

Annual Report 2023

Australian Spine Registry









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Contents

List of Figures4
List of Tables
Foreword
Acknowledgements9
Data Period
Common Terms, Definitions and Abbreviations10
Executive Summary12
The Australian Spine Registry's Vision14
Industry Funding Supporters
Snapshot of the Australian Spine Registry 16
Prologue
Summary of the ASR20
Surgeon and Hospital Engagement20
Patient Uptake21
Registry Communications and Responses 23
Surgeon Reported Data23
Overview of ASR Patients
Patient Demographics26
Patient Sub-groups25
Surgery27
Neuromonitoring27
Navigation28
Surgical Approach28
Surgeon Reported Comorbidities (SRCs) and ASA30
Patient Reported Outcome Measures - Total Cohort32
EQ-5D-3L Quality Of Life
Oswestry Disability Index (ODI)
Neck Disability Index (NDI)
Cohort Analysis
Single Level Lumbar Discectomy40
Single Level Lumbar Discectomy40 Demographics41
Single Level Lumbar Discectomy40 Demographics41 Surgeon Reported Comorbidities and ASA42
Single Level Lumbar Discectomy40 Demographics41 Surgeon Reported Comorbidities and ASA42 Glassman Classification Scores

Anterior Cervical Discectomy	F 4
and Fusion (ACDF)	54
Demographics	55
Surgeon Reported Comorbidities and ASA	56
PROMs Analysis	56
L4-L5 Degenerative Spondylolisthesis (L4-L5-DS)	62
Demographics	63
Surgeon Reported Comorbidities and ASA	64
Glassman Classification Scores	65
PROMs Analysis	65
L5-S1 Isthmic Spondylolisthesis (L5-S1 IS).	72
Demographics	73
Surgeon Reported Comorbidities and ASA	74
Glassman Classification Scores	75
PROMs Analysis	75
Complex Surgery	82
Demographics	83
Surgeon Reported Comorbidities and ASA	84
Glassman Score For 'Symptoms' Among Complex Surgery Patients	85
Paediatric ASR: from concept to reality	92
pASR as at Jan 2024	92
Future Directions	94
Publications	95
Registry Presentations in 2023	95
Appendices	96
References	104

List of Figures

Figure 1: Age distribution for Medicare Item 51023 processed from July 2019 to November 2023
Figure 2: Age distribution for Medicare Item 51024 processed from July 2019 to November 2023
Figure 3: Age distribution for Medicare Item 51025 processed from July 2019 to November 2023
Figure 4: Age distribution for Medicare Item 51026 processed from July 2019 to November 2023
Figure 5: (A) Number of hospital sites approved and pending approval with the ASR across Australia; (B) Total number of private to public hospitals in the registry across Australia
Figure 6: Accumulation rate of patients from registry launch on 15 January 2018 to 15 January 2024
Figure 7: Patient recruitment by year
Figure 8: Reason for patient opt-out (n)22
Figure 9: Surgeon data entry completion rate
Figure 10: Patient age distribution at the time of surgery26
Figure 11: Percentage of neuromonitoring use between 2018 – 2023 for ALL reported spine procedures
Figure 12: Percentage of navigation use between 2018 – 2023 for ALL reported spine procedures
Figure 13: Frequency of surgical approaches in ALL captured procedures29
Figure 14: ASA score reported in ALL patients where ASA scores were recorded
Figure 15: Breakdown of number of comorbidities reported in all patients
Figure 16: EQ-5D-3L scores for each domain for all patients who completed any EQ-5D-3L at pre-op, 6, 12 and 24-months post-op in

Figure 17: EQVAS distribution for all patients who completed any EQVAS at pre-op, 6, 12 and 24-months post-op. Note, the higher the score, the better the perception of overall health......35 Figure 18: ODI distribution for all patients who completed any ODI at pre-op, 6, 12 and Figure 19: NDI distribution for all patients who completed any NDI at pre-op, 6, 12 and Figure 20: Discectomy procedures by patient age and gender41 Figure 21: Glassman Score for 'Symptoms' among discectomy patients43 Figure 22: ODI distribution for discectomy patients who completed any ODI at pre-op, 6, 12 and 24-months post-op...... 44 Figure 23: Box plots showing the differences in low, medium and high ODI patients pre-op and the change in their ODIs at 12 months Figure 24: Box plots showing the change in the ODI scores for the low medium and high ODI patients over 12 months......50 Figure 25: EQVAS distribution for discectomy patients who completed any EQVAS at pre-op, 6, 12 and 24-months post-op52 Figure 26: ACDF procedures by patient age and gender......55 Figure 27: NDI distribution for ACDF patients who completed any NDI questionnaires at pre-op, 6,12 and 24-months post-op57 Figure 28: EQVAS distribution for ACDF patients who completed any EQVAS at pre-op, 6,12 and 24-months post-op......61 Figure 29: L4-L5 Spondylolisthesis cohort by patient age and gender63 Figure 30: Glassman Score for 'Symptoms' among L4-L5 DS patients (n=189)65 **Figure 31:** ODI distribution for L4-L5 DS patients who completed any ODI at pre-op, 6, 12 and

24-months post-op66

Figure 32: EQVAS distribution for L4-L5 DS patients who completed any EQVAS at pre-op, 6, 12 and 24-months post-op
Figure 33: Isthmic spondylolisthesis cohort by patient age and gender73
Figure 34: Glassman Score for 'Symptoms' among L5-S1 IS patients75
Figure 35: ODI distribution for L5-S1 IS patients who completed any ODI at pre-op, 6, 12 and 24-months post-op76
Figure 36: EQ-VAS mean and median scores for isthmic spondylolisthesis who completed any EQ-VAS at pre-op, 6, 12 and 24-months post-op
Figure 37: Complex Surgery patients by age and gender
Figure 38: Percentage of patients who underwent multi-staged procedures for the "complex surgery" patients cohort
Figure 39: Percentage of patients of "complex surgery" patients that had had previous spine surgery
Figure 40: Glassman Score for 'Symptoms' among complex surgery patients85
Figure 41: ODI distribution for Complex Surgery patients who completed any ODI at pre-op, 6, 12 and 24-months post-op
Figure 42: EQVAS distribution for Complex Surgery patients who completed any EQVAS at

List of Tables

Table 1: Percentage of patients by treatment types 26
Table 2: EQVAS mean and median scoresfor all patients who completed any EQVAS atpre-op, 6, 12 and 24-months post-op
Table 3: ODI Scoring
Table 4: ODI mean and median scoresfor all patients who completed any ODI atpre-op, 6, 12 and 24-months post-op
Table 5: NDI Scoring
Table 6: NDI mean and median scores forall patients who completed any NDI at pre-op,6, 12 and 24-months post-op38
Table 7: Number of discectomy patientsdiagnosed with any comorbidity prior tosurgery
Table 8: Breakdown of number of comorbidities reported in discectomy patients
Table 9: ASA score reported for "Discectomy"patients compared to all ASR patients
Table 10: ODI mean and median scores fordiscectomy patients who completed any ODIat pre-op, 6, 12 and 24-months post-op
Table 11: ODI mean scores for each domainfor discectomy patients who completed anyODI at pre-op, 6, 12 and 24-monthspost-op
Table 12: MCID for ODI from pre-op to6-months post-op for discectomy patients 47
Table 13: MCID for ODI from pre-op to12-months post-op for discectomy patients 47
Table 14: MCID for ODI from pre-op to24-months post-op for discectomy patients 47
Table 15: Characteristics of the low medium and high ODI discectomy cohort
Table 15: Characteristics of the low medium and high ODI discectomy cohort

Table 18: Number of ACDF patients diagnosedwith any comorbidity prior to surgery
Table 19: Breakdown of number of SRCsreported in ACDF patients
Table 20: ASA scores for ACDF patientscompared to all ASR patients56
Table 21: NDI mean and median scores forACDF patients who completed any NDI atpre-op, 6, 12 and 24-months post-op
Table 22: NDI mean scores for each domain for ACDF patients who completed any EQVAS at pre-op, 6, 12 and 24-months post-op
Table 23: MCID for NDI from pre-op to6-months post-op for ACDF patients
Table 24: MCID for NDI from pre-op to12-months post-op for ACDF patients
Table 25: MCID for NDI from pre-op to24-months post-op for ACDF patients
Table 26: EQ-5D-3L scores for each domainfor ACDF patients at pre-op, 6 and 12 and24-months post-op60
Table 27: EQVAS mean and median scores forACDF patients who completed any EQVAS atpre-op, 6, 12 and 24-months post-op60
Table 28: Number of L4-L5 DS patients withany comorbidity prior to surgery
Table 29: ASA score reported for L4-L5 DSpatients compared to all ASR patients
Table 30: ODI mean and median scores forL4-L5 DS patients who completed any ODI atpre-op, 6, 12 and 24-months post-op
Table 31: ODI mean scores for each domainfor L4-L5 DS patients who completed anyODI at pre-op, 6, 12 and 24-monthspost-op
Table 32: MCID for ODI from pre-op to6-months post-op for L4-L5 DS patients
Table 33: MCID for ODI from pre-op to12-months post-op for L4-L5 DS patients69
Table 34: MCID for ODI from pre-op to24-months post-op for L4-L5 DS patients69

Table 35: EQ-5D-3L scores for each domainfor L4-L5 DS patients at pre-op, 6, 12 and24-months post-op displayed in order ofimprovement of some and extremeproblems.70
Table 36: EQVAS mean and median scoresfor L4-L5 DS patients who completed anyEQVAS at pre-op, 6, 12 and 24-monthspost-op
Table 37: Number of L5-S15 IS patients withany comorbidity prior to surgery
Table 38: ASA score reported for patientswith isthmic spondylolisthesis comparedto all ASR patients
Table 39: ODI mean and median scores forL5-S1 IS patients who completed any ODIat pre-op, 6, 12 and 24-months post-op
Table 40: ODI mean scores for each domainfor L5-S1 IS patients who completed any ODIat pre-op, 6, 12 and 24-months post-op
Table 41: MCID for ODI from pre-op to6-months post-op for L5-S1 IS patients
Table 42: MCID for ODI from pre-op to12-months post-op for L5-S1 IS patients
Table 43: MCID for ODI from pre-op to24-months post-op for L5-S1 IS patients
Table 44: EQ-5D-3L scores for each domainfor L4-L5 DS patients at pre-op, 6, 12 and24-months post-op displayed in orderof improvement of some and extremeproblems80
Table 45: EQ-VAS mean and median scoresfor isthmic spondylolisthesis who completedany EQ-VAS at pre-op, 6, 12 and 24-monthspost-op
Table 46: Number of Complex Surgery patients with any comorbidity prior to surgery
Table 47: Breakdown of number of comorbidities reported in Complex Surgery patients 84
Table 48: ASA score reported for "Complex Surgery" patients compared to all ASR patients

Table 49: ODI mean and median scoresfor Complex Surgery patients who completedany ODI at pre-op, 6, 12 and 24-monthspost-op
Table 50: MCID for ODI from pre-op to6-months post-op for Complex Surgerypatients88
Table 51: MCID for ODI from pre-op to12-months post-op for Complex Surgerypatients88
Table 52: MCID for ODI from pre-op to24-months post-op for Complex Surgerypatients88
Table 53: EQ-5D-3L scores for each domainfor Complex Surgery patients from pre-op, to24-months post-op89
Table 54: EQVAS mean and median scores for Complex Surgery patients who completed any EQVAS at pre-op, 6, 12 and 24-months post-op

Foreword

It is with great pleasure that we present the Australian Spine Registry 2023 Annual Report.

In 2023 we were back in full swing with recruitment of patients and the staged expansion of the registry. We are pleased to announce that we have recruited the Royal Perth Hospital, Royal Adelaide Hospital, Ballarat Base Hospital, St John of God Ballarat and Epworth Geelong. At the time of publishing this annual report, the registry had reached 5000 patients and patient follow up and data collection compliance remained close to 80%.

The ASR has also been working on establishing a paediatric registry pilot (pASR). Based at the Queensland Children's Hospital in Brisbane, the pilot, as at publishing this report, has commenced and will evaluate recruitment and data collection for children with scoliosis. Initially, children undergoing surgery will be recruited with the future aim to collect data from children and families who receive conservative and surgical treatment. The pASR will also have the ability to be expanded nationally. Sincere thanks to the team at QUT and QCH for all their hard work in making the pASR possible.

Stakeholder engagement was a key activity in 2023. Nationally, the ASR attended Spine Week in Melbourne and presented an update to key stakeholders during the conference. It also presented an overview of the registry at the Neurosurgical Society ASM in September 2023.

On the international front, in March, the ASR attended and presented in person at the 1st International Meeting of Spinal Registries at the Royal National Orthopaedic Hospital Stanmore Middlesex, UK, and presented remotely at the 2nd Meeting of the International Spinal Registries at the meeting of EUROSPINE Messe Frankfurt 5th and 6th October 2023. This was the first time that spine registries from around the world got together to showcase their registries, to discuss their data collection and the problems that each registry was facing. It was enlightening to hear that the hurdles that the ASR faced and continues to struggle with were similar across most spine registries.

The ASR also met various funding milestones. The ASR was awarded another 4 years of funding by the Commonwealth government, and it continued to receive grants from industry. The ASR is very grateful for the continued support from the Commonwealth government, industry, health insurers and the Spine Society of Australia.

Another important piece of news is that this will be the last year that the ASR will be working with Monash University. The ASR will be moving under the umbrella of the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) from July 2024. The registry could not have launched and grown without the expert guidance of the Monash University team under the leadership of Professor Susannah Ahern. The ASR is very grateful for the support that Monash has provided over the last 7 years.

Finally, the ASR would like to thank Dr Esther Apos, our Registry Manager, the steering committee and the entire ASR team and staff at Monash for their tireless efforts to bring this publication to fruition.



Mr Michael Johnson MBBS, FRACS (Orth), GAICD

Chairman, Australian Spine Registry Steering Committee Clinical Lead, Australian Spine Registry

Acknowledgements

The ASR can continue to grow only through the efforts of many people.

It is essential that we thank:

- The patients, whose willingness to be involved and to complete the registry specific questionnaires both pre-operatively and post-operatively,
- All participating surgeons and their practice and hospital support staff who enter the data into the registry database and keep it up to date.
- The ASR governance committees who are also pivotal for the ongoing success of the registry.
- The ASR team, Dr Esther Apos, Registry Manager, Ms Charis Brown, Senior Research Coordinator, Mr Sean Bulmer and Ms Trieu-Anh Truong, Research Assistants.
- Dr Geoff Askin, Dr Adam Parr, Ms Maree Izatt and Ms Selina Ho for all their assistance with developing the pASR.
- Professor Susannah Ahern and her biostatisticians and support staff at the Clinical Outcomes data Reporting and Research Program (CORRP), Monash University.
- Mr Philippe Roussouly, Guillaume Floret and Thibaut Bastien and team for the support and continuous improvement of the registry webbased interface.
- The SSA Board for their continuing support
- The members of the ASR Steering Committee and the SSA Registry Committee, for their time and commitment.
- Ms Sally Raynor, Director, and Mr Antony Kerslake - Clinical Quality Registry Section, Health Modelling, Partnerships and Evaluation Branch, Australian Government Department of Health and Aged Care, for their advice, direction and support.

Data Period

The data contained in this document was extracted from the Australian Spine Registry database and represents data collected between 15 January 2018 and 15 January 2024. As the registry does not capture data in real time, there may be a lag period between the treatment date and the capture of data in the registry database, KEOPs.

Common Terms, Definitions and Abbreviations

ACDF	Anterior Cervical Discectomy and Fusion, or Anterior Cervical Decompression and Fusion
ACSQHC	Australian Commission on Safety and Quality in Health Care
AOA	Australian Orthopaedic Association
ASA	American Society of Anesthesiologists (ASA) physical status classification system
ASR	Australian Spine Registry
Cauda equina syndrome	A condition that occurs when the bundle of nerves below the end of the spinal cord known as the cauda equina is damaged. Signs and symptoms include low back pain, pain that radiates down the legs, numbness around the anus, and loss of bowel, bladder control or sexual function
Cervical	Between the occiput and T1
Claudication	Impairment in walking, or pain, discomfort, numbness, or tiredness in the legs that occurs during walking or standing and is relieved by rest
Complex Surgery	Surgery where \geq 7 contiguous vertebrae have been fused in one procedure
CORRP	Clinical Outcomes Data Reporting and Research Program
Deformity	A loss of the normal curvature of the spine
Discectomy	A type of surgery to decompress nerve compression secondary to disc herniation
DS	Degenerative Spondylolisthesis
EQ-5D-3L	EQ-5D 3-Level
EQVAS	EQ Visual Analogue Score
EuroQoL™ EQ-5D-3L	EQ-5D is a standardised measure of health status developed by the EuroQol Group in order to provide a simple, generic measure of health for clinical and economic appraisal. ¹ 5D represents five dimensions; 3L represents three levels.

Fusion	Surgery to permanently join two or more vertebrae in the spine eliminating motion between them.
Glassman Classification	A diagnostic classification of symptoms, pathology and site of neural compression for lumbar spine registry usage
MCID	Minimum Clinical Important Difference
MDC	Minimum Detectable Change
Mths	Months
Motion Segment	Motion segment is defined as including all anatomical structures (including traversing and exiting nerve roots) between and including the top of the pedicle above to the bottom of the pedicle below ^a
Navigation	Spinal navigation refers to the use of technologies, such as computer- assisted navigation systems, to guide surgeons during spinal surgery
Neuromonitoring	A technique used during spinal surgery to monitor the function of the nerves and spinal cord
NDI	Neck Disability Index
ODI	Oswestry Disability Index
Opt-out	Patients who have been provided a registry information brochure and who have elected not to have their data included in the registry
pASR	Paediatric Australian Spine Registry
Post-op	6, 12 and 24-months follow-up after surgical treatment
Pre-op	Up to 3 months prior to surgery
PROMs	Patient Reported Outcome Measures
QCH	Queensland Children's Hospital
QoL	Quality of Life
SMS	Short Message Service
SOP	Standard Operating Procedure
Spondylolisthesis	A condition in which one vertebra slips forward over the one below it
SRC(s)	Surgeon Reported Comorbidity (ies)
SSA	Spine Society of Australia
Staged Procedure	A surgical procedure that is performed in multiple planned stages
Thoracolumbar	Between T1 and the pelvis

^a Definition taken from: Changes to MBS Items for Spinal Surgery Services Last updated: 12/10/2018

Executive Summary

The Australian Spine Registry (ASR) is proud to present its sixth Annual Report.

The data presented in this report was collected for all patients recruited between 15 January 2018 and 15 January 2024 and an analysis was made of both the entire patient group and specific patient cohorts. This year we have added one new cohort of patients; patients who presented with isthmic spondylolisthesis. We have also expanded on our data analysis. We have subdivided one of our cohorts and examined those patients with low, medium and high ODI scores post-surgery.

In addition, we are reporting on the progress of the establishment of the pASR, a collaborative project with the Queensland Children's hospital.

One of the ASR's strengths has been data acquisition, and the ASR has consistently maintained patient data completion and surgeon data entry at approximately 75%.

A quick glance at ASR patient data shows, at time of data cut off:

- The registry had a total of 20 participating surgeons.
- The registry had a total of 8 public hospitals and 12 private hospitals approved.
- The registry had a total of 4554 participants who had surgery. This comprised 2378 (52%) males, 2173 (48%) females and 3 (0.06%) gender not defined. Median age at the time of surgery was 62 years for males and 65 years for females.
- The largest decile having spine surgery was 70 -79 years, followed by 60-69 years.
- There is a discrepancy of the data between surgeon reported comorbidities (SRCs) and American Society of Anesthesiologists classification (ASA) in all cohorts. For example, for the entire ASR cohort, SRC show that 63.1% of patients had no comorbidities compared to ASA where 22.5% of patients were scored ASA 1. This is probably due to under-reporting of comorbidities by surgeons.

- Discectomy, ACDF and Isthmic Spondylolisthesis patients were generally younger (median age of 49.4, 55.0 and 48.0 years respectively) and had fewer comorbidities when compared to the total patient cohort.
- Patients who presented with L4-L5 degenerative spondylolisthesis had a median age of 69.4 years.
- Of the patients 60 years old and over who underwent complex surgery, 69% were females. The median age of this cohort was 69.9 years.
- In 2023, only 6.1% of ASR procedures reported the use of neuromonitoring, which was lower than other years.
- In 2023, of the procedures recorded, 33.2% used some type of navigation which was higher than 2022 (28.4%).
- Patient reported outcome questionnaire analysis showed:
 - Based on the ODI and NDI scores, 80% of patients of the entire cohort indicated an improvement at 6, 12 and 24-months post operatively.
 - For thoracolumbar and spinal deformity patients, the median ODI pre-op score was 44 compared to median follow up scores of 18 (6 months) and 16 (12 and 24 months).
 - For cervical patients, the median NDI pre-op score was 42 compared to median follow up scores of 14 (6 months), 16 (12 months) and 13.7 (24 months).
 - » EQ-5D-3L scores improved at the 6, 12 and 24-month time points for the entire cohort, with improvements across all domains.
 - » 84.9%, 83.4% and 82.6% of the patients in the discectomy cohort exceeded the ODI MCID (12.8) at 6, 12 and 24-months respectively, which indicates an improvement postsurgery.

- » 55.2% and 63.1% and 61.7% of the patients in the ACDF cohort exceeded the NDI MCID (17.0) at 6, 12 and 24-months respectively.
- » 67.5%, 69.2% and 74.2% of the patients in the L4-L5 degenerative spondylolisthesis cohort exceeded the ODI MCID (12.8) at 6, 12 and 24 months.
- » 69.0%, 82.2% and 81.1% of the patients in the L5-S1 isthmic spondylolisthesis cohort exceeded the ODI MCID (12.8) at 6, 12 and 24 months.
- » For the complex surgery cohort, the median age was 70.
- » EQ-5D-3L scores for these complex surgery patients indicated a more gradual improvement with scores continuing to improve at 24 months.
- » There is approximately 20% of the complex surgery cohort that remain with ODI scores greater than 40 at two years.

Sustainable funding has always been a key goal of the ASR. The Commonwealth Government's 2023-2024 Budget announced that it would fund more Clinical Quality Registries (\$40m) to ensure patients are receiving the best quality medical procedures and treatments. We are pleased to report that the ASR was one of the registries identified for this funding package. The ASR has received another 4 years of funding from the Commonwealth Government (\$1.8m).

Additional funding support for the registry was also gratefully received in 2023 from medical device companies, health insurers and the Spine Society of Australia (SSA).

The Australian Spine Registry's Vision



The Australian Spine Registry aims to be a world class, state of the art clinical quality registry.

The ASR aims to assist spine care professionals to improve patient care through providing improved access to outcome data and facilitating research.

- World class registry
- Clinician-focused
- Patient-centered
- Ethical
- Innovative
- Robustly analytical
- Collaborative
- Relevant to stakeholders

Industry funding supporters

The Australian Spine Registry is supported by funding from the Australian Government Department of Health and the following industry organisations in 2023:



Medtronic



stryker



Snapshot of The Australian Spine Registry



*Total number of patients entered into the database with or without entered questionnaire or surgeon reported data.

**Data collected directly from families or practices

Prologue

Spine surgery techniques range from relatively simple decompressive and stabilising procedures to complex spinal surgery including vertebral reconstruction and deformity correction surgery.

Spine surgery, especially fusion, has been recognised as one of the most expensive interventions amongst clinical diseases, conditions and disorders.²

- Whilst the average total cost of a single level discectomy is approximately \$6,000, private health insurers estimate the average cost of instrumented single motion spinal fusion to be approximately \$25,000^b. More complex surgery for adult scoliosis can be in excess of \$120,000.
- AIHW data shows the rate of spine fusion greater than 3 motion segments is growing faster than other categories of spine procedures.³ This group has a higher implantable device cost component, and higher rates of complications.⁴

In the 2018-19 Budget, the Government announced changes to the MBS items for spinal surgery. The revised spinal surgery listings were recommended by the independent MBS Review Taskforce, following a comprehensive review of the MBS items by clinicians, health system experts and consumers and came into effect November 2018. Examination of the Services Australia statistics for Medicare Item numbers related to fusion of greater than 3 motion segments (51023 – 51026) revealed that the age demographic which is undergoing more complicated spine surgeries is also getting older. For cervical, thoracic and lumbar surgical operations using spinal instrumentation between 3 motion segments (Figure 1 - Figure 4), the 65-74 and 75-84 age deciles were the predominant age groups undergoing these procedures with females having more of the more complex procedures (>12 motion segments) than men (Figure 4).

Furthermore, the ASR steering committee decided to explore other methods of analysis. Of the many possibilities, it was decided to examine the change in ODI score based on the severity of preoperative symptoms in the discectomy group. Only this group was of sufficient sample size to be considered for analysis.

We hope you enjoy reading our 2023 Annual Report.

^b https://www.medibank.com.au/health-support/hospital-assist/costs/spinal-fusion/ https://www.hcf.com.au/cost-calculator?pid=43 (accessed Jan 4, 2024)



Figure 1: Age distribution for Medicare Item 51023 processed from July 2019 to November 2023 as reported by Services Australia

Figure 2: Age distribution for Medicare Item 51024 processed from July 2019 to November 2023 as reported by Services Australia





Figure 3: Age distribution for Medicare Item 51025 processed from July 2019 to November 2023 as reported by Services Australia

Figure 4: Age distribution for Medicare Item 51026 processed from July 2019 to November 2023 as reported by Services Australia



Summary of the ASR

Surgeon and Hospital Engagement

Spine surgery is performed by both orthopaedic surgeons and neurosurgeons. In 2023, the ASR had 19 active users (16 orthopaedic spine surgeon and 3 neurosurgeons).

Figure 5: (A) Number of hospital sites approved and pending approval with the ASR across Australia; (B) Total number of private to public hospitals in the registry across Australia



Patient Uptake

Recruitment into the ASR continues to slowly increase. Surgeon recruitment has been the main activity for the ASR. Hurdles to more rapid recruitment include the need to comply with hospital governance requirements and logistics related to surgeon and practice staff education. Furthermore, two key surgeons retired in 2023 which also impacted patient recruitment numbers. As a consequence of this, ASR patient recruitment during 2023 was lower than expected (Figure 7).



Figure 6: Accumulation rate of patients from registry launch on 15 January 2018 to 15 January 2024



Figure 7: Patient recruitment by year

The opt-out rate for the registry (2.7%) remains the same as for 2022. Main reasons for opt-out has been identified as "not interested" or "other". The percentage of patients that have been reported to the registry as deceased also remained the same (0.6%). The registry acknowledges that this figure may be under-represented. The ASR has received approval for data linkage to the National Death Index and will be conducting bi-annual data checks to ensure that the ASR database patient living status is accurate.

Figure 8: Reason for patient opt-out (n)



Registry Communications and Responses

The registry actively communicates with patients to ensure that their contact details remain up to date. The ASR includes a patient detail verification form with every post-operative questionnaire letter and the bi-annual thank you letter. As a result, the registry has been able to collect 89.7% email addresses and 97.5% mobile phone numbers for patients in the registry.

Surgeon Reported Data

The registry management consistently provides feedback and support to surgeons and their practice staff regarding patient recruitment and data completeness. The data entry completion rate by surgeons for the 2023 reporting period is shown in Figure 9.

Figure 9: Surgeon data entry completion rate



Data completeness trending was instigated in February 2019, and the registry has set an 80% data completeness threshold. Data completion by many practises is generally good although variable between practices. Public hospital data entry completion between hospital and depends on hospital resources. The registry is actively engaging with public hospitals during the recruitment phase to try and ensure that adequate support resources are made available. Different models have been employed by different public hospitals to ensure that all eligible patients are captured, and pre-operative data entered. Two successful models that have been identified by the registry are

(i) the direct engagement of research nurses with the registry, and

(ii) the employment of surgical support staff who have the registry activities as part of their position description. This has resulted in a streamlined approach to ASR patient recruitment and data collection.

Overview of ASR Patients

Annual Report 2023 | 25

Patient Demographics

4554 patients were eligible for analysis. There were 2378 (52%) males and 2173 (48%) females with 3 patients not identifying as male or female. 73% of male and 75% of female patients were over the age of 50. (Figure 10). We note that the most common decile having spine surgery is between 70-79 years of age, representing 27% of the patients undergoing spine surgery. This data is in line with the MBS data as discussed previously, which further confirms that more older Australians are having spine surgery.



Figure 10: Patient age distribution at the time of surgery

Patient Sub-groups

The data collection software categorises patients into 3 basic groups:

- Cervical
- Deformity
- Thoracolumbar

The breakdown of patients in each group is shown below (Table 1). The majority of patients in the registry undergo thoracolumbar procedures which has been an ongoing trend by the registry. It must be noted that given that the ASR only has 2 neurosurgeons, the number of cervical cases may be under represented.

Table 1: Percentage of patients by treatment types

Treatment Type	N (%)
Total	4554
Cervical	657 (14.4)
Deformity	196 (4.3)
Thoraco-lumbar	3701 (81.3)

Given the small number of sites and surgeons currently participating in the registry, these figures are not indicative of the percentage breakdown of procedures that typically occur within Australia.

Surgery

ASR reports on the frequency of:

- The use of neuromonitoring in spine surgery
- The use of navigation
- Surgical approaches used in spine surgery.

The ASR also reports on the outcomes of the total surgical cohort as well as specific cohorts.

Neuromonitoring

Neuromonitoring in spine surgery involves the use of various techniques to monitor the integrity and function of the nervous system during surgical procedures involving the spine. The primary goal of neuromonitoring is to minimize the risk of neurological damage by detecting any changes in nerve function in real-time, allowing surgeons to adjust their approach accordingly and mitigate potential complications.

As shown in Figure 11, the use of neuromonitoring pre COVID-19 was between 11-15%. During 2021 and 2022 the rate of neuromonitoring decreased. This was possibly due to Category 1 and 2A elective surgery restriction in the larger jurisdictions in this period. A return to pre-COVID levels has not been demonstrated at this stage.



Figure 11: Percentage of neuromonitoring use between 2018 – 2023 for ALL reported spine procedures

Yes No

Navigation

Navigation in spine surgery refers to the use of advanced imaging technology and computer-assisted systems to aid surgeons in precisely planning and executing procedures on the spine. It offers real-time guidance during surgery, enhancing accuracy and safety.

Whilst navigation tends to be used in more complex surgery, its usage in more standard surgery is surgeon dependent. In 2023, the ASR expanded the navigation categories and have subdivided them to include robotic and non-robotic navigation.

As shown in Figure 12, the frequency of navigation use in surgery is increasing over time.



Figure 12: Percentage of navigation use between 2018 – 2023 for ALL reported spine procedures.

Surgical Approach

Surgical approach refers to the specific technique or pathway used by the surgeon to access the area of the spine requiring treatment. The choice of surgical approach depends on various factors, including the location and nature of the spinal pathology, the patient's anatomy, the surgeon's expertise, and the desired surgical outcome. Different surgical approaches offer distinct advantages and are selected based on the individual patient's needs.

Anterior Approach: In an anterior approach, the surgeon accesses the spine from the front of the body, typically through an incision made in the abdomen or neck. This approach allows direct access to the vertebral bodies, intervertebral discs, and spinal cord or nerve roots from the front. Anterior approaches are commonly used for procedures such as spinal fusion, disc replacement, corpectomy and some types of scoliosis correction.

Posterior Approach: A posterior approach involves accessing the spine from the back of the body, usually through an incision made along the midline of the back. This approach provides access to the spinal canal, lamina, facet joints, and nerve roots. Posterior approaches are often used for procedures such as laminectomy, laminotomy, decompression, spinal fusion, and instrumentation.

Lateral Approach: In a lateral approach, the surgeon accesses the spine from the side of the body, typically through a small incision made in the flank or abdomen. This approach allows access to the disc space and vertebral bodies from the side, without disrupting the spinal muscles and structures in the back. Lateral approaches are commonly used for procedures such as lateral lumbar interbody fusion (LLIF) and lateral access surgery for spinal deformities.

Minimally Invasive Approach: Minimally invasive surgical approaches involve smaller incisions and less disruption of surrounding tissues compared to traditional open approaches. These approaches may utilize specialized instruments, endoscopic techniques, or navigation systems to access the spine with minimal trauma. Minimally invasive approaches can be applied to various surgical procedures, including discectomy, decompression, fusion, and instrumentation.

Combined Approaches: In some cases, surgeons may employ a combination of anterior, posterior, lateral, or minimally invasive approaches to address complex spinal conditions or achieve specific surgical goals. Combined approaches may be necessary to adequately decompress the spinal cord and nerve roots, restore spinal alignment, and achieve spinal stability.

The selection of the most appropriate surgical approach in spine surgery requires careful consideration of the patient's clinical condition, imaging findings, surgical goals, and potential risks and benefits. Surgeons often tailor the approach to each patient's specific needs to optimize outcomes and minimize complications.

The ASR has collected data on the frequency of surgical approach. Of all the procedures captured by the registry, 78% are carried out using a posterior approach. Only 5% of procedures are carried out using both anterior and posterior approaches. These procedures typically represent more complex surgery and may include staged procedures (Figure 13).



Figure 13: Frequency of surgical approaches in ALL captured procedures.

Surgeon Reported Comorbidities (SRCs) and ASA

Many patients undergoing spine surgery have general health comorbidities especially as the most common age group for surgical interventions is people between 60 and 80 years of age⁵. Within this cohort, there are a common range of comorbidities, which may contribute to outcomes following surgery. These comorbidities include cardiovascular disease, chronic pulmonary conditions, cerebrovascular disease, diabetes, renal disease, liver disease, dementia, cancer and depression⁶.

To stratify patient co-morbidities, the ASR has analysed both SRCs and ASA scores.

The ASA classification system, developed by the American Society of Anesthesiologists (ASA), is a widely used method to assess a patient's overall health status and risk factors prior to surgery⁷. It is primarily used by anaesthetists and surgeons to stratify patients into different risk categories. This can assist with perioperative risk assessment and management⁸. It is a scored system 1-6^c and classifies the following:

ASA I	A 'normal', healthy patient without acute or chronic disease, overweight or obesity
ASA II	A patient with 'mild' disease without significant limitation – includes smoker, pregnancy, overweight or obesity, diabetes, high blood pressure and lung disease
ASA III	A patient with 'severe' disease and substantial limitation – as above plus end stage kidney disease, stroke, and treated cardiovascular disease
ASA IV	A patient with 'severe' disease that is a constant threat to life – includes recent heart attack, stroke, dialysis, heart failure
ASA V	A patient declining in health not expected to survive without operation
ASA VI	A patient declared brain dead whose organs are being harvested for transplant

ASA scores were recorded for 2423 (53%) of patients in the registry.

When comparing the ASA scores with the SRCs, variability was noted. For example, 22.5% of patients were given an ASA score of 1 indicating that these patients were healthy at the time of their surgery (Figure 14).

In comparison, SRCs indicated that 63.1% of patients had no comorbidities (Figure 15).

For the comorbidities that were reported, hypertension was the most common reported comorbidity (data not shown).

^c https://www.asahq.org/standards-and-guidelines/asa-physical-status-classification-system (accessed 21 Feb 2024)



Figure 14: ASA score reported in ALL patients where ASA scores were recorded

When SRCs were broken down by surgeon, the rate of reporting varied, suggesting that there may be an under reporting of comorbidities by some surgeons (Data not shown).

The registry is currently exploring other methods of comorbidity reporting such as patient reported comorbidities and data linkage with the Pharmaceutical Benefits Scheme (PBS) to improve the accuracy of comorbidity data.

Figure 15: Breakdown of number of comorbidities reported in all patients



Patient Reported Outcome Measures - Total Cohort

Patient-reported outcome measures (PROMs) in spine surgery are tools used to assess patients' perceptions of their health status, functional abilities, and quality of life before and after undergoing spinal procedures. These measures capture subjective information directly from patients, providing valuable insights into the effectiveness of treatment from the patient's perspective. PROMs are essential for evaluating treatment outcomes, guiding clinical decision-making, and improving patient-centered care in spine surgery.

The registry surveys patients before surgery and at 6, 12 and 24-months post-surgery to assess functional and quality of life improvement.

EQ-5D-3L Quality of Life

Figure 16 shows the EQ-5D-3L scores for any patient that has completed the EQ-5D-3L for each of the 5 domains (of mobility, pain/discomfort, usual activity, self-care, and depression/anxiety) to 24 months.

For each of the domains, an improvement was observed. The data indicates that these improvements are sustained after 12 months in the order of apparent importance.

- Pain/discomfort: 98% of patients reported some or extreme problems pre-operatively as compared to 67% at 6 months, 64% at 12 months and 61% at 24 months.
- Usual activity: Some/extreme problems were reported for 88% pre-operatively compared to 48% post-operatively at 24 months post-surgery, a 41% reduction.
- Mobility: 78% experienced some/extreme mobility problems pre-operatively and this reduced to 39% at 6 months and remained stable. Given the age demographic distribution some of the persisting mobility problems may be non-spinal in origin.
- Self-care: 62% of patients reported that they had no problems with their self-care at pre-op. For the 38% that reports some or extreme problems with self-care, there was a reduction to 17% which is over a 50% improvement.
- Depression/anxiety: Patient who experienced some/extreme anxiety/depression decreased from 55% at pre-op to approximately 31% at all post-op timepoints; a reduction of 24%.

Figure 16: EQ-5D-3L scores for each domain for all patients who completed <u>any</u> EQ-5D-3L at pre-op, 6, 12 and 24-months post-op in order of apparent importance.

Extreme Problems

No Problems

Some Problems







Mobility



The EQ-5D includes a visual analogue scale (VAS), often referred to as the EQ-VAS. This is a patient reported measure of overall health on a scale from 0 to 100, with 0 representing the worst imaginable health state and 100 representing the best imaginable health state. The EQ-VAS provides a single index value that can be used to assess overall health status and changes over time.

A higher score with the EQ-VAS indicates improved patient perception of general health. The median EQ-VAS scores improved by 20 points from a median score of 60 pre-operatively, to a median score of 79 at 6 months and 80 at 12 months post-operatively. This improved score of 80 was maintained at 24 months follow up (Table 2; Figure 17).

Table 2: EQVAS mean and median scores for all patients who completed <u>any</u> EQVAS at pre-op, 6, 12 and 24-months post-op

EQVAS	Pre-operative	6-months	12-months	24-months
n	3640	3180	2864	2185
Mean (SD)	57.9 (20.5)	73.6 (18.1)	74.1 (18.4)	74.8 (18.2)
Median (IQR)	60.0 (40.0, 71.0)	79.0 (65.0, 88.0)	80.0 (65.0, 90.0)	80.0 (65.0, 90.0)





Oswestry Disability Index (ODI)

The Oswestry Disability Index (ODI) is a widely used disease specific questionnaire designed to assess the impact of low back pain on a person's functional status and ability to perform activities of daily living. It is specifically tailored to evaluate disability related to back pain and is commonly used in clinical practice and research settings.

The ODI consists of ten questions, each addressing a different aspect of functional limitation due to low back pain.

Table 3: ODI Scoring

ODI Score	Level of Disability	
0 - 20	Minimal disability	
21 - 40	Moderate disability	
41 - 60	Severe disability	
61 - 80	Crippled	
81 - 100	Bed bound	

These questions cover topics such as pain intensity, ability to lift objects, ability to walk, and ability to sit or stand for prolonged periods. The ODI is scaled using a 6-point Likert Scale where each question is scored 0-5 with the higher the number indicating major functional disability due to symptoms. The scores for all ten questions are then summed and converted into a percentage score, with higher scores indicating greater disability. The maximum possible score is 100, representing total disability, while a score of 0 indicates no disability.

The ODI is completed by patients who undergo thoraco-lumbar surgery or who fall into the 'deformity' category of patients which are predominately adult degenerative scoliosis patients. There are 10 domains examined by the ODI which provide individual domain scores and an overall ODI score. The levels of patient disability based on score is shown in Table 3⁹.

The higher the score the higher the level of disability.

The overall ODI scores were analysed for all patients who completed the ODI questionnaire at any time point. As shown in Table 4, after surgery, median preoperative ODI scores reduced from 44 points (within the severe disability range) to 18 points at 6 months and 16 points at 12 and 24 months (within the minimal disability range).

Table 4: ODI mean and median scores for all patients who completed any ODI at pre-op, 6, 12 and24-months post-op

ODI	Pre-operative	6-months	12-months	24-months
n	3179	2746	2469	1880
Mean (SD)	43.6 (17.9)	21.7 (18.2)	20.7 (18.5)	20.1 (18.5)
Median (IQR)	44.0 (31.0, 56.0)	18.0 (7.0, 33.0)	16.0 (6.0, 32.0)	16.0 (4.0, 31.0)

Figure 18 illustrates the shift in ODI scores. Patients whose scores indicated severe disabled or worse (ODI score > 41) reduced from 56.1% preoperatively to 16.8% at 6 months, 16.3% at 12 months, and 15.8% at 24 months.


Figure 18: ODI distribution for all patients who completed <u>any</u> ODI at pre-op, 6, 12 and 24-months post-op

Neck Disability Index (NDI)

The Neck Disability Index (NDI) is a questionnaire designed to assess the impact of neck pain on a person's functional status and ability to perform activities of daily living. It is similar to the Oswestry Disability Index (ODI) but focuses specifically on neck-related disability. The NDI consists of ten questions that address different aspects of functional limitation due to neck pain. These questions cover areas such as pain intensity, ability to perform specific activities (e.g., lifting, working, driving), and the impact of pain on personal care and leisure activities. For each question, the respondent selects one of six

Table 5: NDI Scoring

NDI Score	Level of Disability
0 – 4	No disability
5 – 14	Mild disability
15 – 24	Moderate disability
25 – 34	Severe disability
35 or over	Complete disability

statements that best describes their current level of disability, with each statement assigned a score ranging from 0 to 5. The scores for all ten questions are then summed and converted into a percentage score, with higher scores indicating greater disability. The maximum possible score is 50¹⁰, representing total disability, while a score of 0 indicates no disability.

The NDI is completed by patients who have undergone surgery in the cervical region of the spine. This cohort represents 14.4% of patients in the ASR. For the NDI, 10 domains are examined which provide individual domain scores and an overall score. The classification of patient disability based on score is shown in Table 5.

A higher score indicates a higher level of disability.

As shown in Table 6, median preoperative NDI scores reduced from 42 (complete disability) to 14 (mild disability) at 6 months post-operatively, and was sustained at 14 at 24 months' follow up.

Preoperatively, 70.7% of patients had an NDI score of >15 indicating a score consistent with moderate disability or worse. This reduced to 25.4% of patients at 6 months with improvement remaining stable at 12 and 24 months (Figure 19).

Table 6: NDI mean and median scores for all patients who completed <u>any</u> NDI at pre-op, 6, 12 and 24-months post-op

NDI	Pre-operative	6-months	12-months	24-months
n	478	448	403	312
Mean (SD)	41.8 (19.7)	19.6 (17.7)	19.8 (18.6)	18.6 (18.0)
Median (IQR)	42.0 (28.0, 56.0)	14.0 (6.0, 30.0)	16.0 (6.0, 28.0)	13.7 (4.0, 28.0)



Figure 19: NDI distribution for all patients who completed <u>any</u> NDI at pre-op, 6, 12 and 24-months post-op.

Cohort Analysis

The ASR has previously reported on the following specific patient cohorts:

- Patients who have undergone single level lumbar discectomy.
- Patients who have undergone Anterior Cervical Discectomy and Fusion (ACDF).
- Patients who were diagnosed with L4-L5 Degenerative Spondylolisthesis (DS).
- Patients who have undergone complex surgery (CS).

In 2023, the ASR introduced the following new cohort:

• Patients who were diagnosed with L5-S1 Isthmic Spondylolisthesis (IS).

Single Level Lumbar Discectomy

Lumbar discectomy is one of the most common spinal procedures¹¹. It's frequently performed to relieve symptoms such as lower back pain, sciatica, and neurological deficits caused by compression of spinal nerves due to herniated or bulging discs in the lumbar spine. Herniation is usually treated conservatively but discectomy may be performed for persistent or severe pain, significant weakness or bladder and bowel incontinence and sexual dysfunction.

For analysis, discectomy cohort patients were selected based on the following inclusion criteria:

Patients from within this group were excluded if:

- Their discectomy surgery was revision surgery
- They had a scoliosis
- They also had a fusion
- Surgery Type Lumbar Discectomy only
- Number of levels =1
- Number of stages =1

Images courtesy of Assoc. Prof John Cunningham





Demographics

546 patients met the discectomy cohort inclusion criteria which represents 12% of patients undergoing thoracolumbar procedures.

The single level lumbar discectomy procedures were performed predominately on male patients. There were 329 males (60%) and 217 females (40%) in this group as shown in Figure 20. The median age of males was 47 and females was 48 years, which is younger than the median patient age from the total ASR patient cohort (62 years for males and 65 years for females respectively). This has not changed from previous annual reports.

Figure 20: Discectomy procedures by patient age and gender



Number of Patients

Surgeon Reported Comorbidities and ASA

The number of patients that were reported with a comorbidity is shown in Table 7 below.

Examination of SRCs in this group identified that discectomy patients had fewer comorbidities when compared to all patients in the registry. 20.9% of discectomy patients were reported to have at least one comorbidity whereas 36.9% of the entire registry patient population were reported to have at least one comorbidity. Patients were further categorised into groups by the number of SRCs reported (Table 8).

Table 7: Number of discectomy patients diagnosed with <u>any</u> comorbidity prior to surgery

Any reported comorbidity	All (n=4554) n (%)	Discectomy (n=546) n (%)
Yes	1681 (36.9)	115 (21.1)
No	2873 (63.1)	431 (78.9)

Table 8: Breakdown of number of comorbidities reported in discectomy patients

Number of reported comorbidities	All patients (n=4554) n (%)	Discectomy patients (n=546) n (%)
None	2873 (63.1)	431 (78.9)
1	750 (16.5)	66 (12.1)
2	469 (10.3)	27 (4.9)
3	297 (6.5)	17 (3.1)
4	98 (2.2)	2 (0.4)
5+	67 (1.5)	3 (0.5)

62% of discectomy patients had ASA data recorded.

When ASA scores were examined for discectomy patients, 45% of the patients were scored with an ASA of 1 indicating that these patients were 'normal', healthy patients without acute or chronic disease, overweight or obesity. An additional, 40.3% of patients had mild disease without significant limitations. Only 10% of patients had severe disease (Table 9). This demonstrated similarity between SRCs and ASA data as that seen for the total cohort.

Table 9: ASA score	reported for	"Discectomy	" patients	compared t	o all ASR	patients
		2.0000000.00	100.000.000	001110011001	0 0/11 / 10/11	p 0

ASA Classification	All (n=2423) n (%)	Discectomy (n=340) n (%)
1	544 (22.5)	153 (45.0)
2	1108 (45.7)	148 (43.5)
3	745 (30.7)	39 (11.5)
4	26 (1.1)	0 (0)

Glassman Classification Scores

The Glassman Classification Scores are a simple diagnostic classification scheme which categorises the patient's primary characteristics so that the treatment's impact can be linked to the recognised pathology¹². Glassman scores are only reported for patients who have had thoracolumbar or deformity procedures. Glassman scores were reported in 71% of the discectomy cohort.

For patients undergoing a discectomy, acute and chronic leg pain were the most commonly reported symptoms by patients. Dominant back pain infrequently reported, as was neurogenic claudication. This is consistent with the commonly seen clinical presentation of disc herniations (Figure 21).



Figure 21: Glassman Score for 'Symptoms' among discectomy patients (n=388)

PROMs Analysis

The Oswestry Disability Index (ODI) and the EQ-5D-3L scores were evaluated for the discectomy cohort pre-operatively and at 6-months, 12-months and 24-months post-operatively.

It must be noted that these results show unadjusted outcomes and must be interpreted with caution. Adjustments for known predictors of outcomes after spine surgery such as age, sex and severity of a patient's condition at baseline have not been performed at the time of this publication and may account for some of the differences seen in the figures presented below.

Oswestry Disability Index (ODI)

A lower ODI score indicates improved relief in pain and disability. ODI mean, median and overall scores for any questionnaires completed at each time point are shown in Table 9 and Figure 22 respectively. As shown in Table 10, median ODI scores improved from 46 pre-operatively to 8 at 6-months post-operatively, which was sustained at 24 months.

Table 10: ODI mean and median scores for discectomy patients who completed <u>any</u> ODI at pre-op, 6, 12 and 24-months post-op

ODI	Pre-operative	6-months	12-months	24-months
n	434	401	368	305
Mean (SD)	47.4 (18.3)	14.1 (15.4)	13.2 (15.0)	12.5 (14.1)
Median (IQR)	46.0 (34.0, 60.0)	8.0 (2.0, 20.0)	8.0 (2.0, 18.0)	8.0 (2.0, 20.0)

Figure 22 shows that there is a shift to the left (lower scores) in the overall ODI for the discectomy cohort at the 6-month follow up time point indicating improvement over the 6-month period. This was maintained at both 12 and 24 months.



Figure 22: ODI distribution for discectomy patients who completed <u>any</u> ODI at pre-op, 6, 12 and 24-months post-op

(b) Six-month post-operative ODI (n=401)





(c) Twelve-month post-operative ODI (n=368)

(d) Twenty-four-month post-operative ODI (n=305)



Analysis of the ten ODI domains for the discectomy cohort is shown in Table 11.

Mean scores across all domains were lower at 6, 12 and 24-months post-operatively compared to pre-operatively. A lower ODI score indicates an improvement for that domain. The domains of the ODI indicated that the pain caused by disc prolapse affects all aspects of life and all aspects are improved by the surgery.

Table 11: ODI mean scores for each domain for discectomy patients who completed any ODI at pre-op, 6, 12and 24-months post-op

ODI	Pre-operative	6-months	12-months	24-months
n	434	401	368	305
Pain, mean (SD)	2.71 (1.01)	0.86 (0.89)	0.81 (0.91)	0.75 (0.89)
Personal Care, mean (SD)	1.44 (1.18)	0.25 (0.73)	0.21 (0.63)	0.19 (0.58)
Lifting, mean (SD)	2.84 (1.28)	1.22 (1.39)	1.14 (1.31)	1.11 (1.32)
Walking, mean (SD)	1.90 (1.33)	0.36 (0.80)	0.36 (0.83)	0.27 (0.67)
Sitting, mean (SD)	2.50 (1.25)	1.02 (1.05)	0.94 (0.99)	0.88 (0.96)
Standing, mean (SD)	2.49 (1.46)	0.81 (1.09)	0.77 (1.05)	0.76 (1.10)
Sleeping, mean (SD)	1.94 (1.10)	0.63 (0.81)	0.61 (0.79)	0.61 (0.73)
Sex Life*, mean (SD)	2.61 (1.68)	0.52 (1.03)	0.46 (0.98)	0.49 (1.01)
Social Life, mean (SD)	2.76 (1.21)	0.73 (1.11)	0.58 (1.01)	0.54 (0.95)
Traveling, mean (SD)	2.52 (1.38)	0.63 (0.96)	0.64 (0.95)	0.61 (0.90)

* Note: Sex life question is optional; lower numbers of 377, 364, 328 and 283 (for each time-point, respectively).

The Minimum Clinically Important Difference (MCID) is a threshold used to measure the effect of clinical treatments. It is based on Minimum Detectable Change (MDC) which is generally considered in the literature to be a MCID of 12.8 for the ODI¹³. This figure has been used to define MCID for this patient cohort.

82.6% of discectomy patients <u>exceeded</u> this MCID (improved), as shown by ODI scores, 24-months post-operatively.

ODI*	All (n=2310) n (%)	Discectomy (n=331) n (%)
Exceeding the MCID (Improved)	1494 (64.7)	281 (84.9)
Within the MCID (Unchanged)	740 (32.0)	41 (12.4)
Exceeding the MCID (Worsened)	76 (3.3)	9 (2.7)

Table 12: MCID for ODI from pre-op to 6-months post-op for discectomy patients

Table 13: MCID for ODI from pre-op to <u>12-months</u> post-op for discectomy patients

ODI*	All (n=2069) n (%)	Discectomy (n=296) n (%)
Exceeding the MCID (Improved)	1365 (66.0)	247 (83.4)
Within the MCID (Unchanged)	646 (31.2)	47 (15.9)
Exceeding the MCID (Worsened)	58 (2.8)	2 (0.7)

Table 14: MCID for ODI from pre-op to <u>24-months</u> post-op for discectomy patients

ODI*	All (n=1588) n (%)	Discectomy (n=247) n (%)
Exceeding the MCID (Improved)	1048 (66.0)	204 (82.6)
Within the MCID (Unchanged)	487 (30.7)	41 (16.6)
Exceeding the MCID (Worsened)	53 (3.3)	2 (0.8)

*Only patients that have completed both timepoint questionnaires are included.

Discectomy cohort - Low, medium and high Pre-operative ODI analysis

We further examined the discectomy cohort specifically looking at patients who reported low (0 to 30), medium (30 to <61) and high (61 to 100) ODI scores pre-op to determine the change in ODI scores amongst these patient subsets post-operatively. Patients were selected based on ODI questionnaires being completed at both pre-operative and 12-month post-operative time points. Box plots were used to analyse the data.

The three patient populations characteristics are shown in Table 15.

In the low ODI group, there were more men than women having discectomies compared to the medium and high ODI groups where it was almost even. The median age was very similar across all groups. When looking at the change in the ODI, each group improved however the high ODI group showed the greatest change (Figure 24 and Figure 25).

There did not appear to be a sex relationship in the medium and high ODI groups. SRCs, ASA and age did not appear to be significant. For data analysis, please refer to Appendix 6.

Table 15: Characteristics of the low medium and high ODI discectomy cohort

	Low	Medium	High
N	54	172	68
Male	40 (74.1%)	98 (57.0%)	34 (50.0%)
Female	14 (25.9%)	74 (43.0%)	34 (50.0%)
Age, mean (SD)	48.1 (14.9)	51.7 (15.9)	48.7 (15.0)
Age, median (IQR)	46.0 (36.0, 62.0)	49.0 (40.0, 65.5)	46.0 (36.0, 61.5)
Exceeding the MCID (Improved)	30 (55.6%)	152 (88.4%)	64 (94.1%)
Within the MCID (Unchanged)	22 (40.7%)	20 (11.6%)	4 (5.9%)
Exceeding the MCID (Worsened)	2 (3.7%)	0 (0.0%)	0 (0.0%)

The potential benefit of discectomy surgery may vary based on severity of disc herniation before operation. This possibility is explored with the following figures and tables which only include discectomy patients who have completed both pre-operative and 12-months post-operative ODI PROMs. 12-month ODI scores, changes in scores, and patient characteristics are compared across three groups: those with low (0 to <30), moderate (30 to <61) and high (61 to 100) pre-operative ODI scores. Those with larger ODI scores have higher burden.

Out of the 546 discectomy patients, 72 did not have pre-operative ODI scores available (but had 12-month scores), 138 did not have 12-month scores (but had pre-operative scores available), and 40 had neither of these. 296 patients have scores at both timepoints and are included in the following figures (Figure 23 and Figure 24).

Figure 23: Box plots showing the differences in low, medium and high ODI patients pre-op and ODIs at 12 months post-op^{*}



Pre-operative ODI score group

*The boxes mark the first quartile (Q1), median and third quartile (Q3) of ODI score. Tukey values have been used for the whiskers. The lower whisker value is the smallest value that is greater or equal to Q1 - 1.5*IQR. The upper whisker value is the largest value that is less than or equal to Q3 + 1.5*IQR.





Pre-operative ODI score group

*The boxes mark the first quartile (Q1), median and third quartile (Q3) of change in ODI score. Tukey values have been used for the whiskers. The lower whisker value is the smallest value that is still greater or equal to Q1 - 1.5*IQR. The upper whisker value is the largest value that is still less than or equal to Q3 + 1.5*IQR.

The proportion that patients improve (based on MCID threshold) appears to be greater as initial severity of symptoms increases. It would appear patients with less severe symptoms would potentially obtain a lower proportional benefit after surgery.

(The ability to investigate the relationship between initial burden of disease and outcomes 12-months post-operation may be limited/ confounded by sample imbalances in sex and Glassman score for symptoms. Therefore, these results should be interpreted with caution. This analysis identified several findings:

- Analysis of Glassman classification demonstrated that surgery performed in less than 3 months was significantly more common in patients with more severe symptoms (*p* = 0.003; Appendix 6).
- Patients with more severe preoperative symptoms obtained more proportional benefit from the surgery.
- There was no significant difference in the postoperative ODI scores between the three cohorts (*p*=0.061)
- Age, gender, or the frequency of comorbidities were not statistically relevant.

EQ-5D-3L Quality of Life Analysis – Total Discectomy cohort

The discectomy cohort EQ-5D-3L domain scores and the EQVAS were analysed and indicate improvement across all domains at all time points (Table 16 and Figure 25). Mobility, pain/discomfort and usual activities domain were the three domains which showed the most improvement over the 24-month period.

Table 16: EQ-5D-3L scores for each domain for discectomy patients at pre-op, 6, 12 and 24-months post-op displayed in order of improvement of some and extreme problems

Discectomy Patients EQ-5D-3L						
Domain	Level of problem	Pre-op (%) n=435	6-months (%) n=400	12-months (%) n=369	24-months (%) n=305	
Mobility	1 – no problems	14.5	74.3	75.9	78.0	
	2 – some problems	82.1	25.8	23.8	22.0	
	3 – extreme problems	3.4	0.0	0.3	0.0	
Pain/	1 – no problems	6.7	58.8	62.9	65.9	
discomfort	2 – some problems	63.0	38.8	34.4	32.5	
	3 – extreme problems	30.3	2.5	2.7	1.6	
Usual	1 – no problems	52.2	90.3	90.2	91.5	
activities	2 – some problems	45.5	9.8	9.5	8.2	
	3 – extreme problems	2.3	0.0	0.3	0.3	
Self-care	1 – no problems	2.1	45.0	48.0	51.1	
	2 – some problems	51.7	52.0	47.7	45.9	
	3 – extreme problems	46.2	3.0	4.3	3.0	
Anxiety/	1 – no problems	46.4	75.8	77.8	76.1	
depression	2 – some problems	46.0	22.5	20.3	21.6	
	3 – extreme problems	7.6	1.8	1.9	2.3	

The EQVAS identifies the way in which patients perceive their general health at a given time point. A shift to the right in the EQVAS indicates an improvement of patient perception of their general health status. As shown in Table 17 median patient scores improved from 57 pre-operatively to 81 at 12 months post-operatively and were sustained until 24 months (Figure 25).

Table 17: EQVAS mean and median scores for discectomy patients who completed <u>any</u> EQVAS at pre-op, 6,12 and 24-months post-op

EQVAS	Pre-operative	6-Months	12-Months	24-Months
n	435	400	369	305
Mean (SD)	54.4 (20.4)	78.0 (16.2)	79.5 (15.5)	79.4 (15.5)
Median (IQR)	57.0 (40.0, 70.0)	80.0 (70.0, 90.0)	81.0 (73.0, 90.0)	81.0 (70.0, 90.0)



Figure 25: EQVAS distribution for discectomy patients who completed <u>any</u> EQVAS at pre-op, 6, 12 and 24-months post-op

(b) Six-month post-operative EQVAS (n=400)





(c) Twelve-month post-operative EQVAS (n=369)

(d) Twenty-four-month post-operative EQVAS (n=305)



Anterior Cervical Discectomy and Fusion (ACDF)

ACDF is a surgical procedure performed on the cervical (neck) region of the spine to relieve pressure on the spinal cord or nerve roots caused by herniated discs or bone spurs. ACDF surgery aims to alleviate symptoms such as pain, weakness, numbness, or tingling in the neck, shoulders, arms, and hands that are caused by pressure on the spinal cord or nerve roots. It can also be done to address problems from degenerative disc disease, spinal stenosis and/or osteoarthritis in the cervical spine.

The surgery is typically performed through the front of the neck (anterior approach). This approach allows the surgeon to access the cervical spine while minimizing disruption to muscles and other tissues in the back of the neck. The surgeon removes the problematic disc or discs that are causing compression on the spinal cord or nerve roots. This involves carefully removing the damaged or herniated disc material to decompress the affected nerve structures. After the disc or discs are removed, the space between the vertebrae is often filled with a bone graft. This bone graft encourages the vertebrae to fuse together over time, creating a solid bone structure that stabilizes the spine. In some cases, metal plates, screws, or cages may be used to further stabilize the area during the fusion process.

For analysis, the ACDF cohort was selected using the following criteria:

Inclusions:

- Surgery Type Cervical Discectomy AND
 - Anterior approach AND
 - Fusion
- Number of levels ≤2
- Number of stages =1

Exclusions:

Scoliosis



Images courtesy of Dr Rob Kuru

Demographics

240 ACDF procedures that met the eligibility criteria were analysed. These occurred more commonly on male patients especially in the younger age brackets. There were 140 males (58%) and 100 females (42%) in this cohort as shown in Figure 26. The median age for males was 54 years, with a median of 57 years for females, which is slightly younger than the median patient age from the total ASR patient cohort (62 years for males and 65 years for females).





Number of Patients

Surgeon Reported Comorbidities and ASA

Examination of the SRCs in this group identified that ACDF patients were not significantly different when compared to all patients in the registry (Table 20, Table 19). Examination of the ASA scores for this cohort revealed that only 50% of the ACDF procedures had listed an ASA score. Of the data collected, 26% of the patients were considered "normal" healthy patients with 48% with mild disease and 25.5% with severe disease which closely resembles the ASA score percentages for the total ASR patient cohort.

Table 18: Number of ACDF patients diagnosed with <u>any</u> comorbidity prior to surgery

Any reported comorbidity	All (n=4554) n (%)	ACDF (n=240) n (%)	
Yes	1681 (36.9)	99 (41.3)	
No	2873 (63.1)	141 (58.8)	

Table 19: Breakdown of number of SRCs reported in ACDF patients

Number of reported comorbidities	All patients (n=4554) n (%)	ACDF patients (n=240) n (%)
None	2873 (63.1)	141 (58.80)
1	750 (16.5)	47 (19.60)
2	469 (10.3)	26 (10.80)
3	297 (6.5)	16 (6.70)
4	98 (2.2)	8 (3.30)
5+	67 (1.5)	2 (0.80)

Table 20: ASA scores for ACDF patients compared to all ASR patients

ASA Classification	All patients (n=2423) n (%)	ACDF patients (n=139) n (%)
1	544 (22.5)	36 (25.9)
2	1108 (45.7)	67 (48.2)
3	745 (30.7)	34 (24.5)
4	26 (1.1)	2 (1.4)

PROMs Analysis

The Neck Disability Index (NDI) and the EQ-5D-3L scores were analysed for the ACDF cohort pre-operatively and at 6, 12 and 24-months post-operatively. A lower NDI score indicates an increase in relief from pain and disability.

Neck Disability Index (NDI)

Median NDI scores (Table 21) reduced from 42 preoperatively, to 16 at 6-months post operatively, and continued to improve to 14 at 24-months postoperatively. These results are further detailed in Figure 27.

Table 21: NDI mean and median scores for ACDF patients who completed <u>any</u> NDI at pre-op, 6, 12 and24-months post-op

NDI	Pre-operative	6-months	12-months	24-months
n	175	162	146	109
Mean (SD)	43.7 (18.5)	20.9 (16.8)	19.3 (16.2)	20.1 (19.3)
Median (IQR)	42.0 (30.0, 56.0)	18.0 (8.0, 30.0)	16.0 (6.0, 28.0)	14.0 (6.0, 30.0)



Figure 27 : NDI distribution for ACDF patients who completed <u>any</u> NDI questionnaires at pre-op, 6,12 and 24-months post-op

Analysis of each of the ten NDI domains for the ACDF cohort is shown in Table 21. This table presents the mean number of NDI domain points pre-operatively and at 6, 12 and 24-months post-operatively. Average scores across all domains were lower at all post operative time points which indicate that all NDI domains improved.

Table 22: NDI mean scores for each domain for ACDF patients who completed <u>any</u> EQVAS at pre-op, 6, 12 and 24-months post-op

NDI	Pre-operative	6-Months	12-Months	24-Months
n	175	162	146	109
Personal Care, mean (SD)	1.07 (1.07)	0.32 (0.70)	0.32 (0.68)	0.44 (0.84)
Concentration, mean (SD)	1.30 (1.15)	0.64 (0.92)	0.52 (0.80)	0.59 (0.87)
Headaches, mean (SD)	1.81 (1.60)	0.94 (1.15)	0.88 (1.12)	1.08 (1.26)
Reading, mean (SD)	1.97 (1.25)	1.00 (1.09)	1.03 (1.13)	1.05 (1.13)
Driving [*] , mean (SD)	2.27 (1.55)	0.91 (1.24)	0.84 (1.03)	0.84 (1.13)
Work, mean (SD)	2.49 (1.41)	1.26 (1.30)	1.17 (1.24)	1.13 (1.30)
Pain, mean (SD)	2.38 (1.20)	1.03 (0.94)	0.90 (0.89)	0.88 (1.01)
Lifting, mean (SD)	2.72 (1.44)	1.67 (1.51)	1.53 (1.53)	1.28 (1.49)
Sleeping, mean (SD)	2.81 (1.32)	1.39 (1.22)	1.31 (1.23)	1.39 (1.41)
Recreation, mean (SD)	3.01 (1.40)	1.28 (1.29)	1.14 (1.18)	1.37 (1.51)

* Note: Driving question is optional; lower numbers of 171, 158, 141 and 107 (for each time-point, respectively).

The Minimum Clinically Important Difference (MCID) can be defined as the smallest change in the PROMs scores needed to achieve a level of clinical improvement¹⁴. ACDF specific MCID is highly variable depending on the calculation techniques used. The ASR has used the MCID threshold as specified by Parker et al (2013) which have been reported to be 17.3 for the NDI¹⁵. We note that in the literature there is considerable variation in the MCIDs reported for cervical surgery.

Table 23 and Table 24 shows patient data for all patients and ACDF patients who completed the NDI.

<u>All patients</u> were <u>within or exceeded</u> this MCID for NDI from pre-op to 6-months,12-months and 24-months post-operatively.

NDI*	All Cervical (n=318) n (%)	1-2 Level ACDF (n=118) n (%)
Exceeding the MCID (Improved)	177 (53.8)	69 (55.2)
Within the MCID (Unchanged)	152 (46.2)	56 (44.8)
Exceeding the MCID (Worsened)	0 (0.0)	0 (0.0)

Table 23: MCID for NDI from pre-op to <u>6-months</u> post-op for ACDF patients

Table 24: MCID for NDI from pre-op to <u>12-months</u> post-op for ACDF patients

NDI*	All Cervical (n=284) n (%)	1-2 Level ACDF (n=107) n (%)
Exceeding the MCID (Improved)	166 (57.6)	68 (61.3)
Within the MCID (Unchanged)	121 (42.0)	43 (38.7)
Exceeding the MCID (Worsened)	1 (0.3)	0 (0.0)

Table 25: MCID for NDI from pre-op to 24-months post-op for ACDF patients

NDI*	All Cervical (n=223) n (%)	1-2 Level ACDF (n=78) n (%)
Exceeding the MCID (Improved)	126 (56.3)	50 (61.7)
Within the MCID (Unchanged)	93 (41.5)	29 (35.8)
Exceeding the MCID (Worsened)	5 (2.2)	2 (2.5)

*Only patients that have completed both timepoint questionnaires are included.

EQ-5D-3L Quality of Life

The ACDF cohort EQ-5D-3L dimension scores and the EQVAS were examined. Review of the domain scores at each time point showed marked improvement for all domains (Table 26). The pain/discomfort domain showed the most improvement at 6 months followed by the 'usual activities' domain. For the pain/discomfort domain, 97.2% of patients reporting some or extreme pain/discomfort pre-operatively which reduced to 65.6% at 6-months post-surgery and to 51.0% at 24-months post-surgery. For the usual activities' domain, 82.4% of patients report some or extreme problems with carrying out their usual activities which reduced to 49.1% 6-months post-surgery and 38.1% at 24-months post-surgery.

AC	CDF Patients E	Q-5D-3L							
		ACDF Patients EQ-5D-3L							
Level of problem	Pre-op (%) n=182	6-months (%) n=163	12-months (%) n=147	24-months (%) n=110					
1 – no problems	2.7	34.4	37.4	49.1					
2 – some problems	68.1	60.7	57.1	45.5					
3 – extreme problems	29.1	4.9	5.4	5.5					
1 – no problems	55.5	78.5	81.0	77.3					
2 – some problems	44.0	21.5	19.0	22.7					
3 – extreme problems	0.5	0.0	0.0	0.0					
1 – no problems	67.6	86.5	84.4	83.6					
2 – some problems	31.9	13.5	15.6	16.4					
3 – extreme problems	0.5	0.0	0.0	0.0					
1 – no problems	17.6	50.9	53.7	61.8					
2 – some problems	61.5	46.0	41.5	33.6					
3 – extreme problems	20.9	3.1	4.8	4.5					
1 – no problems	41.8	63.8	67.3	62.7					
2 – some problems	48.9	32.5	29.9	31.8					
3 – extreme problems	9.3	3.7	2.7	5.5					
	Level of problem 1 – no problems 2 – some problems 3 – extreme problems 4 – no problems 2 – some problems 3 – extreme problems 4 – no problems 2 – some problems 3 – extreme problems 4 – no problems 2 – some problems 3 – extreme problems 4 – no problems 5 – some problems 5 – some problems 6 – some problems 6 – some problems 7 – some problems 7 – some problems 9 – some problems	Level of problemPre-op (%) n=1821 - no problems2.72 - some problems68.13 - extreme problems29.11 - no problems55.52 - some problems44.03 - extreme problems0.54 - no problems67.62 - some problems31.93 - extreme problems0.51 - no problems0.52 - some problems0.52 - some problems0.53 - extreme problems0.54 - no problems17.62 - some problems61.53 - extreme problems20.91 - no problems41.82 - some problems48.93 - extreme problems9.3	Level of problem Pre-op (%) n=182 6-months (%) n=163 1 - no problems 2.7 34.4 2 - some problems 68.1 60.7 3 - extreme problems 29.1 4.9 1 - no problems 55.5 78.5 2 - some problems 44.0 21.5 3 - extreme problems 0.5 0.0 1 - no problems 67.6 86.5 2 - some problems 31.9 13.5 3 - extreme problems 0.5 0.0 1 - no problems 0.5 0.0 1 - no problems 17.6 50.9 2 - some problems 17.6 50.9 2 - some problems 61.5 46.0 3 - extreme problems 20.9 3.1 1 - no problems 41.8 63.8 2 - some problems 48.9 32.5 3 - extreme problems 9.3 3.7	Pre-op (%) n=1826-months (%) n=16312-months (%) n=1471 - no problems2.734.437.42 - some problems68.160.757.13 - extreme problems29.14.95.41 - no problems55.578.581.02 - some problems44.021.519.03 - extreme problems0.50.00.04 - no problems67.686.584.42 - some problems31.913.515.63 - extreme problems0.50.00.01 - no problems67.686.584.42 - some problems17.650.953.72 - some problems17.650.953.72 - some problems20.93.14.81 - no problems41.863.867.32 - some problems48.932.529.93 - extreme problems9.33.72.7					

Table 26: EQ-5D-3L scores for each domain for ACDF patients at pre-op, 6 and 12 and 24-months post-op

The EQVAS median scores improved from 60 pre-operatively to 75 at 6 months, and was sustained until 24 months (Table 27). These are further detailed in Figure 28.

Table 27: EQVAS mean and median scores for ACDF patients who completed <u>any</u> EQVAS at pre-op, 6, 12 and 24-months post-op

EQVAS	Pre-operative	6-months	12-months	24-months
n	182	163	147	110
Mean (SD)	57.6 (18.5)	72.2 (18.5)	73.2 (16.4)	73.2 (18.2)
Median (IQR)	60.0 (40.0, 71.0)	75.0 (64.0, 85.0)	75.0 (65.0, 85.0)	78.5 (65.0, 87.0)







All Patients (%)





(c) Twelve-month post-operative EQVAS (n=147)





L4-L5 Degenerative Spondylolisthesis (L4-L5 DS)

Spondylolisthesis is defined as an anterior displacement of a vertebral body in relation to the one below it.

Degenerative L4-L5 spondylolisthesis is a condition where one vertebra slips forward over the one beneath it in the lumbar (lower back) region of the spine. This condition typically occurs due to age-related wear and tear on the spinal discs and facet joints, leading to instability and eventual loss of alignment of the vertebrae. As a result of this, the central canal narrows and the nerves become compressed. Typically, DS occurs at the L4-L5 and less commonly at other lumbar levels.

It most commonly presents as leg pain restricting walking and standing but other symptoms can include:

- Lower back pain, often worsened by activity and relieved by rest.
- Pain that radiates into the buttocks and thighs (sciatica).
- Numbness, tingling, or weakness in the legs.
- Difficulty walking or standing for prolonged periods.
- Changes in posture or gait.

It is reported that DS is strongly age and gender specific ¹⁶ and is uncommon under the age of 50¹⁷.

For analysis, the L4-L5 DS cohort was selected using the following criteria:

Inclusions:

- Type of spondylolisthesis degenerative
- Only at the L4-L5 level
- All grades (1-4) including spondyloptosis or retrolisthesis

Exclusions:

• Scoliosis

As of 15 January 2024, 243 patients met the L4-L5 DS cohort inclusion criteria.

Images courtesy of Mr Michael Johnson



Demographics

There were 93 males (38%) and 150 females (62%) who were diagnosed with L4-L5 DS as shown in Figure 29.

The median age for males was 72 years and 70 years for females, which is older than the median patient age from the total ASR patient cohort (62 years for males and 65 years for females).





Number of Patients

Surgeon Reported Comorbidities and ASA

The number of patients who were reported to have a comorbidity is shown in Table 28; 67.5% of L4-L5 DS patients were reported to have at least one comorbidity compared to 36.9% of the total patients. Patients were further categorised by their ASA score (Table 29). For the patient who had an ASA score recorded, 90.3% had mild to severe disease which was consistent with this cohort's age profile.

Table 28: Number of L4-L5 DS patients with <u>any</u> comorbidity prior to surgery

Any reported comorbidity	All (n=4554) n (%)	L4-L5 DS (n=243) n (%)
Yes	1681 (36.9)	164 (67.5)
No	2873 (63.1)	79 (32.5)

Table 29: ASA score reported for L4-L5 DS patients compared to all ASR patients

ASA Classification	All (n=2072) n (%)	L4-L5 DS (n=158) n (%)
1	544 (22.5)	17 (9.7)
2	1108 (45.7)	92 (52.6)
3	745 (30.7)	64 (36.6)
4	26 (1.1)	2 (1.1)

Glassman Classification Scores

The Glassman classification scores for L4-L5 DS cohort was examined. Analysis of the "Symptoms" category indicate that for most of these patients, surgery was performed for neurocompressive pain (Figure 30).



Figure 30: Glassman Score for 'Symptoms' among L4-L5 DS patients (n=189)

PROMs Analysis

The Oswestry Disability Index (ODI) and the EQ-5D-3L scores were analysed for the L4-L5 DS cohort. As indicated previously, these results show unadjusted outcomes and must be interpreted with caution.

Oswestry Disability Index (ODI)

ODI median scores improved from 38 pre-operatively to 14 at 6-months post-operatively with further slight improvement at 12 and 24 months (Table 29). Figure 31 describes this in further detail. The ODI at 24 months shows that there is small proportion of patients with an ODI score over 40. Further analysis of these patients is currently being carried out.

Table 30: ODI mean and median scores for L4-L5 DS patients who completed <u>any</u> ODI at pre-op, 6, 12 and 24-months post-op

ODI	Pre-operative	6-months	12-months	24-months
n	203	188	172	152
Mean (SD)	39.4 (17.3)	17.9 (17.0)	16.2 (16.4)	16.3 (16.0)
Median (IQR)	38.0 (26.0, 51.0)	14.0 (4.0, 27.0)	11.5 (4.0, 26.0)	12.0 (2.0, 27.0)

Figure 31: ODI distribution for L4-L5 DS patients who completed <u>any</u> ODI at pre-op, 6, 12 and 24-months post-op



(b) Six-month post-operative ODI (n=188)





(c) Twelve-month post-operative ODI (n=172)

(d) Twenty-four-month post-operative ODI (n=152)



The ten ODI domains for the L4-L5 DS patients that completed any questionnaires were analysed. Table 31 shows the mean number of ODI domain scores pre-operatively and at 6, 12 and 24-months post-operatively. Mean scores across all ODI domains were lower at 6, 12 and 24-months postoperatively with pain and standing showing the largest improvement after 24 months.

Table 31: ODI mean scores for each domain for L4-L5 DS patients who completed <u>any</u> ODI at pre-op, 6, 12 and 24-months post-op

ODI	Pre-operative	6-months	12-months	24-months
n	203	188	172	152
Standing, mean (SD)	2.74 (1.31)	1.23 (1.32)	1.22 (1.32)	1.23 (1.37)
Pain, mean (SD)	2.32 (1.09)	0.95 (0.99)	0.82 (0.97)	0.86 (1.02)
Social Life, mean (SD)	2.28 (1.24)	0.99 (1.31)	0.81 (1.22)	0.84 (1.14)
Sex Life*, mean (SD)	1.90 (1.90)	0.71 (1.42)	0.74 (1.48)	0.48 (1.20)
Walking, mean (SD)	2.15 (1.24)	0.77 (1.11)	0.73 (1.12)	0.76 (1.12)
Traveling, mean (SD)	1.83 (1.27)	0.74 (1.09)	0.66 (1.03)	0.63 (0.92)
Lifting, mean (SD)	2.39 (1.28)	1.56 (1.50)	1.42 (1.42)	1.43 (1.51)
Sleeping, mean (SD)	1.48 (1.04)	0.63 (0.76)	0.61 (0.70)	0.60 (0.77)
Sitting, mean (SD)	1.59 (1.18)	0.86 (0.91)	0.77 (0.91)	0.76 (0.88)
Personal Care, mean (SD)	0.95 (1.04)	0.37 (0.83)	0.31 (0.77)	0.38 (0.91)

* Note: Sex life question is optional; lower numbers of 124, 121, 110, 104 (for each time-point, respectively).

As indicated previously, the Minimum Clinically Important Difference (MCID) is a threshold used to measure the effect of clinical treatments and has been reported to be 12.8 for the ODI¹³.

For the L4-L5 DS patients, 98.7% **exceeded or were within** the MCID for ODI at the 6-month time point. This was sustained at 12 and 24 months (Table 31 and 32). Table 33 shows the MCID for 12-months post-operatively; 69.2% of patients showed an improvement at this time point. Table 34 shows the MCID for 24-months post-operatively, where 74.2% of patients showed an improvement.

It is interesting to note that for this group of patients, the median age of patients undergoing surgery for DS is 72 for males, and 70 for females. Despite this age profile, these patients are still benefitting from their procedures.

Table 32: MCID for ODI from pre-op to 6-months post-op for L4-L5 DS patients

ODI	All (n=2310) n (%)	L4-L5 DS (n=160) n (%)
Exceeding the MCID (Improved)	1494 (64.7)	108 (67.5)
Within the MCID (Unchanged)	740 (32.0)	50 (31.3)
Exceeding the MCID (Worsened)	76 (3.3)	2 (1.3)

Table 33: MCID for ODI from pre-op to <u>12-months</u> post-op for "L4-L5 DS" patients

All (n=2069) n (%)	L4-L5 DS (n=146) n (%)
ding the MCID (Improved) 1365 (66.0)	101 (69.2)
the MCID (Unchanged) 646 (31.2)	43 (29.5)
ding the MCID (Worsened) 58 (2.8)	2 (1.4)
n (%) ding the MCID (Improved) 1365 (66.0) the MCID (Unchanged) 646 (31.2) ding the MCID (Worsened) 58 (2.8)	n (%) 101 (69.2) 43 (29.5) 2 (1.4)

Table 34: MCID for ODI from pre-op to 24-months post-op for "L4-L5 DS" patients

ODI	All (n=1588) n (%)	L4-L5 DS (n=128) n (%)	
Exceeding the MCID (Improved)	1048 (66.0)	95 (74.2)	
Within the MCID (Unchanged)	487 (30.7)	28 (21.9)	
Exceeding the MCID (Worsened)	53 (3.3)	5 (3.9)	

*Only patients that have completed both timepoint questionnaires are included.

EQ-5D-3L Quality of Life

The L4-L5 DS cohort EQ-5D-3L dimension scores and the EQVAS were analysed (Table 35 and Figure 32). It is important to note that this group of patients have multifactorial health issues, and it is not unexpected that these patients have residual pain. In addition, this questionnaire asks about any pain, not specific pain.

Examination of the EQ-5D responses indicate general patient improvement across all domains. The mobility domain showed the highest improvement. 83.4% of patients reported some or extreme problems with mobility pre-operatively. This was reduced to 35.4% at 6-months post-surgery; a reduction of 47.5%. For the pain/discomfort domain, 97.0% of patients reported some or extreme pain/ discomfort pre-operatively which reduced to 57.6% at 6-months post-surgery; a reduction of 39.4%. For the usual activities' domain, 86.8% of patients reported some or extreme problems with carrying out their usual activities. This was reduced to 47.6% 6-months post-surgery; a reduction of 39.2%.

Table 35: EQ-5D-3L scores for each domain for L4-L5 DS patients at pre-op, 6, 12 and 24-months post-op displayed in order of improvement of some and extreme problems

EQ-5D-3L L4-L5 DS patients					
Domain	Level of problem	Pre-op (%) n=204	6-months (%) n=189	12-months (%) n=174	24-months (%) n=152
	1 – no problems	16.7	64.6	66.1	62.5
Mobility	2 – some problems	81.9	35.4	33.9	37.5
	3 – extreme problems	1.5	0.0	0.0	0.0
Pain/	1 – no problems	2.9	42.3	50.6	44.1
Discomfort	2 – some problems	58.8	53.4	46.0	52.0
	3 – extreme problems	38.2	4.2	3.4	3.9
Usual	1 – no problems	13.2	52.4	58.0	61.2
Activities	2 – some problems	75.5	44.4	40.8	36.8
	3 – extreme problems	11.3	3.2	1.1	2.0
	1 – no problems	52.5	73.5	77.0	77.6
Anxiety/ Depression	2 – some problems	42.2	24.3	20.1	20.4
	3 – extreme problems	5.4	2.1	2.9	2.0
Self-Care	1 – no problems	72.5	87.8	89.1	91.4
Sell-Care	2 – some problems	27.0	12.2	10.9	8.6
	3 – extreme problems	0.5	0.0	0.0	0.0

Table 36: EQVAS mean and median scores for L4-L5 DS patients who completed <u>any</u> EQVAS at pre-op, 6, 12 and 24-months post-op

EQVAS	Pre-operative	6-months	12-months	24-months
n	204	189	174	152
Mean (SD)	59.8 (20.2)	74.8 (17.8)	77.1 (17.0)	78.6 (15.1)
Median (IQR)	60.0 (50.0, 75.0)	80.0 (70.0, 87.0)	80.0 (70.0, 90.0)	80.0 (70.0, 90.0)

When examining EQVAS a shift to the right indicates an improvement of patient perception of their general health status. As shown in Figure 32, this cohort showed improvement in their general perception of their health 6, 12 and 24-months post-operatively.



3.3

41-50

51-60

61-70

71-80

81-90

1.3

31-40

0.7

21-30

5

0

0-10

0.7

11-20

Figure 32: EQVAS distribution for L4-L5 DS patients who completed <u>any</u> EQVAS at pre-op, 6, 12 and 24-months post-op

91-100

L5-S1 Isthmic Spondylolisthesis (L5-S1 IS)

Isthmic spondylolisthesis is a specific type of spondylolisthesis, a condition where one vertebra slips forward over the vertebra below it. In isthmic spondylolisthesis, this slippage is caused by a defect or developmental abnormality in a part of the vertebra called the pars interarticularis. This defect is often associated with repetitive stress or trauma to the lower back, particularly during childhood or adolescence when the bones are still developing.

Studies have shown that the occurrence of isthmic spondylolisthesis varies depending on factors such as age, gender, and ethnicity. In children, it's estimated to be approximately 2.6% ¹⁸. However, in the general adult population, the prevalence of asymptomatic isthmic spondylolisthesis ranges from 3.7% to over 25% ¹⁹ ²⁰ ²¹ ²² ²³. This condition, along with spondylolysis, is more prevalent in males, with a male-to-female ratio of around 3:1 ¹⁸.

The condition most frequently occurs at L5/S1, but can occur at all levels of the spine.

The prevalence of isthmic spondylolisthesis can be notably higher among athletes participating in sports²⁴ involving rotational or hyperextension movements of the lumbar spine. Such sports include gymnastics, football, rowing, weightlifting, cricket (and in particular fast bowling), and swimming ¹⁹.

There are two main subtypes of isthmic spondylolisthesis based on the underlying cause:

Lytic Spondylolysis: This subtype occurs when there is a defect or stress fracture in the pars interarticularis, being the small bony bridge that connects the facet joints at the back of the vertebra. This defect weakens the connection between the upper and lower parts of the vertebra, allowing for the slippage to occur.

Dysplastic Spondylolisthesis: The slippage is believed to result from an elongation of the pars interarticularis, leading to instability and gradual forward displacement of the vertebra.

Symptoms of isthmic spondylolisthesis can vary depending on the degree of slippage and whether it causes compression of nearby nerves or the spinal cord. Common symptoms may include lower back pain, stiffness, muscle spasms, leg pain (sciatica), numbness, tingling, or weakness in the legs.



For analysis, the IS cohort was selected using the following criteria:

Inclusions:

- Type of Spondylolisthesis isthmic AND/OR dysplastic
- Only at the L5 S1 level
- All grades (1-4)

Exclusions:

- Retrolisthesis
- Scoliosis

As of 15 January 2024, 64 patients met the IS cohort inclusion criteria.
Demographics

There were 35 males (38%) and 29 females (62%) who were diagnosed with L5-S1 IS as shown in Figure 33.

The median age for males was 49 years and 47 years for females, which is younger than the median patient age from the total ASR patient cohort (62 years for males and 65 years for females). The demographic data would appear to indicate that symptoms are usually more manageable in younger life but become more difficult to manage conservatively over the age of 40.





Number of Patients

Surgeon Reported Comorbidities and ASA

The number of patients who were reported to have a comorbidity is shown in Table 37. 39.1% of L5-S1 IS patients were reported to have at least one comorbidity compared to 36.9% of the total patients. Patients were further categorised by their ASA score (Table 38). For the patient who had an ASA score recorded, 71.7% were reported to have mild to severe disease.

Table 37: Number of L5-S15 IS patients with <u>any</u> comorbidity prior to surgery

Any reported comorbidity	All patients (n=4554) n (%)	lsthmic spondylolisthesis patients (n=64) n (%)
Yes	1681 (36.9%)	25 (39.1%)
No	2873 (63.1%)	39 (60.9%)

Table 38: ASA score reported for patients with isthmic spondylolisthesis compared to all ASR patients

ASA Classification	All patients (n=2423) n (%)	Isthmic spondylolisthesis patients (n=52*) n (%)
1	544 (22.5%)	15 (28.8%)
2	1108 (45.7%)	30 (57.7%)
3	745 (30.7%)	7 (13.5%)
4	26 (1.1%)	0 (0.0%)

* Number who also have at least one non-missing ASA score: 52

Glassman Classification Scores

The Glassman classification scores for L5-S1 IS cohort was examined. Analysis of the "Symptoms" category indicate that for most of these patients, surgery was performed for neurocompressive pain (Figure 34).





PROMs Analysis

The Oswestry Disability Index (ODI) and the EQ-5D-3L scores were analysed for the L5-S1 IS cohort. As indicated previously, these results show unadjusted outcomes and must be interpreted with caution.

Oswestry Disability Index (ODI)

ODI median scores improved from 44 pre-operatively to 16 at 6-months post-operatively with minimal improvement at 12 and 24 months (Table 39). Figure 35 describes this in further detail. The ODI at 24 months shows that there is small proportion of patients with an ODI score over 40. Further analysis of these patients is currently being carried out.

Table 39: ODI mean and median scores for L5-S1 IS patients who completed <u>any</u> ODI at pre-op, 6, 12 and24-months post-op

ODI	Pre-operative	6-months	12-months	24-months
n	58	44	47	40
Mean (SD)	43.5 (17.7)	19.8 (16.7)	18.7 (18.5)	21.1 (17.0)
Median (IQR)	44.0 (32.0, 56.0)	16.0 (7.0, 28.0)	14.0 (6.0, 28.0)	16.0 (8.0, 32.0)

Figure 35: ODI distribution for L5-S1 IS patients who completed <u>any</u> ODI at pre-op, 6, 12 and 24-months post-op



(b) Six-month post-operative ODI (n=44)





(c) Twelve-month post-operative ODI (n=47)

(d) Twenty-four-month post-operative ODI (n=40)



The ten ODI domains for the L5-S1 IS patients that completed any questionnaires were analysed. Table 40 shows the mean number of ODI domain scores pre-operatively and at 6, 12 and 24-months post-operatively. Mean scores across all ODI domains were lower at 6, 12 and 24-months post-operatively with standing and social life followed by lifting showing the largest improvement.

Table 40: ODI mean scores for each domain for L5-S1 IS patients who completed <u>any</u> ODI at pre-op, 6, 12 and 24-months post-op

ODI	Pre-operative	6-months	12-months	24-months
n	58	44	47	40
Standing, mean (SD)	2.86 (1.29)	0.98 (1.11)	1.11 (1.18)	1.27 (1.11)
Social Life, mean (SD)	2.59 (1.11)	1.11 (1.40)	0.96 (1.32)	1.00 (1.24)
Lifting, mean (SD)	2.72 (1.24)	1.80 (1.41)	1.32 (1.42)	1.33 (1.27)
Pain, mean (SD)	2.53 (1.03)	1.14 (0.90)	1.09 (0.95)	1.25 (0.95)
Sitting, mean (SD)	2.28 (1.07)	1.25 (1.10)	1.28 (1.12)	1.40 (1.10)
Traveling, mean (SD)	2.26 (1.38)	0.93 (1.02)	0.85 (1.08)	1.00 (0.96)
Sex Life, mean (SD)	2.17 (1.68)	1.18 (1.67)	1.15 (1.51)	1.21 (1.64)
Sleeping, mean (SD)	1.72 (0.99)	0.77 (0.86)	0.83 (0.99)	0.98 (0.70)
Walking, mean (SD)	1.40 (1.28)	0.32 (0.56)	0.45 (0.75)	0.47 (0.64)
Personal Care, mean (SD)	1.21 (1.18)	0.43 (0.95)	0.40 (0.88)	0.63 (1.05)

* Note: Sex life question is optional; lower numbers of 53, 39, 39 and 39 (for each time-point, respectively).

As indicated previously, the Minimum Clinically Important Difference (MCID) is a threshold used to measure the effect of clinical treatments and has been reported to be 12.8 for the ODI¹³.

For the L5-S1 IS patients, 97.6% were within or exceeded the MCID for ODI at the 6 month time point (Table 41). This was sustained at 12 and 24 months (Table 42, Table 43).

ODI.	All (n=2310) n (%)	Isthmic spondylolisthesis (n=42) n (%)
Exceeding the MCID (Improved)	1494 (64.7%)	29 (69.0%)
Within the MCID (Unchanged)	740 (32.0%)	12 (28.6%)
Exceeding the MCID (Worsened)	76 (3.3%)	1 (2.4%)

Table 41: MCID for ODI from pre-op to <u>6-months</u> post-op for L5-S1 IS patients

Table 42: MCID for ODI from pre-op to <u>12-months</u> post-op for L5-S1 IS patients

ODI.	All (n=2069) n (%)	lsthmic spondylolisthesis (n=45) n (%)
Exceeding the MCID (Improved)	1365 (66.0%)	37 (82.2%)
Within the MCID (Unchanged)	646 (31.2%)	8 (17.8%)
Exceeding the MCID (Worsened)	58 (2.8%)	0 (0.0%)

Table 43: MCID for ODI from pre-op to 24-months post-op for L5-S1 IS patients

ODI.	All (n=1588) n (%)	Isthmic spondylolisthesis (n=37) n (%)
Exceeding the MCID (Improved)	1048 (66.0%)	30 (81.1%)
Within the MCID (Unchanged)	487 (30.7%)	6 (16.2%)
Exceeding the MCID (Worsened)	53 (3.3%)	1 (2.7%)

*Only patients that have completed both timepoint questionnaires are included.

EQ-5D-3L Quality of Life

The L5-S1 IS cohort EQ-5D-3L dimension scores and the EQVAS were analysed (Table 35 and Figure 32). It is important to note that this group of patients have multifactorial health issues, and it is not unexpected that these patients have residual pain. In addition, this questionnaire asks about any pain, not specific pain.

Examination of the EQ-5D responses indicate general patient improvement across most domains. The mobility domain showed the highest improvement. 84.4% of patients reported some or extreme problems with mobility pre-operatively. This was reduced to 24.4% at 6-months post-surgery; a reduction of 60%. For the pain/discomfort domain, 98.3% of patients reported some or extreme pain/ discomfort pre-operatively which reduced to 64.4% at 6-months post-surgery; a reduction of 29.9%. For the usual activities' domain, 89.6% of patients reported some or extreme problems with carrying out their usual activities. This was reduced to 52.5% 24-months post-surgery; a reduction of 37.1%.

EQ-5D-3L L5-S1 IS Patients					
Domain	Level of problem	Pre-op (%) n=58	6-months (%) n=45	12-months (%) n=48	24-months (%) n=40
Mobility	1 – no problems	15.5	75.6	70.8	67.5
	2 – some problems	81.0	24.4	27.1	32.5
	3 – extreme problems	3.4	0.0	2.1	0.0
Self-Care	1 – no problems	56.9	82.2	79.2	77.5
	2 – some problems	36.2	17.8	20.8	22.5
	3 – extreme problems	6.9	0.0	0.0	0.0
Usual	1 – no problems	10.3	46.7	45.8	47.5
Activities	2 – some problems	65.5	44.4	47.9	45.0
	3 – extreme problems	24.1	8.9	6.3	7.5
Pain/	1 – no problems	1.7	35.6	31.3	25.0
Discomfort	2 – some problems	62.1	62.2	62.5	70.0
	3 – extreme problems	36.2	2.2	6.3	5.0
Anxiety/	1 – no problems	39.7	60.0	56.3	57.5
Depression	2 – some problems	48.3	31.1	33.3	40.0
	3 – extreme problems	12.1	8.9	10.4	2.5

Table 44: EQ-5D-3L scores for each domain for L5-S1 IS patients at pre-op, 6, 12 and 24-months post-op displayed in order of improvement of some and extreme problems

When examining EQVAS a shift to the right indicates an improvement of patient perception of their general health status. As shown in Table 45 and in Figure 36, this cohort showed conservative improvement in their general perception of their health 6, 12 and 24-months post-operatively.

Table 45: EQVAS mean and median scores for isthmic spondylolisthesis who completed <u>any</u> EQVAS at pre-op, 6, 12 and 24-months post-op

EQVAS	Pre-operative	6-months	12-months	24-months
n	58	45	48	40
Mean (SD)	53.8 (21.1)	71.0 (19.9)	72.6 (21.3)	74.2 (19.4)
Median (IQR)	57.5 (40.0, 70.0)	71.0 (60.0, 85.0)	80.0 (60.5, 90.0)	80.0 (65.0, 90.0)



0-10

11-20

21-30

31-40

41-50

51-60

61-70

71-80

81-90



91-100

Complex Surgery

This cohort of patients has been selected using all the following inclusion criteria:

- 1. Any patient 60 years old or over at the time of surgery.
- 2. Patients with a degenerative diagnosis, excluding infection and tumour.
- 3. Surgery performed on greater than or equal to 6 motion segments (7 contiguous vertebrae).

This cohort is not uniform by diagnosis or symptoms leading to some degree of cohort heterogeneity.

0

Images courtesy of Dr Michael Johnson

Demographics

166 patients met the inclusion criteria which represents 4.5% of patients undergoing thoracolumbar procedures. As indicated in Figure 37, the demographic distribution demonstrates a disproportionate number of females in comparison to Australian gender balance statistics^d. This patient group has the following characteristics:

- 40% of patients in this cohort received planned multi-stage surgery (Figure 38)
- Greater than 60% of the patients had had previous spine surgery (Figure 39).

Figure 37: Complex Surgery patients by age and gender



Figure 38: Percentage of patients who underwent multi-staged procedures for the "complex surgery" patients cohort.



Figure 39: Percentage of patients of "complex surgery" patients that had previous spine surgery.



^d https://www.aihw.gov.au/reports/older-people/older-australians/contents/demographic-profile#Sex (Accessed 6 April 2023)

n=166

Surgeon Reported Comorbidities and ASA

This surgical cohort suggests higher associated SRCs in comparison to the overall spine surgery population (Table 46, Table 47). Whilst there was a variability between SRCs and ASA score, this trend was consistent.

Table 46: Number of Complex Surgery patients with <u>any</u> comorbidity prior to surgery

Comorbidity Diagnosis	All (n=4554) n (%)	Complex Surgery (n=166) n (%)
No	2873 (63.1)	46 (27.7)
Yes	1681 (36.9)	120 (72.3)

Table 47: Breakdown of number of SRCs reported in Complex Surgery patients

Number of comorbidities	All (n=4554) n (%)	Complex Surgery (n=166) n (%)
None	2873 (63.1)	46 (27.7)
1	750 (16.5)	53 (31.9)
2	469 (10.3)	40 (24.1)
3	297 (6.5)	15 (9.0)
4	98 (2.2)	6 (3.6)
5+	67 (1.5)	6 (3.6)

Table 48: ASA score reported for "Complex Surgery" patients compared to all ASR patients

ASA Classification	All (n=2423) n (%)	Complex Surgery (n=160) n (%)
1	544 (22.5)	3 (1.9)
2	1108 (45.7)	56 (35.0)
3	745 (30.7)	98 (61.3)
4	26 (1.1)	3 (1.9)

Glassman Score for 'Symptoms' among Complex Surgery patients

As indicated in Figure 40, these patients reported a higher proportion of back pain as their primary complaint. The Glassman classification does not describe for complaints related to postural imbalance which is a frequent complaint in this patient cohort.



Figure 40: Glassman Score for 'Symptoms' among complex surgery patients (n=126)

Oswestry Disability Index (ODI)

ODI scores for complex surgery patients were examined and analysed. Preoperatively, the ODI scores were higher than for the other cohorts.

ODI median scores improved from 49 pre-operatively to 30 6-months post-operatively. There was a gradual improvement over the following 18 months (Table 49).

Table 49: ODI mean and median scores for Complex Surgery patients who completed <u>any</u> ODI at pre-op, 6,12 and 24-months post-op

ODI	Pre-operative	6-months	12-months	24-months
n	152	117	114	85
Mean (SD)	48.1 (16.2)	31.4 (17.9)	30.5 (17.6)	28.7 (19.6)
Median (IQR)	48.5 (38.0, 60.0)	30.0 (18.0, 44.0)	29.0 (16.0, 42.0)	29.0 (13.0, 38.0)

There was, however, a greater proportion of patients with ODI scores greater than 40 at the 2-year time point in comparison to other patient groups (Figure 41).



Figure 41: ODI distribution for Complex Surgery patients who completed <u>any</u> ODI at pre-op, 6, 12 and 24-months post-op

(b) Six-month post-operative ODI (n=117)





(c) Twelve-month post-operative ODI (n=114)

(d) Twenty-four-month post-operative ODI (n=85)



Using the ODI MCID of 12.8 for degenerative adult scoliosis ^{25,26}, 52% of patients undergoing complex spine surgery have a clinically meaningful improvement (Figure 42). Unlike the other cohorts where improvements are stable at 12 months and 24 months, in this cohort, recovery appears to be more prolonged (Table 50, 51 and 52). Benefit from surgery appears to be less marked and reliable.

There is a significant group where the benefit is limited. Approximately 20%, remain with an ODI greater than 40 at the 24-month time point (Figure 42). The ASR is carrying out further analysis of this cohort to establish factors associated with prognosis.

ODI	All Thoracolumbar Patients (n=2310) n (%)	Complex Surgery (n=111) n (%)
Exceeding the MCID (Improved)	1494 (64.7)	61 (55.0)
Within the MCID (Unchanged)	740 (32.0)	48 (43.2)
Exceeding the MCID (Worsened)	76 (3.3)	2 (1.8)

Table 50: MCID for ODI from pre-op to 6-months post-op for Complex Surgery patients

Table 51: MCID for ODI from pre-op to <u>12-months</u> post-op for Complex Surgery patients

ODI	All Thoracolumbar Patients (n=2069) n (%)	Complex Surgery (n=109) n (%)
Exceeding the MCID (Improved)	1365 (66.0)	62 (56.9)
Within the MCID (Unchanged)	646 (31.2)	45 (41.3)
Exceeding the MCID (Worsened)	58 (2.8)	2 (1.8)

Table 52: MCID for ODI from pre-op to <u>24-months</u> post-op for Complex Surgery patients

ODI	All Thoracolumbar Patients (n=1588) n (%)	Complex Surgery (n=80) n (%)
Exceeding the MCID (Improved)	1048 (66.0)	51 (63.7)
Within the MCID (Unchanged)	487 (30.7)	26 (32.5)
Exceeding the MCID (Worsened)	53 (3.3)	3 (3.8)

EQ-5D-3L Quality of Life

All domains of the EQ5D showed improvements from pre-op to 24 months.

 Table 53: EQ-5D-3L scores for each domain for Complex Surgery patients from pre-op, to 24-months post-op

Complex Surgery Patients EQ-5D-3L					
Domain	Level of problem	Pre-op (%)n=157	6-months (%) n=122	12-months (%) n=119	24-months (%) n=88
Mobility	1 – no problems	0.6	18.0	19.3	21.6
	2 – some problems	49.7	77.0	76.5	68.2
	3 – extreme problems	49.7	4.9	4.2	10.2
Anxiety/	1 – no problems	7.6	18.0	26.9	28.4
Depression	2 – some problems	70.7	73.8	65.5	63.6
	3 – extreme problems	21.7	8.2	7.6	8.0
Pain/	1 – no problems	8.9	32.8	34.5	34.1
Discomfort	2 – some problems	87.9	65.6	63.9	64.8
	3 – extreme problems	3.2	1.6	1.7	1.1
Self-Care	1 – no problems	42.0	55.7	64.7	60.2
	2 – some problems	49.7	43.4	32.8	35.2
	3 – extreme problems	8.3	0.8	2.5	4.5
Usual	1 – no problems	54.1	60.7	55.5	63.6
Activities	2 – some problems	43.9	38.5	43.7	35.2
	3 – extreme problems	1.9	0.8	0.8	1.1

Table 54: EQVAS mean and median scores for Complex Surgery patients who completed <u>any</u> EQVAS at pre-op, 6, 12 and 24-months post-op

EQVAS	Pre-operative	6-months	12-months	24-months
n	157	122	119	88
Mean (SD)	56.0 (20.0)	70.2 (18.4)	70.2 (18.8)	70.5 (19.7)
Median (IQR)	60.0 (40.0, 70.0)	70.5 (60.0, 85.0)	72.0 (60.0, 85.0)	75.0 (60.0, 85.0)



Figure 42: EQVAS distribution for Complex Surgery patients who completed <u>any</u> EQVAS at pre-op, 6, 12 and 24-months post-op

(b) Six-month post-operative EQVAS (n=122)





(c) Twelve-month post-operative EQVAS (n=119)

(d) Twenty-four-month post-operative EQVAS (n=88)



Paediatric ASR: from concept to reality

It is critical to monitor children and their spine deformity progression throughout their growing years as their deformities can progress quickly to a severity that warrants surgical intervention. Early diagnosis provides the opportunity for a number of conservative and fusionless interventions that aim to halt progression and avoid or delay the need for extensive surgical spine fusion. This makes the paediatric registry different to the adult registry as the ultimate aim is to also register and evaluate patients being managed with non-surgical interventions, as well as those who have surgical treatment (instrumented spine fusion, vertebral body tethering, growing rods for early onset scoliosis). The pilot cohort will consist of children aged 10 - 17 years with scoliosis who have presented at the Queensland Children's Hospital requiring surgical interventions such as posterior or thoracoscopic spinal fusions and vertebral body tethering. This inclusion criteria of elective one-off surgeries allows the pilot study to assess the operation and effectiveness of the registry to record surgical cases. The pilot study will continue for 2 years with plans to progress to a larger cohort of all ages and include more surgery types as well as patients managed with non-surgical interventions (e.g. bracing). It is expected that approximately 50 patients per year will be recruited and entered into the pASR during the pilot study.

pASR as at Jan 2024

It has been a lengthy journey to achieve the milestone of launching the first paediatric Australian Spine Registry (pASR) at the Queensland Children's Hospital (QCH), Brisbane. After much planning and perseverance, the pASR team would like to thank all those who have been involved along the way, in preparation to enter the first of many paediatric spine surgery cases. Initial discussions regarding the creation of the first pASR were first held in early 2021. One of the key requirements for the pASR was the need to have a registry that was suitable for a nation-wide roll-out and with multi-site accessibility.

The most appropriate choice for pASR was to partner with the already established Australian Spine Registry (ASR). The ASR allowed the use of pre-existing infrastructure, skilled staff members, and established connections to support this exciting initiative to achieve success. By August 2023, local and national ethics and governance approvals were achieved, minimal dataset discussions were established, and software changes to the KEOPS platform were initiated. A KEOPS test account for the Paediatric ASR was provided in late 2023 with minor changes and improvements still ongoing. As of January 2024, 26 patients have agreed to be entered into the paediatric ASR since recruitment commenced in June 2023.

The mean age of the patients at the time of consent is 13.9 years, with four (15.4%) males and 22 (84.6%) females. This imbalance is to be expected since idiopathic scoliosis affects more females than males. Most patients (n=25, 96.2%) had an idiopathic scoliosis deformity, with one patient having congenital scoliosis (3.8%). There were 23 posterior spinal instrumented fusions (88.5%), one vertebral body tethering surgery (3.8%), one thoracoscopic anterior fusion (3.8%), and one patient who has not undergone surgery yet.



At the time of publishing this report, the pASR had been launched and had commenced data input. Whilst the pASR platform was being finalised, the QCH spine team had secured the support of the QCH with the part-time employment of a Spine Clinical Nurse Case Manager to assist with patient recruitment and data entry. The QCH Spine Orthopaedic Surgeons, the QCH Spine Outpatient Clinic team and the QUT Biomechanics and Spine Research Group are dedicated to seeing our site, the first paediatric Australian Spine Registry public hospital site, succeed and flourish.

Images courtesy of Ms Maree Izatt





Future Directions

One of the key activities is the transition of the ASR from Monash to the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). The ASR will also be engaging with state-of-the-art data base and IT infrastructure providers AWS and their strategic IT partners so that in a world challenged by cybersecurity issues the ASR data remains secure and protected.

Another key objective of the ASR is to continuously improve our data collection practices for both surgeons and patients. Our analyses indicate the need for further research and software development for optimal methods of comorbidity collection, updates to surgical processes, instrumentation and implants. The ASR is also considering a simplified complications menu.

As such the registry will be:

- evaluating a patient self-reported comorbidity questionnaire to allow for more detailed insights into the challenges our patients face. Research indicates that patient reported comorbidity collection provides a reliable source for data capture in spine surgery²⁷.
- refinement of complications data collection through our data entry program utilised by our registry users.
- updates to the KEOPs platform.

The ASR is now also at a point where it can grow from a research perspective. It has formed a research committee to stimulate use of the database for research activities and new research will be actively reviewed and supported by this committee.

Most importantly, recruitment remains at the forefront of the ASRs agenda. This is critical for the growth of the registry and remains one of the major focus areas for 2024 and beyond.

The entire ASR team look forward to reporting new milestones and achievements in future annual reports.

Publications

Quigley M, Apos E, Truong T-A, Ahern S, Johnson MA. (2023) Comorbidity data collection across different spine registries: an evidence map. European Spine Journal 32(3):753-77

Ahern S, Apos E, McNeil JJ, Cunningham J, Johnson M. Monitoring outcomes in spine surgery: rationale behind the Australian Spine Registry. ANZ J Surg. 2018 Oct;88(10): 950-951. doi: 10.1111/ans.14562.

Registry Presentations in 2023

Presentations at the SSA Annual Scientific Meeting May 2023 -Title of papers:	Spine Week, Melbourne, 01-03 May 2023
 Society Session: Update on the Australian Spine Registry 	
 Development of the Paediatric Australian Spine Registry (pASR) 	
 Australian spine registry stakeholder presentation 	
The Australian Spine Registry (ASR): 4 Years of engaging surgeons and patients in data	1st International Meeting of Spinal Registries 23rd March 2023
collection.	Royal National Orthopaedic Hospital Stanmore Middlesex, UK
Australian Spine Registry	Neurosurgical Society of Australia ASM – Port Douglas 28 September 2023
PROMS and Patients, Maximizing Compliance. The ASR experience	Meeting of the International Spinal Registries at the meeting of EUROSPINE Messe Frankfurt 5th and 6th October 2023
The Australian Spine Registry (ASR) From Pilot to Expansion.	67th Annual Congress of the Korean Orthopaedic Association, Incheon, Republic of Korea 12 October 2023
Princess Alexandra Hospital internal craft group – ASR data update	October 2023

Appendices

Appendix 1 - ASR Committees

SSA Registry Committee

A/Prof Matthew Scott-Young	Immediate Past President SSA, Orthopaedic Spine Surgeon
Dr Davor Saravanja	SSA secretary, Orthopaedic Spine Surgeon
A/Prof Greg Malham	SSA member, Neurosurgeon

ASR Steering Committee

Mr Michael Johnson	ASR Clinical Lead, Steering Committee Chair
Professor Susannah Ahern	Head, Clinical Outcomes data Reporting and Research Program (CORRP), Monash University
Adjunct A/Prof John Cunningham	Orthopaedic Spine Surgeon
Dr Rob Kuru	Orthopaedic Spine Surgeon
Professor Ilana Ackerman	Professor (Research), Clinical Epidemiology
Dr Ralph Stanford	Orthopaedic Spine Surgeon
Dr Gordon Dandie	Neurosurgical Spine Surgeon
Ms Maree Izatt	Project Coordinator, QUT Biomechanics & Spine Research Group (BSRG)

ASR Management Team

Mr Michael Johnson	Clinical Lead
Professor Susannah Ahern	Academic Lead
Dr Esther Apos	Registry Manager and Coordinator

ASR Operations Team

Dr Esther Apos	Registry Manager
Ms Charis Brown	Senior Research Coordinator
Ms Trieu-Anh Truong	Research Assistant/Data Analyst
Mr Sean Bulmer	Research Assistant
Mr Patrick Garduce	Data Analyst
Dr Ahmad Reza Pourghaderi	Principal Data Science Lead

A	D	pendix 2	- Partici	pating S	uraeons

State	Participating Surgeon	Specialisation	
Victoria	Michael Johnson	Orthopaedic Spine Surgeon	
	Peter Turner	Orthopaedic Spine Surgeon	
	John Cunningham	Orthopaedic Spine Surgeon	
	Yi Yang	Orthopaedic Spine Surgeon	
	Radek Kindl	Orthopaedic Spine Surgeon	
	Kris Lundine	Orthopaedic Spine Surgeon	
	Lawrence Tee	Orthopaedic Spine Surgeon	
New South Wales	Rob Kuru	Orthopaedic Spine Surgeon	
	Simon Abson	Orthopaedic Spine Surgeon	
	Ralph Stanford	Orthopaedic Spine Surgeon	
	Mark Davies	Neurosurgeon	
	Kevin Seex	Neurosurgeon	
Queensland	Dihan Aponso	Orthopaedic Spine Surgeon	
	Steven Yang	Orthopaedic Spine Surgeon	
	Peter McCoombe	Orthopaedic Spine Surgeon	
	Dennis Hartig	Orthopaedic Spine Surgeon	
	Leo Zeller	Orthopaedic Surgeon	
	Adam Parr	Orthopaedic Spine Surgeon	
	David Nielsen	Orthopaedic Spine Surgeon	
	John Albietz	Orthopaedic Spine Surgeon	
	Kate Campbell	Orthopaedic Spine Surgeon	
Tasmania	lmogen lbbet	Orthopaedic Spine Surgeon	
Western Australia	Peter Woodland	Orthopaedic Spine Surgeon	
	Farhaan Altaf	Orthopaedic Spine Surgeon	
	Siamak Seresti	Orthopaedic Spine Surgeon	
	Edward Baddour	Orthopaedic Spine Surgeon	
	David Dillon	Orthopaedic Spine Surgeon	

Appendices

Appendix 3 - pASR Participating Surgeon and Staff

Location	Name
QCH Orthopaedic Spine Surgeons	Dr Dennis Hartig
	Dr Simon Gatehouse
	Dr Anthony Athanasiov
	Dr Robert Labrom
	Dr Geoff Askin
	Dr Adam Parr
Queensland Children's Hospital Spine Outpatient Clinic	Rebecca Bruce, RN, Clinical Nurse Case Manager, Scoliosis and Spinal Deformity Service, Qld Children's Hospital, Brisbane
pASR Team at Queensland University of Technology - Biomechanics and Spine Research Group (BSRG)	Maree Izatt, BPhty, QUT Biomechanics & Spine Research Group, Brisbane, ASR Steering Committee member
	Selina Ho, BEng (Med), QUT Biomechanics & Spine Research Group, Brisbane

Appendix 4 - Approved Hospitals

State	Hospital
Victoria	Epworth Richmond
	Royal Melbourne Hospital
	Epworth Eastern
	Warringal Private Hospital
	Epworth Geelong
	The Avenue Hospital
New South Wales	John Hunter Hospital
	Newcastle Private Hospital
	Nepean Public Hospital
	Lake Macquarie Private Hospital
	Macquarie University Hospital
	Nepean Private Hospital
	Prince of Wales Hospital
	Prince of Wales Private Hospital
	St George Private Hospital
	St George Public Hospital
Queensland	Princess Alexandra Hospital
	Royal Brisbane and Women's Hospital
Tasmania	Calvary Private Hospital – Lenah Valley
Western Australia	St John of God Subiaco Hospital
	Royal Perth Hospital

Appendix 5 – Governance Overview

The ASR reports directly to the Spine Society of Australia which is the legal entity that owns the ASR.

SSA Registry Committee

The SSA Registry Committee is responsible for overall direction and financial management of the Spine Registry.

ASR Steering Committee

The ASR Steering Committee Membership comprises a multidisciplinary group of experts that are responsible for the governance of the ASR whose focus is on providing strategic direction and ensuring deliverables are met by the ASR.



Data Custodian

Monash University and the SSA have shared custodianship of the data, which includes accountability of the privacy, security and integrity of patient information held within the registry.

Research Ethics and Governance

The ASR received ethics approval under the National Mutual Acceptance (NMA) scheme through Melbourne Health, Victoria, in August 2016 (HREC approval number: 2016-165). All participating public and private hospitals have governance authorisation.

Appendices

Appendix 6 – Registry Methodology

Registry Population

The registry population includes any person undergoing elective surgery at participating private and public hospitals in Australia that involves the spine.

Inclusion Criteria

- Patients 18 years of age and older with surgery date which falls within the time frame specified for inclusion. This date will vary per institution/surgeon.
- Patients willing and able to provide informed consent and willing to accept the registry requirements.

Exclusion Criteria

- Patients under 18 years of age
- Trauma patients
- People whose primary language is other than
 English
- People with a cognitive impairment, an intellectual disability, or a mental illness

Patient identified as requiring spine surgery at a participating hospital $\dot{\mathbf{v}}$ Patient informed about ASR and given **Patient Information Brochure OPT-OUT?** NO YES Patient details and demographic data collected by practice. Pre-op Can be done by informing surgeon or questionnaires completed by the patient calling the freecall number **SURGERY** ÷ **DETAILS OF DIAGNOSIS & SURGERY RECORDED** ÷ At 6, 12 & 24 months post surgery outcome questionnares sent to patient via email or letter. **COMPLETED?** NO YES Patients contacted by the registry

Registry Process

Appendix 7 – Data Collection Process

ASR Database

Data is collected by practices/hospitals, surgeons and Monash registry staff and entered into the ASR database using a spine specific data management tool, pre-operatively and at 6, 12 and 24-months post surgery.

Data Collected

Diagnoses (including comorbidities) and surgical information (including complications) are entered into the database directly by surgeons. A list of the data collected is shown in Appendix 5.

Glassman Classification

The registry database also includes the globally recognised Glassman Classification. This is a diagnostic coding matrix that codes three primary elements commonly used in clinical decision making¹²:

Patient Reported Outcome Measures

The ASR collects patient reported outcome measures (PROMs).

The ASR uses the following validated questionnaires:

1. The Oswestry Disability Index (ODI) for lower back pain.⁹

2. The Neck Disability Index (NDI) for acute or chronic disability of the neck28^{10,29,30}

3. General quality of life (QoL) EuroQol five dimension (EQ-5DTM-3L) questionnaire³⁰

Appendix 8 - Patient diagnoses and surgical data collected by the ASR

Comorbidities

- Diabetes Type 1
- Diabetes Type 2
- Endocrine-metabolic
- Gastrointestinal
- Hepatic
- Hypertension
- Neurological
- Osteoporosis
- Psychiatric/Behavioural
- Renal
- Rheumatological
- Thrombo-embolic
- Vascular
- Current Smoker
- BMI >35kg/m²
- Other

Deformity

- **Degenerative disease**
- **Glassman classification**
- Infection
- Inflammation
- **Revision surgery**
- **Spondylolisthesis**
- Tumour

Surgical treatment information includes:

- Surgical approach
- Staging
- Neuromonitoring
- Navigation
- Type of surgery and instrumentation
- Bone grafting

Appendices

Appendix 9 – Data for the discectomy cohort

Data for the discectomy cohort low, medium and high ODI analysis.

p-values were calculated using Fisher's exact and Kruskal-Wallis tests for categorical variables and continuous variables respectively.

	Low pre-operative ODI	Moderate pre-operative ODI	High pre-operative ODI	p-value
	(0 to <30)	(30 to <61)	(61 to 100)	
n	54	174	68	
Pre-operative ODI score				
mean (SD)	20.8 (6.6)	46.0 (8.4)	72.2 (8.7)	
median (IQR)	22.0 (18.0, 26.0)	46.0 (40.0, 54.0)	70.0 (66.0, 77.0)	N/A
12-month post-operative ODI score				
mean (SD)	9.2 (11.2)	13.5 (14.2)	16.1 (18.2)	
median (IQR)	6.0 (0.0, 14.0)	8.0 (2.0, 20.0)	11.0 (2.0, 20.0)	0.061
ODI score change				
mean (SD)	-11.6 (11.8)	-32.5 (16.1)	-56.2 (20.2)	
median (IQR)	-14.0 (-20.0, -8.0)	-36.0 (-43.0, -23.0)	-59.5 (-70.0, -47.0)	<0.001
Improved				
(ODI decreased by at least 12.8)				<0.001
Yes	30 (55.6%)	153 (87.9%)	64 (94.1%)	
No	24 (44.4%)	21 (12.1%)	4 (5.9%)	
Age				
mean (SD)	48.1 (14.9)	52.0 (16.1)	48.7 (15.0)	
median (IQR)	46.0 (36.0, 62.0)	49.5 (40.0, 66.0)	46.0 (36.0, 61.5)	0.12
Sex				0.02
Male	40 (74.1%)	99 (56.9%)	34 (50.0%)	
Female	14 (25.9%)	75 (43.1%)	34 (50.0%)	
Comorbidities reported				0.46
Yes	15 (27.8%)	36 (20.7%)	13 (19.1%)	
No	39 (72.2%)	138 (79.3%)	55 (80.9%)	

Number of Comorbidities reported				0.88
0	39 (72.2%)	138 (79.3%)	55 (80.9%)	
1	10 (18.5%)	19 (10.9%)	7 (10.3%)	
2	3 (5.6%)	9 (5.2%)	5 (7.4%)	
3	1 (1.9%)	5 (2.9%)	1 (1.5%)	
4	0 (0.0%)	1 (0.6%)	0 (0.0%)	
5+	1 (1.9%)	2 (1.1%)	0 (0.0%)	
ASA Classification				0.15
1	23 (42.6%)	46 (26.4%)	24 (35.3%)	
2	9 (16.7%)	57 (32.8%)	16 (23.5%)	
3	4 (7.4%)	10 (5.7%)	6 (8.8%)	
4	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Not stated	18 (33.3%)	61 (35.1%)	22 (32.4%)	
Glassman score for symptoms				0.003
Back pain dominant, acute	0 (0.0%)	1 (0.6%)	0 (0.0%)	
Leg pain dominant, acute	6 (11.1%)	38 (21.8%)	28 (41.2%)	
Back pain = Leg pain, acute	0 (0.0%)	1 (0.6%)	1 (1.5%)	
Back pain dominant, chronic	1 (1.9%)	2 (1.1%)	1 (1.5%)	
Leg pain dominant, chronic	35 (64.8%)	81 (46.6%)	22 (32.4%)	
Back pain = Leg pain, chronic	0 (0.0%)	2 (1.1%)	0 (0.0%)	
Neurogenic claudication	0 (0.0%)	0 (0.0%)	1 (1.5%)	
Cauda equina syndrome	0 (0.0%)	0 (0.0%)	1 (1.5%)	
Not stated	12 (22.2%)	49 (28.2%)	14 (20.6%)	

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