Does Dynamic Ventral Plate Fixation Provide Adequate Stability for Traumatic Subaxial Cervical Spine Fractures in Mid-term Follow-up?

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Research article

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Abstract

Background

It remains questionable if the treatment of cervical fractures with dynamic plates in trauma surgery provides adequate stability for fractures with disco-ligamentous injuries. The primary goal of this study was to assess the radiological and mid-term patient-reported outcome of traumatic subaxial cervical fractures treated with a dynamic plate compared to rigid locking plate system.

Patients and Methods

Patients, treated with anterior cervical discectomy and fusion (ACDF) between 2001 and 2015, using either a dynamic plate (DP: Mambo™, Ulrich, Germany) or a rigid locking plate (RP: CSLP™, Depuy Synthes, USA), were identified. Only patients with complete radiological follow (pre- and postoperatively and minimum one year after surgery) were included in the study. Next to the sagittal alignment, the sagittal anterior translation and the bony consolidation were evaluated. After at least two years the patient reported outcome measures (PROM) were evaluated using the German Short-Form 36 (SF-36) with the physical components summary (PCS) and mental components summary (MCS), Neck Disability Index (NDI) and the EuroQol in 5 Dimensions (EQ-5D) score.

Results

33 patients met the in- and exclusion criteria. 26 patients suffered from an AO Type B or C fracture. 13 patients were treated with a dynamic plate and 20 with a rigid locking plate. Both, the sagittal alignment, and the sagittal translation could be sufficiently restored with no differences between the two groups ($p \geq 0.05$). No significant loss of reduction could be observed at the follow-up in both groups ($p \geq 0.05$). Bony consolidation could be observed in 30 patients (91%) with no significant differences between both groups (DP: 12/13 (92%); RP: 18/20 (90%); ($p \geq 0.05$)). In 20 patients PROMs could be evaluated after a mean follow-up of 71.2±25.5 months. No significant differences between DP and RP could be detected in EQ-5D, SF- 36 (PCS and MCS) or NDI (EQ-5D: 72±5; SF-36 PCS 41.9±16.2, MCS 45.4±14.9; NDI: 11±9).

Conclusion

The dynamic plate concept provides enough stability without a difference in fusion rates in comparison to rigid locking plates in a population that mostly suffered AO Type B and C fractures.

Background

In degenerative spine surgery as well as in trauma surgery, anterior cervical discectomy and fusion (ACDF) combining a cage or bone-graft with an anterior plate is an established treatment of various cervical pathologies (1, 2). Anterior cervical fixation procedures with different plate- and screw-systems with the goal of solid fusion of the segment have evolved since the 1960´s (3, 4). Implant-associated complications like pseudarthrosis, kyphotic segmental deformations, graft dislocation, screw and plate displacements were reported (5, 6). Consequently, dynamic plates were introduced, allowing a greater axial load on the bone graft which might contribute to solid fusion. Few meta-analyzes have evaluated the benefits of dynamic plate systems compared to static systems, however, most of the clinical studies were conducted for degenerative indications (7, 8). The results regarding a benefit of dynamic plates on the fusion rates are controversial, with a trend to favor the dynamic concept especially for multi-segmental fusions (9). In terms of clinical outcome, no clear advantages of dynamic plates versus rigid plates have been reported (8, 10). The literature on the use of dynamic plate systems in the treatment cervical disco-ligamentous injuries and fractures is sparse. In contrast to degenerative pathologies, traumatic pathologies of the cervical spine inherit remarkable instability, especially when the posterior spinal elements are injured (11). For this reason, it is questionable, if a dynamic plate system provides adequate stability to ensure stable fracture reduction and consolidation over time.

The current study aims to analyze the radiological and mid-term patient reported outcome measures after ACDF of cervical disco-ligamentous injuries and cervical spine fractures comparing a dynamic plate system (Mambo™, Ulrich Medical) and a rigid system (CSLP™, Depuy Synthes) in a cohort of 33 trauma patients.

Methods

Inclusion and exclusion criteria

Patients with traumatic subaxial, cervical spinal fractures, who received a plate fixation by an anterolateral approach either with a dynamic (DP) or a rigid plate (RP) in our trauma department (level 1 trauma center) between 01/2001 and 01/2015 were identified for this study. Patients younger than 18 years, as well as patients with a pathological fracture (including osteoporotic fractures), ankylosing spondylitis, incomplete radiological follow-up (minimum one year) or complete paralysis were excluded. Next to the patient related data (sex, age), injury mechanism, Injury Severity Score (ISS), fracture type and the treatment details (surgical strategy; adverse events) were assessed. After at least two years patient reported outcome measures (PROM) were prospectively collected.

Radiographic assessment

All included patients received pre- and postoperative CT scans and lateral X-rays of the cervical spine at follow-up. The height of the anterior and the posterior column (Fig. 1A) and the sagittal translation (Fig. 1B) was measured. The mono-segmental (mEA) and bisegemental endplate angel (bEA) respectively were measured as shown in Fig. 1A depending on the number of segments that were fused (12). Negative values indicate lordosis, and positive values kyphosis. All measurements were performed digitally using the software package OsiriX MD (Pixmeo, Bernex, Switzerland).

Patient-reported Outcome Measures (PROM)

The German Short-Form 36 (SF-36) (13), Neck Disability Index (NDI) (14) and EuroQol in 5 Dimensions (EQ-5D) were used to assess the PROM and quality of life. Patients were contacted by telephone and asked for their participation in the study, starting two years after surgery. If patients were not reachable by phone, forms were sent to the last registered address. As a reference, normative data from Germany, were used on SF-36 (15) and EQ-5D (16). For the SF-36, the physical components summary (PCS) and mental components summary (MCS) were calculated as described by Ellert et al. (15).

Statistics

Statistical analysis was carried out using SPSS software version 24 (SPSS Inc, Chicago, Illinois). The Mann-Whitney U and Kruskal-Wallis tests were performed to compare categorical variables; the independent t-test was used to compare continuous variables. Pearson´s correlation coefficient was used in the subgroup analysis of PROM. Due to the low number of failures statistical evaluation is limited to bivariate analysis. P-values < 0.05 were considered significant. Data are presented as mean ± standard deviation (SD) for continuous variables and as absolute and relative frequencies for categorical data.

Results

33 patients (8 females, 25 males, mean age 48.2 ± 22.2 years) met the in- and exclusion criteria including a complete radiological follow-up (29.8 ± 24.3 months). 20 patients (6 females, 14 males, mean age 48.3 ± 22.0 years) completed the PROM questionnaires after a mean follow-up of 71.2 ± 25.5 months. The loss follow-up was 39%.

Trauma Mechanism and Fracture Classification

12 patients (36%) suffered traffic accidents, 4 (12%) from a fall from more than 3 meters, and 15 (46%) less than 3 meters. 2 patients (6%) had an unclassified cause of trauma. 14 patients (42%) suffered from multiple injuries with an Injury Severity Score (ISS) ≥ 16. Out of those, 7 patients completed the PROM questionnaires.

The segment C6/7 was the most frequently affected segment (n = 12, 36%). Fractures were classified as AO Type B and C fractures in 26 cases (79%) and there was no significant difference in fracture type distribution between the two groups (Table 1). Preoperatively, 12 patients (36%) suffered neurological impairment with motor deficits in 6 cases (18%) and sensory disturbances in 6 cases (18%). A motor deficit persisted postoperatively in 4 cases (12%) and a sensory deficit in n = 2 (6%) cases.

Table 1
Distribution of Patient data, surgery information and fracture classification

	Dynamic plate design N = 13	Rigid plate design N = 20	P
Mean age [years]	47.9 ± 24.5	48.5 ± 21.3	0.95
Female	N = 4 (30.8%)	N = 4 (20.0%)	
Male	N = 9 (69.2%)	N = 16 (80.0%)	0.49
Polytrauma	N = 6 (46.2%)	N = 8 (40.0%)	0.73
ICBG	N = 10 (76.9%)	N = 17 (85.0%)	0.71
Cage	N = 3 (23.1%)	N = 3 (15.0%)	
AO Type A	N = 4 (30.8%)	N = 3 (15.0%)	0.64
AO Type B	N = 2 (15.4%)	N = 5 (25.0%)	
AO Type C	N = 7 (53.8%)	N = 12 (60.0%)	

No statistically significant differences were observed for mean age, sex, polytrauma, ICBG/cage, and AO Classification between the two groups (dynamic and rigid plate system).

Treatment strategy and Complications

A dynamic plate was used in 13 patients (39%). Rigid plate fixation was performed in 20 patients (61%) (Table 1). 23 patients (70%) were treated with a one-level ACDF, 8 (24%) with a two-level fixation and 2 (6%) with a three-level ACDF. Looking at the three-level fixations, one dynamic and one rigid plate concept was applied. In 27 cases (82%) an iliac crest bone graft (ICBG) and in 6 cases (18%) a titanium cage was used to provide fusion.

Adverse events

The overall complication rate was 30% (10/33) with 3 (9%) medical complications and 7 (21%) surgery associated complications: Two patients suffered from a transient dysphagia. In one case inadequate reduction was noticed in the postoperative CT scan, which was revised. Moreover, one case with relevant loss-of-reduction by 22°, that also showed signs of implant loosening and pseudarthrosis (RP) had to be revised 20.8 months after surgery. Altogether, in three patients no fusion could be achieved after a mean radiological follow-up of 19.3 ± 4.5 months and all of them were revised. Therefore, revision surgery was necessary in 4 patients (12%).

We observed no differences between the two plate concepts regarding complication rate or revision rate ($p \geq 0.05$). Furthermore, no differences in pseudarthrosis rates between ICBG and cages could be observed ($p \geq 0.05$).

Radiological Outcome

Reduction and loss of reduction in terms of mEA and bEA

Monosegmental injuries showed a mean mEA of 11°±15° ranging from − 17° to 33°, whereas bisegmental injuries ranged from − 9° to 20° with a mean bEA of 5°±10°.

With the rigid plate system, an increase of lordosis of 9°±18° with mono- and of 1°±2° with bisegmental fixation could be reached (both $p \geq 0.05$). There was no significant loss of reduction (-1°±3°) during the follow-up in the mEA (Fig. 2A). We observed a loss in the bEA by 8°±9° ($p \geq 0.05$) (Fig. 2B). Notably, in this group one patient had to be revised due to a clinically relevant loss of lordosis by 22°.

With the dynamic plate system, a reduction of 10°±13° with mono- and of 1°±8° with bisegmental fixation could be reached. There was no significant loss of reduction by -0°±2.6° during the follow-up in the mEA (Fig. 2A). We observed a loss in the bEA of 2°±5° ($p \geq 0.05$) (Fig. 2B).

Anterior translation

With both plate systems, the preoperative translation could be significantly reduced when compared to the follow-up (both $p < 0.01$; no significant differences between plate systems). During the follow-up time we observed a loss of reduction by 0.2 mm ($p \geq 0.05$) in both groups (Fig. 3).

The anterior column and posterior elements

In the monosegmental fusions the anterior column was significantly restored by 3.0 ± 4.3 mm ($p < 0.01$). There was no significant change in the height of the posterior column postoperatively ($p \geq 0.05$). During the follow-up there was a significant loss in height, both in the anterior (0.6 ± 1.3 mm) and in the posterior column (0.7 ± 1.1 mm) (both $p < 0.05$). In bisegmental fusions the height of both the anterior and posterior column did not decrease during the follow-up (both $p \geq 0.05$). Analyzing the subgroup of the dynamic plate system shows that no significant loss of reduction of the anterior or posterior column in mono- and bisegmental fusions during the follow-up occurred (all $p \geq 0.05$).

Fusion rate

Bony consolidation could be observed in 30/33 patients (91%) with no significant differences between both groups (DP: 12/13 (92%); RP: 18/20 (90%); ($p \geq 0.05$)).

Health related quality of life

The mean EQ VAS reached 72.0 ± 4.9 points and the mean EQ-5D Index was 0.8 ± 0.1 at the follow-up. There was no difference in the EQ VAS or -Index depending on dynamic or rigid procedures (all $p \geq 0.05$). Figure 4 displays the subdimensions of EQ-5D.

The mean NDI of the total cohort was 11.0 ± 9.3 points indicating mild disability. Again, no significant difference was observed between the plate concepts (all $p \geq 0.05$).

Looking at the SF-36, the mean PCS of the whole cohort was 41.9 ± 16.2 and the mean MCS was 45.4 ± 14.9. No statistically significant difference in the PCS and the MCS was detected, comparing the DP (PCS 35.9 ± 17.9; MCS 45.8 ± 17.7) and the RP (PCS 48.8 ± 9.4; MCS 44.8 ± 10.6) group (all $p \geq 0.05$).

The ISS and the EQ VAS and EQ-5D Index revealed a significant Pearson correlation of -0.46 and − 0.79 (each $p < 0.05$), respectively. There were 7 severely injured patients with an ISS ≥ 16 that returned the PROM questionnaires. The mean ISS in this group was 36 ± 15 points. In a subgroup analysis, the PROMs of the 13 patients with an ISS < 16 points were evaluated: Table 2 displays the results of the 8 main SF-36 items for the population of patients with ISS < 16 in comparison to the normative data of the German population (15).

Table 2
The main SF-36 items

SF-36 Item	German reference population 2013 (15)	Study population ISS < 16 (n = 13)	Significant differences
Physical functioning	89.5 (81.0–84.5)	75.0 ± 33.8	p = 0.166
Role physical	85.5 (84.1–86.9)	68.8 ± 37.1	p = 0.146
Role emotional	86.8 (85.3–88.2)	69.4 ± 38.8	p = 0.150
Vitality	60.7 (59.4–61.9)	55.8 ± 20.5	p = 0.429
Emotional Well-Being	72.8 (71.6–73.9)	74.7 ± 18.2	p = 0.730
Social functioning	85.6 (84.2–87.1)	82.3 ± 27.4	p = 0.684
Bodily Pain	75.3 (73.6–76.9)	76.1 ± 23.4	p = 0.910
General health	69.9 (68.8–71.1)	67.0 ± 19.3	p = 0.608

The eight main SF-36 items results of a population with ISS < 16 in comparison to the normative data of the German population (14). The reference values are presented as mean with 95% confident interval. There is no significant difference between the study group (ISS **< 16)** and a healthy German population in all main items.

Discussion

This study for the first time demonstrates that a dynamic plate concept provides adequate stability for traumatic cervical fractures including AO Type B and C fractures. The dynamic plate concept was similar to the conventional rigid plate system in terms of postoperative loss of reduction and PROM. The use of anterior cervical locking plates evolved to treat cervical disco-ligamentous injuries and fractures of the cervical spine during the last decade. The procedure has been proven to be safe and efficient (17, 18). The data on the performance of dynamic plate concepts in traumatic cervical fractures, concerning loss of reduction, fusion-rates and PROM were observed.

Pitzen et al. investigated the biomechanical effectiveness of dynamic and rigid cervical plates in a C4-7 spine segments cadaver model (11). They discovered that with both cervical plate systems a single segment flexion distraction injury could be stabilized, with the dynamic plate design being in advantage in extension. The dynamic plate transmitted 30% less strain through the plate than the rigid plate did.

Possible clinical advantages of dynamic plate designs have been shown again by Pitzen et al. in their prospective, controlled, randomized, radiological and clinical follow-up of 132 patients (10). In the group treated with dynamic plates, no implant complications were documented, whereas implant associated complications were found in 4 cases of the control-group, including plate-breakage and screw loosening. Interestingly, the speed of fusion was faster using a dynamic plate. However, the indications for routine ACDF were heterogeneous with mostly degenerative disc disease. Only 9 patients with cervical fractures were included. In contrast, our study population exclusively consists of trauma patients without known degenerative spinal diseases. We found three incomplete fusions, two in patients treated with the rigid plate system and one in a patient with the dynamic plate concept after a mean radiological follow-up of 19.3 months in those three cases. The overall fusion rate of 91% can be considered satisfactory, without a statistical difference between the groups (DP: 92%; RP 90%). Similarly, Goldberg et al. did not find significant differences between the fusion rates between dynamic (89.0%) and static plates (87.8%) in their short-term review of two-level ACDFs (19).

We could not identify any differences in fusion-, complication-rates, loss of reduction or PROM between the usage of an ICBG or a cage. This is in line with the majority of recent studies that report satisfactory radiological and clinical outcomes independent of the usage of a cage or an ICBG (20, 21).

In terms of the radiological follow-up, we demonstrated, that with both plate systems, stabilization of the anterior column can be performed efficiently in mono- and bisegmental fusions. We observed a relevant decrease of the anterior (0.6 mm) and posterior (0.7 mm) column. This finding suggests that the loss was due to subsidence.

In a radiographic review of 87 patients with either unilateral or bilateral facet dislocations or fracture/dislocations treated with ACDF, and plating with static plate systems Johnson et al. observed radiographic failures in 13% of the cases (22). Failure was defined as a change in translation of greater than 4 mm and/or change in angulation of greater than 11 degrees between the immediate postoperative films and the follow-up. If these criteria were applied on our cohort, failure was only present in one case in the rigid plate group with a translation of 4 mm and change in angulation of 21.9°, that had to be revised 20.8 months after surgery, when also implant loosening was seen. No comparable loss of reduction was observed in the dynamic plate group. Looking at the whole study population, a significant reduction could be reached with ACDF and both systems could secure this reduction over a mean radiological follow-up of 29.8 months. However, a statistical insignificant change as well in the mEA and the bEA was seen in both groups at the follow-up. Again, subsidence must be considered and that measurements of the postoperative CT scan in lying position and of lateral X-rays at the follow-up in standing position were compared.

In line with our findings Dubois et al. noted no difference in the clinical outcome in their retrospective analysis of 52 patients who underwent two- or three-level ACDF with a rigid or a dynamic plate (23). They were not able to conclude any clinical or radiographic advantages of the dynamic plate during 20.9 months of follow-up, compared to the rigid plate (follow-up of 13.9 months). However, the authors did not asses objective outcome measures, rather the Odom´s scale. Similar results regarding the Odom scale were reported by Stancić et al. (24).

We showed satisfactory results in terms of the mean EQ-5D VAS of 72.0 ± 4.9 points and a mean NDI of 11.0 ± 9.3 points in the total study cohort without a significant difference between the two groups. Due to the trauma setting, there were no preoperative subjective patient reporting that could be compared to. There were no relevant differences in PROM between the two study groups. For these reasons, our results suggest, that dynamic and rigid cervical plating is a suitable method to achieve an adequate stabilization and aim for a solid fusion and good quality of life after traumatic injury of the cervical spine. Unlike other studies we showed that an important factor for good PROM was the ISS: In our cohort the less severe injured patients with an ISS < 16 even reached the level of a healthy German population in terms of the SF-36 in the mid-term follow-up.

Conclusion

An initial traumatic instability or anterolisthesis could be reduced and stabilized using both, the dynamic and the rigid plate. The dynamic plate provided enough stability in a fragile fracture situation with no relevant loss of reduction during the follow-up. In terms of fusion rate and complication the dynamic plate system was not inferior to the dynamic plate concept. Patient-reported outcome is similar to a healthy reference population in non-polytraumatized patients (ISS < 16) in the mid-term follow-up.

List Of Abbreviations

ACDF Anterior cervical discectomy and fusion

bEA Bisegmental endplate angle

CT Computed tomography

DP Dynamic plate

EQ-5D EuroQol in 5 Dimensions

ICBG Iliac crest bone graft

ISS Injury Severity Score

MCS Mental components summary

mEA Monosegmental endplate angle

NDI Neck Disability Index

PCS Physical components summary

PROM Patient reported outcome measure

RP Rigid plate

SF-36 Short Form 36

VAS Visual analogue scale

Declarations

Research Ethics Committee

This study was carried out in accordance with the Declaration of Helsinki and approved by the ethics committee at the University of Regensburg in 03/2017, Z-2017-0799-7. Written informed consent was obtained from all patients included in the study.

Consent for publication

This manuscript does not contain any individual person’s data in any form.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

Financial and personal relationships: The Author Carsten Neumann is a consultant for Ulrich medical Germany.

Potential competing interests: None.

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No funding has been received for this study.

Authors' contributions

SL helped to design the study, conduct the study, analyze the data, and write the manuscript.

SL has seen the original study data, reviewed the analysis of the data, approved the final manuscript, and is the author responsible for archiving the study files.

CN helped to conduct the study.

CN has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.

LF helped to conduct the study.

LF has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.

VA helped to conduct the study.

VA has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.

ML helped to conduct the study.

ML has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.

MK helped to design the study, analyze the data, and write the manuscript. He is the corresponding author of this manuscript.

MK has seen the original study data, reviewed the analysis of the data, and approved the final manuscript.

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Figures

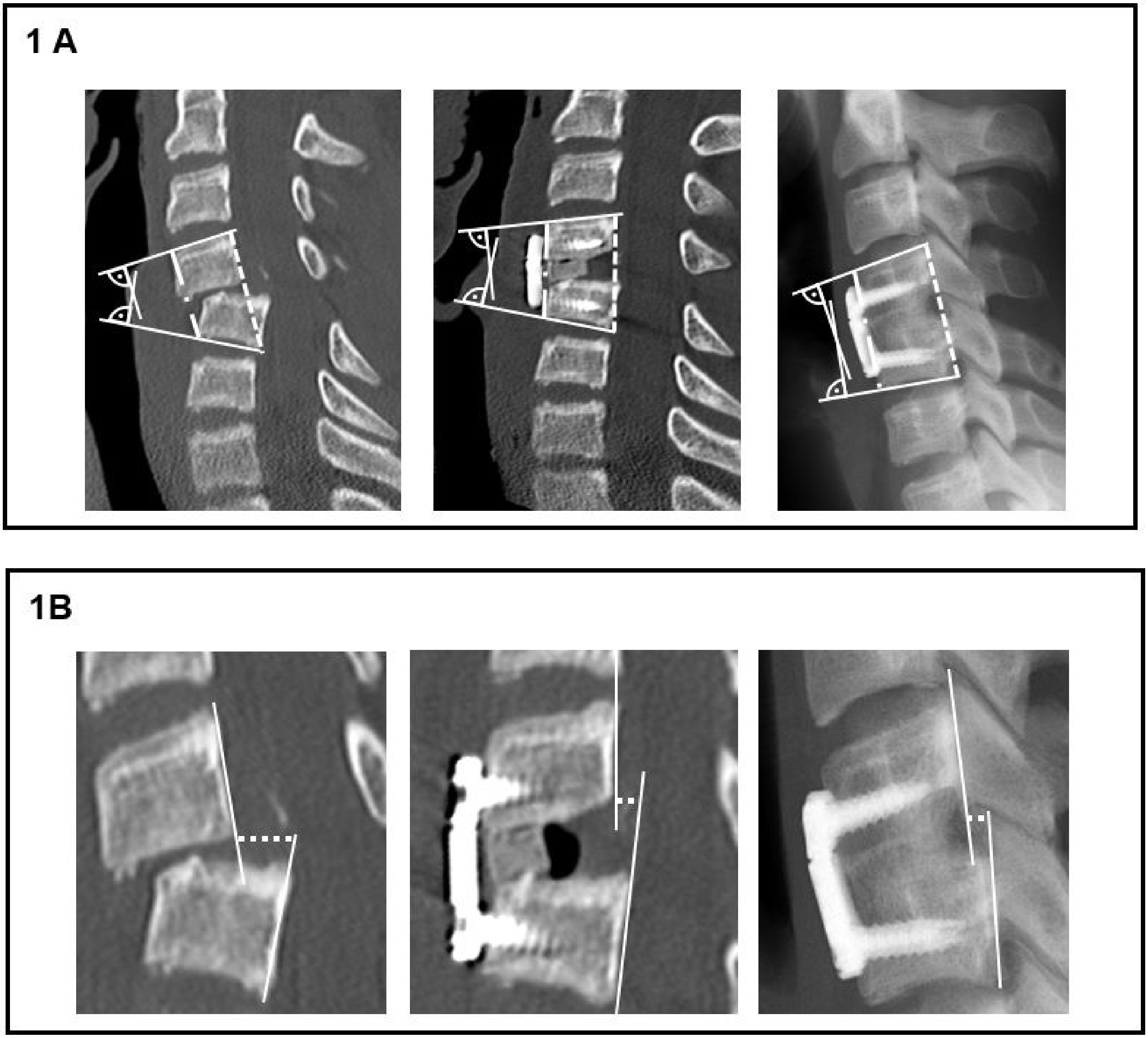

Figure 1

A: The mEA (respectively bEA) was measured between the upper endplate of the superior vertebra and the inferior endplate of the inferior vertebra of the affected segment. The dotted lines indicate the measurement of the ventral and dorsal column, respectively. B: The dotted lines mark the measurement of the sagittal translation.

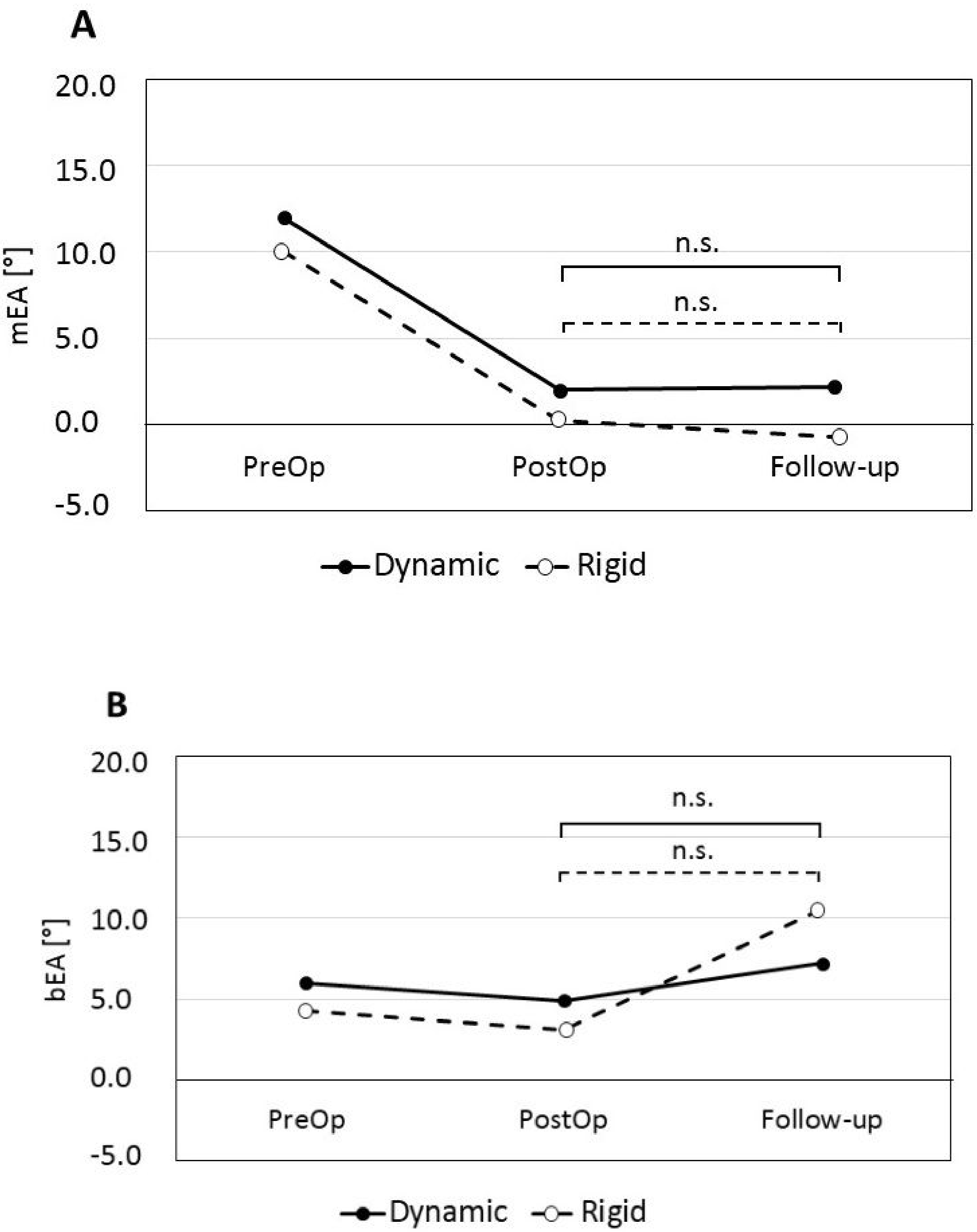

Figure 2

Changes in the mEA (A) and bEA (B) in the dynamic and rigid plate system. There was no significant loss of reduction during the follow up in both groups (A and B). A Changes in the Monosegmental Endplate Angle B Changes in the Bisegmental Endplate Angle

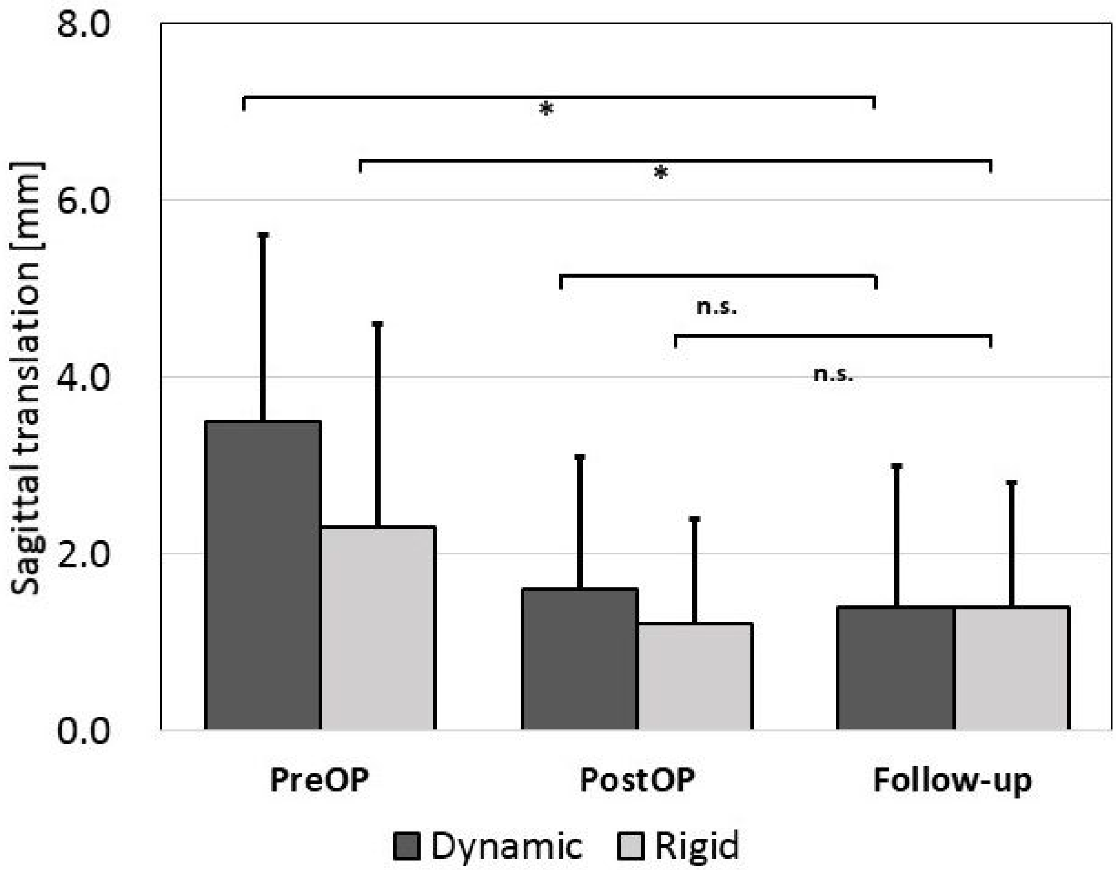

Figure 3

Sagittal translation pre-, postoperative and at the time of the last radiological follow-up. Bars indicate mean values and whiskers the SD. * indicates $p < 0.05$.

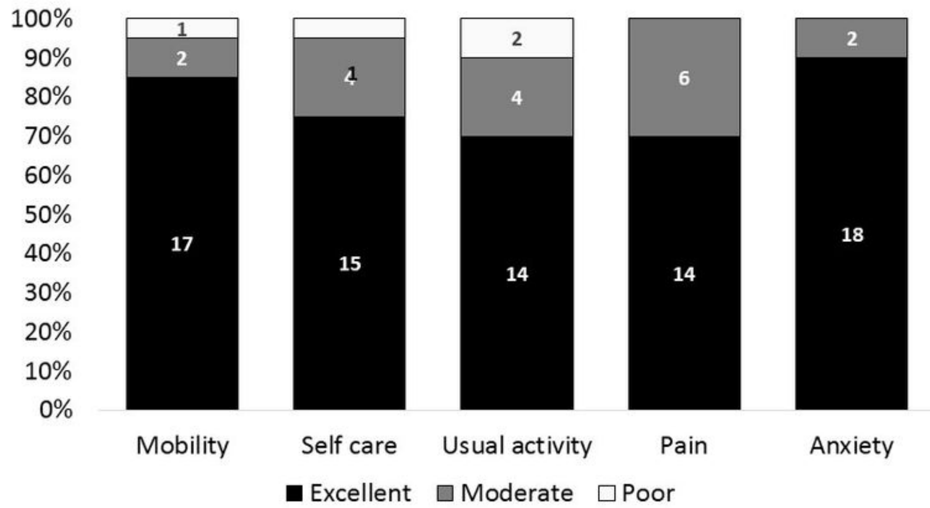

Figure 4

Subdimension of EQ-5D. Categories differ between excellent, moderate and poor results. The bars represent 100% of the included cases.