received hybrid multilevel implantations. The VAS and ODI scores decreased significantly at 3 months after surgery and were maintained until 3 years postoperative. Lorio et al. [11] presented a retrospective product safety analysis of 20 DSS® cases. Indications were symptomatic debilitating lumbar degenerative disease (including grade 1 spondylolisthesis), stenosis, and salvage or protection of adjacent levels (topping off). After a mean follow-up of 18 months, 2 halo formations (symptomatic and asymptomatic), 1 anterior column induced instability and 1 bilateral rod hardware failure were observed. The overall symptomatic case complication rate and concomitant revision rate was in a range of 10%.

For various other pedicle screw based dynamic stabilization devices good clinical short to mid- term results with postoperative improvement of pain, function and disability were described. Scores reported are comparable to the outcomes in the current study [3].

The Dynesys dynamic stabilization system (Zimmer Spine) is the most extensively used posterior dynamic stabilization device and with respect to long term results the limited literature is focused on Dynesys. Investigations examined its long term outcome and stability in patients with degenerative spondylolisthesis [12, 13] and could demonstrate long lasting clinical improvement at least 4 years postoperative. The investigation of Di Silvestre et al. on 29 elderly patients with degenerative scoliosis treated with Dynesys showed significant improvement of VAS leg and back pain as well as ODI and Roland Morrison Questionnaire after a mean follow-up of 54 months [14].These results are conform to our analysis. We could demonstrate significant improvement after surgery with no significant deterioration of the COMI score or the NRS leg and back pain during the follow-up period of up to 4 years. Satisfaction of patients treated with Dynesys is comparable to our findings where 83.9 % of patients stated that the operation had helped or helped a lot. Sapkas et al reported that 74% of the patients were very satisfied and 89% would undergo the surgery again after a mean follow-up of 6.8 years [15]. With a complication rate of 25% (22 screw loosenings, 2 infections, 5 back pain and 2 leg pain exacerbations, 1 vertebral endplate fracture) and a revision rate of 5.6% the authors concluded that the spinal stabilization with Dynesys can be considered for treatment of degenerative diseases, but recommend long-term follow-up due to the relatively high complication and revision rates, mainly for screw loosening [15]. With 2.6% our revision rate was lower, but since no systematic radiographic evaluation was made, the complication rates are not directly comparable.

Comparing our results to fusion surgery as gold standard of care is difficult since various different fusion techniques are available and indications as well as study designs reported in the literature differ.

Robinson et al. [16] analysed the outcome of a large cohort of 1310 patients with degenerative disc disease within the SWESPINE registry and evaluated the patient outcome and quality of life according to the fusion technique. Quality of life and back pain improved at the 2 year follow-up irrespective of the surgical procedure (non-instrumented and instrumented posterolateral fusion and instrumented interbody fusion). The postoperative VAS back pain improved from 62-65 preoperative to 33-40 postoperative, the VAS leg pain from 45-46 preoperative to 29-32 at the 2 year follow-up [16]. Liu et al. [17] reported varying postoperative back pain levels between 1.2-4.7 in his meta-analysis about posterior interbody fusion (PLIF) and posterolateral fusion (PLF). Our own 2 year results are within these ranges: the VAS back pain improved from preoperative mean 6.2 to 3.2 at the 2 years follow-up, the VAS leg pain improved from a mean 7.1 to 2.9 at the 2 year follow-up. Hence the clinical outcomes were comparable to those of fusion surgeries. Our revision rate of 2.6% is rather low compared to revision rates reported for fusion techniques within the literature, but one has to consider that only revisions that were performed at the first author´s institution were detected. The meta-analysis comparing PLIF with PLF in patients with spondylolisthesis [17] reported re-operation rates between 3.6-17.3%. The outcome analysis of the SPORT trial in patients with degenerative spondylolisthesis reported a 4 year re-operation rate of 18% for PLF and 14% for posterolateral fusion with pedicle screws (PPS) [18]. A retrospective analysis of 1680 PLIFs with a mean follow-up of 5 years found a re-operation rate of 13.2% whereby pseudarthrosis was the most common reason for revision surgery with 4.5% [1]. Within this analysis decompensation of adjacent segments was observed in 2.8% of patients on average, and in 2.3% for mono- and bi-segmental fusions. In our investigation 8 patients (2.1%) required a revision surgery or an additional surgery due to an adjacent level pathology (3 revisions of the DSS system, 5 DSS enlargements). A radiographic evaluation was not performed and therefore no statement about asymptomatic adjacent segment degeneration was possible. Complications like screw loosening or other radiological findings were not detected as well. In his literature review, Park reported higher incidences of symptomatic adjacent segment disease (12.2-18.5%) after instrumented lumbar fusion and also noted that asymptomatic, i.e. radiographic adjacent segment disease was common but did not correlate with clinical outcome [2].

A coincidental finding of the current study was how the postoperative course of the outcome correlates with the number of followup visits in daily clinical practice. Patients with 3 or 4 visits showed a trend towards poorer postoperative pain alleviation and function or a loss of the initial treatment effect. These findings can only be generalized in a very limited way since the insurance status of the patient and the healthcare system may have a strong influence on the number of postoperative patient-surgeon encounters. On the other hand one may conclude that patients with only one or two postoperative visits in the short-term follow-up interval present their final and, at least from the patient`s point of view, satisfactory outcome since they don`t return for further follow-ups. Some may indeed change the treating physician if the outcome is poor, but in those cases the “final” recorded outcome by the initially treating physician and/or the patient will also be poor. Hence, the previously described observation that the “final” outcome of a spine surgery is already visible in the early postoperative stages [19] may especially apply for the good outcomes while dissatisfied patients will keep presenting to their surgeon until they are reoperated or decide to change the physician. Again, in both cases the poor outcome in a documenting institution should become obvious with a correspondingly rated follow-up or outcome form or a reoperation/revision form.

The Spine Tango registry is often criticized for its lack of long-term outcome data. Critics ignore the

fact that a registry mirrors clinical reality and that patients with a good outcome will neither be invited nor present for long-term follow-ups in the surgeons` busy practices. In some healthcare systems these follow-ups wouldn`t even be reimbursed by the insurances. The current investigation presents an elegant, cost effective and feasible solution in that a patient cohort of interest can be identified by a database query and then followed-up by a postal survey. Important and interesting outcome data can be generated that way. Dissatisfied or symptomatic patients may take this reaching-out of their surgeon as a good reason to present themselves again and a radiographic assessment with a physician based follow-up documentation may be a consequence. Asymptomatic patients would not receive such diagnostics anyway and a quickly completed and mailed outcome form seems as a good way for the surgeon to reassure himself of the long-term success of his treatment which is also recorded as data points in the registry.

Limitations

The surgeon based follow-up was only available for short- to mid-term intervals since the postal survey included only the COMI patient questionnaire. Our long term conclusions are hence more valid for the patient based outcome. The treatment of all patients was performed by one surgeon who is very experienced with the DSS implant. To gain a better external validity of the clinical results multicentric data would be more useful. Finally, the majority of patients in this study had a lumbar spinal stenosis. To avoid subsequent re-operations due to instability, an additional dynamic stabilization is generally performed in our center. We acknowledge that other surgeons might have decided to use simple decompression surgery in some of the patients included in the study. Studies comparing long-term outcomes between decompression alone and dynamic stabilization are needed in the future.

Conclusions

The DSS stabilization system does deliver good and stable clinical mid-term outcomes in patients with degenerative lumbar spinal disease and seems to be a valid alternative to fusion surgery with comparable clinical outcomes but fewer reoperations.

Conflict of interest / funding

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Figure 1: Distribution of COMI Score, NRS back pain and NRS leg pain over the follow-up period.

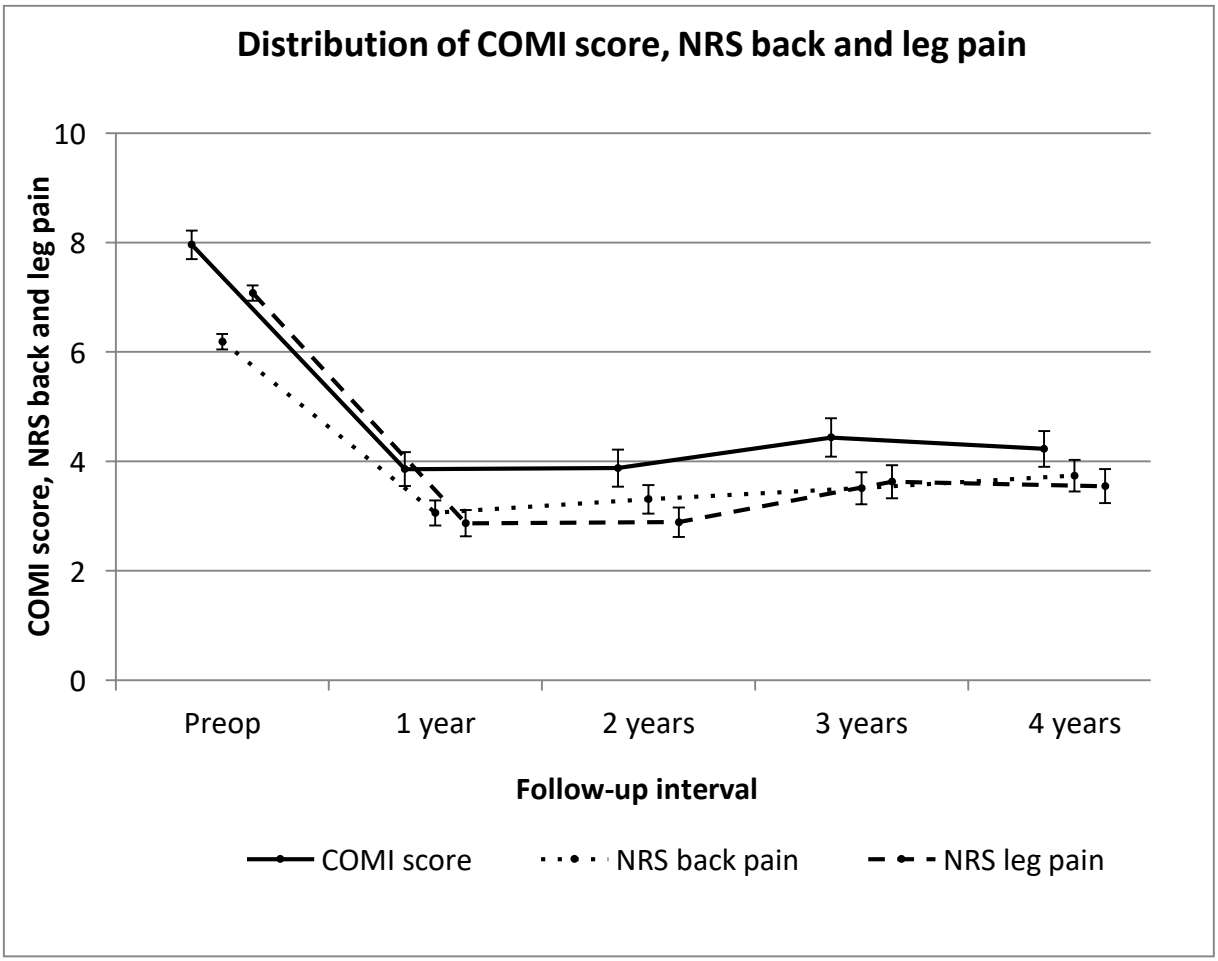

Figure 2: COMI score stratified by number of available postoperative COMI questionnaires per patient.

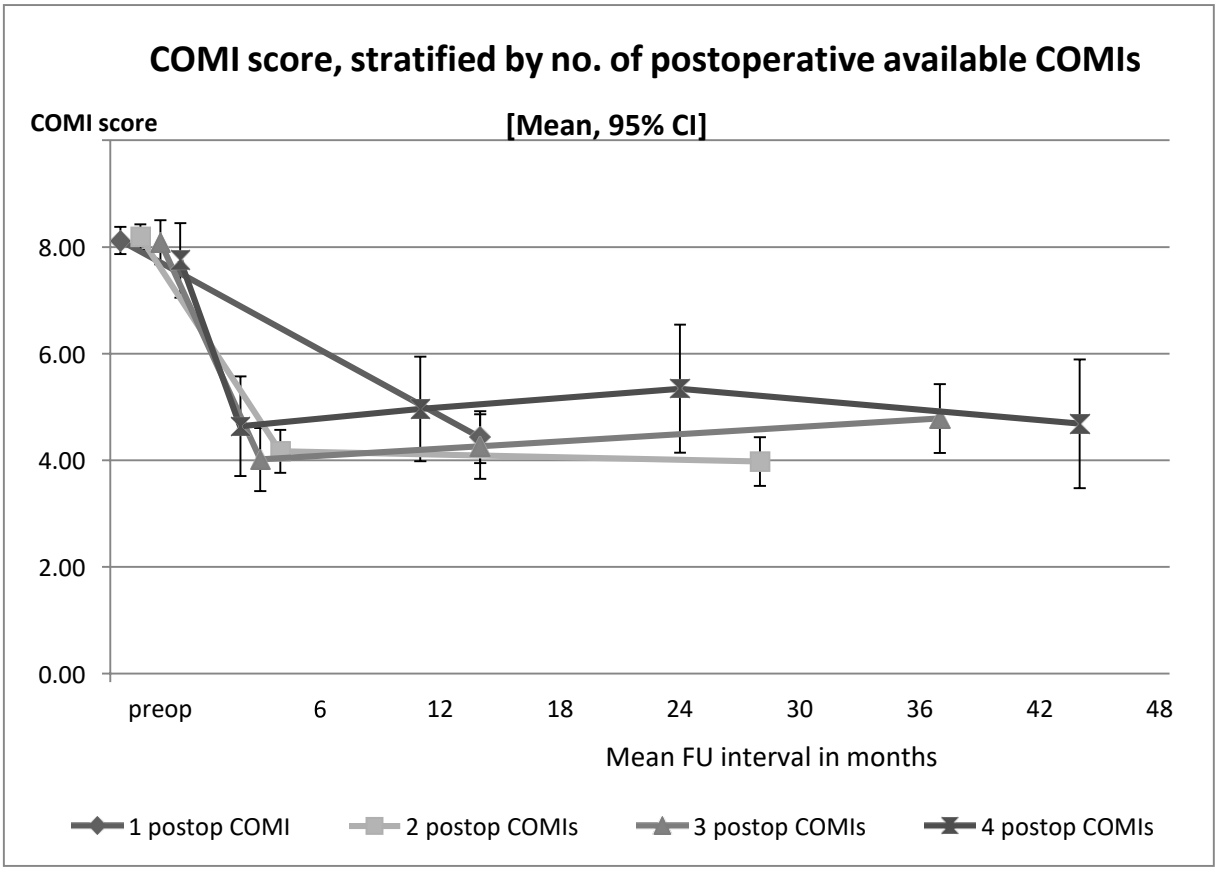

Figure 3: NRS back pain stratified by number of available postoperative COMI questionnaires per patient.

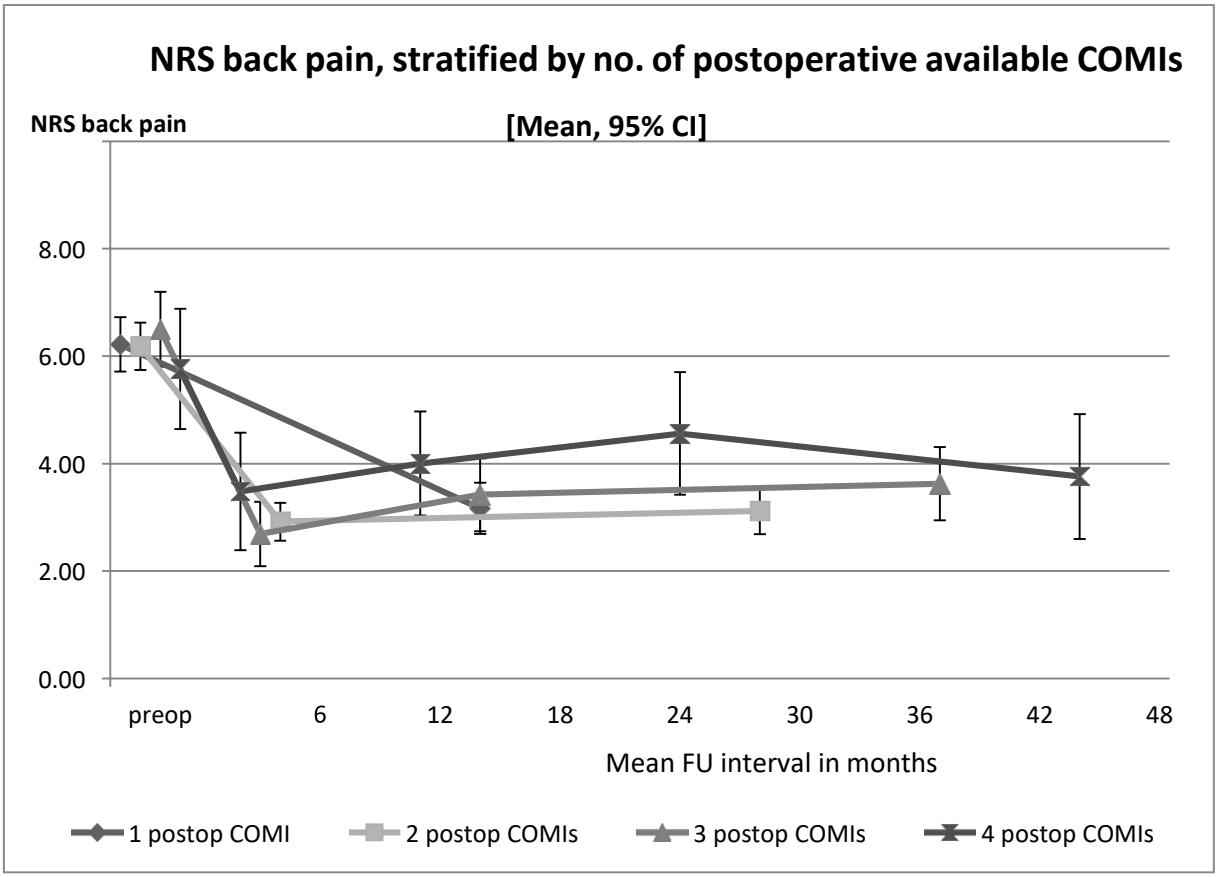

Figure 4: NRS leg pain stratified by number of available postoperative COMI questionnaires per patient.

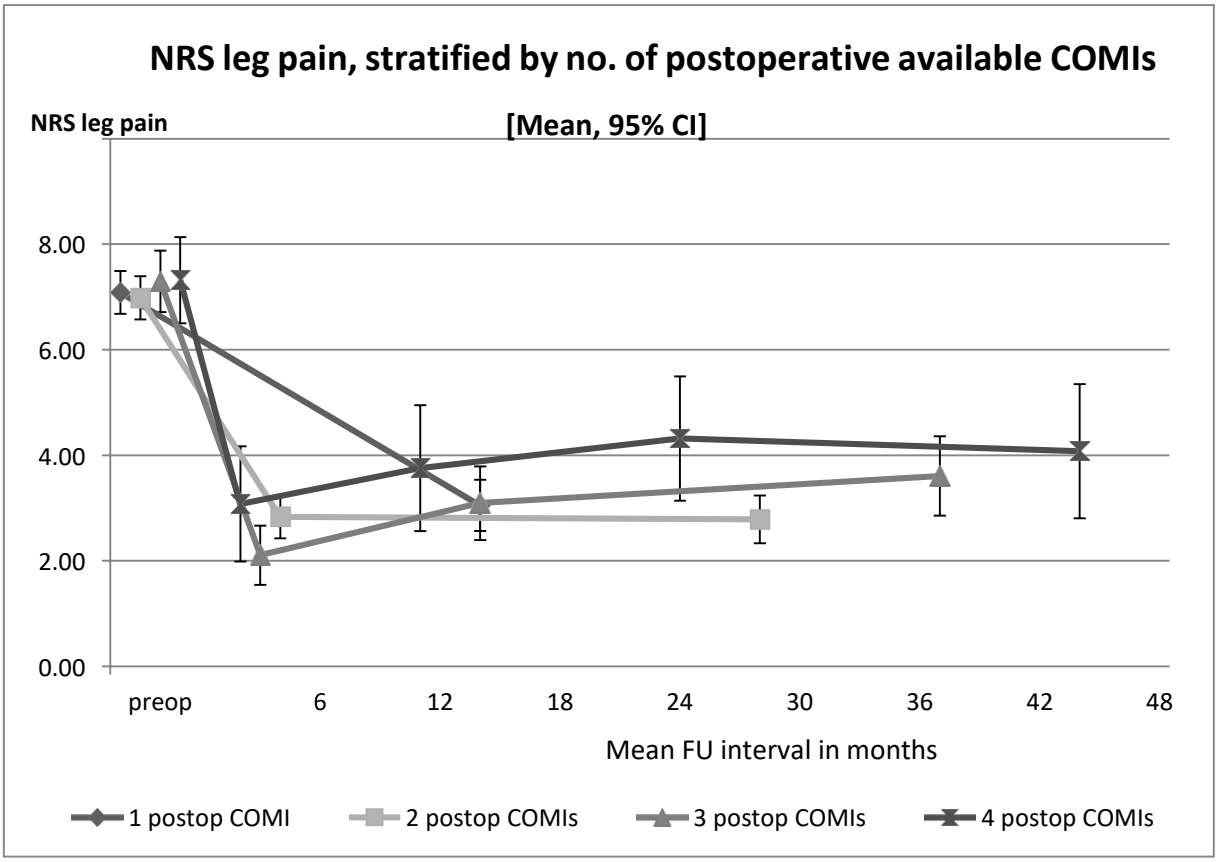

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Table 1: distribution of COMI score and NRS back and leg pain at follow-up intervals (shown are the model means and standard errors of the mean (SEM))

	Preop (N=387)	1 year (N=131)	2 years (N=98)	3 years (N=78)	4 years (N=76)
COMI score	7.96 (± 0.26)	3.86 (± 0.31)	3.88 (± 0.34)	4.44 (± 0.35)	4.23 (± 0.33)
NRS back pain	6.19 (± 0.14)	3.06 (± 0.23)	3.31 (± 0.26)	3.51 (± 0.29)	3.74 (± 0.29)
NRS leg pain	7.08 (± 0.14)	2.87 (± 0.24)	2.89 (± 0.27)	3.63 (± 0.30)	3.55 (± 0.31)

*Note: there are a total of 770 postop COMI forms, only the 1-4 year intervals were included in the model (N=383)

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Table 2: pairwise comparison of non-inferiority between the year 1 and subsequent outcome assessments (shown are the difference of model means and adjusted 90% confidence intervals)

	Year 1 compared with 2 years (N=98)	Year 1 compared with 3 years (N=78)	Year 1 compared with 4 years (N=76)
COMI score	0.02 (-0.81 to 0.84)	0.58 (0.30 to 1.46)	0.37 (-0.53 to 1.27)
NRS back pain	0.25 (-0.62 to 1.12)	0.45 (-0.46 to 1.36)	0.68 (-0.23 to 1.59)
NRS leg pain	0.02 (-0.90 to 0.94)	0.76 (-0.20 to 1.73)	0.68 (-0.29 to 1.65)

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Table 3: Crude COMI score and NRS back and leg pain for patients stratified by number of available postoperative COMIs

		Patients with 1 postoperative COMI (N=119)	Patients with 2 postoperative COMIs (N=141)	Patients with 3 postoperative COMIs (N=64)	Patients with 4 postoperative COMIs (N=25)
Pre-operative Mean (SD)	COMI Score	8.1 (± 1.4)	8.2 (± 1.4)	8.1 (± 1.7)	7.8 (± 1.7)
	NRS back pain	6.2 (± 2.8)	6.2 (± 3.6)	6.5 (± 2.8)	5.8 (± 2.7)
	NRS leg pain	7.1 (± 2.2)	7.0 (± 2.5)	7.3 (± 2.3)	7.3 (± 1.9)
1st COMI: follow-up interval in months: Mean (range)		13.7 (1.5-47.8)	4.0 (1.3-29.1)	2.6 (1.3-6.6)	2.4 (1.6-3.5)
1st COMI Mean (SD)	COMI Score	4.4 (± 2.7)	4.17 (± 2.41)	4.0 (± 2.4)	4.6 (± 2.3)
	NRS back pain	3.2 (± 2.6)	2.9 (± 2.1)	2.7 (± 2.4)	3.5 (± 2.7)
	NRS leg pain	3.1 (± 2.7)	2.8 (± 2.5)	2.1 (± 2.3)	3.1 (± 2.6)
2nd COMI: follow-up interval in months: Mean (range)		n.a.	27.7 (4.1-53.1)	13.9 (3.2-37.7)	11.1 (3.0-20.7)
2nd COMI Mean (SD)	COMI Score	n.a.	4.0 (± 2.7)	4.3 (± 2.4)	5.0 (± 2.4)
	NRS back pain	n.a.	3.1 (± 2.6)	3.4 (± 2.7)	4.0 (± 2.4)
	NRS leg pain	n.a.	2.8 (± 2.7)	3.1 (± 2.8)	3.8 (± 2.9)
3rd COMI: follow-up interval in months: Mean (range)		n.a.	n.a.	37.2 (7.9-52.6)	24.0 (11.4-38.7)
3rd COMI Mean (SD)	COMI Score	n.a.	n.a.	4.8 (± 2.6)	5.3 (± 2.9)
	NRS back pain	n.a.	n.a.	3.6 (± 2.7)	4.6 (± 2.7)
	NRS leg pain	n.a.	n.a.	3.6 (± 3.0)	4.3 (± 2.9)
4th COMI: follow-up interval in months: Mean (range)		n.a.	n.a.	n.a.	44.3 (28.8-51.8)
4th COMI Mean (SD)	COMI Score	n.a.	n.a.	n.a.	4.7 (± 2.9)
	NRS back pain	n.a.	n.a.	n.a.	3.8 (± 2.8)
	NRS leg pain	n.a.	n.a.	n.a.	4.1 (± 3.1)

n.a.: not applicable