

Sample Manufacturer Sample Implant

Containing usage data up to 23/01/2024

Created on 23/01/2024

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Notes

This report has been produced by NEC Software Solutions on behalf of EUROSPINE. It represents activity recorded in Spine Tango for Combo based on data collected up to the specified date. This report is made available to Combo under the Spine Tango Agreement between the parties. Usage and distribution of this report is restricted as detailed in the EUROSPINE Subscriber Terms and Conditions.

Notes on Comparator

This report compares usage and outcomes recorded for Sample Implants against all other surgical cases recorded within the Spine Tango registry. This comparison is provided for information purposes only and does not imply agreement that this forms a reasonable comparator. The implant under review may be used in specific cases not representative of the wider data set. You should satisfy yourself that the comparator allows for meaningful analysis.

Notes on Data Quality

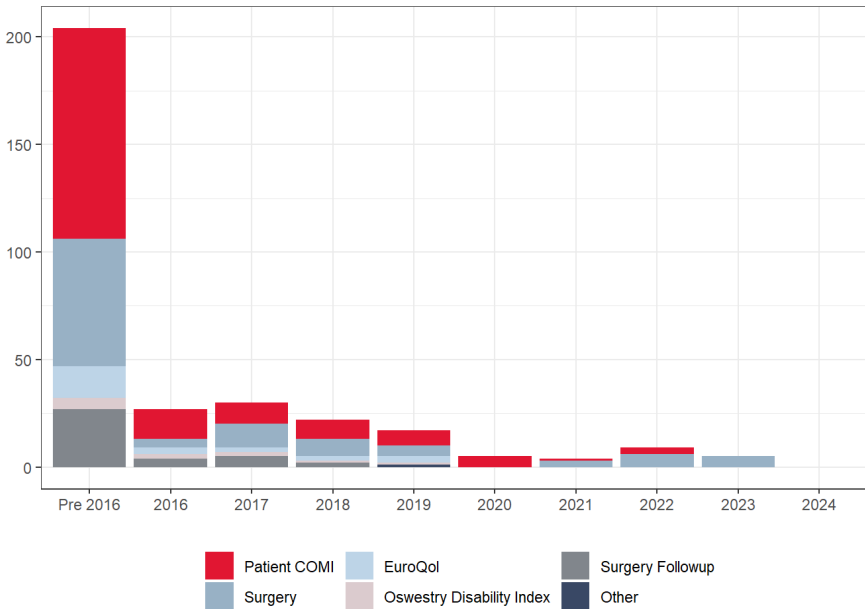
This report reflects data recorded in the Spine Tango Registry between 2004 and the specified date. Missing data and issues with the quality of data recorded may impact the results shown. Data from earlier years of the Registry may be less complete than current submissions. In interpreting this report you should satisfy yourself that the quality and completeness of data allows meaningful analysis of the usage and outcomes of the implant.

Notes on Methodology

Please see the accompanying Methodology and Guidance Notes for further information.

Activity Overview

First Recorded Procedure	05/02/2007
Last Recorded Procedure	21/12/2023
Number of Patients	100
Number of Procedures	101



Form Type	Pre 2016	2016	2017	2018	2019	2020	2021	2022	2023	2024	Total
Patient COMI	98	14	10	9	7	5	1	3	0	0	147
Surgery	59	4	11	8	5	0	3	6	5	0	101
EuroQol	15	3	2	2	3	0	0	0	0	0	25
Oswestry Disability Index	5	2	2	1	1	0	0	0	0	0	11
Surgery Followup	27	4	5	2	0	0	0	0	0	0	38
Other	0	0	0	0	1	0	0	0	0	0	1
Total	204	27	30	22	17	5	4	9	5	0	323

Activity Tables

Surgery Activity

Country	Dept.	Pre 2016	2016	2017	2018	2019	2020	2021	2022	2023	2024
Austria	1	1	0	0	0	0	0	0	0	0	0
Austria	2	1	0	0	0	0	0	0	0	0	0
Belgium	3	1	0	0	0	0	0	0	0	0	0
Belgium	4	1	0	0	2	0	0	1	0	0	0
Germany	5	0	0	0	2	1	0	0	0	0	0
Italy	6	0	0	4	0	0	0	0	0	0	0
Italy	7	0	1	0	0	0	0	0	0	0	0
Portugal	8	0	0	0	1	0	0	0	0	0	0
Slovenia	9	0	0	0	1	1	0	0	0	0	0
Switzerland	10	1	0	0	0	0	0	0	0	0	0
Switzerland	11	1	0	0	0	0	0	0	0	0	0
Switzerland	12	0	0	1	0	0	0	0	0	0	0
Switzerland	13	1	0	0	0	0	0	0	0	0	0
Switzerland	14	2	0	0	0	0	0	0	0	0	0
Switzerland	15	1	0	1	0	0	0	0	0	0	0
Switzerland	16	0	0	0	1	0	0	0	0	0	0
Switzerland	17	1	0	0	0	0	0	0	0	0	0
Switzerland	18	0	0	1	0	1	0	0	1	0	0
Switzerland	19	0	1	0	0	0	0	0	0	0	0
Switzerland	20	0	0	0	0	0	0	0	1	0	0
Switzerland	21	1	0	0	0	0	0	0	0	0	0
Switzerland	22	2	0	0	0	0	0	0	0	0	0
Switzerland	23	12	1	2	0	1	0	0	0	0	0
Switzerland	24	0	0	0	0	0	0	0	0	1	0
Switzerland	25	0	0	0	0	0	0	0	0	1	0
Switzerland	26	0	0	0	0	0	0	0	0	1	0
Switzerland	27	0	0	0	0	0	0	0	1	0	0
Switzerland	28	0	0	0	0	0	0	1	0	0	0
Switzerland	29	0	0	0	0	0	0	1	0	0	0
Switzerland	30	0	0	0	0	0	0	0	0	1	0
Switzerland	31	0	0	0	0	0	0	0	0	1	0

Country	Dept.	Pre 2016	2016	2017	2018	2019	2020	2021	2022	2023	2024
Switzerland	32	0	0	0	0	0	0	0	1	0	0
United Kingdom	34	3	0	1	0	0	0	0	0	0	0
United Kingdom	35	7	0	1	1	1	0	0	2	0	0
United Kingdom	36	1	1	0	0	0	0	0	0	0	0
United Kingdom	37	3	0	0	0	0	0	0	0	0	0
United States	38	1	0	0	0	0	0	0	0	0	0
United States	39	1	0	0	0	0	0	0	0	0	0
United States	40	1	0	0	0	0	0	0	0	0	0
United States	41	2	0	0	0	0	0	0	0	0	0
United States	42	2	0	0	0	0	0	0	0	0	0
United States	43	1	0	0	0	0	0	0	0	0	0
United States	44	2	0	0	0	0	0	0	0	0	0
Unspecified	45	9	0	0	0	0	0	0	0	0	0
Total		59	4	11	8	5	0	3	6	5	0

COMI Activity

Country	Dept.	Pre 2016	2016	2017	2018	2019	2020	2021	2022	2023	2024	Mean (Years)	Range (Years)
Belgium	1	1	0	0	0	0	0	0	0	0	0	2.02	2.02-2.02
Belgium	2	2	1	0	1	0	2	0	1	0	0	1.60	1.00-2.02
Italy	3	0	0	2	3	0	0	0	0	0	0	0.56	0.25-0.93
Italy	4	0	1	0	0	0	0	0	0	0	0	0	0
Portugal	5	0	0	0	1	0	0	0	0	0	0	0	0
Slovenia	6	0	0	0	0	4	3	1	1	0	0	1.00	0.28-2.24
Switzerland	7	3	0	0	0	0	0	0	0	0	0	0.62	0.25-0.98
Switzerland	8	2	0	0	0	0	0	0	0	0	0	0.22	0.15-0.28
Switzerland	9	1	0	0	0	0	0	0	0	0	0	0	0
Switzerland	10	2	0	0	0	0	0	0	0	0	0	0	0
Switzerland	11	1	0	1	0	0	0	0	0	0	0	0	0
Switzerland	12	0	0	0	1	0	0	0	0	0	0	0.10	0.10-0.10
Switzerland	13	1	0	0	0	0	0	0	0	0	0	0.12	0.12-0.12
Switzerland	14	0	2	1	0	0	0	0	0	0	0	0.28	0.12-0.44
Switzerland	15	0	0	0	0	0	0	0	1	0	0	0	0
Switzerland	16	1	1	0	0	0	0	0	0	0	0	0.13	0.13-0.13
Switzerland	17	1	0	0	0	0	0	0	0	0	0	0	0
Switzerland	18	40	5	0	0	0	0	0	0	0	0	1.23	0.22-5.04
United Kingdom	19	10	1	2	1	1	0	0	0	0	0	1.09	0.19-2.05
United Kingdom	20	10	3	4	2	2	0	0	0	0	0	1.25	0.24-2.80
United Kingdom	21	2	0	0	0	0	0	0	0	0	0	0.13	0.13-0.13
United States	22	1	0	0	0	0	0	0	0	0	0	2.24	2.24-2.24
United States	23	1	0	0	0	0	0	0	0	0	0	2.53	2.53-2.53
United States	24	3	0	0	0	0	0	0	0	0	0	0.15	0.12-0.18
Unspecified	25	16	0	0	0	0	0	0	0	0	0	0.30	0.04-1.09
Total		98	14	10	9	7	5	1	3	0	0	1.02	0.04-5.04

EQ-5D-3L Activity

Country	Dept.	Pre 2016	2016	2017	2018	2019	2020	2021	2022	2023	2024	Mean (Years)	Range (Years)
Austria	1	1	0	0	0	0	0	0	0	0	0	0	0
Italy	2	0	1	0	0	0	0	0	0	0	0	0	0
Portugal	3	0	0	0	1	1	0	0	0	0	0	0.75	0.75-0.75
Switzerland	4	1	1	0	0	0	0	0	0	0	0	0.13	0.13-0.13
Switzerland	5	1	0	0	0	0	0	0	0	0	0	0	0
United Kingdom	6	9	1	2	1	2	0	0	0	0	0	1.17	0.24-2.29
United States	7	1	0	0	0	0	0	0	0	0	0	2.23	2.23-2.23
United States	8	2	0	0	0	0	0	0	0	0	0	0.18	0.18-0.18
Total		15	3	2	2	3	0	0	0	0	0	1.08	0.13-2.29

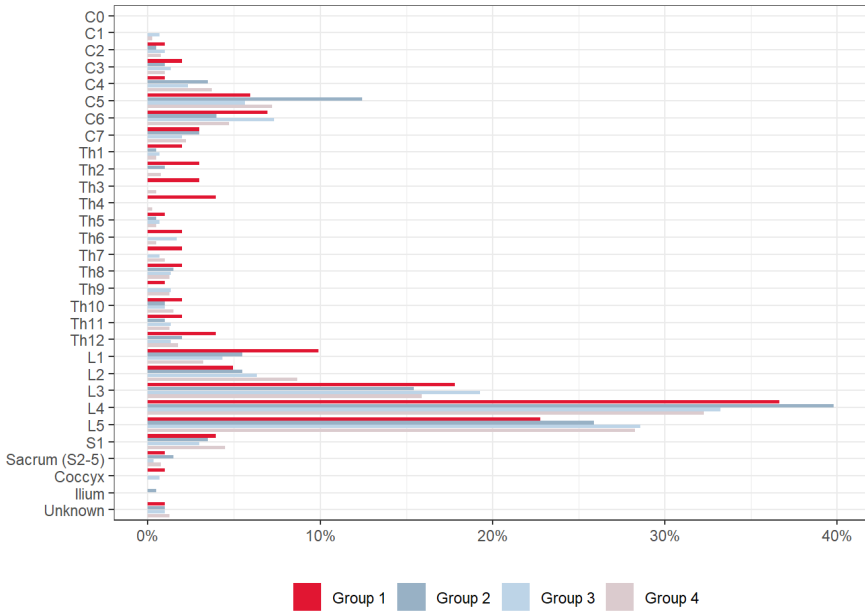
Oswestry Disability Index Activity

Country	Dept.	Pre 2016	2016	2017	2018	2019	2020	2021	2022	2023	2024	Mean (Years)	Range (Years)
Italy	1	0	1	0	0	0	0	0	0	0	0	0	0
Portugal	2	0	0	0	1	1	0	0	0	0	0	0.75	0.75-0.75
Switzerland	3	0	1	0	0	0	0	0	0	0	0	3.76	3.76-3.76
Switzerland	4	2	0	0	0	0	0	0	0	0	0	0.22	0.15-0.28
Switzerland	5	0	0	2	0	0	0	0	0	0	0	0.05	0.03-0.08
Switzerland	6	1	0	0	0	0	0	0	0	0	0	0	0
United Kingdom	7	2	0	0	0	0	0	0	0	0	0	0.13	0.13-0.13
Total		5	2	2	1	1	0	0	0	0	0	0.74	0.03-3.76

Surgery Follow-up Activity

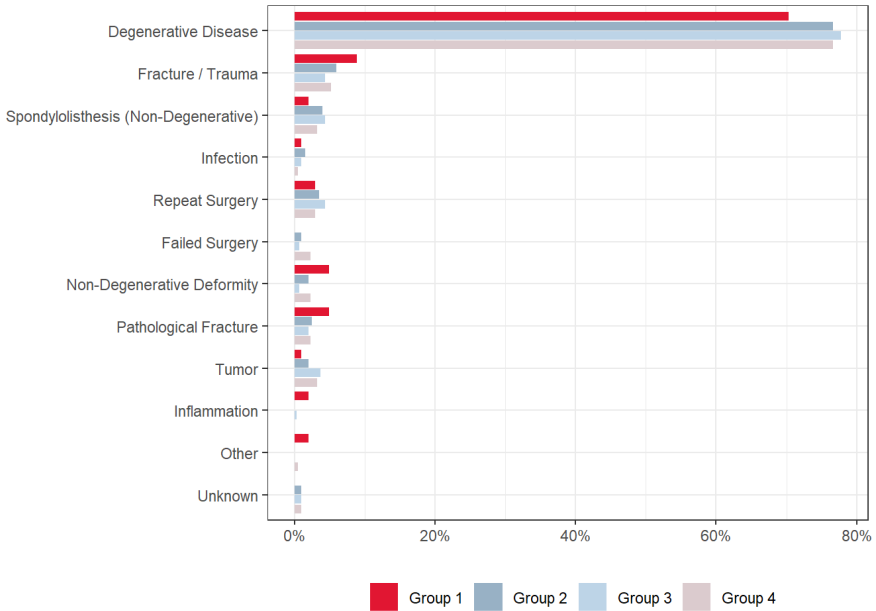
Country	Dept.	Pre 2016	2016	2017	2018	2019	2020	2021	2022	2023	2024	Mean (Years)	Range (Years)
Switzerland	1	1	0	0	0	0	0	0	0	0	0	0	0
Switzerland	2	2	0	0	0	0	0	0	0	0	0	0.22	0.15-0.28
Switzerland	3	0	0	0	1	0	0	0	0	0	0	0	0
Switzerland	4	1	0	0	0	0	0	0	0	0	0	0	0
Switzerland	5	0	0	1	0	0	0	0	0	0	0	0.03	0.03-0.03
Switzerland	6	0	1	0	0	0	0	0	0	0	0	0	0
Switzerland	7	16	3	3	1	0	0	0	0	0	0	0.48	0.12-1.52
United Kingdom	8	1	0	1	0	0	0	0	0	0	0	0.22	0.19-0.25
United States	9	1	0	0	0	0	0	0	0	0	0	0	0
Unspecified	10	5	0	0	0	0	0	0	0	0	0	0.54	0.12-1.08
Total		27	4	5	2	0	0	0	0	0	0	0.43	0.03-1.52

Level of Procedure



Level of Procedure	Group 1	Group 2	Group 3	Group 4
Upper Cervical	1.0% (1)	0.5% (1)	1.3% (4)	1.0% (4)
Mid-Lower Cervical	14.9% (15)	15.9% (32)	14.6% (44)	13.6% (55)
Cervico-Thoracic	4.0% (4)	3.5% (7)	2.3% (7)	2.5% (10)
Thoracic	9.9% (10)	4.5% (9)	5.0% (15)	7.7% (31)
Thoraco-Lumbar	11.9% (12)	7.0% (14)	5.3% (16)	4.5% (18)
Lumbar	47.5% (48)	53.2% (107)	51.5% (155)	50.6% (204)
Lumbo-Sacral	23.8% (24)	26.4% (53)	28.9% (87)	29.0% (117)
Sacral	1.0% (1)	1.5% (3)	0.3% (1)	0.7% (3)
Coccyx	1.0% (1)	0.0% (0)	0.7% (2)	0.0% (0)
Ilium	0.0% (0)	0.5% (1)	0.0% (0)	0.0% (0)
Unknown	1.0% (1)	1.0% (2)	1.0% (3)	1.2% (5)

Main Pathology



Main Pathology	Group 1	Group 2	Group 3	Group 4
Degenerative Disease	70.3% (71)	76.6% (154)	77.7% (234)	76.7% (309)
Fracture / Trauma	8.9% (9)	6.0% (12)	4.3% (13)	5.2% (21)
Spondylolisthesis (Non-Degenerative)	2.0% (2)	4.0% (8)	4.3% (13)	3.2% (13)
Infection	1.0% (1)	1.5% (3)	1.0% (3)	0.5% (2)
Repeat Surgery	3.0% (3)	3.5% (7)	4.3% (13)	3.0% (12)
Failed Surgery	0.0% (0)	1.0% (2)	0.7% (2)	2.2% (9)
Non-Degenerative Deformity	5.0% (5)	2.0% (4)	0.7% (2)	2.2% (9)
Pathological Fracture	5.0% (5)	2.5% (5)	2.0% (6)	2.2% (9)
Tumor	1.0% (1)	2.0% (4)	3.7% (11)	3.2% (13)
Inflammation	2.0% (2)	0.0% (0)	0.3% (1)	0.0% (0)
Other	2.0% (2)	0.0% (0)	0.0% (0)	0.5% (2)
Unknown	0.0% (0)	1.0% (2)	1.0% (3)	1.0% (4)

Preoperative Profile

	Group 1	Group 2	Group 3	Group 4
Mean Age	57.4	59.2	58.2	59.5
< 18	0.0% (0)	1.0% (2)	1.0% (3)	1.0% (4)
18-39	20.8% (21)	10.0% (20)	12.6% (38)	11.4% (46)
40-49	11.9% (12)	20.9% (42)	18.3% (55)	15.1% (61)
50-59	19.8% (20)	15.9% (32)	17.3% (52)	18.6% (75)
60-79	37.6% (38)	43.3% (87)	44.2% (133)	45.2% (182)
≥ 80	9.9% (10)	9.0% (18)	6.6% (20)	8.7% (35)
Gender				
Male	50.5% (51)	46.8% (94)	48.8% (147)	49.1% (198)
Female	49.5% (50)	53.2% (107)	51.2% (154)	50.9% (205)
Smoker				
No	39.6% (40)	32.8% (66)	35.2% (106)	32.0% (129)
Yes	7.9% (8)	9.5% (19)	6.0% (18)	10.4% (42)
Unknown	52.5% (53)	57.7% (116)	58.8% (177)	57.6% (232)
Median BMI	26.1	26.9	28.4	27.3
< 20	7.9% (8)	4.5% (9)	2.0% (6)	2.5% (10)
20-25	24.8% (25)	18.4% (37)	18.9% (57)	20.8% (84)
26-30	23.8% (24)	18.4% (37)	23.3% (70)	21.1% (85)
31-35	10.9% (11)	14.4% (29)	10.6% (32)	10.2% (41)
> 35	5.0% (5)	5.5% (11)	5.0% (15)	4.7% (19)
Unknown	27.7% (28)	38.8% (78)	40.2% (121)	40.7% (164)
Number of Segments Affected				
1	36.6% (37)	35.8% (72)	35.2% (106)	35.0% (141)
2-3	29.7% (30)	26.9% (54)	26.9% (81)	29.3% (118)
≥ 4	7.9% (8)	6.0% (12)	4.7% (14)	4.7% (19)
Unknown	25.7% (26)	31.3% (63)	33.2% (100)	31.0% (125)
Previous Surgeries (Any Level)				
0	67.3% (68)	71.1% (143)	73.4% (221)	69.0% (278)
1	23.8% (24)	17.4% (35)	16.9% (51)	20.8% (84)
> 1	8.9% (9)	9.5% (19)	8.6% (26)	8.9% (36)
Unknown	0.0% (0)	2.0% (4)	1.0% (3)	1.2% (5)

Perioperative Profile

Characteristic	Group 1	Group 2	Group 3	Group 4
Blood Loss				
< 100 ml	37.6% (38)	33.8% (68)	40.9% (123)	40.2% (162)
100 - 500 ml	34.7% (35)	38.3% (77)	33.2% (100)	33.0% (133)
500 - 1000 ml	6.9% (7)	6.5% (13)	10.3% (31)	6.5% (26)
1000 - 2000 ml	2.0% (2)	4.0% (8)	2.0% (6)	3.0% (12)
> 2000 ml	1.0% (1)	0.5% (1)	0.7% (2)	0.7% (3)
Unknown	17.8% (18)	16.9% (34)	13.0% (39)	16.6% (67)
Blood Transfusion				
None	55.4% (56)	51.7% (104)	51.8% (156)	52.9% (213)
< 2 units	2.0% (2)	1.0% (2)	0.7% (2)	0.2% (1)
≥ 2 units	1.0% (1)	0.5% (1)	1.0% (3)	0.5% (2)
Cell Saver	8.9% (9)	3.5% (7)	6.0% (18)	5.5% (22)
Unknown	33.7% (34)	44.3% (89)	40.5% (122)	41.2% (166)
Prophylaxis				
None	2.0% (2)	1.5% (3)	0.3% (1)	2.5% (10)
Infection	45.5% (46)	38.8% (78)	42.5% (128)	40.7% (164)
Thromboembolism	34.7% (35)	33.3% (67)	37.2% (112)	30.5% (123)
Ossification	0.0% (0)	0.0% (0)	0.3% (1)	0.5% (2)
Other	0.0% (0)	0.5% (1)	0.0% (0)	0.0% (0)
Unknown	51.5% (52)	57.2% (115)	54.2% (163)	55.3% (223)
Technology				
Conventional	49.5% (50)	36.8% (74)	44.5% (134)	44.2% (178)
MISS / LISS	12.9% (13)	15.4% (31)	11.6% (35)	9.9% (40)
Loops	5.9% (6)	7.0% (14)	5.3% (16)	6.2% (25)
Endoscope	0.0% (0)	1.0% (2)	0.7% (2)	0.7% (3)
Microscope	38.6% (39)	49.3% (99)	50.5% (152)	47.6% (192)
CASS	0.0% (0)	0.5% (1)	1.0% (3)	0.7% (3)
Neuromonitoring	4.0% (4)	2.5% (5)	2.7% (8)	3.0% (12)
Intraoperative 3d-Imaging	1.0% (1)	0.5% (1)	0.7% (2)	1.2% (5)
Other	3.0% (3)	2.5% (5)	2.3% (7)	2.7% (11)
Unknown	9.9% (10)	12.9% (26)	5.3% (16)	8.7% (35)

Characteristic	Group 1	Group 2	Group 3	Group 4
Operation Time				
< 1 hr.	25.7% (26)	23.4% (47)	23.3% (70)	18.6% (75)
1-2 hrs.	26.7% (27)	33.3% (67)	32.9% (99)	35.5% (143)
2-3 hrs.	17.8% (18)	11.4% (23)	19.3% (58)	17.9% (72)
3-4 hrs.	10.9% (11)	10.0% (20)	7.6% (23)	7.9% (32)
4-5 hrs.	3.0% (3)	4.0% (8)	5.0% (15)	4.2% (17)
5-6 hrs.	1.0% (1)	1.5% (3)	1.7% (5)	2.2% (9)
6-8 hrs.	4.0% (4)	0.5% (1)	1.0% (3)	1.7% (7)
8-10 hrs.	0.0% (0)	1.0% (2)	1.0% (3)	0.2% (1)
> 10 hrs.	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Unknown	10.9% (11)	14.9% (30)	8.3% (25)	11.7% (47)
Anterior Access				
No Anterior Access	88.1% (89)	83.6% (168)	83.1% (250)	88.3% (356)
Transoral	1.0% (1)	0.0% (0)	0.0% (0)	0.0% (0)
Anterolateral	6.9% (7)	9.5% (19)	10.6% (32)	8.7% (35)
Cervicothoracic Anterolateral	1.0% (1)	2.5% (5)	1.0% (3)	0.5% (2)
Cervicothoracic With Sternotomy	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Cervicothoracic Anterolat With Sternotomy	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Thoracotomy	0.0% (0)	1.0% (2)	0.3% (1)	0.2% (1)
Cervicothoracic Anterolat With Thoracotomy	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Thoracoabdominal	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Retroperitoneal	3.0% (3)	0.5% (1)	3.7% (11)	2.0% (8)
Thoraco-Phrenico-Lumbotomy	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Transperitoneal	0.0% (0)	0.0% (0)	0.7% (2)	0.0% (0)
Trans-Psoas (XLIF)	0.0% (0)	2.0% (4)	0.7% (2)	0.0% (0)
Other	0.0% (0)	1.0% (2)	0.0% (0)	0.2% (1)
Posterior Access				
No Posterior Access	15.8% (16)	19.4% (39)	16.3% (49)	14.9% (60)
Midline	70.3% (71)	69.7% (140)	71.8% (216)	68.2% (275)
Paramedian	11.9% (12)	9.0% (18)	8.6% (26)	11.4% (46)
Posterolateral	0.0% (0)	1.0% (2)	0.7% (2)	2.0% (8)
Percutaneous	0.0% (0)	0.5% (1)	1.0% (3)	2.0% (8)
Para-Coccygeal (AxialIF)	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Other	2.0% (2)	0.5% (1)	0.7% (2)	0.5% (2)
Unknown	0.0% (0)	1.0% (2)	1.0% (3)	1.0% (4)

Surgical Measures

Decompression

Characteristic	Group 1	Group 2	Group 3	Group 4
Decompression				
None	23.8% (24)	11.4% (23)	9.0% (27)	10.9% (44)
Discectomy	40.6% (41)	46.8% (94)	45.8% (138)	47.6% (192)
Vertebrectomy Partial	3.0% (3)	2.5% (5)	1.7% (5)	1.7% (7)
Vertebrectomy Full	0.0% (0)	0.5% (1)	1.0% (3)	0.2% (1)
Osteotomy	1.0% (1)	1.0% (2)	2.0% (6)	1.0% (4)
Laminotomy	16.8% (17)	25.4% (51)	28.6% (86)	30.5% (123)
Hemi-Laminectomy	4.0% (4)	6.5% (13)	9.0% (27)	7.2% (29)
Laminectomy	14.9% (15)	10.9% (22)	14.6% (44)	13.6% (55)
Facet Joint Resection Partial	18.8% (19)	28.4% (57)	28.9% (87)	27.3% (110)
Facet Joint Resection Full	7.9% (8)	9.5% (19)	7.6% (23)	6.2% (25)
Flavectomy	38.6% (39)	35.3% (71)	35.9% (108)	33.7% (136)
Foraminotomy	18.8% (19)	25.9% (52)	28.9% (87)	25.1% (101)
Sequestrectomy	9.9% (10)	13.9% (28)	18.9% (57)	14.4% (58)
Flavotomy	4.0% (4)	1.5% (3)	2.7% (8)	1.5% (6)
Uncoforaminotomy	1.0% (1)	2.5% (5)	2.0% (6)	1.0% (4)
Other	3.0% (3)	4.5% (9)	4.7% (14)	4.7% (19)
Unknown	0.0% (0)	1.5% (3)	1.3% (4)	1.7% (7)

Fusion

Characteristic	Group 1	Group 2	Group 3	Group 4
Fusion Promoting Measures				
None	54.5% (55)	52.2% (105)	54.8% (165)	56.1% (226)
Posterolateral Fusion	14.9% (15)	11.4% (23)	13.3% (40)	11.7% (47)
Posterior Fusion	11.9% (12)	9.0% (18)	5.3% (16)	8.7% (35)
Interbody Fusion (A-IF)	9.9% (10)	9.5% (19)	9.0% (27)	5.2% (21)
Interbody Fusion (PLIF)	5.9% (6)	4.5% (9)	4.7% (14)	3.5% (14)
Interbody Fusion (TLIF)	8.9% (9)	11.9% (24)	7.6% (23)	9.9% (40)
Interbody Fusion (XLIF)	0.0% (0)	2.0% (4)	1.0% (3)	0.0% (0)
Other Interbody Fusion	1.0% (1)	1.0% (2)	2.7% (8)	3.0% (12)
Ilio-Sacral Fusion	0.0% (0)	0.5% (1)	0.0% (0)	0.0% (0)
Other	4.0% (4)	10.9% (22)	12.3% (37)	11.2% (45)
Unknown	0.0% (0)	2.0% (4)	2.3% (7)	2.5% (10)

Stabilisation

Characteristic	Group 1	Group 2	Group 3	Group 4
Rigid Stabilisation				
None	47.5% (48)	49.3% (99)	52.5% (158)	53.3% (215)
Interbody Stabilisation With Cage	25.7% (26)	29.4% (59)	29.6% (89)	25.8% (104)
Interbody Stabilisation With Auto-/ Allograft	2.0% (2)	0.5% (1)	0.7% (2)	1.7% (7)
Vertebral Body Replacement By Cage	0.0% (0)	1.0% (2)	1.7% (5)	0.7% (3)
Plates	5.0% (5)	6.5% (13)	6.3% (19)	5.7% (23)
Pedicle Screws With Rod	19.8% (20)	23.4% (47)	23.9% (72)	21.6% (87)
Pedicle Screws With Plate	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Facet Screws	0.0% (0)	1.0% (2)	0.0% (0)	0.2% (1)
Transarticular Screw	0.0% (0)	0.5% (1)	0.7% (2)	0.0% (0)
Transarticular Screw C1-C2	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Laminar Hooks	2.0% (2)	1.0% (2)	0.0% (0)	0.0% (0)
Pedicle Hooks	2.0% (2)	0.0% (0)	0.3% (1)	0.5% (2)
Lateral Mass Screw	1.0% (1)	2.0% (4)	1.0% (3)	1.2% (5)
Odontoid Screws	0.0% (0)	0.0% (0)	0.3% (1)	0.0% (0)
Laminar Screws	1.0% (1)	0.0% (0)	0.0% (0)	0.0% (0)
Pedicle Screws Cemented	2.0% (2)	1.0% (2)	1.0% (3)	1.7% (7)
Pedicle Screws Uncemented	9.9% (10)	7.0% (14)	4.0% (12)	6.5% (26)
Other	1.0% (1)	1.5% (3)	1.0% (3)	2.2% (9)
Unknown	3.0% (3)	3.5% (7)	2.7% (8)	2.2% (9)
Motion Preserving Stabilisation				
None	96.0% (97)	92.5% (186)	95.3% (287)	94.8% (382)
Disc Replacement	1.0% (1)	1.5% (3)	1.7% (5)	2.5% (10)
Dynamic Stabilization	3.0% (3)	4.0% (8)	2.3% (7)	2.0% (8)
Interspinous Spacer	0.0% (0)	1.0% (2)	0.7% (2)	0.5% (2)
Other	0.0% (0)	1.0% (2)	0.0% (0)	0.5% (2)

Complications

General Complications

	Group 1	Group 2	Group 3	Group 4
Intraoperative General Complications				
None	73.3% (74)	67.2% (135)	66.8% (201)	69.0% (278)
Anaesthesiological	0.0% (0)	0.5% (1)	0.0% (0)	0.0% (0)
Cardiovascular	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Pulmonary	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Thromboembolism	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Death	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Other	0.0% (0)	0.0% (0)	0.3% (1)	0.2% (1)
Not Documented	26.7% (27)	32.3% (65)	32.9% (99)	30.8% (124)
Postoperative General Complications Before Discharge				
None	64.4% (65)	55.7% (112)	59.1% (178)	60.0% (242)
Cardiovascular	0.0% (0)	0.0% (0)	1.3% (4)	0.0% (0)
Pulmonary	0.0% (0)	0.0% (0)	0.7% (2)	0.5% (2)
Cerebral	0.0% (0)	0.0% (0)	1.3% (4)	0.0% (0)
Kidney / Urinary	0.0% (0)	1.0% (2)	0.7% (2)	0.2% (1)
Liver / Gi	0.0% (0)	0.5% (1)	0.0% (0)	0.5% (2)
Thromboembolism	0.0% (0)	0.0% (0)	0.0% (0)	0.2% (1)
Death	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Positioning-Related	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Other	0.0% (0)	0.5% (1)	0.7% (2)	1.5% (6)
Not Documented	35.6% (36)	42.8% (86)	37.2% (112)	37.2% (150)

Surgical Complications

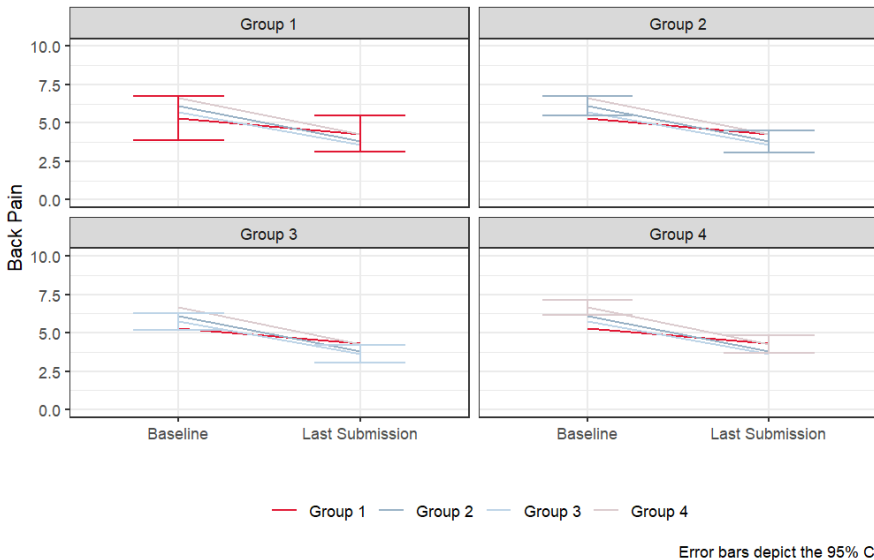
	Group 1	Group 2	Group 3	Group 4
Intraoperative Surgical Complications				
None	70.3% (71)	61.2% (123)	63.8% (192)	66.3% (267)
Nerve Root Damage	0.0% (0)	0.0% (0)	0.3% (1)	0.2% (1)
Spinal Cord Damage	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Dural Lesion	2.0% (2)	5.5% (11)	2.7% (8)	2.2% (9)
Vascular Injury	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Fracture Vertebral Structures	0.0% (0)	0.5% (1)	0.0% (0)	0.2% (1)
Other	1.0% (1)	0.5% (1)	0.3% (1)	0.5% (2)
Not Documented	26.7% (27)	32.3% (65)	32.9% (99)	30.8% (124)
Postoperative Surgical Complications Before Discharge				
None	61.4% (62)	56.7% (114)	59.8% (180)	59.8% (241)
Epidural Hematoma	0.0% (0)	0.0% (0)	0.7% (2)	0.7% (3)
Other Hematoma	0.0% (0)	0.0% (0)	0.0% (0)	0.5% (2)
Radiculopathy	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
CSF Leak / Pseudomeningocele	0.0% (0)	0.0% (0)	0.3% (1)	0.0% (0)
Motor Dysfunction	1.0% (1)	0.0% (0)	0.0% (0)	1.0% (4)
Sensory Dysfunction	0.0% (0)	0.0% (0)	0.0% (0)	0.5% (2)
Bowel / Bladder Dysfunction	0.0% (0)	0.0% (0)	0.0% (0)	0.2% (1)
Wound Infection Superficial	0.0% (0)	0.5% (1)	1.0% (3)	0.2% (1)
Wound Infection Deep	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Implant Malposition	0.0% (0)	0.0% (0)	0.3% (1)	0.0% (0)
Implant Failure	0.0% (0)	0.0% (0)	0.3% (1)	0.2% (1)
Wrong Level	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Recurrent Nerve Paresis	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Other	2.0% (2)	0.0% (0)	0.7% (2)	0.0% (0)
Not Documented	35.6% (36)	42.8% (86)	37.2% (112)	37.5% (151)

COMI Analysis - Back / Legs

Summary

Group	Patients	Baseline	≤ 3 Months	≤ 6 Months	≤ 1 Year	≤ 2 Years	> 2 Years	Mean (Years)	Range (Years)
Group 1	52	39	20	16	13	17	18	0.98	0.00-5.04
Group 2	100	91	45	28	29	45	31	1.12	0.01-8.59
Group 3	166	146	81	40	54	69	50	1.05	0.00-6.21
Group 4	204	176	89	58	64	87	68	1.08	0.00-9.25

Back Pain Analysis

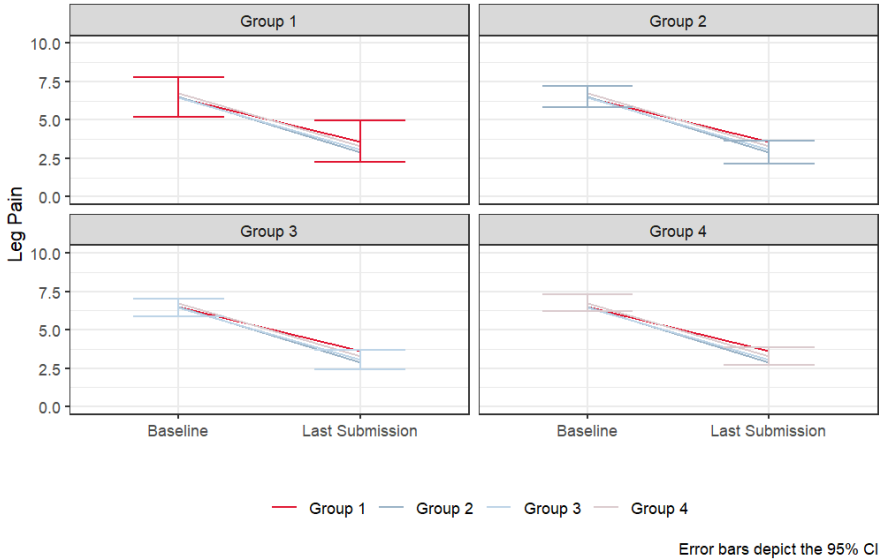


Group	Paired Observations	Baseline			Last Submission			p-value
		Mean	CI (95%)	SD	Mean	CI (95%)	SD	
Group 1	23	5.30	3.86-6.75	3.53	4.30	3.13-5.48	2.88	0.17

Group	Paired Observations	Baseline			Last Submission			p-value
		Mean	CI (95%)	SD	Mean	CI (95%)	SD	
Group 3	100	5.73	5.18-6.28	2.80	3.61	3.04-4.18	2.91	< 0.001
Group 4	118	6.65	6.15-7.15	2.77	4.26	3.71-4.82	3.06	< 0.001

Note: p-values were calculated using a one-sided Wilcoxon test

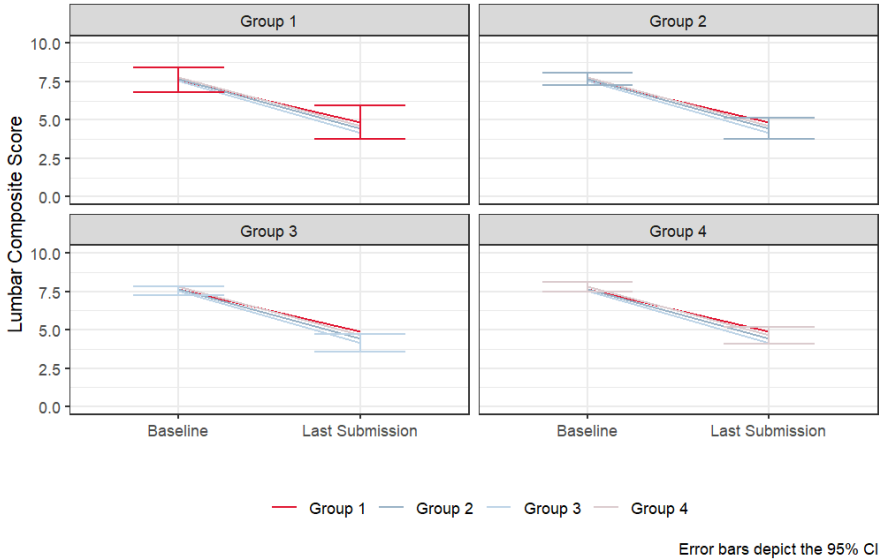
Leg Pain Analysis



Group	Paired Observations	Baseline			Last Submission			p-value
		Mean	CI (95%)	SD	Mean	CI (95%)	SD	
Group 1	23	6.48	5.19-7.76	3.15	3.61	2.24-4.97	3.34	< 0.001
Group 2	64	6.52	5.81-7.22	2.88	2.91	2.18-3.64	2.98	< 0.001
Group 3	100	6.44	5.88-7.00	2.84	3.07	2.44-3.70	3.22	< 0.001
Group 4	118	6.75	6.20-7.29	3.04	3.29	2.69-3.89	3.31	< 0.001

Note: p-values were calculated using a one-sided Wilcoxon test

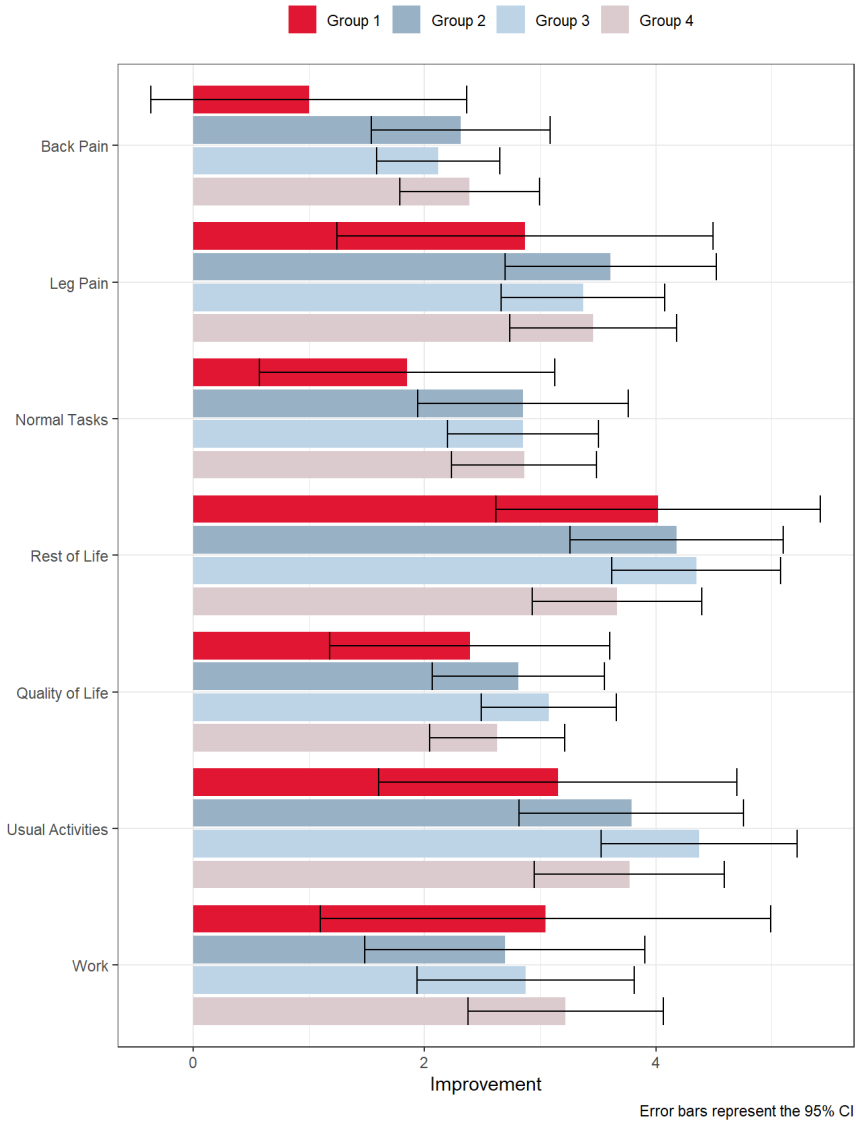
Composite Score Analysis



Group	Paired Observations	Baseline			Last Submission			p-value
		Mean	CI (95%)	SD	Mean	CI (95%)	SD	
Group 1	23	7.63	6.83-8.42	1.95	4.87	3.77-5.97	2.70	< 0.001
Group 2	64	7.65	7.25-8.06	1.64	4.44	3.75-5.14	2.84	< 0.001
Group 3	100	7.54	7.23-7.84	1.57	4.14	3.59-4.70	2.83	< 0.001
Group 4	118	7.80	7.47-8.12	1.81	4.65	4.11-5.18	2.97	< 0.001

Note: p-values were calculated using a one-sided Wilcoxon test

Domain Analysis

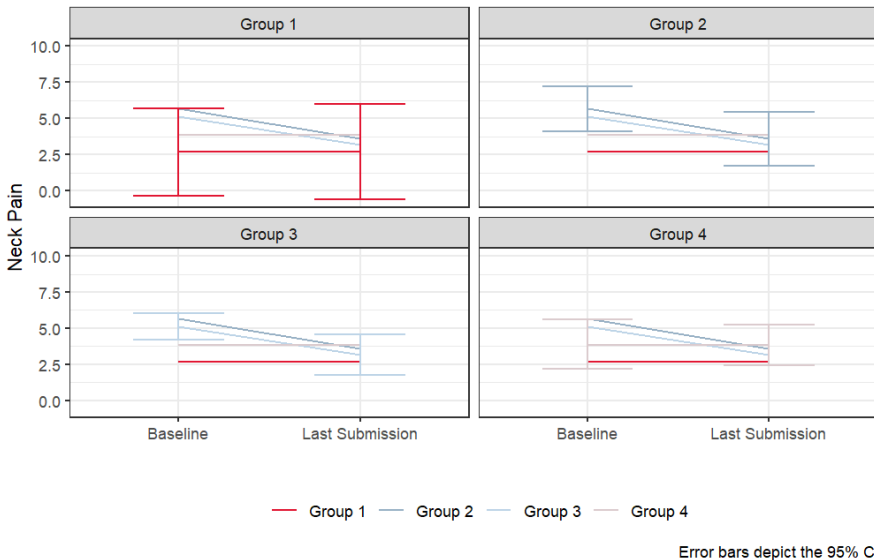


COMI Analysis - Neck / Arms

Summary

Group	Patients	Baseline	≤ 3 Months	≤ 6 Months	≤ 1 Year	≤ 2 Years	> 2 Years	Mean (Years)	Range (Years)
Group 1	9	9	5	3	0	9	4	1.08	0.04-4.97
Group 2	22	18	4	8	5	13	11	1.29	0.03-5.31
Group 3	34	25	11	12	15	16	12	1.02	0.01-4.99
Group 4	38	24	11	8	12	21	11	1.36	0.02-5.92

Neck Pain Analysis

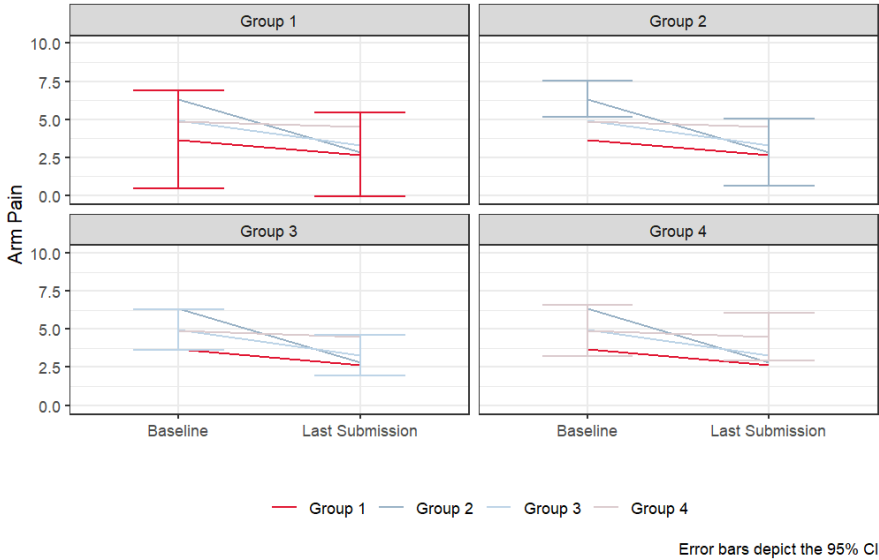


Group	Paired Observations	Baseline			Last Submission			p-value
		Mean	CI (95%)	SD	Mean	CI (95%)	SD	
Group 1	6	2.67	-0.36-5.69	3.78	2.67	-0.64-5.97	4.13	1

Group	Paired Observations	Baseline			Last Submission			p-value
		Mean	CI (95%)	SD	Mean	CI (95%)	SD	
Group 3	18	5.11	4.18-6.05	2.03	3.17	1.76-4.58	3.05	0.04
Group 4	18	3.89	2.18-5.59	3.69	3.83	2.41-5.25	3.07	0.72

Note: p-values were calculated using a one-sided Wilcoxon test

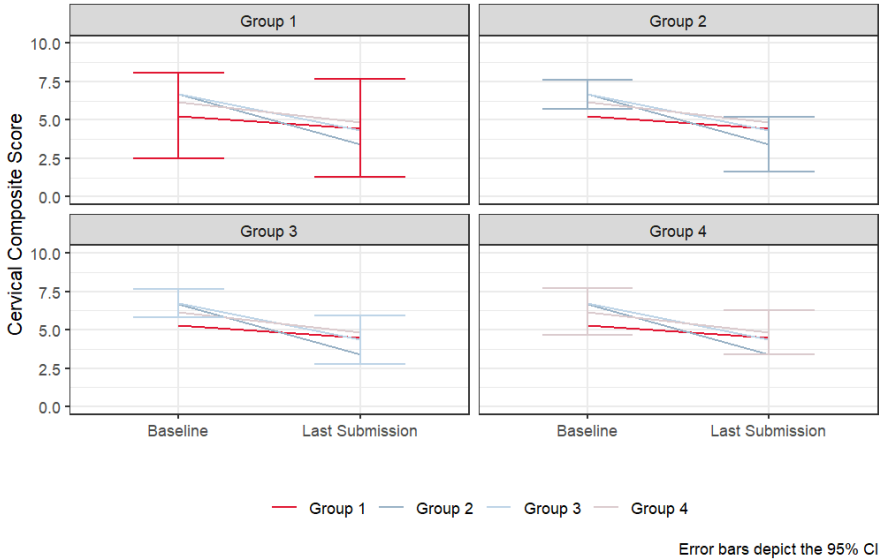
Arm Pain Analysis



Group	Paired Observations	Baseline			Last Submission			p-value
		Mean	CI (95%)	SD	Mean	CI (95%)	SD	
Group 1	6	3.67	0.44-6.89	4.03	2.67	-0.09-5.42	3.44	0.79
Group 2	12	6.33	5.14-7.52	2.10	2.83	0.61-5.06	3.93	0.01
Group 3	18	4.94	3.60-6.28	2.90	3.28	1.96-4.59	2.85	0.06
Group 4	18	4.89	3.21-6.56	3.63	4.50	2.94-6.06	3.38	0.8

Note: p-values were calculated using a one-sided Wilcoxon test

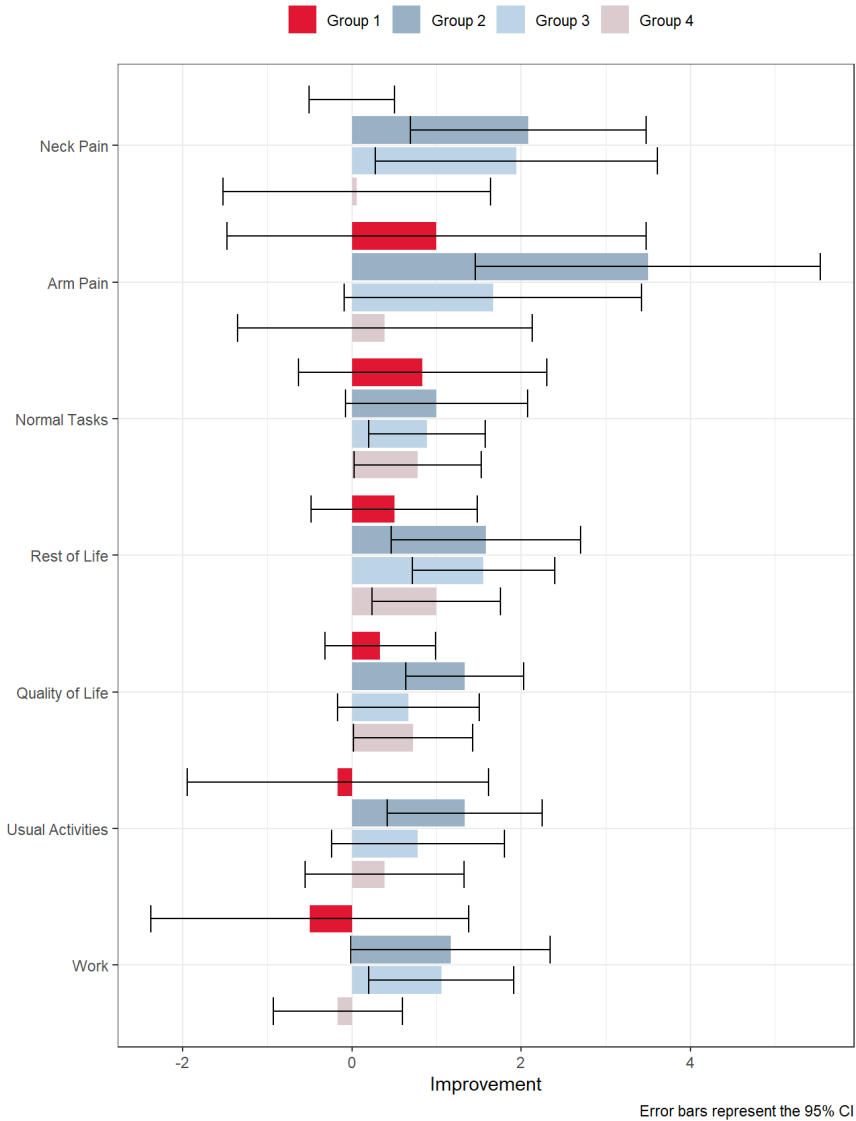
Composite Score Analysis



Group	Paired Observations	Baseline			Last Submission			p-value
		Mean	CI (95%)	SD	Mean	CI (95%)	SD	
Group 1	6	5.28	2.50-8.05	3.47	4.47	1.30-7.65	3.96	0.59
Group 2	12	6.68	5.73-7.64	1.69	3.42	1.62-5.21	3.17	0.02
Group 3	18	6.71	5.79-7.62	1.98	4.35	2.76-5.94	3.44	0.03
Group 4	18	6.17	4.66-7.68	3.27	4.83	3.41-6.25	3.08	0.11

Note: p-values were calculated using a one-sided Wilcoxon test

Domain Analysis

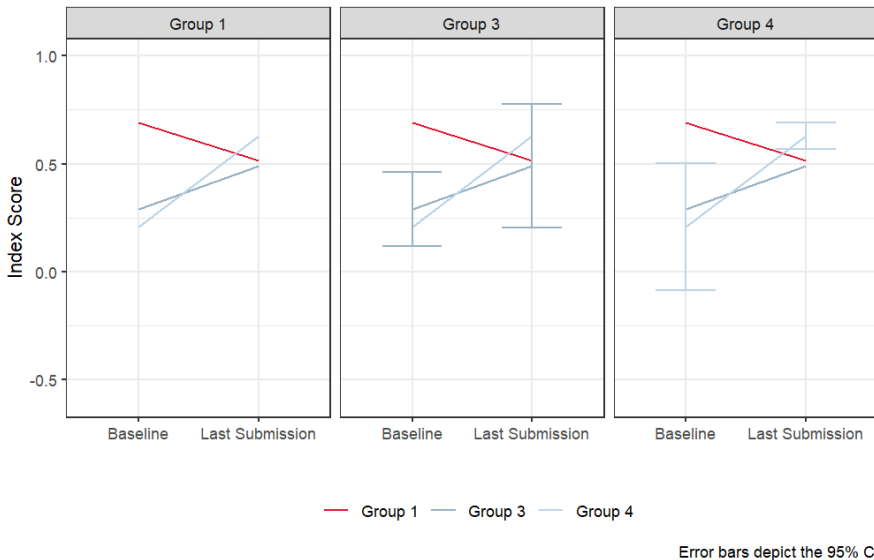


EQ-5D-3L Analysis

Summary

Group	Patients	Baseline	≤ 3 Months	≤ 6 Months	≤ 1 Year	≤ 2 Years	> 2 Years	Mean (Years)	Range (Years)
Group 1	15	11	3	4	1	3	5	1.12	0.06-4.73
Group 2	33	25	9	7	5	11	7	0.95	0.03-8.59
Group 3	52	34	17	13	6	14	19	1.14	0.03-6.21
Group 4	61	39	16	14	7	21	12	1.03	0.02-9.25

Index Score Analysis

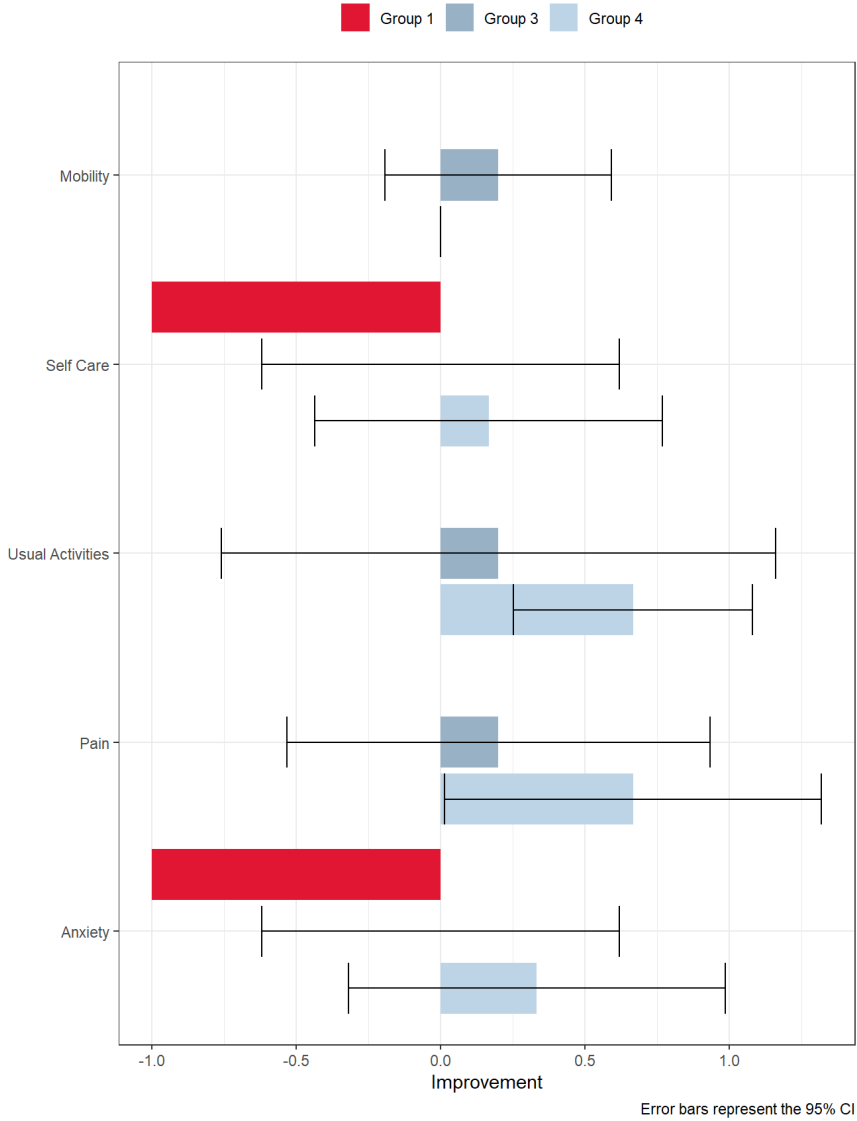


Group	Paired Observations	Baseline			Last Submission			p-value
		Mean	CI (95%)	SD	Mean	CI (95%)	SD	
Group 1	1	0.69	Undefined	Undefined	0.52	Undefined	Undefined	1

		Baseline			Last Submission			
Group	Paired Observations	Mean	CI (95%)	SD	Mean	CI (95%)	SD	p-value
Group 4	6	0.21	-0.09-0.50	0.37	0.63	0.57-0.69	0.08	0.09

Note: p-values were calculated using a one-sided Wilcoxon test

Domain Analysis



Oswestry Disability Index Analysis

Summary

Group	Patients	Baseline	≤ 3 Months	≤ 6 Months	≤ 1 Year	≤ 2 Years	> 2 Years	Mean (Years)	Range (Years)
Group 1	7	4	4	1	1	0	1	1.24	0.03-4.73
Group 2	28	27	5	6	4	5	6	1.18	0.05-8.59
Group 3	47	37	14	12	13	5	9	0.94	0.01-6.21
Group 4	58	51	20	7	12	15	6	0.96	0.01-9.25

Surgery Follow-up

A Surgery Follow-up form is completed by the examining surgeon. This section of the report is based upon the surgeon's clinical assessment.

Summary

Group	Patients	6 Weeks	3 Months	6 Months	1 Year	2 Years	Other	Mean (Years)	Range (Years)
Group 1	26	20	9	1	5	0	2	0.32	0.03-1.52
Group 2	79	49	29	16	20	4	6	0.53	0.07-3.31
Group 3	110	77	44	21	23	7	6	0.46	0.07-4.00
Group 4	139	88	58	25	27	10	14	0.49	0.04-3.86

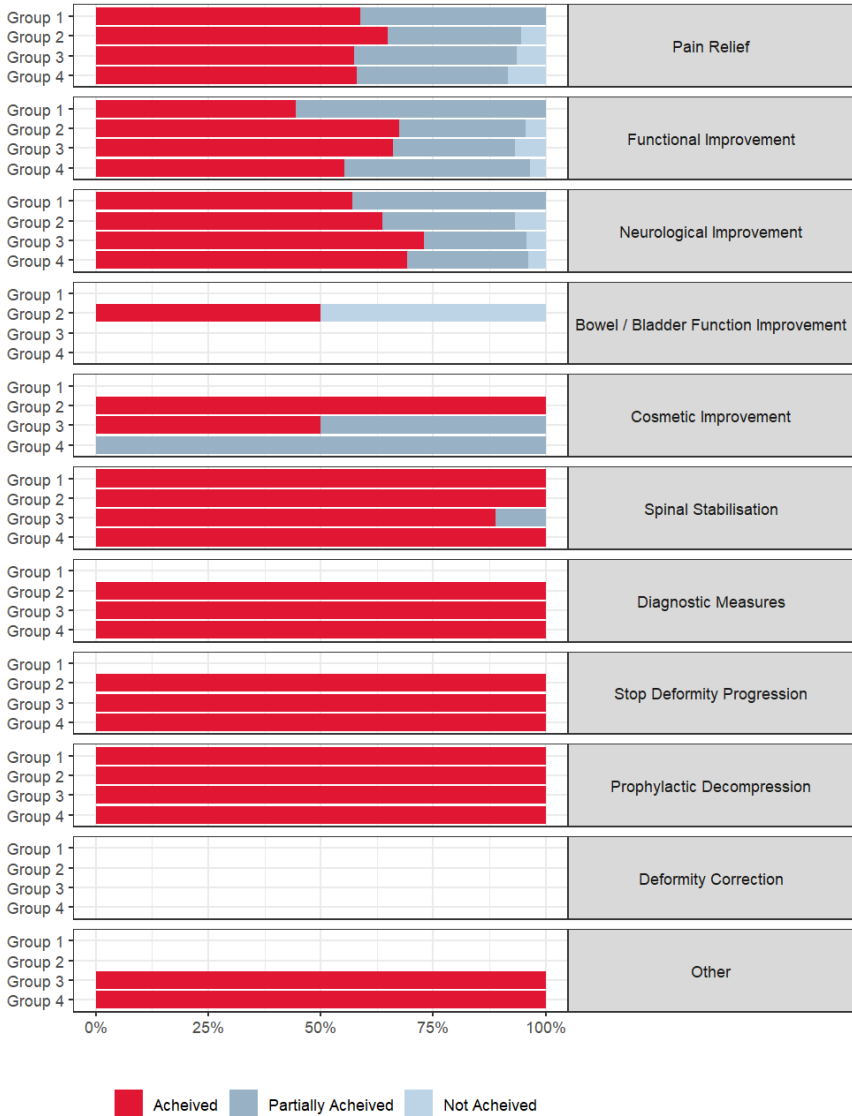
Outcome

Outcome	Group 1	Group 2	Group 3	Group 4
Excellent	16.0% (4)	30.9% (25)	31.5% (35)	25.2% (35)
Good	72.0% (18)	50.6% (41)	47.7% (53)	52.5% (73)
Fair	8.0% (2)	12.3% (10)	13.5% (15)	15.1% (21)
Poor	4.0% (1)	4.9% (4)	6.3% (7)	6.5% (9)
Not Applicable	0.0% (0)	0.0% (0)	0.0% (0)	0.7% (1)

Work Status

Work Status	Group 1	Group 2	Group 3	Group 4
Not at work since OP	20.0% (5)	29.6% (24)	19.8% (22)	25.9% (36)
Started partially, same job	8.0% (2)	12.3% (10)	7.2% (8)	7.2% (10)
Fully reintegrated	12.0% (3)	17.3% (14)	21.6% (24)	12.9% (18)
Resumed work, but quit again	0.0% (0)	0.0% (0)	0.9% (1)	1.4% (2)
Resumed work, different job	0.0% (0)	0.0% (0)	0.0% (0)	0.7% (1)
Has been dismissed	0.0% (0)	0.0% (0)	0.0% (0)	2.2% (3)
Retired since OP	4.0% (1)	0.0% (0)	0.0% (0)	1.4% (2)
Retired before OP	52.0% (13)	32.1% (26)	38.7% (43)	38.1% (53)
Housewife/man	0.0% (0)	4.9% (4)	7.2% (8)	6.5% (9)
Child/student	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Other	4.0% (1)	2.5% (2)	3.6% (4)	3.6% (5)

Therapeutic Goals



Therapeutic Goals (Table)

Goal	Goal Status	Group 1	Group 2	Group 3	Group 4
Pain Relief	Acheived	58.8% (20)	64.9% (72)	57.4% (89)	58.1% (111)
Pain Relief	Partially Acheived	41.2% (14)	29.7% (33)	36.1% (56)	33.5% (64)
Pain Relief	Not Acheived	0.0% (0)	5.4% (6)	6.5% (10)	8.4% (16)
Functional Improvement	Acheived	44.4% (8)	67.4% (31)	66.1% (39)	55.3% (47)
Functional Improvement	Partially Acheived	55.6% (10)	28.3% (13)	27.1% (16)	41.2% (35)
Functional Improvement	Not Acheived	0.0% (0)	4.3% (2)	6.8% (4)	3.5% (3)
Neurological Improvement	Acheived	57.1% (4)	63.6% (28)	72.9% (35)	69.2% (36)
Neurological Improvement	Partially Acheived	42.9% (3)	29.5% (13)	22.9% (11)	26.9% (14)
Neurological Improvement	Not Acheived	0.0% (0)	6.8% (3)	4.2% (2)	3.8% (2)
Bowel / Bladder Function Improvement	Acheived	0.0% (0)	50.0% (1)	0.0% (0)	0.0% (0)
Bowel / Bladder Function Improvement	Partially Acheived	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Bowel / Bladder Function Improvement	Not Acheived	0.0% (0)	50.0% (1)	0.0% (0)	0.0% (0)
Cosmetic Improvement	Acheived	0.0% (0)	100.0% (1)	50.0% (1)	0.0% (0)
Cosmetic Improvement	Partially Acheived	0.0% (0)	0.0% (0)	50.0% (1)	100.0% (1)
Cosmetic Improvement	Not Acheived	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Spinal Stabilisation	Acheived	100.0% (2)	100.0% (8)	88.9% (8)	100.0% (10)
Spinal Stabilisation	Partially Acheived	0.0% (0)	0.0% (0)	11.1% (1)	0.0% (0)
Spinal Stabilisation	Not Acheived	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Diagnostic Measures	Acheived	0.0% (0)	100.0% (1)	100.0% (1)	100.0% (1)
Diagnostic Measures	Partially Acheived	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Diagnostic Measures	Not Acheived	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Stop Deformity Progression	Acheived	0.0% (0)	100.0% (2)	100.0% (2)	100.0% (2)
Stop Deformity Progression	Partially Acheived	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Stop Deformity Progression	Not Acheived	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Prophylactic Decompression	Acheived	100.0% (2)	100.0% (2)	100.0% (2)	100.0% (3)
Prophylactic Decompression	Partially Acheived	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Prophylactic Decompression	Not Acheived	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Deformity Correction	Acheived	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Deformity Correction	Partially Acheived	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Deformity Correction	Not Acheived	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Other	Acheived	0.0% (0)	0.0% (0)	100.0% (1)	100.0% (1)
Other	Partially Acheived	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Other	Not Acheived	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)

Postoperative Complications

Complications?	Group 1	Group 2	Group 3	Group 4
No	89.5% (34)	86.2% (106)	93.8% (165)	89.1% (196)
Yes	10.5% (4)	13.8% (17)	6.2% (11)	10.9% (24)
Complication Type	Group 1	Group 2	Group 3	Group 4
Sensory dysfunction	0.0% (0)	4.9% (6)	0.6% (1)	2.7% (6)
Motor dysfunction	0.0% (0)	3.3% (4)	0.6% (1)	2.3% (5)
Bowel/ bladder dysfunction	0.0% (0)	0.8% (1)	0.0% (0)	0.0% (0)
Non-union	5.3% (2)	0.0% (0)	0.0% (0)	0.0% (0)
Implant failure	0.0% (0)	0.0% (0)	0.6% (1)	1.4% (3)
Instability	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
CSF leak/ pseudomeningocele	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Wound infection superficial	2.6% (1)	0.8% (1)	1.1% (2)	1.4% (3)
Wound infection deep	0.0% (0)	1.6% (2)	0.0% (0)	0.0% (0)
Spondylitis	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Discitis	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Epidural hematoma	0.0% (0)	0.0% (0)	0.6% (1)	0.0% (0)
Extravertebral hematoma	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Wrong level	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Implant malposition	0.0% (0)	0.8% (1)	0.0% (0)	0.9% (2)
Recurrence of symptoms	0.0% (0)	3.3% (4)	0.6% (1)	2.7% (6)
Graft complication	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Internal medicine	0.0% (0)	0.8% (1)	0.6% (1)	0.0% (0)
Sequelae anaesthesia	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Adjac. segment pathology	0.0% (0)	0.0% (0)	0.6% (1)	0.5% (1)
Recurrent tumor	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Decompensation of spine	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Cardiovascular	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Gastrointestinal	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Central nervous system	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Fracture vertebral structures	0.0% (0)	0.0% (0)	0.0% (0)	0.5% (1)
Thromboembolism	0.0% (0)	0.0% (0)	0.0% (0)	0.0% (0)
Other	2.6% (1)	2.4% (3)	1.1% (2)	0.9% (2)
None	89.5% (34)	86.2% (106)	93.8% (165)	89.1% (196)

Complication Time



Reoperation Analysis for Group 1

Summary

Number of Reoperations at any level	14
Number of Reoperations at an adjacent level	2
Number of Reoperations at the same level	6

Cumulative Reoperation Rates

Time (Years)	At Risk	Any Level		Adjacent Level		Same Level	
		Reoperations	CRR (95% CI)	Reoperations	CRR (95% CI)	Reoperations	CRR (95% CI)
0	101	0	0.0% (0.0%-0.0%)	0	0.0% (0.0%-0.0%)	0	0.0% (0.0%-0.0%)
1	91	5	5.2% (0.7%-9.5%)	0	0.0% (0.0%-0.0%)	3	3.1% (0.0%-6.5%)
2	81	5	10.5% (4.1%-16.5%)	0	0.0% (0.0%-0.0%)	1	4.2% (0.1%-8.1%)
3	73	4	15.1% (7.4%-22.1%)	2	2.5% (0.0%-5.8%)	2	6.5% (1.3%-11.5%)
4	73	0	15.1% (7.4%-22.1%)	0	2.5% (0.0%-5.8%)	0	6.5% (1.3%-11.5%)
5	71	0	15.1% (7.4%-22.1%)	0	2.5% (0.0%-5.8%)	0	6.5% (1.3%-11.5%)
6	61	0	15.1% (7.4%-22.1%)	0	2.5% (0.0%-5.8%)	0	6.5% (1.3%-11.5%)
7	51	0	15.1% (7.4%-22.1%)	0	2.5% (0.0%-5.8%)	0	6.5% (1.3%-11.5%)
8	49	0	15.1% (7.4%-22.1%)	0	2.5% (0.0%-5.8%)	0	6.5% (1.3%-11.5%)
9	45	0	15.1% (7.4%-22.1%)	0	2.5% (0.0%-5.8%)	0	6.5% (1.3%-11.5%)
10	34	0	15.1% (7.4%-22.1%)	0	2.5% (0.0%-5.8%)	0	6.5% (1.3%-11.5%)
11	28	0	15.1% (7.4%-22.1%)	0	2.5% (0.0%-5.8%)	0	6.5% (1.3%-11.5%)
12	23	0	15.1% (7.4%-22.1%)	0	2.5% (0.0%-5.8%)	0	6.5% (1.3%-11.5%)

Time (Years)	At Risk	Any Level		Adjacent Level		Same Level	
		Reoperations	CRR (95% CI)	Reoperations	CRR (95% CI)	Reoperations	CRR (95% CI)
14	14	0	15.1% (7.4%-22.1%)	0	2.5% (0.0%-5.8%)	0	6.5% (1.3%-11.5%)
15	13	0	15.1% (7.4%-22.1%)	0	2.5% (0.0%-5.8%)	0	6.5% (1.3%-11.5%)
16	5	0	15.1% (7.4%-22.1%)	0	2.5% (0.0%-5.8%)	0	6.5% (1.3%-11.5%)

Reasons for Reoperation

Reason for Reoperation	Any Level			Adjacent Level			Same Level		
	Percent (Count)	Mean (Years)	Range (Years)	Percent (Count)	Mean (Years)	Range (Years)	Percent (Count)	Mean (Years)	Range (Years)
Hardware Removal	14.3% (2)	1.43	0.91-1.95	0.0% (0)	Undefined	Undefined	16.7% (1)	0.91	0.91-0.91
Instability	7.1% (1)	0.91	0.91-0.91	0.0% (0)	Undefined	Undefined	16.7% (1)	0.91	0.91-0.91
Other	7.1% (1)	0.91	0.91-0.91	0.0% (0)	Undefined	Undefined	16.7% (1)	0.91	0.91-0.91
Unknown	85.7% (12)	1.45	0.11-2.75	100.0% (2)	2.01	2.01-2.02	83.3% (5)	1.14	0.11-2.02

Appendix A - Component List

Supplier	Description	Article Number	Number Implanted
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Appendix B - Complications by Country

Summary

Country	Complications
Austria	1
Belgium	1
Germany	0
Italy	0
Portugal	1
Slovenia	0
Switzerland	18
United Kingdom	4
United States	1
Unspecified	1

Complications - Austria

Surgical Complications

Surgical Complications	Intraoperative	Postoperative (Before Discharge)
Other	1	0

Complications - Belgium

Surgical Complications

Surgical Complications	Intraoperative	Postoperative (Before Discharge)
Motor Dysfunction	0	1

Complications - Portugal

Surgical Complications

Surgical Complications	Intraoperative	Postoperative (Before Discharge)
Dural Lesion	1	0

Complications - Switzerland

Surgical Complications

Surgical Complications	Intraoperative	Postoperative (Before Discharge)
Dural Lesion	1	0
Other	0	2

Surgery Follow-up Complications

Complication Type	Early (< 28 Days)	Sub-acute (2-6 Months)	Late (> 6 Months)
Non-union	0	0	2
Wound infection superficial	1	0	0

Reoperation Reasons

Reason for Reoperation	Any Level			Adjacent Level			Same Level		
	Percent (Count)	Mean (Years)	Range (Years)	Percent (Count)	Mean (Years)	Range (Years)	Percent (Count)	Mean (Years)	Range (Years)
Hardware Removal	14.3% (2)	1.43	0.91-1.95	0.0% (0)	Undefined	Undefined	16.7% (1)	0.91	0.91-0.91
Instability	7.1% (1)	0.91	0.91-0.91	0.0% (0)	Undefined	Undefined	16.7% (1)	0.91	0.91-0.91
Other	7.1% (1)	0.91	0.91-0.91	0.0% (0)	Undefined	Undefined	16.7% (1)	0.91	0.91-0.91
Unknown	57.1% (8)	1.61	0.11-2.75	50.0% (1)	2.02	2.02-2.02	50.0% (3)	0.87	0.11-2.02

Complications - United Kingdom

Reoperation Reasons

Reason for Reoperation	Any Level			Adjacent Level			Same Level		
	Percent (Count)	Mean (Years)	Range (Years)	Percent (Count)	Mean (Years)	Range (Years)	Percent (Count)	Mean (Years)	Range (Years)
Unknown	21.4% (3)	1.30	0.79-2.01	50.0% (1)	2.01	2.01-2.01	33.3% (2)	1.56	1.11-2.01

Complications - United States

Surgery Follow-up Complications

Complication Type	Early (< 28 Days)	Sub-acute (2-6 Months)	Late (> 6 Months)
Other	1	0	0

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