Australian Spine Registry

Annual Report 2022

MONASH University

Australian Spine Registry

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Foreword

It is with great pleasure that I present the Australian Spine Registry 2022 Annual Report.

2022 was a year of playing catch up following the difficult COVID-19 restrictions. Even with the relaxing of the COVID-19 restrictions, patients, surgeons, practice staff and hospitals continued to be affected, however, patient recruitment by the participating practices continued to grow. At the time of publishing this annual report, the registry had over 4000 patients and patient follow up and data collection compliance remained over 80%.

The ASR also met various milestones. The registry signed the Commonwealth Government agreement and received its first tranche of funding. As a direct result, the ASR was able to increase its team with the addition of 2 new staff members. In late December the ASR submitted a comprehensive evidence map on how other spine registries collect and analyse comorbidity data to the European Spine Journal. This was published as an open access paper in early January 2023.

In 2022 the planned staged expansion of the registry slowly commenced. We initiated communications with the Royal Perth Hospital, North Shore Private, Ballarat Base Hospital, St John of God Ballarat and Epworth Geelong. Four of these hospitals are now in the governance approval process. Royal Adelaide Hospital, which was first approached in 2021, is now also in the final throws of the governance approval process.

The ASR also engaged nationally for the first time in 2 years with surgeons, stakeholders and industry at the 2022 Spine Society of Australia Annual Scientific Meeting in Darwin. Several papers were presented at the meeting showing the advancement of the ASR database, infrastructure, and data analysis.

Although the ASR secured the two-year Commonwealth Government grant, the ASR continues to seek industry support and it is very grateful for the continued support from industry, health insurers and the Spine Society of Australia.

We also need to thank Dr Esther Apos, our Registry Manager 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)

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

Acknowledgements

The growth of the ASR is only possible through the efforts of many people.

It is essential that we thank:

- our patients, whose willingness to be involved and to complete the registry specific questionnaires both pre-operatively and post-operatively, makes the registry possible.
- all the 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. With their oversight, strategic planning and direction, the registry continues to make steady progress.
- the ASR team, Dr Esther Apos, Registry Manager, Ms Charis Brown, Senior Research Coordinator, Mr Sean Bulmer, our research assistant.
- Mr Matthew Quiqley for oversight and expertise with the comorbidity mapping project which was published in January 2023 in the European Spine Journal.
- Professor Susannah Ahern and her 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 web-based interface.
- Mr Raj Khatri, the ASR Business Manager.
- 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 Ms Rosalind Martin, Assistant Director - Quality, Performance and Reporting Section, Health Economics and Modelling 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 2023. 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 leg, numbness around the anus, and loss of bowel or bladder control
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 ≥ 7 contiguous vertebrae have been fused in one procedure
CORRP	Clinical Outcomes 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
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
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
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

Executive Summary

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

The data presented in this report was collected for all patients recruited between 15 January 2018 and 15 January 2023 and an analysis was made of both the entire patient group and specific patient cohorts. This year we have added a new cohort of patients (patients that have "complex surgery" on greater than seven levels of the spine) and have provided aggregated data on the use of navigation systems and neuromonitoring in spinal surgery.

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 80%. Another key initiative of the registry was the addition of a surgeon specific dashboard. Launched in mid-2022, the dashboard allows for surgeons to easily review their data and compare it with the larger registry cohort.

A quick glance at ASR patient data shows:

- The registry had a total of 3733 participants who had surgery and comprised 1942 (52%) males and 1791 (48%) females, with a median age at the time of surgery of 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 between surgeon related comorbidities (SRCs) and American Society of Anesthesiologists classification (ASA) in all cohorts. For example, for the entire ASR cohort, SRC show that 62% of patients had no comorbidities compared to ASA where 24% of patients were scored ASA 1. This is likely due to under-reporting of co-morbidities by surgeons.
- Discectomy and ACDF patients were generally younger (median age of 48 years and 55 years respectively) and had fewer comorbidities when compared to the total patient cohort.
- Patients who presented with L4-L5 spondylolisthesis had a median age of 71 years.
- Of the patients 60 years old and over who underwent complex surgery, 69% were females. The median age of this cohort was 69.
- In 2022, only 6% of ASR procedures reported the use of neuromonitoring, which was lower than other years.
- In 2022, of the procedures recorded, 28.5% used some type of navigation.

- 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), 14 (12 months) and 12 (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.
  - » 85%, 84% and 83% of the patients in the discectomy cohort exceeded the ODI MCID (12.8) at 6, 12 and 24-months respectively, which indicates a significant improvement post-surgery.
  - » 54%, 63% and 60% of the patients in the ACDF cohort exceeded the NDI MCID (17) at 6, 12 and 24-months respectively.
  - » 68%, 70% and 76% of the patients in the L4-L5 spondylolisthesis cohort exceeded the ODI MCID (12.8) at 6, 12 and 24 months.
  - » 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.

In February 2022, the ASR was pleased to receive a Federal funding grant of $900,000 to allow further expansion nationally of the registry. Additional funding support for the registry was also gratefully received from medical device companies, health insurers and the Spine Society of Australia (SSA).

The Australian Spine Registry's Vision

Our Vision

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

Our Mission

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

Our Values

- 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:

Key Milestones of the ASR in 2022

February 2022

Commonwealth government funding secured for 2 years for the ASR.

Formation of SSA ASR Oversight Committee.

May 2022

Fourth ASR Annual Report published.

October 2022

Appointment of a new Registry Coordinator and Business manager.

December 2022

Comorbidities evidence map paper accepted by the European Spine Journal.

Paediatric Spine Registry (pASR) pilot sub-study added to the ASR.

Snapshot of The Australian Spine Registry

620

Increase in the number of patents in the past 12 months from January 15 2022 to January 15 2023.

3198

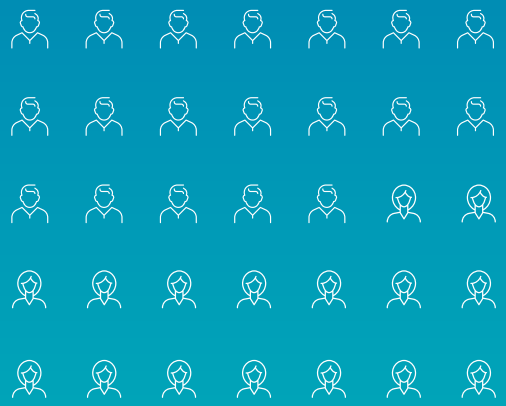
Total number of procedures captured.

96 (2.6%)
opted-out

22 (0.6%)
deceased**

1942
Male

1791
Female



52%

48%

PROMs completion	Pre-Op	6 Mth	12 Mth	24 Mth
Patients eligible (n)	3725	3406	3061	2223
Complete data (n)	2996	2698	2444	1662
Complete data (%)	80.4%	79.2%	79.8%	78.2%

(Patients recruited up to 15 January 2023)

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

***Data collected directly from families or practices*

Patients
3756*

Surgeons
19 Actively Recruiting

Sites
20

Prologue

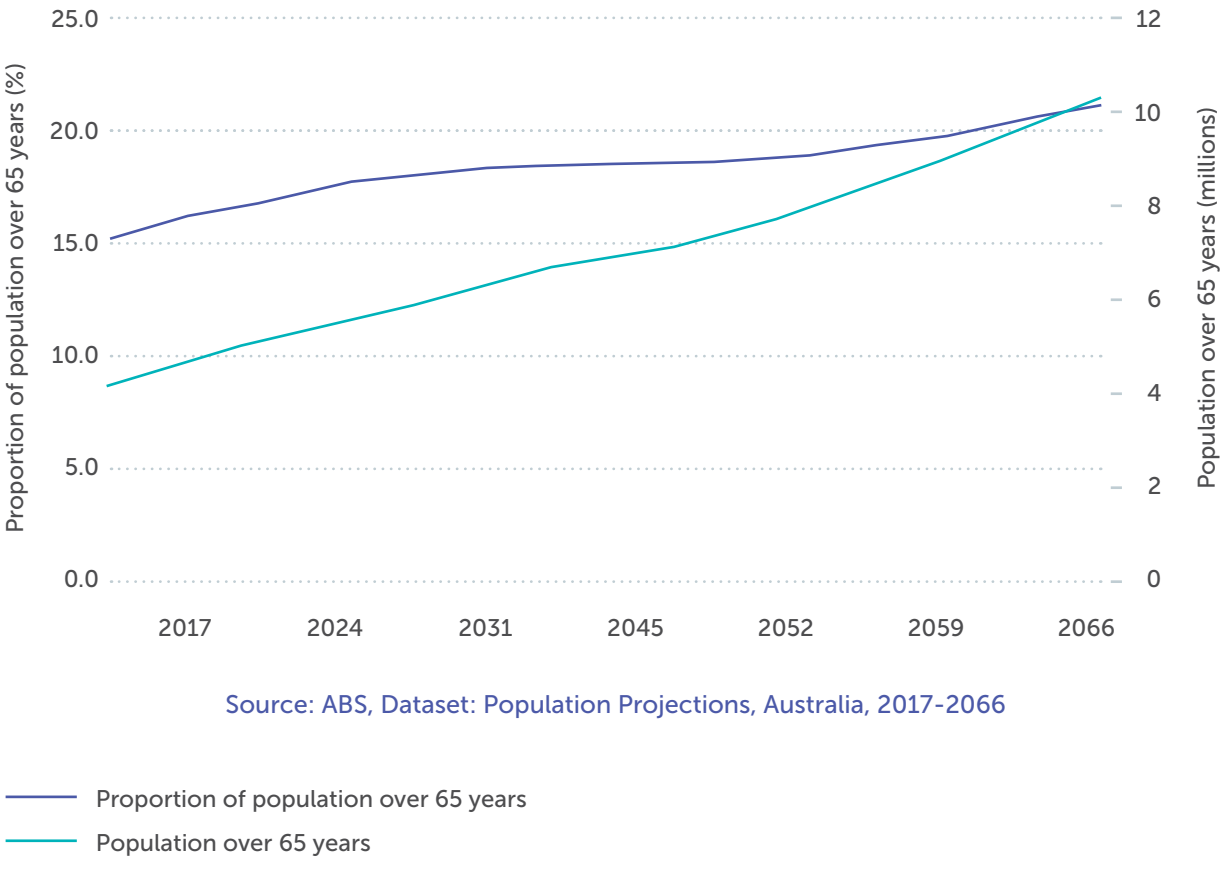
Australians are living longer. The AIHW reports[a] that:

- At June 30 2020, 1 in 6 Australians are aged 65 and over (16%).
- The workforce participation rate of older Australians was 15% in 2021.
- 18% of older Australians had a severe or profound disability in 2018.
- Australian men aged 65 could expect to live another 20 years and women another 23 years.

By 2066, it is projected that:

- There will be just over 4.5 million people aged 65-74 (Figure 1).
- People aged 75-84 will account for one-third (34%, 3.5 million) of people 65 years and over.
- 1 in 5 older people will be aged 85 and over (21%, 2.2 million) (ABS 2018).

Figure 1: Projected Australian population over 65 years and as a proportion of total population over time



Source: ABS, Dataset: Population Projections, Australia, 2017-2066

a https://www.aihw.gov.au/reports-data/population-groups/older-people/overview (accessed 9 April 2023)

This has a profound effect on the Australian healthcare system. The Australian community spends over $1 billion on spine surgery every year alone.

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, more complex surgery for adult scoliosis may cost around $160,000. These complex procedures use sophisticated navigation and neuromonitoring equipment which add to these costs but have the benefits of improved safety and accuracy for patients.
- AIHW data shows the rate of complex spine surgery (Level >3), which has a higher implantable device cost component, and higher rates of complications,[3] is growing faster, compared to other spine procedures categories.[4]

The ASR recognises that with new technologies spine surgery costs may increase. Furthermore, with more older Australians undergoing complex spine surgery, this is a key group that needs to be monitored, evaluated, and analysed. This year the ASR is including an overview of the use of navigation and neuromonitoring in spine surgery and has analysed patients which have undergone complex surgery. We hope you enjoy reading our fifth Annual Report.

Summary of the ASR

Surgeon and Hospital Engagement

Spine surgery is performed by both orthopaedic surgeons and neurosurgeons. In 2022, the ASR had 19 active users (16 orthopaedic spine surgeon and 3 neurosurgeons).

With the registry now moving into a staged expansion, it is anticipated that the number of actively participating surgeons will steadily increase. Active engagement with hospitals, surgeons and practice staff will be paramount to ASR's ongoing success based public hospitals.

Figure 2: (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

8 Public sites approved

12 Private sites approved

Patient Uptake

Victoria started to lift elective surgery restrictions in February 2022 whilst NSW lifted all restrictions on elective surgery on 7 March 2022. According to an analysis by the Australian Medical Association, in January 2023 Victoria had almost 135,000 patients on the elective surgery waitlist, close to 60,000 more people than the estimated backlog of 77,845 in New South Wales.

As a consequence of this, ASR patient recruitment during 2022 was impacted (Figure 4). A return to pre-pandemic recruitment levels will depend on public and private hospitals having the resources to return to pre-pandemic activity.

Only 96 (2.6%) of patients had opted out of the registry (Figure 5). We are aware that 22 (0.6%) have died which we believe might be under-represented. The ASR is currently applying for data linkage permission to the National Death Index. Cause of death is not currently collected by the registry.

Figure 3: Accumulation rate of patients from registry launch on 15 January 2018 to 15 January 2023

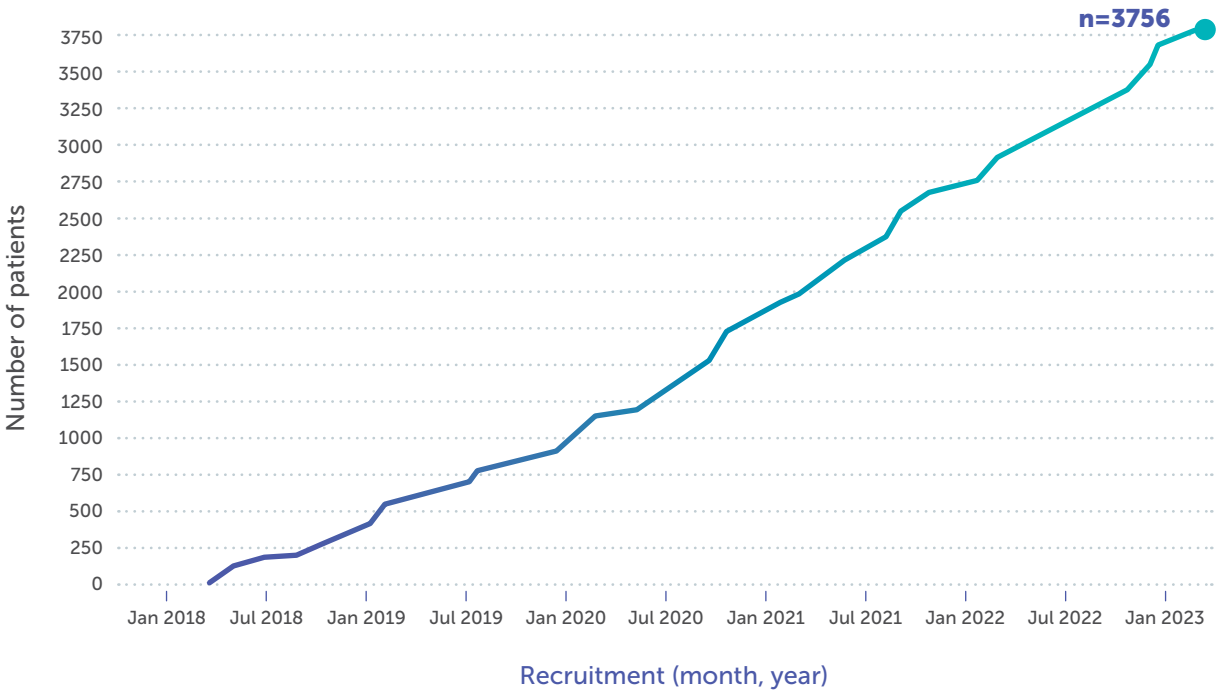
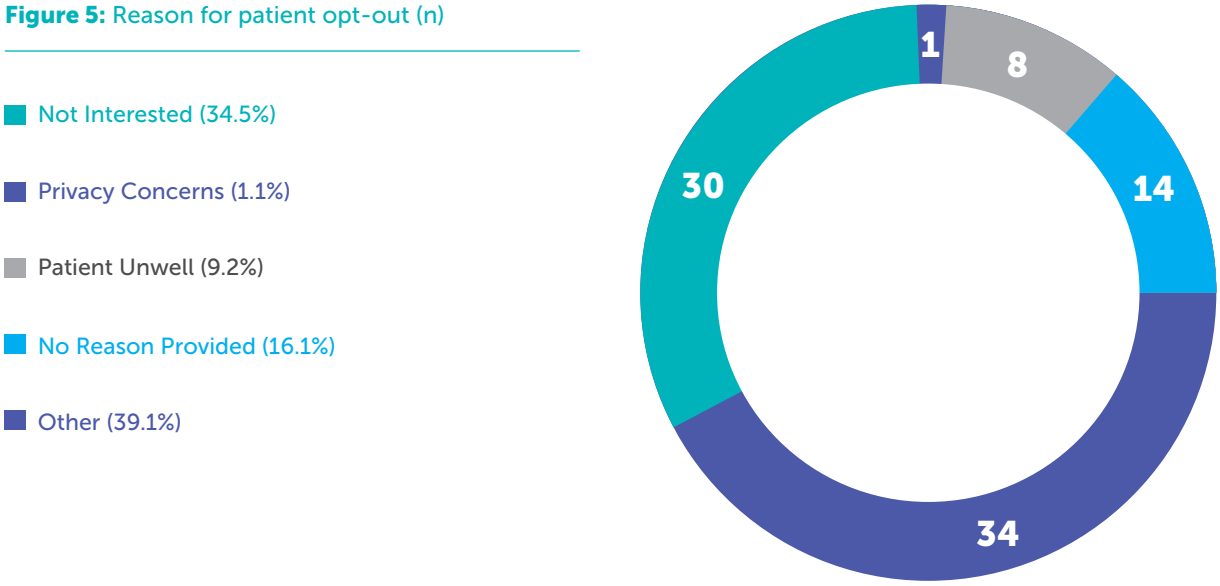


Figure 4: Patient recruitment by year

Figure 5: Reason for patient opt-out (n)

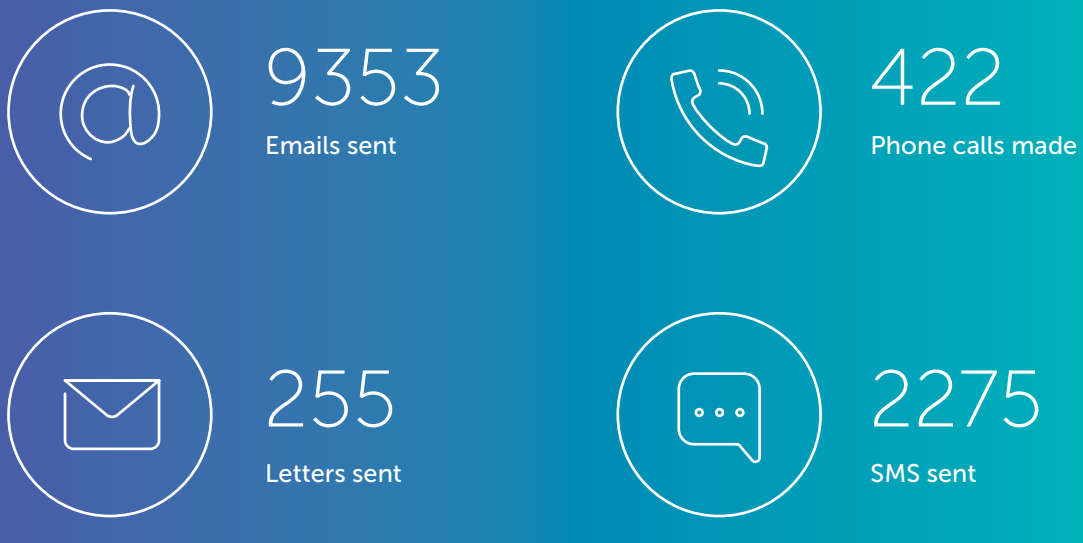


Registry Communications and Responses

Post-operatively, 88.9% of patients automatically received the questionnaires by email at 6, 12 and 24 months after their surgery. The remaining patients receive paper-based questionnaires.

Figure 6 outlines the total number of emails and contact attempts by the registry up to January 15, 2023. For patients with no email address and where paper-based questionnaires are mailed out, patient compliance is high but at a considerably greater expense to the registry when compared to email. SMS reminders were introduced in 2021 and have significantly reduced the number of contact attempts by the registry.

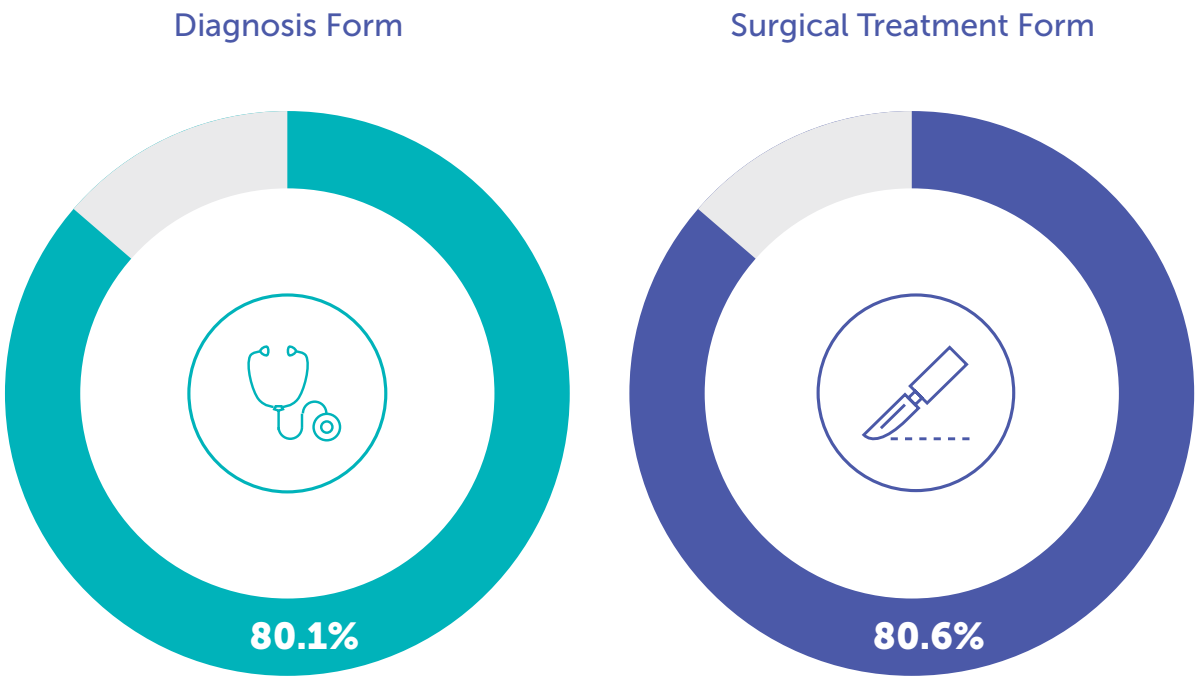
Figure 6: Post-operative communication methods to eligible patients in the period between 15 January 2021 – 15 January 2022



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 2022 AR period is shown in Figure 7.

Figure 7: Surgeon data entry completion rate



Data completeness trending was instigated in February 2019, and the registry has set an 80% data completeness threshold. Each month surgeons receive an SMS update with graphical information displaying their personal data compliance compared to the deidentified data of other participating surgeons. Since the beginning of 2021, data entry by surgeons has remained above 80%. Data completion by many practises is generally good but variable. Public hospital data entry completion varies depending on hospital and 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.

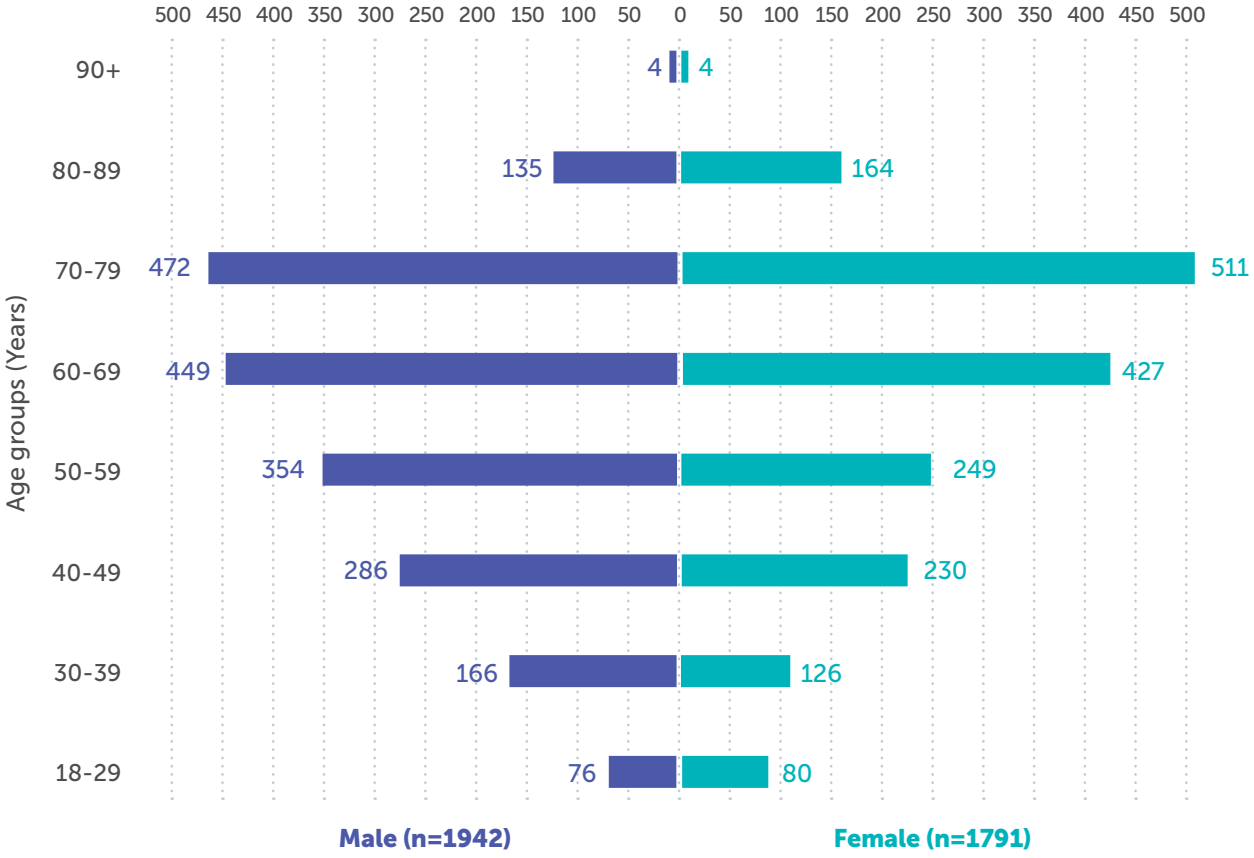
Overview of ASR Patients

The following information is an overview of the collected data and results taken from all registered patients

Patient Demographics

3733 patients were eligible for analysis. There were 1942 (52%) males and 1791 (48%) females. 73% of male and 76% of female patients were over the age of 50. (Figure 8). We note that the most common decile having spine surgery is between 70-79 years of age, representing 26% of the patients undergoing spine surgery.

Figure 8: Patient age distribution at the time of surgery



Treatment types

The data collection software categorises patients into 3 basic groups:

- Cervical
- Deformity
- Thoracolumbar

The breakdown of patients in each group is shown is shown in Table 1. The majority of patients in the registry undergo thoracolumbar procedures.

Table 1: Percentage of patients by treatment types

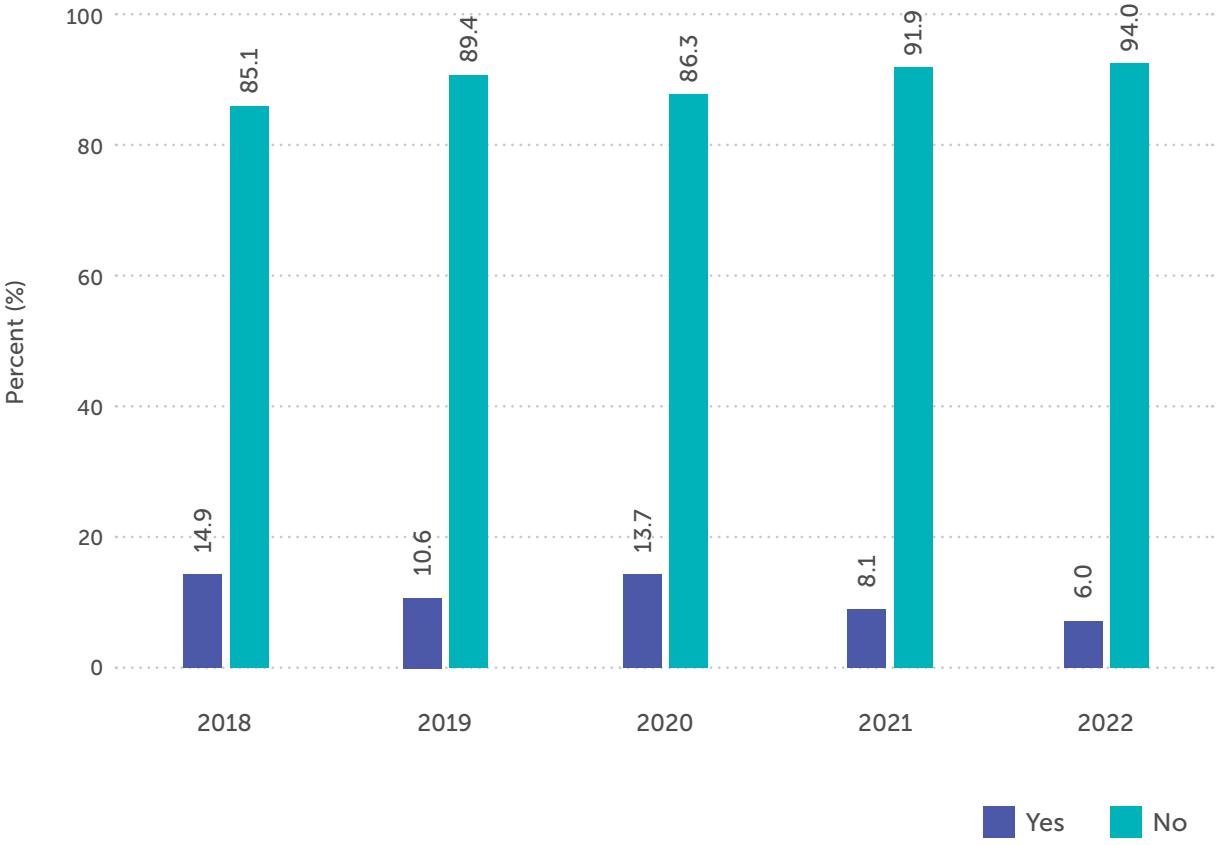
Treatment type	Patients with treatment type (n=3735)
Cervical	533 (14.3%)
Deformity	151 (4.0%)
Thoracolumbar	3051 (81.7%)

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.

Neuromonitoring

Neuromonitoring is a technique used during spine surgery and allows intraoperative assessment of spinal cord function through real-time feedback from sensory tracts, motor tracts, and individual nerve roots. As shown in Figure 9, the use of neuromonitoring pre COVID-19 was between 11-15 %. During 2021 and 2022, when only Category 1 and 2A elective procedures were permitted, the use of neuromonitoring decreased. We plan on completing and reporting a more complete analysis of neuromonitoring in future reports.

Figure 9: Percentage of neuromonitoring use between 2018 – 2022 for ALL reported spine procedures



Navigation

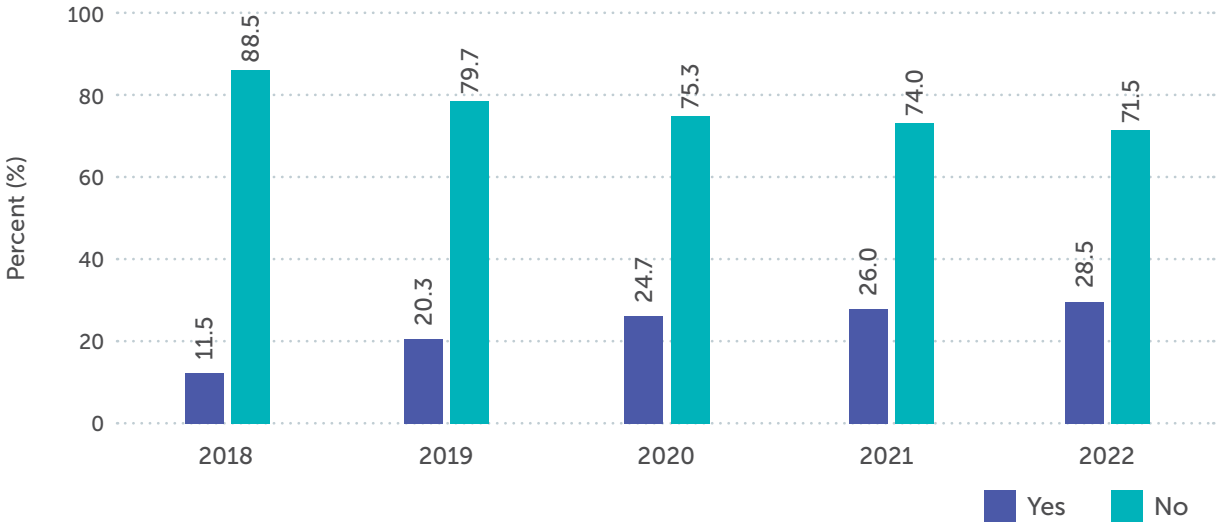
Spinal navigation allows the surgeon to access real-time, three dimensional and virtual images of the spine in relation to the surgical instruments intraoperatively. Whilst navigation tends to be used in more complex surgery, its usage in more standard surgery is surgeon dependent.

We analysed the aggregate frequency of use of the following navigation tools:

- O-arm
- Robotic guidance
- CT Navigation
- Intra-op O-arm
- Increased intensity (II) C-arm
- 7D Flash
- Other

As shown in Figure 10, the frequency of navigation use in surgery has increased over time despite COVID-19 elective surgery restrictions.

Figure 10: Percentage of navigation use between 2018 – 2022 for ALL reported spine procedures



b https://www.wheelessonline.com/issls/section-11-chapter-14-navigation-in-spine-surgery/ (Accessed 9 April 2023)

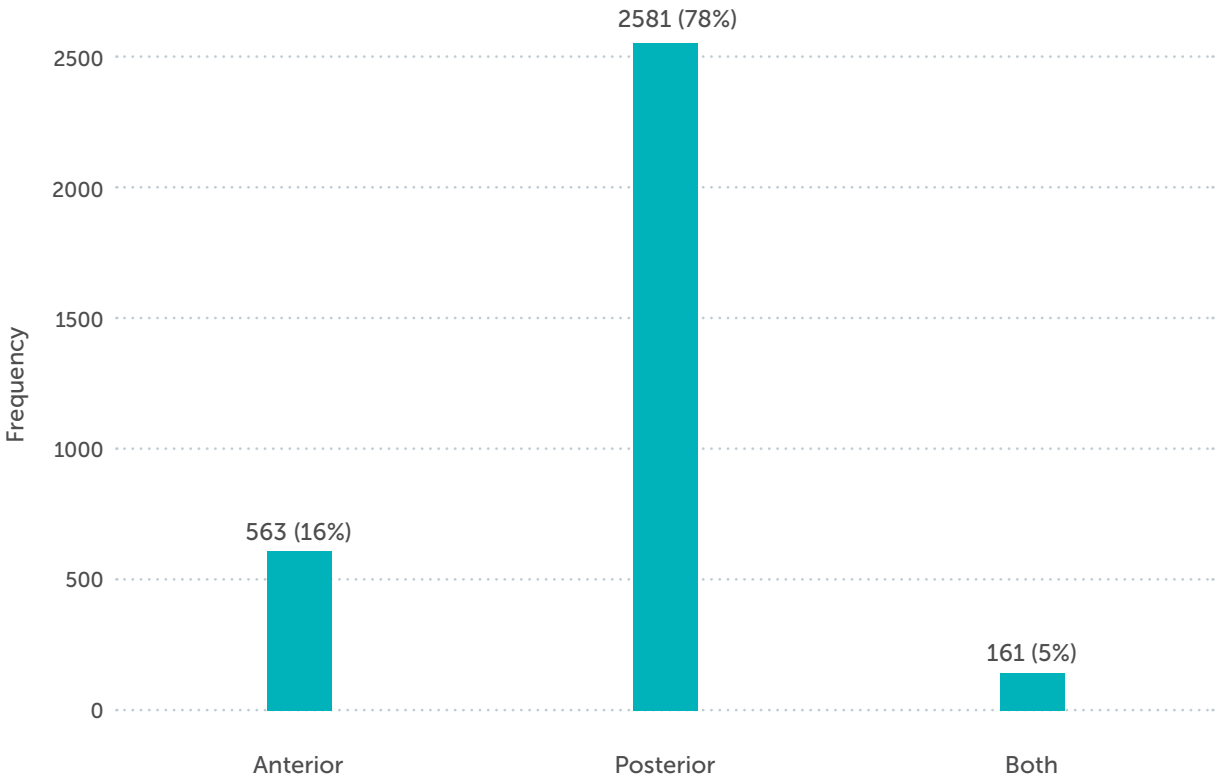
Surgical Approach

Spine surgeries can be performed through anterior, posterior, lateral, or combined anterior–posterior approaches.

The difference between an anterior and posterior approach is how the spine is accessed. Anterior surgery approaches the spine from the front (anterior) of the body, while posterior surgery approaches the spine from the back (posterior) of the body.

Depending on the diagnosis, type of surgery performed and the anatomical location of the pathology, specific approaches are used. The ASR has collected data on the frequency of the different approaches. 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 11).

Figure 11: Frequency of surgical approaches in ALL captured procedures



Surgeon Reported Comorbidities (SRCs) and ASA

Many patients undergoing spine surgery have general health comorbidities. The most common age group for surgical interventions is people between 60 and 80 years of age[5]. 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 depression[6].

In an attempt to stratify patient co-morbidities, the ASR has analysed both SRCs and ASA scores. ASA is used to stratify the preoperative health status and for assessing the risk of intra- and post-operative complications for spine surgery patients[7]. The ASA classification was developed in 1942 and has undergone various revisions with the latest amendment in 2020[8]. 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

When comparing the ASA scores with the SRCs, variability was noted.

76% of patients were given an ASA score of greater than 1 indicating that these patients presented with "mild" to "severe" disease at the time of their surgery (Figure 13). ASR data indicates that 38.1% of patients presented with one or more SRCs (Figure 12). Hypertension was the most common comorbidity reported (data not shown).

When SRCs were compared between surgeons, the rate of reporting varied. This suggests 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.

c https://www.asahq.org/standards-and-guidelines/asa-physical-status-classification-system (accessed 6 April 2023)

Figure 12: Breakdown of number of comorbidities reported in all patients

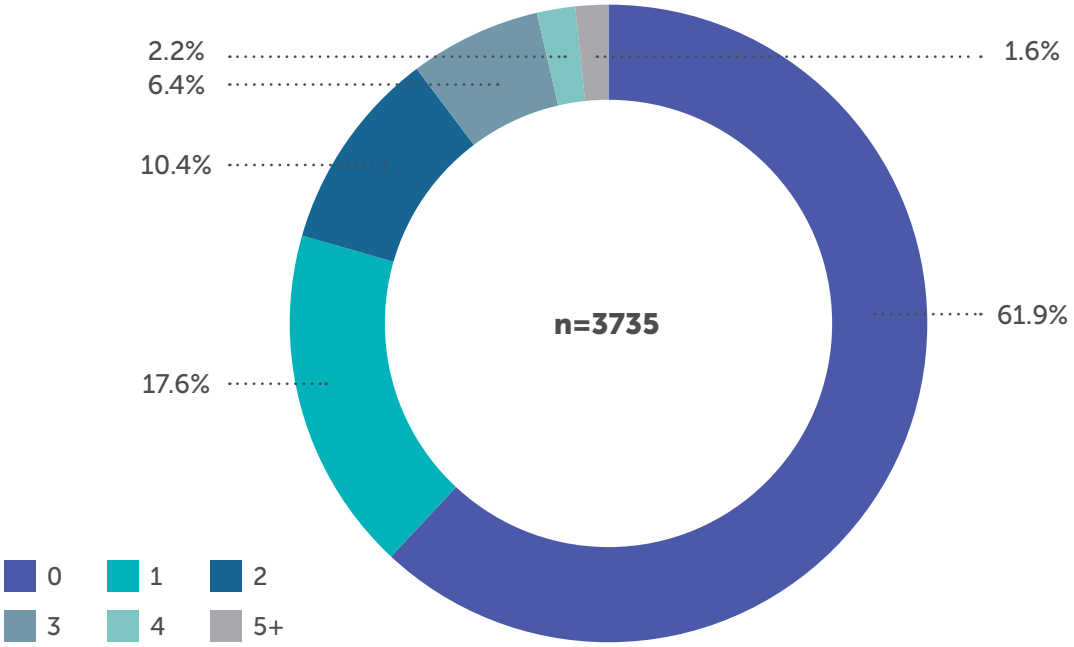
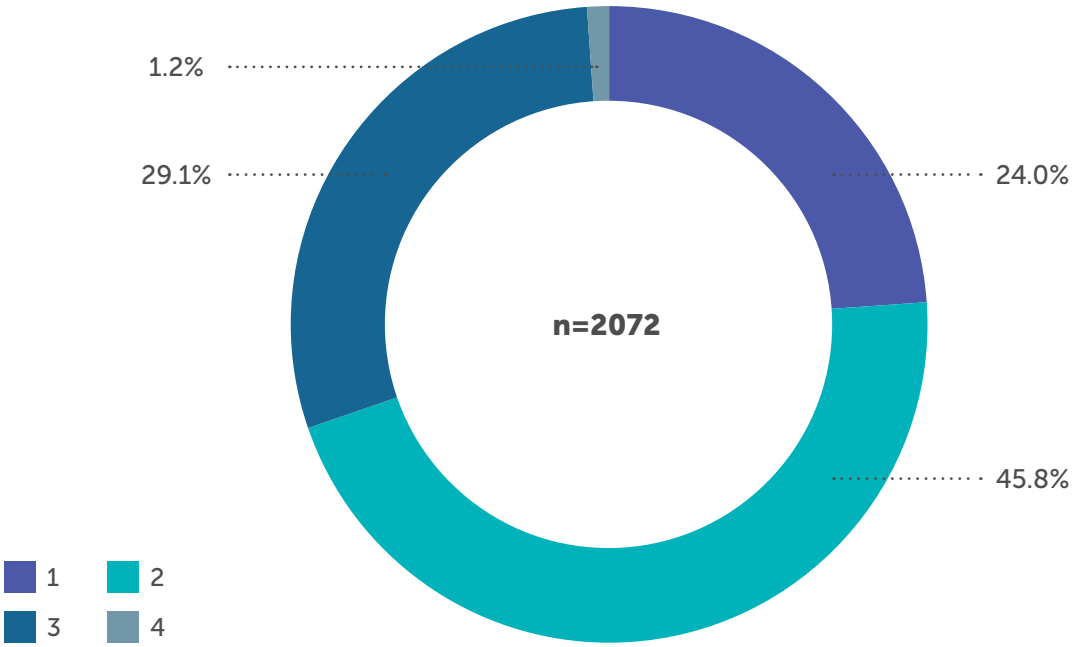


Figure 13: ASA score reported in ALL patients where ASA scores were recorded



Patient Reported Outcome Measures - Total Cohort

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

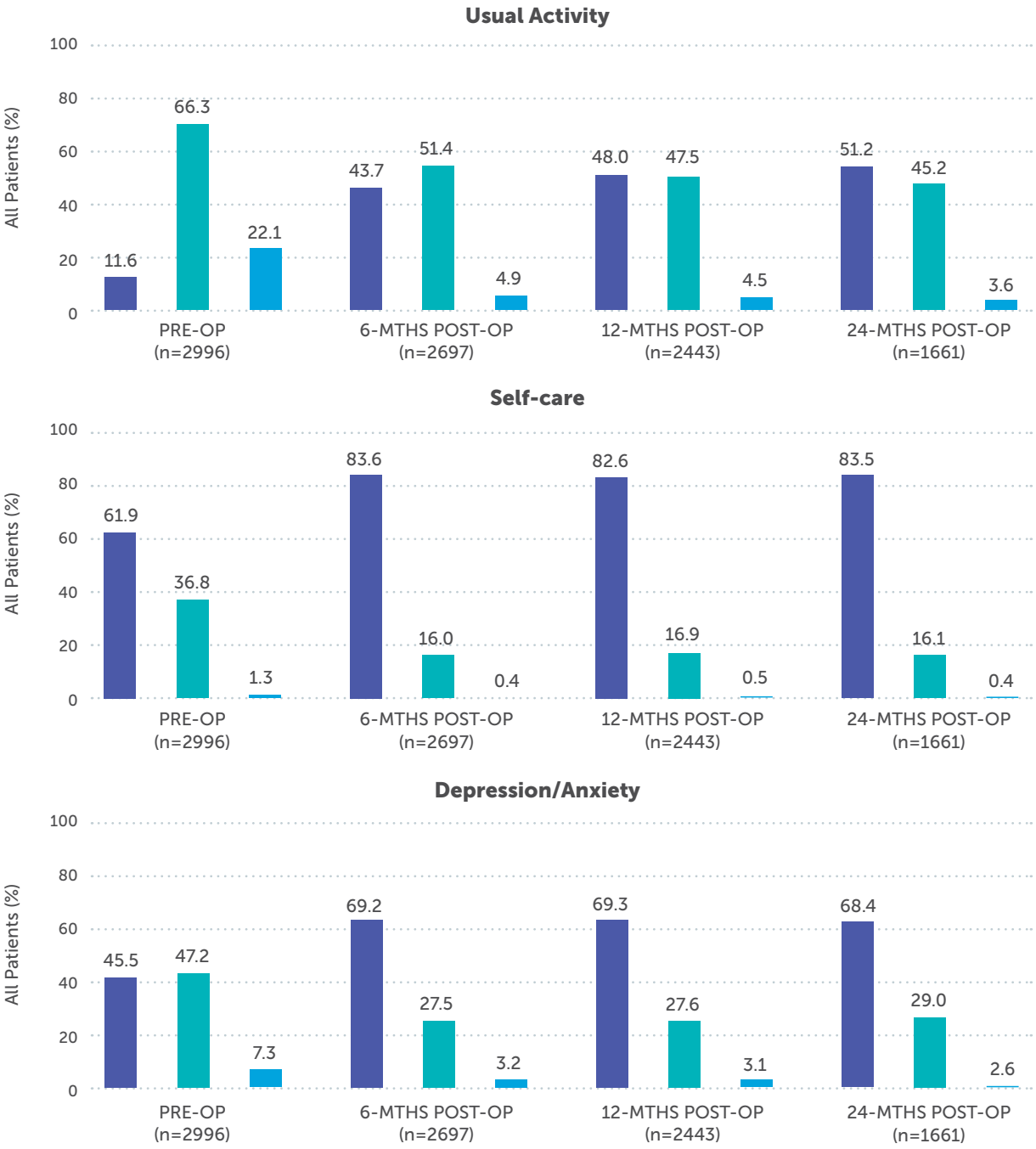
EQ-5D-3L Quality of Life (All Patients)

Figure 14 shows the EQ-5D-3L scores for any patient that has completed the EQ-5D-3L for each of the 5 domains (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 66% at 6 months, 63% at 12 months and 62% at 24 months.
- **Usual activity:** Some/extreme problems were 88% pre-operatively, and reduced to 57% post–operatively, a 31% reduction.
- **Mobility:** The key finding is that 79% experienced some/extreme mobility problems pre-operatively and this reduced by nearly 50% to approx. 39% at 6 months and remained stable. Given the age demographic distribution some of the persisting mobility problems may be non-spinal in origin.
- **Depression/anxiety:** Patient who experienced some/extreme anxiety/depression decreased from 55% at pre-op to approximately 30% at post-op timepoints; a reduction of over 25%.
- **Self-care:** There has been a reduction in self-care problems post-op compared with pre-op from about 38% to 16%, which is over a 50% reduction.

Figure 14: 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



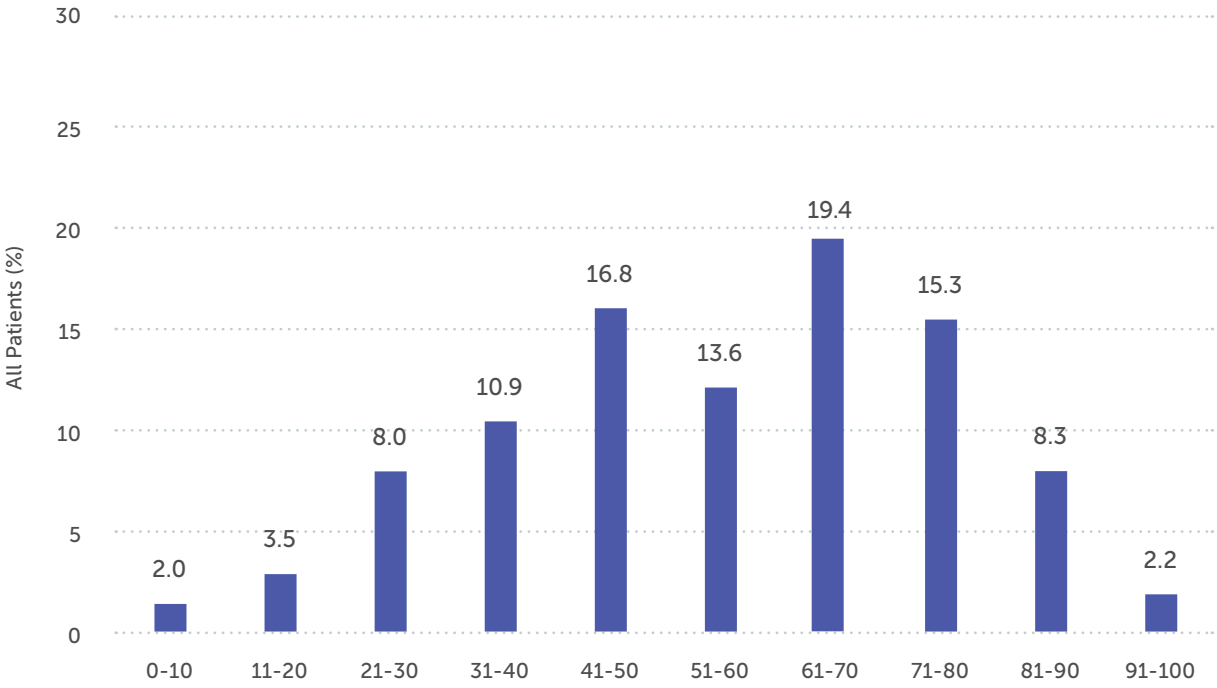
The EQVAS is a general health visual analogue score. A higher score indicates improved patient perception of general health. The median EQVAS scores improved by 20 points from a median score of 60 pre-operatively, to a median score of 79 at 6 months and 80 at 12 months post-operatively. This improved score of 80 was maintained at 24 months follow up (Table 2; Figure 15).

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

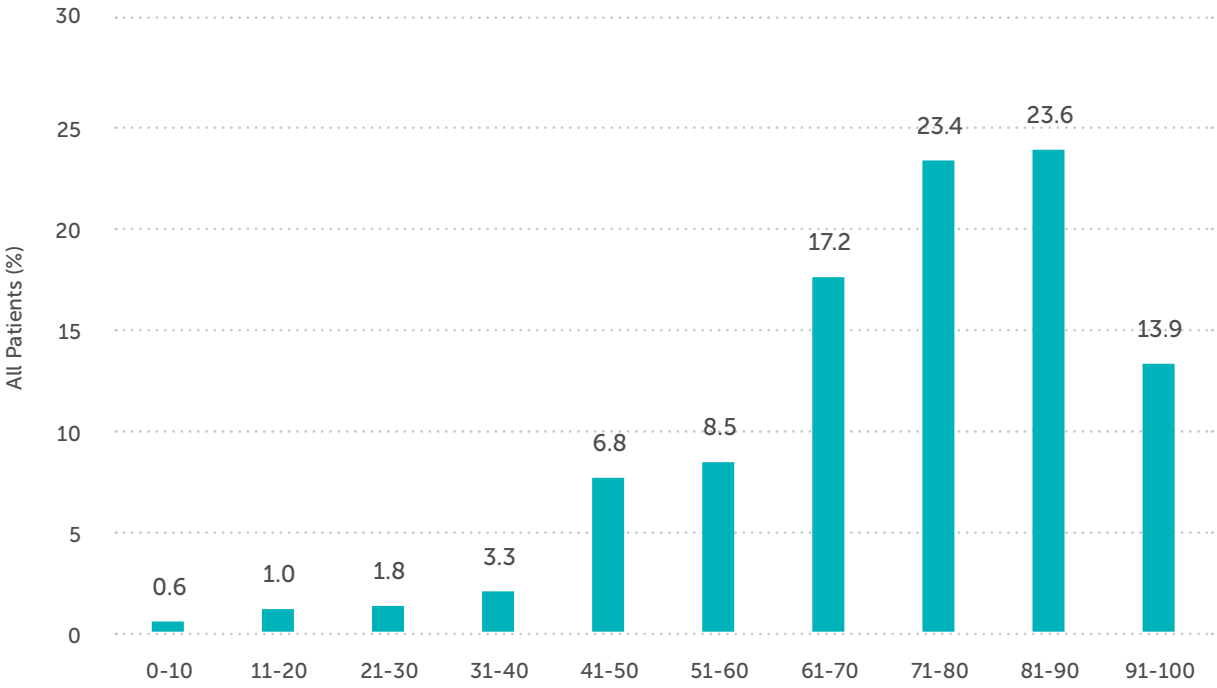
EQVAS	Pre-operative	6-Months	12-Months	24-Months
n	2996	2697	2443	1661
Mean (SD)	57.9 (20.4)	73.8 (17.9)	74.4 (18.2)	75.0 (17.7)
Median (IQR)	60.0 (42.0, 71.0)	79.0 (65.0, 88.0)	80.0 (65.0, 90.0)	80.0 (65.0, 90.0)

Figure 15: 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*

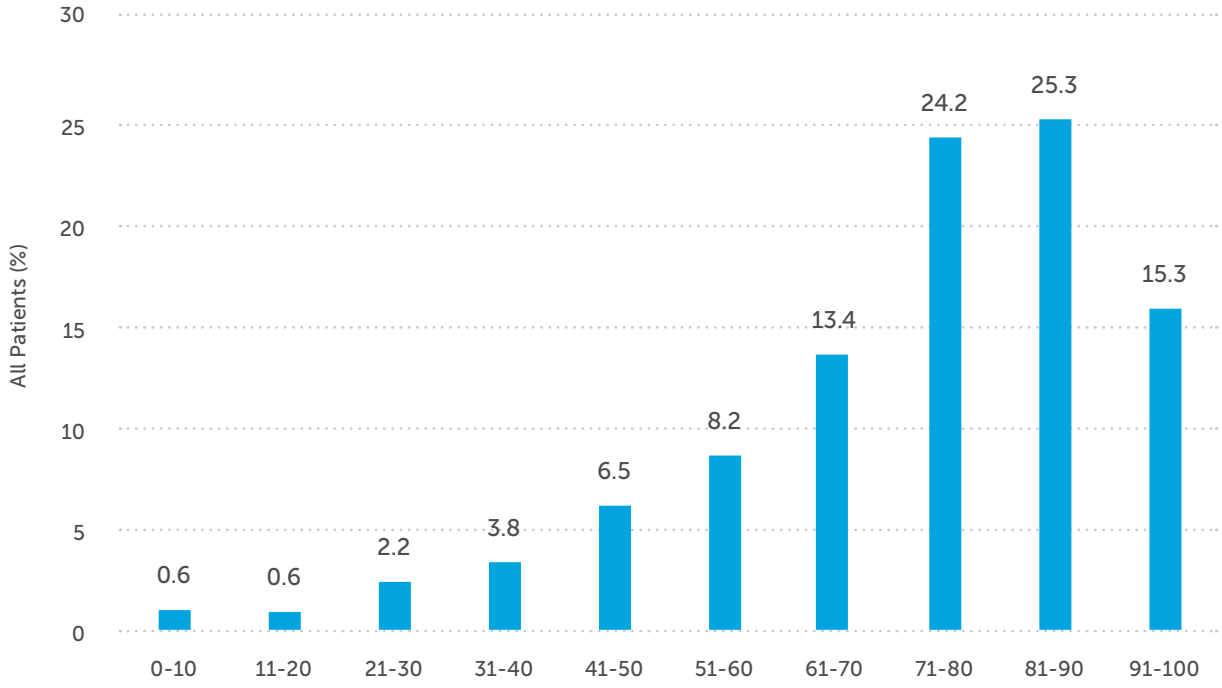
(a) Pre-operative EQVAS (n=2996)



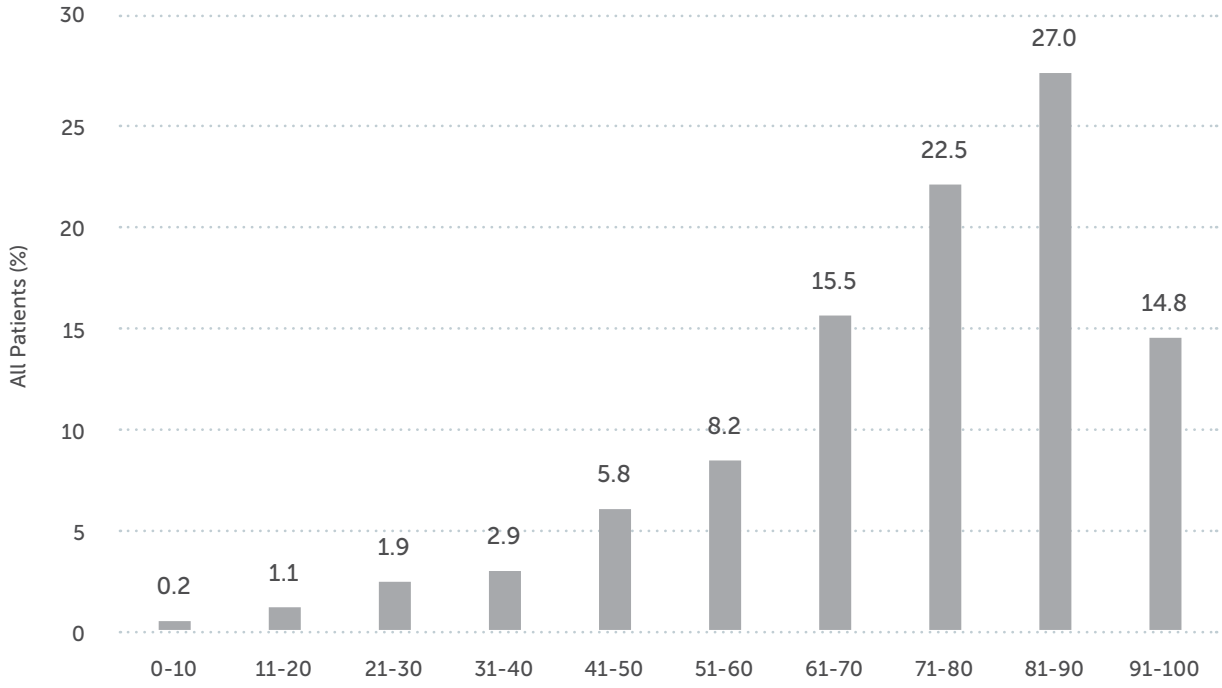
(b) Six-month post-operative EQVAS (n=2697)



(c) Twelve-month post-operative EQVAS (n=2443)



(d) Twenty-four-month post-operative EQVAS (n=1661)



Oswestry Disability Index (ODI)

The ODI is a disease specific questionaire used for lumbar and thoracolumbar surgery particularly in adults. There are 10 domains examined by the ODI which provide individual domain scores and an overall ODI score. The predefined levels of patient disability based on score is shown in Table 3[9]. As indicated in Table 3, a higher score indicates a higher 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 from 12 months (within the minimal disability range).

Table 3: ODI Scoring

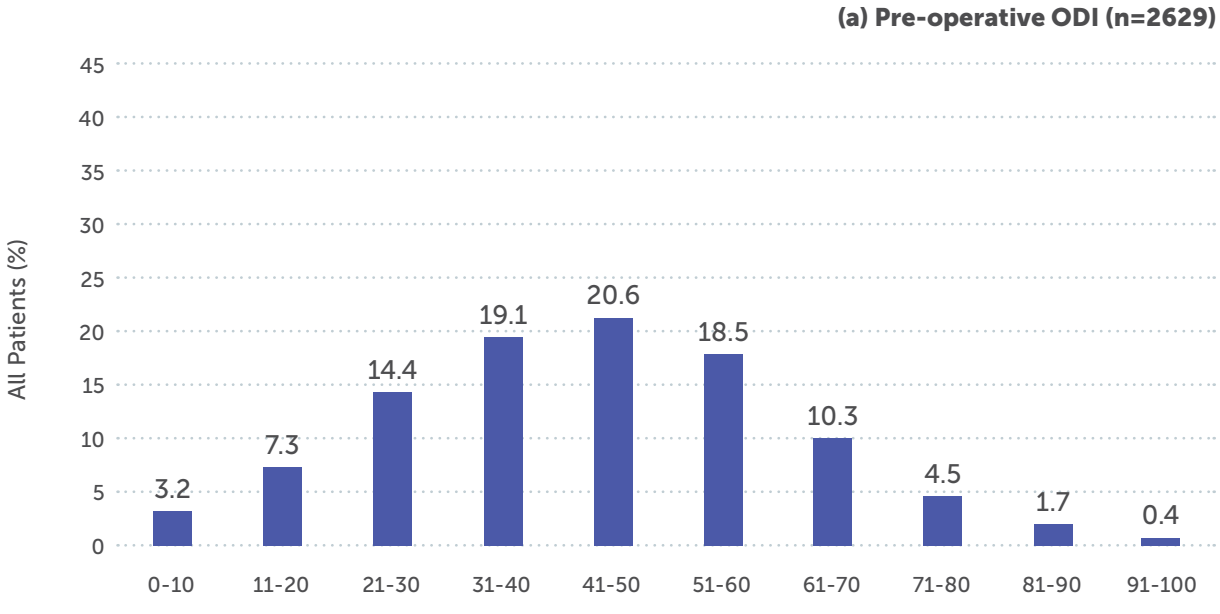
ODI Score	Level of Disability
0 - 20	Minimal disability
21 - 40	Moderate disability
41 - 60	Severe disability
61 - 80	Crippled
81 - 100	Bed bound

Table 4: ODI mean and median scores for all patients who completed any ODI at pre-op, 6, 12 and 24-months post-op

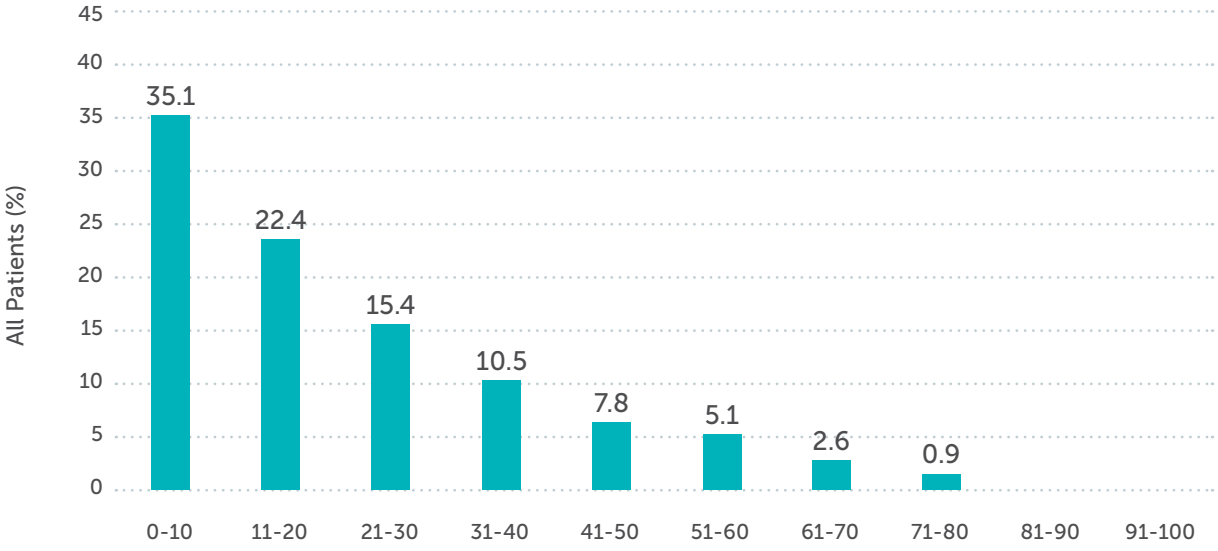
ODI	Pre-operative	6-Months	12-Months	24-Months
n	2629	2332	2111	1441
Mean (SD)	43.6 (17.8)	21.5 (18.2)	20.5 (18.5)	20.2 (18.2)
Median (IQR)	44.0 (31.0, 56.0)	18.0 (7.0, 32.0)	16.0 (6.0, 31.0)	16.0 (6.0, 30.0)

Figure 16 illustrates that the proportion of patients who considered themselves severely disabled or worse (ODI score > 41) reduced from 56% preoperatively to 16.4% at 6 months, 15.2% at 12 months, and 15.5% at 24 months.

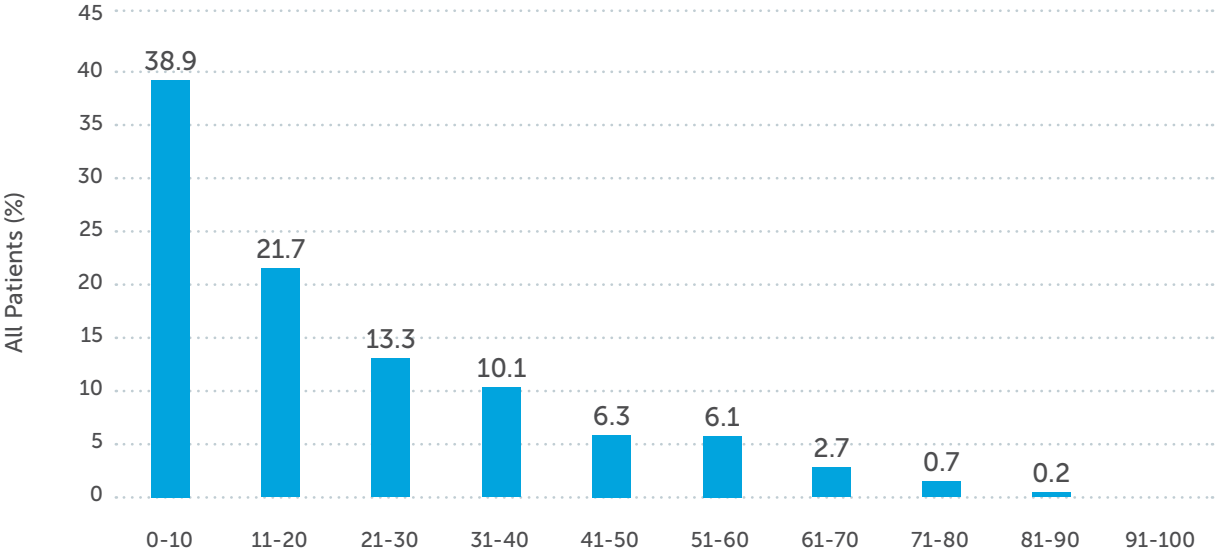
Figure 16: ODI distribution for all patients who completed any ODI at pre-op, 6, 12 and 24-months post-op



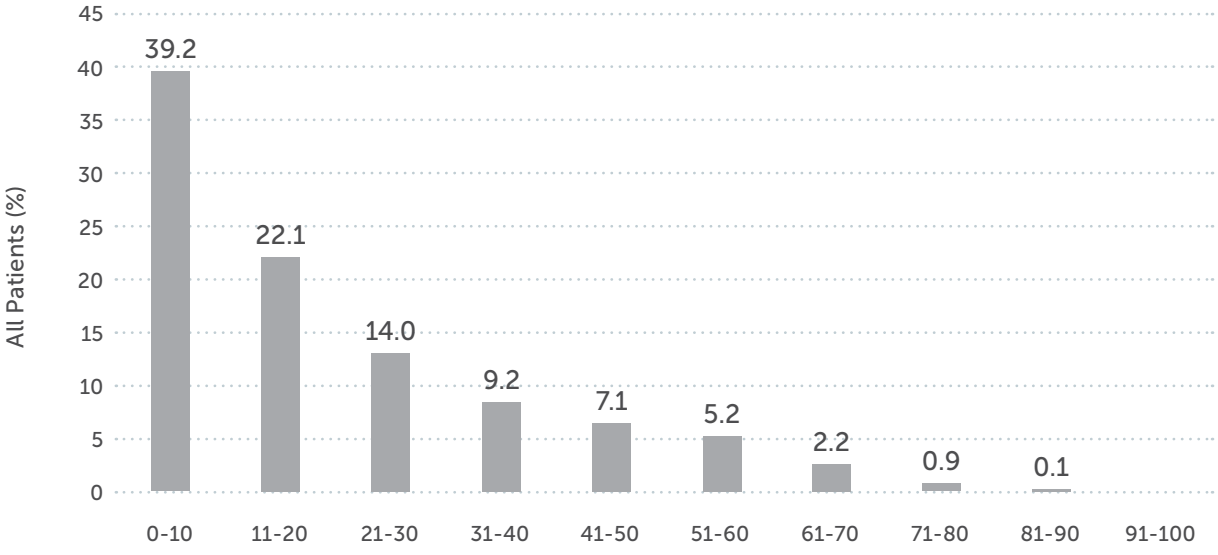
(b) Six-month post-operative ODI (n=2332)



(c) Twelve-month post-operative ODI (n=2111)



(d) Twenty-four-month post-operative ODI (n=1441)



Neck Disability Index (NDI)

The NDI is completed by patients who have undergone surgery in the cervical region of the spine. This cohort represents 14.3% of patients in the ASR. For the NDI, 10 domains are examined which provide individual domain scores and an overall score. Each domain has a score up to 5 for a total score of 50[10]. The classification of patient disability based on score is shown in Table 5 below, where 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 and 12-months post-operatively, reducing further to 12 at 24 months' follow up.

Table 5: NDI Scoring

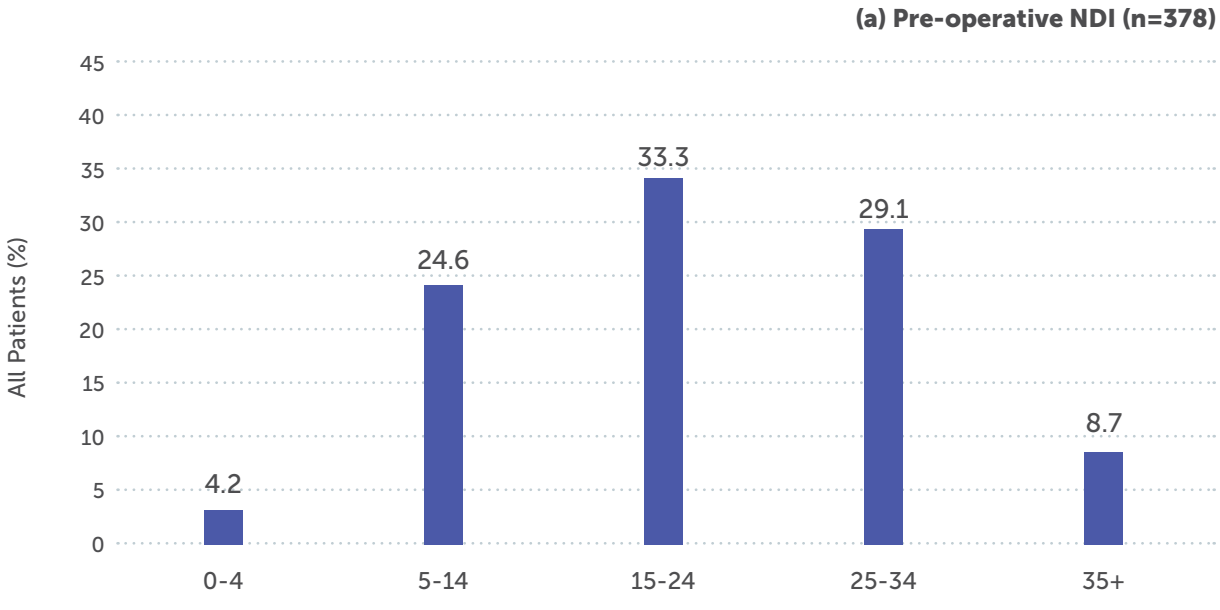
NDI Score	Level of Disability
0 – 4	No disability
5 – 14	Mild disability
15 – 24	Moderate disability
25 – 34	Severe disability
35 or over	Complete disability

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

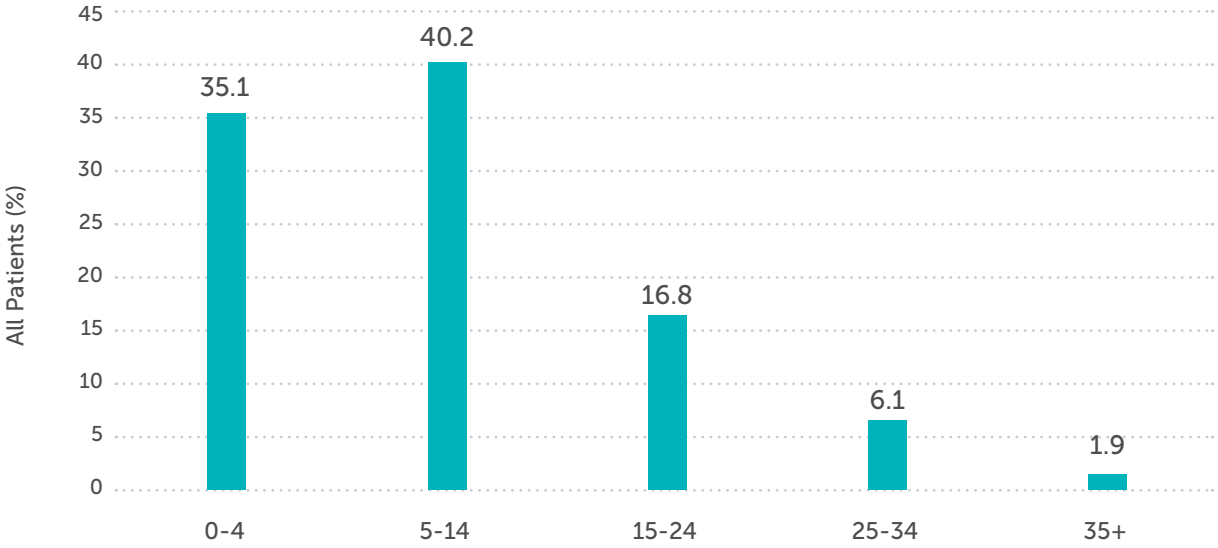
NDI	Pre-operative	6-Months	12-Months	24-Months
n	378	376	337	225
Mean (SD)	42.0 (19.5)	19.3 (17.6)	19.2 (18.6)	18.8 (18.7)
Median (IQR)	42.0 (28.0, 56.0)	14.0 (6.0, 28.0)	14.0 (6.0, 26.7)	12.0 (4.0, 28.0)

Preoperatively, 71.1% of patients had an NDI score of >15 indicating these patients considered themselves to be moderately disabled or worse. At 6 months, only 24.8% of patients considered themselves to be moderately disabled or worse, with improvement remaining stable until 12 and 24 months (Figure 17).

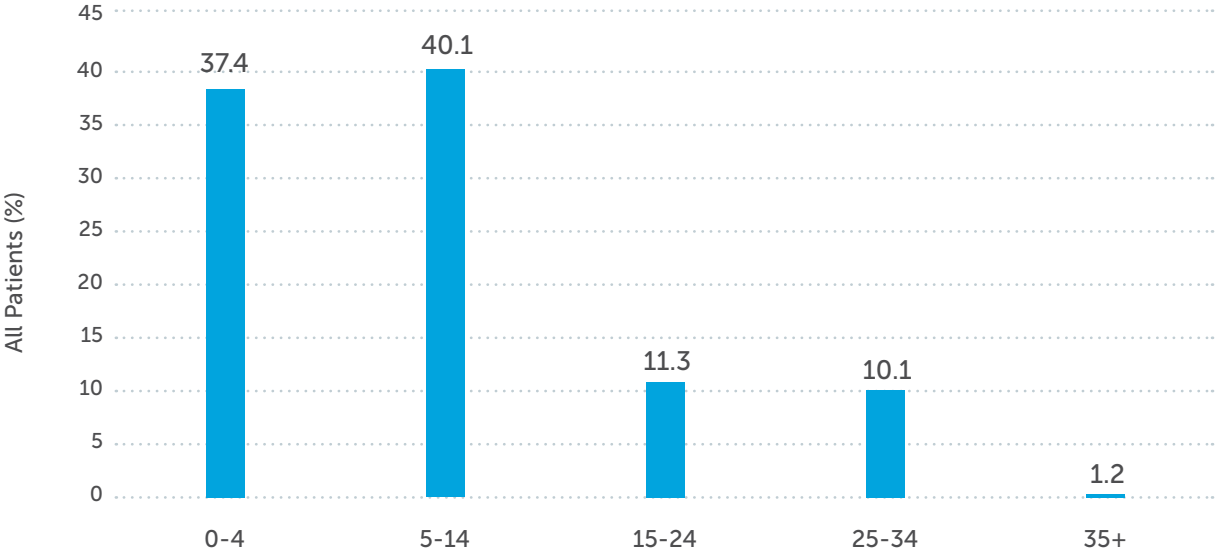
Figure 17: NDI distribution for all patients who completed any NDI at pre-op, 6, 12 and 24-months post-op



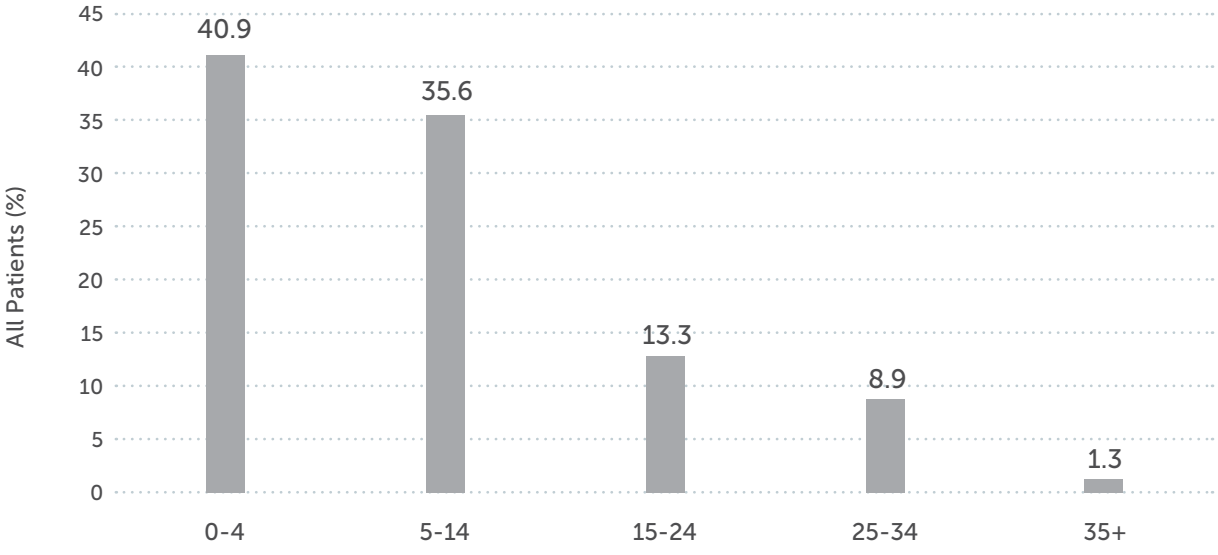
(b) Six-month post-operative NDI (n=376)



(c) Twelve-month post-operative NDI (n=337)



(d) Twenty-four-month post-operative NDI (n=225)



Cohort Analysis

The ASR reports on the following three specific patient cohorts:

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

Lumbar Discectomy

Lumbar discectomy is one of the most common spinal procedures[11]. It is performed to relieve nerve pressure secondary to disc herniation. Disc herniation may cause pain, motor or sensory impairment or incontinence. It is usually treated conservatively but discectomy may be performed for persistent or severe pain, significant weakness or bladder and bowel incontinence. The surgery can be performed in an open or minimally invasive technique.

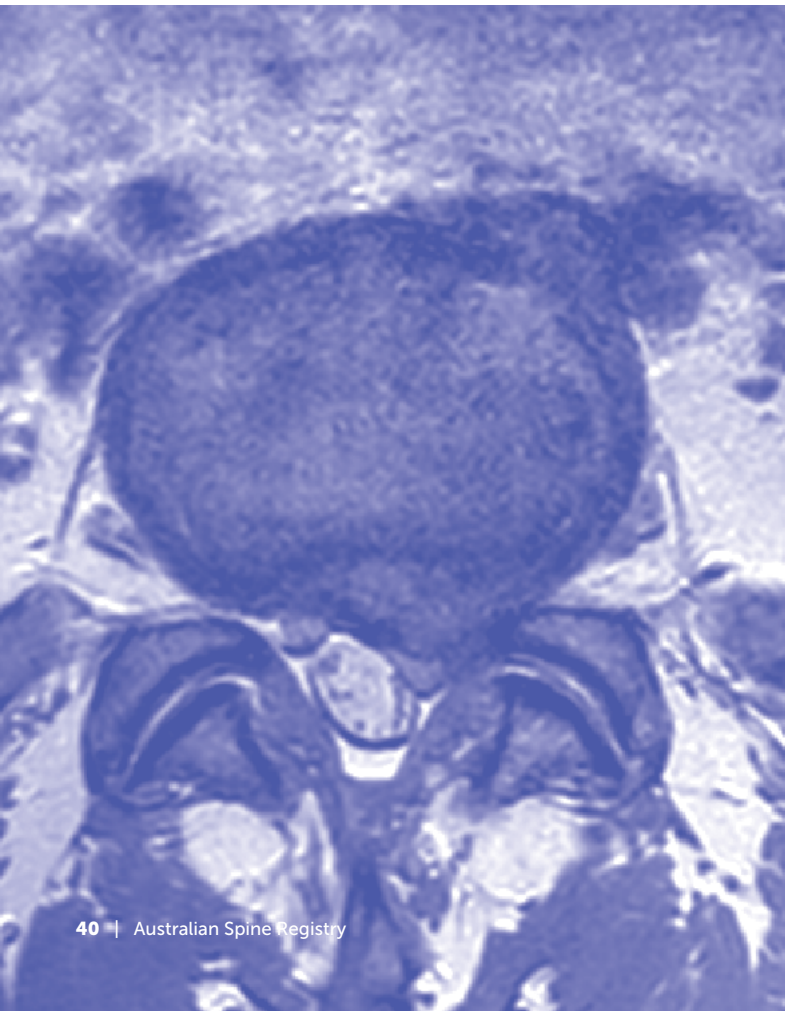
For analysis, discectomy cohort patients were selected based on the following inclusion criteria:

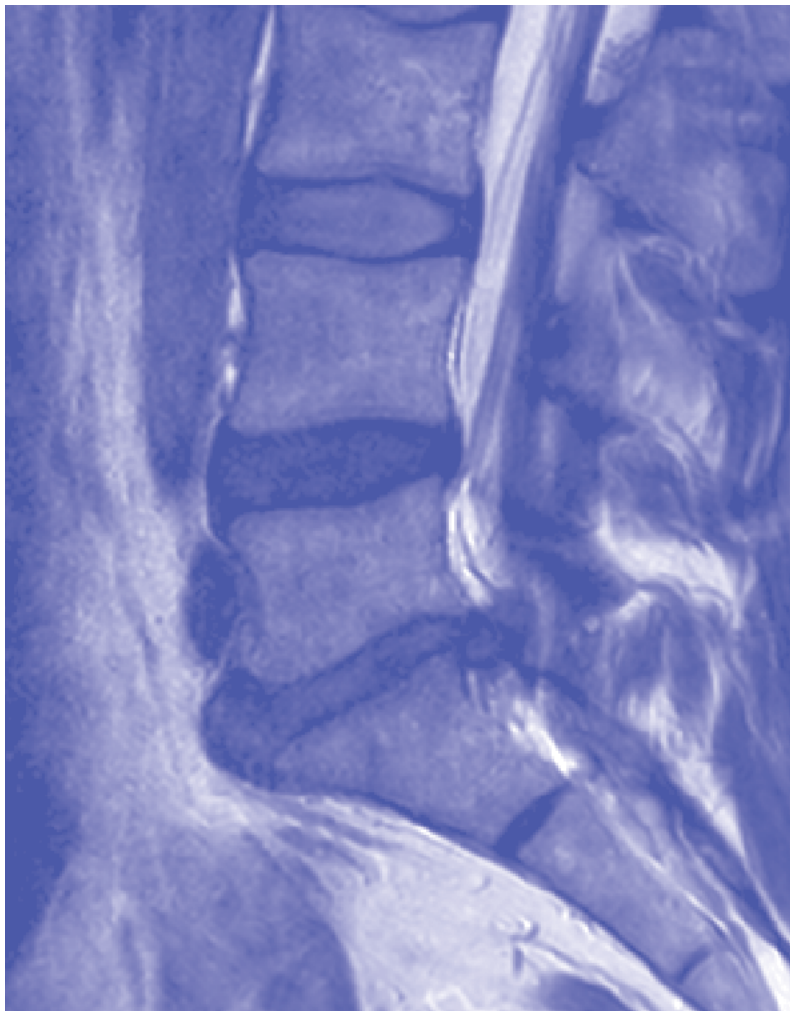
- Surgery Type – Lumbar Discectomy only
- Number of levels =1
- Number of stages =1

Patients from within this group were excluded if:

- Their discectomy surgery was revision surgery
- They had a scoliosis
- They also had a fusion

Images courtesy of Assoc. Prof John Cunningham



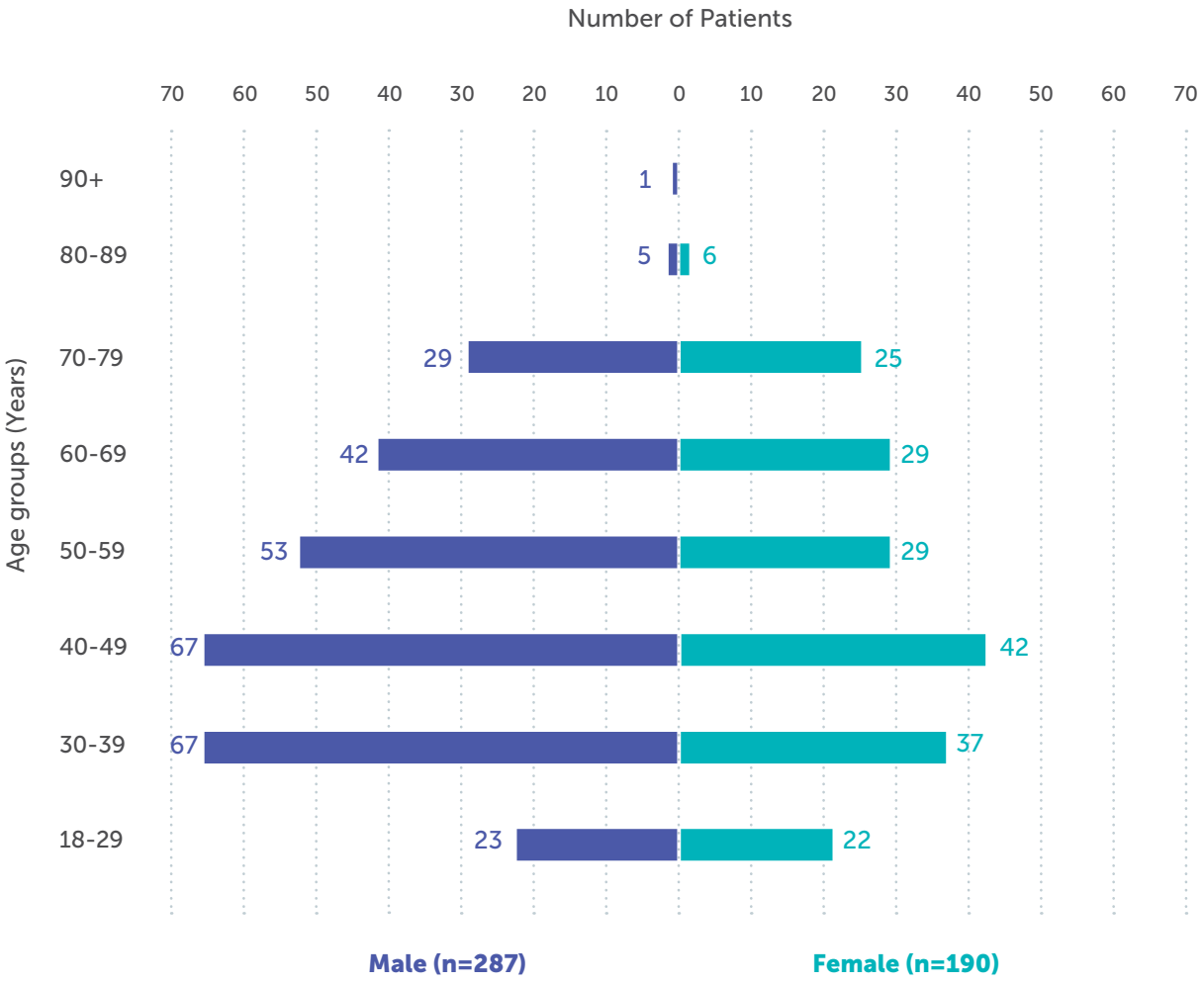


Demographics

477 patients met the discectomy cohort inclusion criteria which represents 15% of patients undergoing thoracolumbar procedures.

The single level lumbar discectomy procedures were performed predominately on male patients. There were 287 males (60%) and 190 females (40%) in this group as shown in Figure 18. 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) and has not changed from previous annual reports.

Figure 18: Discectomy procedures by patient age and gender



Surgeon Reported Comorbidities and ASA

The number of patients that were reported with a comorbidity is shown in Table 7 and Table 8 below. Examination of SRCs in this group identified that discectomy patients had fewer comorbidities when compared to all patients in the registry. 19.5% of discectomy patients were reported to have at least one comorbidity, whereas 38.1% of the entire registry patient population were reported to have at least one comorbidity.

Table 7: Number of discectomy patients diagnosed with any comorbidity prior to surgery

Any reported comorbidity	All (n=3753) n (%)	Discectomy (n=477) n (%)
Yes	1424 (38.1)	93 (19.5)
No	2311 (61.9)	384 (80.5)

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

Number of reported comorbidities	All patients (n=3735) n (%)	Discectomy patient (n=477) n (%)
None	2311 (61.9)	384 (80.5)
1	656 (17.6)	53 (11.1)
2	389 (10.4)	21 (4.4)
3	240 (6.4)	15 (3.1)
4	81 (2.2)	1 (0.2)
5+	58 (1.6)	3 (0.6)

61% of discectomy patients had ASA data recorded.

When ASA scores were examined for discectomy patients 49.7 % 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 similiarity between SRCs and ASA data as that seen for the total cohort.

Table 9: ASA score reported for "Discectomy" patients compared to all ASR patients

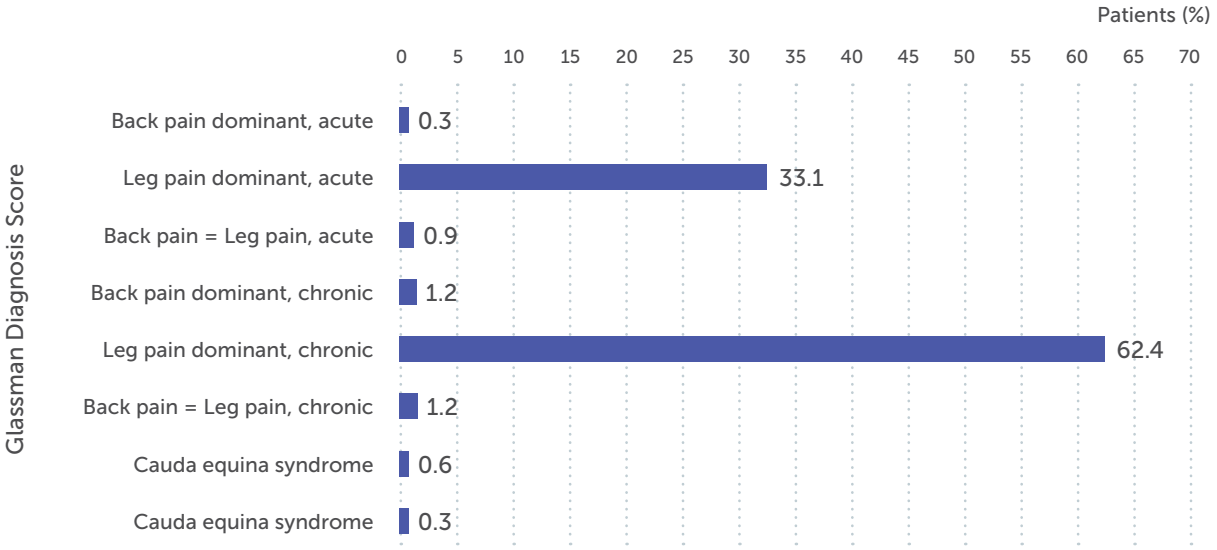
ASA Classification	All (n=2072) n (%)	Discectomy (n=290) n (%)
1	497 (24)	144 (49.7)
2	949 (45.8)	117 (40.3)
3	602 (29.1)	29 (10)
4	24 (1.2)	0 (0)

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 pathology[12]. Glassman scores are only reported for patients who have had thoracolumbar or deformity procedures. Glassman scores were reported in 70.2% of the discectomy cohort.

For patients undergoing a discectomy, acute and chronic leg pain were most commonly reported symptoms by patients. Back pain was less commonly reported, as was neurogenic claudication. This is consistent with the commonly seen clinical presentation of disc herniations (Figure 19).

Figure 19: Glassman Score for 'Symptoms' among discectomy patients (n=335)



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)

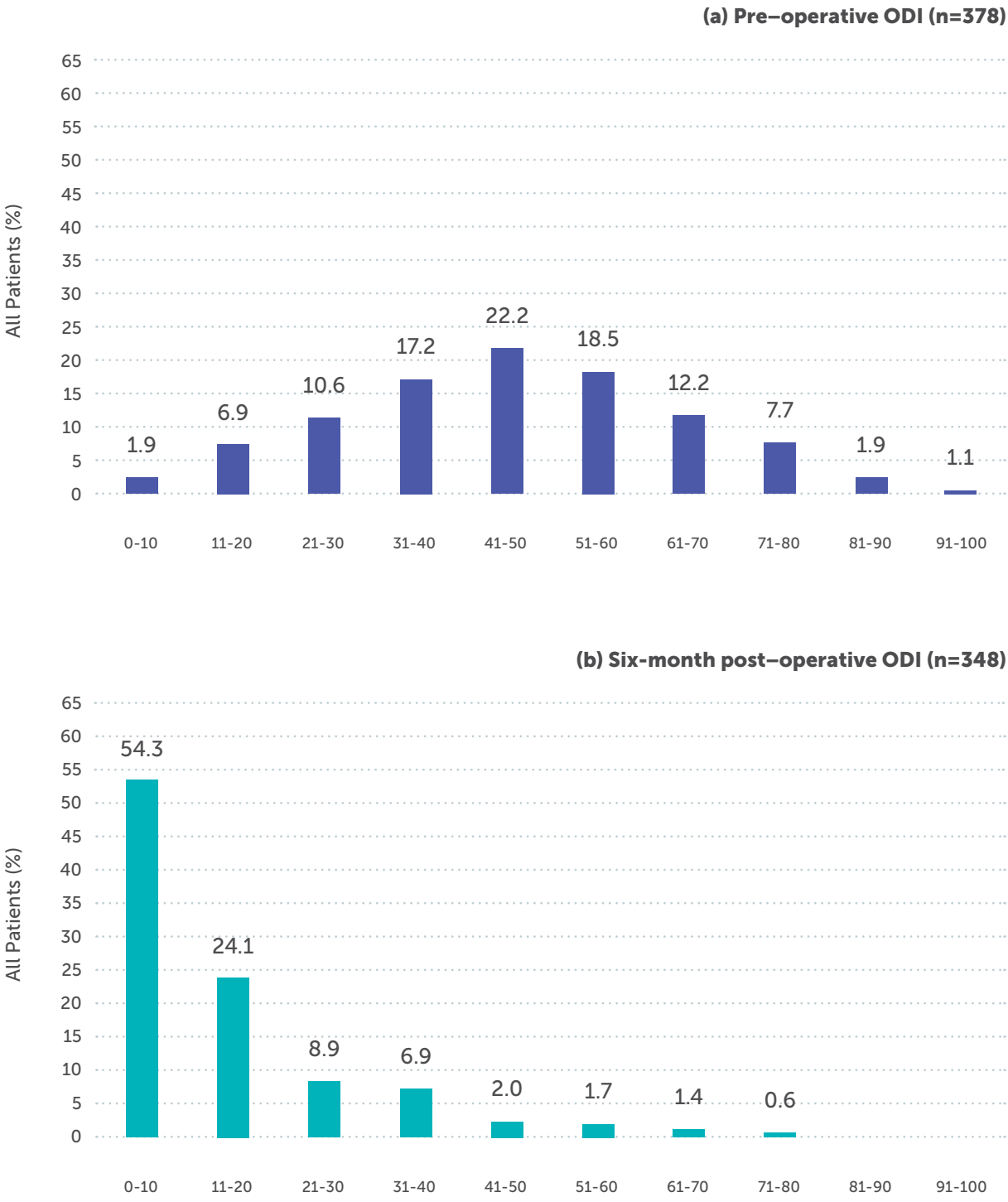
A lower ODI score indicates improved relief from pain and disability. ODI mean, median and overall scores for any questionnaires completed at each time point are shown in Table 10 and Figure 20 respectively. As shown in Table 10, median ODI scores improved from 46 pre-operatively to 8 at 6-months post-operatively, which was sustained until a slight rise to 9 at 24 months.

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

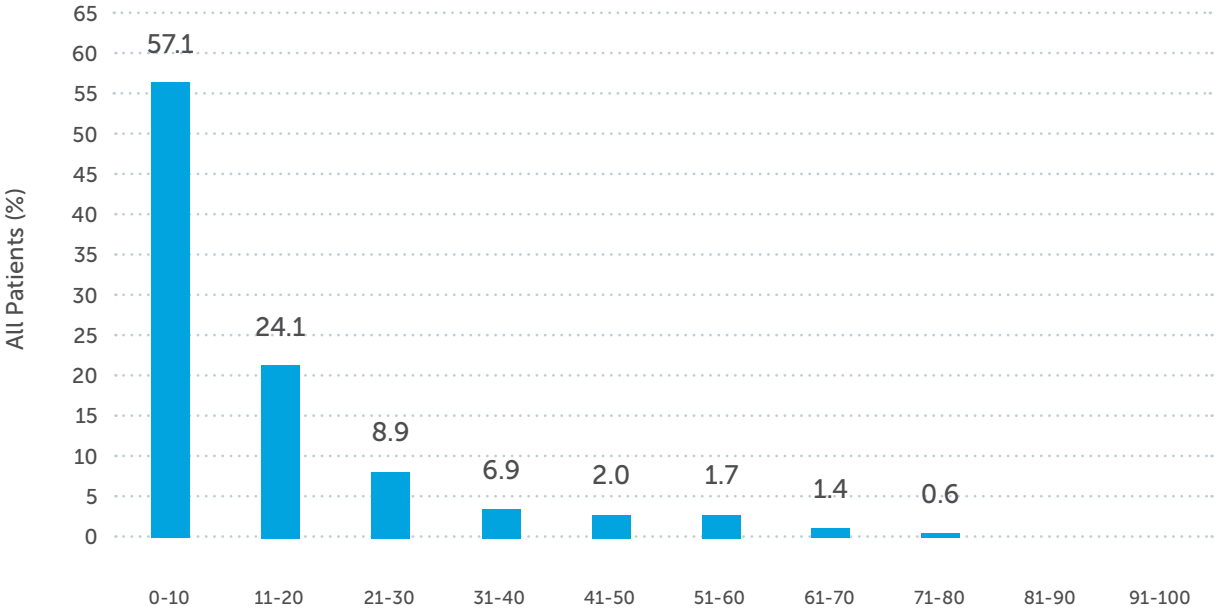
ODI	Pre-operative	6-Months	12-Months	24-Months
n	378	348	333	243
Mean (SD)	47.2 (18.3)	13.9 (14.9)	13.3 (15.1)	12.6 (14.0)
Median (IQR)	46.0 (34.0, 60.0)	8.0 (2.0, 20.0)	8.0 (2.0, 18.0)	9.0 (2.0, 20.0)

Figure 20 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 relating to improvement over the 6-month period. This was maintained at both 12 and 24 months.

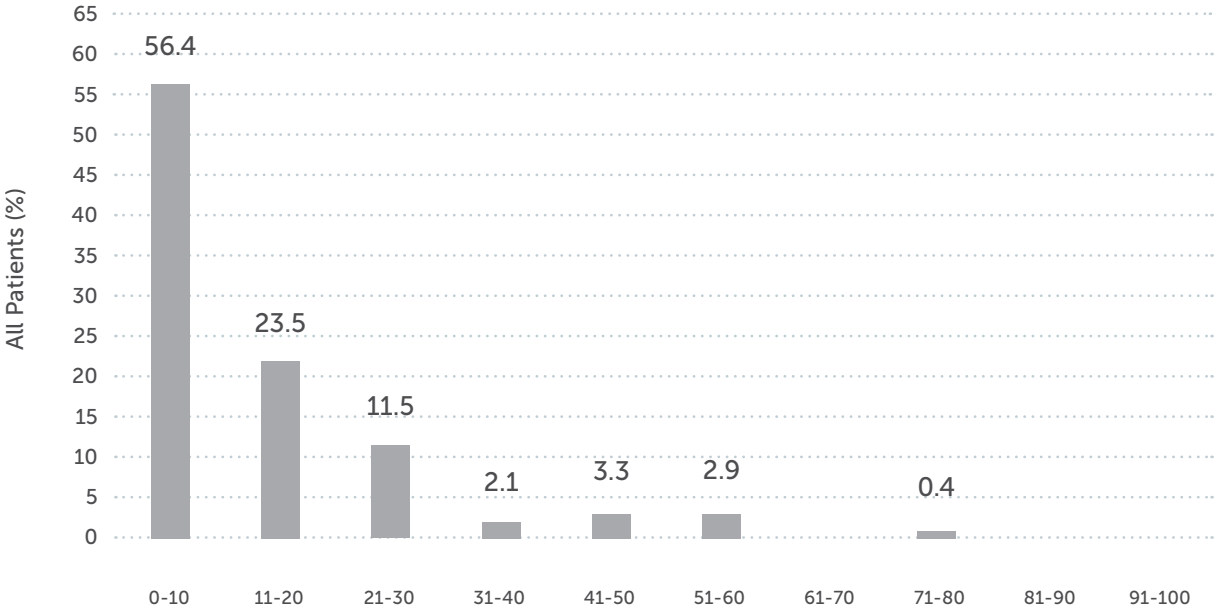
Figure 20: ODI distribution for discectomy patients who completed any ODI at pre-op, 6, 12 and 24-months post-op



(c) Twelve-month post–operative ODI (n=333)



(d) Twenty-four-month post–operative ODI (n=243)



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

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, 12 and 24-months post-op

ODI	Pre-operative	6-Months	12-Months	24-Months
n	**378**	**348**	**333**	**243**
Pain, mean (SD)	2.75 (1.02)	0.85 (0.88)	0.81 (0.91)	0.77 (0.89)
Social Life, mean (SD)	2.76 (1.22)	0.73 (1.10)	0.60 (1.01)	0.52 (0.94)
Lifting, mean (SD)	2.81 (1.28)	1.19 (1.36)	1.15 (1.29)	1.15 (1.31)
Sitting, mean (SD)	2.52 (1.25)	1.01 (1.05)	0.96 (0.98)	0.89 (0.96)
Traveling, mean (SD)	2.49 (1.38)	0.62 (0.95)	0.65 (0.96)	0.60 (0.89)
Standing, mean (SD)	2.48 (1.45)	0.81 (1.09)	0.76 (1.04)	0.79 (1.09)
Sex Life*, mean (SD)	2.56 (1.68)	0.50 (1.01)	0.46 (0.98)	0.45 (0.95)
Sleeping, mean (SD)	1.93 (1.08)	0.61 (0.77)	0.61 (0.79)	0.61 (0.74)
Walking, mean (SD)	1.89 (1.34)	0.35 (0.77)	0.37 (0.82)	0.28 (0.71)
Personal Care, mean (SD)	1.44 (1.18)	0.23 (0.68)	0.21 (0.63)	0.20 (0.61)

* Note: Sex life question is optional; lower numbers of 329, 319, 297, and 224 (for each time-point, respectively).

The Minimum Clinically Important Difference (MCID) is a threshold change on questionnaire scoring indicating a significant clinical improvement. Based on the literature, Minimum Detectable Change (MDC) is considered the most appropriate MCID value and has been reported to be 12.8 for the ODI [13]. This figure has been used to define MCID for this patient cohort.

Greater than 83.1% of discectomy patients exceeded this MCID (improved) for the ODI 24-months post-operatively (Table 12, Table 13 and Table 14).

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

ODI*	All (n=1969) n (%)	Discectomy (n=287) n (%)
Exceeding the MCID (Improved)	1172 (64.9)	243 (84.7)
Within the MCID (Unchanged)	562 (31.7)	37 (12.9)
Exceeding the MCID (Worsened)	44 (3.5)	7 (2.4)

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

ODI*	All (n=1778) n (%)	Discectomy (n=267) n (%)
Exceeding the MCID (Improved)	1172 (65.9)	223 (83.5)
Within the MCID (Unchanged)	562 (31.6)	43 (16.1)
Exceeding the MCID (Worsened)	44 (2.5)	1 (0.4)

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

ODI*	All (n=1,240) n (%)	Discectomy (n=195) n (%)
Exceeding the MCID (Improved)	830 (66.9)	162 (83.1)
Within the MCID (Unchanged)	365 (29.4)	32 (16.4)
Exceeding the MCID (Worsened)	45 (3.6)	1 (0.5)

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

EQ-5D-3L Quality of Life

The discectomy cohort EQ-5D-3L domain scores and the EQVAS were analysed and indicate improvement across all domains by 6 months (Table 15, Table 16 and Figure 21). The mobility, usual activities followed by pain/discomfort domain were the three domains which showed the most improvement over the 6-month period, which were also maintained when measured at the 12 and 24-months time points.

Table 15: EQ-5D-3L scores for each domain for discectomy patients at pre-op, 6, 12 and 24-months post-op

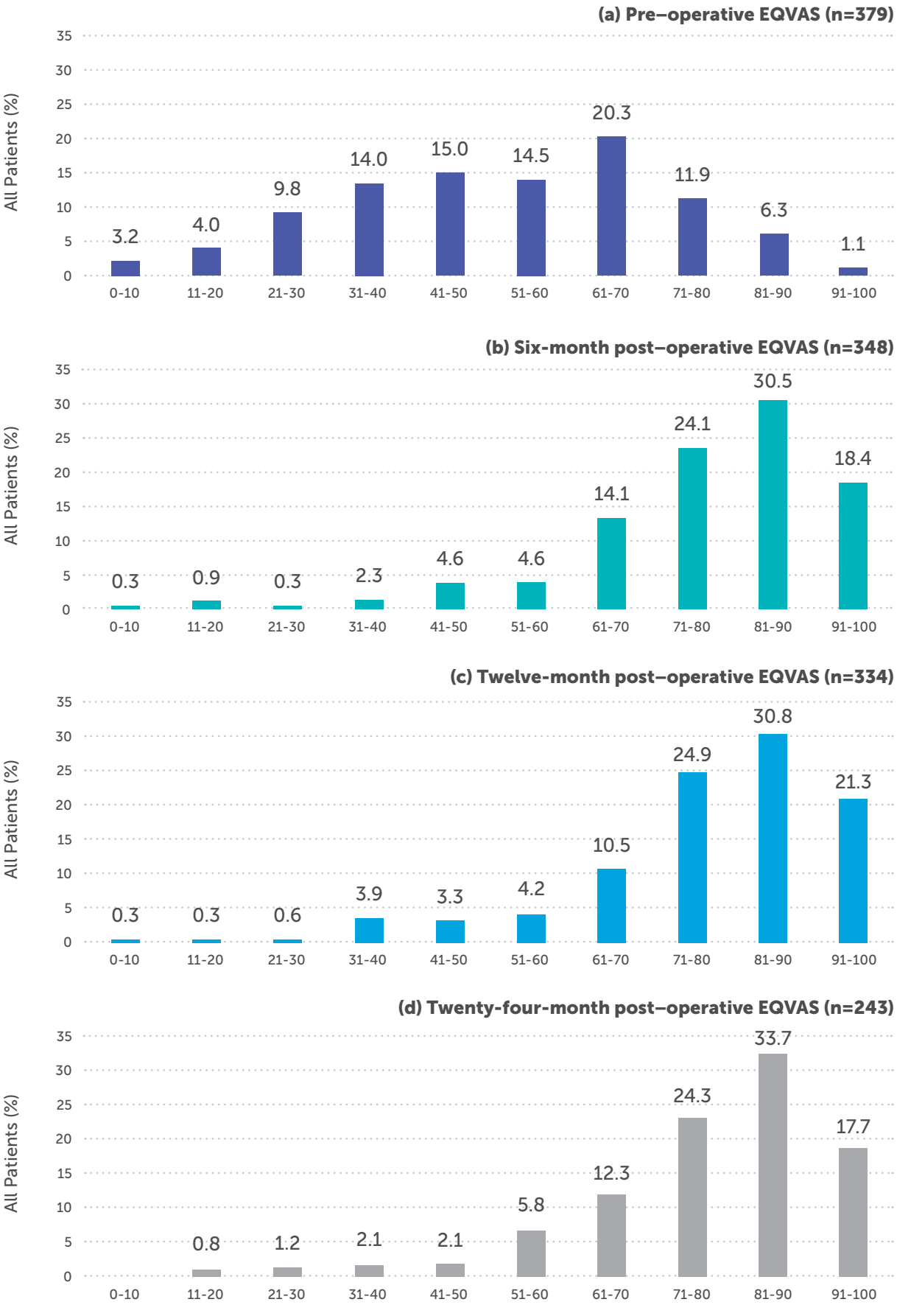
EQ-5D-3L All Patients					
Domain	**Level of problem**	**Pre-op (%) (n=380)**	**6 months (%) (n=348)**	**12-months (%) (n=334)**	**24-months (%) (n=243)**
Mobility	1 – no problems	14.5	73.9	75.4	77.4
	2 – some problems	82.4	26.1	24.3	22.6
	3 – extreme problems	3.2	0.0	0.3	0.0
Self-care	1 – no problems	6.8	58.3	62.0	65.8
	2 – some problems	61.8	39.4	35.3	32.5
	3 – extreme problems	31.3	2.3	2.7	1.6
Usual activities	1 – no problems	1.6	45.1	47.3	49.8
	2 – some problems	51.6	52.0	47.6	47.3
	3 – extreme problems	46.8	2.9	5.1	2.9
Pain/ discomfort	1 – no problems	52.1	90.8	90.7	91.4
	2 – some problems	45.8	9.2	9.0	8.2
	3 – extreme problems	2.1	0.0	0.3	0.4
Anxiety/ depression	1 – no problems	47.4	75.3	76.9	76.5
	2 – some problems	46.1	23.0	21.3	21.8
	3 – extreme problems	6.6	1.7	1.8	1.6

The EQVAS identifies the way in which patients perceive their general health at a given time point. An increase in the EQVAS score indicates an improvement of patient perception of their general health status. As shown in Table 16 median patient scores improved from 56 pre-operatively to 78 12 months post-operatively and were sustained until 24 months (Figure 21).

Table 16: EQVAS mean and median scores for discectomy patients who completed any EQVAS at pre-op, 6, 12 and 24-months post-op

EQVAS	**Pre-operative**	**6-Months**	**12-Months**	**24-Months**
n	379	348	334	243
Mean (SD)	54.5 (20.4)	78.1 (16.1)	79.3 (15.9)	79.2 (15.5)
Median (IQR)	56.0 (40.0, 70.0)	80.0 (70.0, 90.0)	81.0 (73.0, 90.0)	81.0 (71.0, 90.0)

Figure 21: EQVAS distribution for discectomy patients who completed any EQVAS at pre-op, 6, 12 and 24-months post-op



Anterior Cervical Discectomy and Fusion (ACDF)

ACDF surgery is done for symptomatic cervical disc problems, most commonly for a cervical herniated disc. It can also be done to address problems from degenerative disc disease, spinal stenosis and/or osteoarthritis in the cervical spine. The procedure is carried out from the front (anterior) of the spine between the vital structures in the neck. The anterior approach is preferred as the disc can be accessed without disturbing the spinal cord, spinal nerves and strong neck muscles.

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

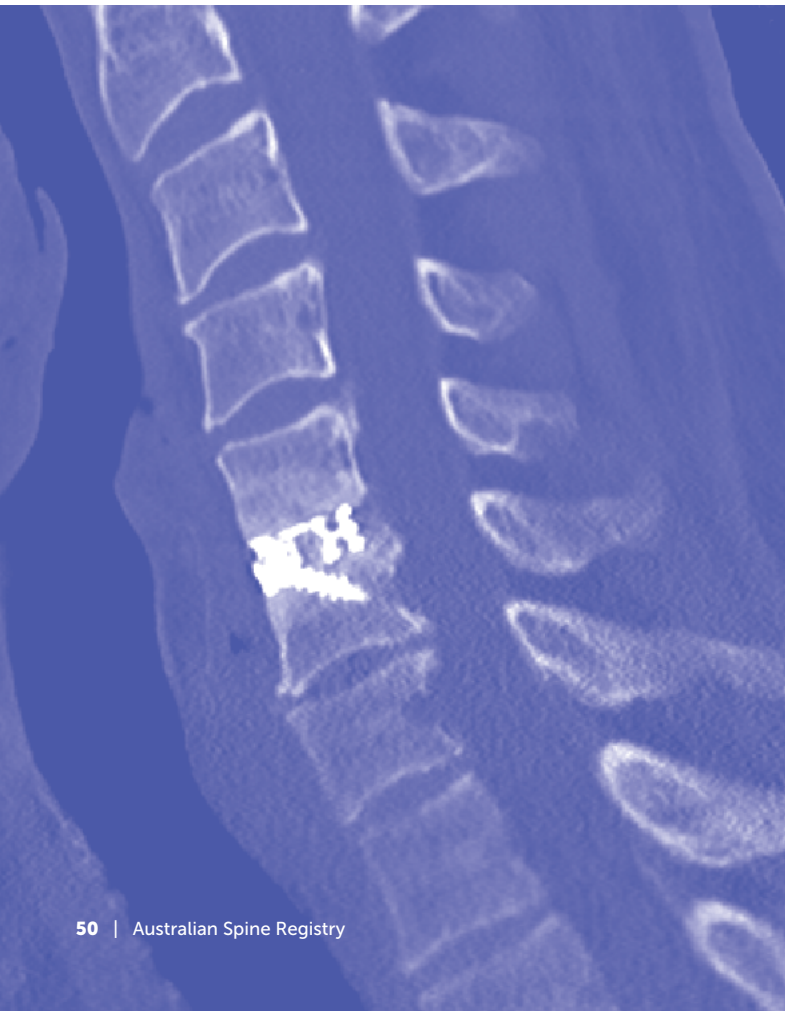
Inclusions:

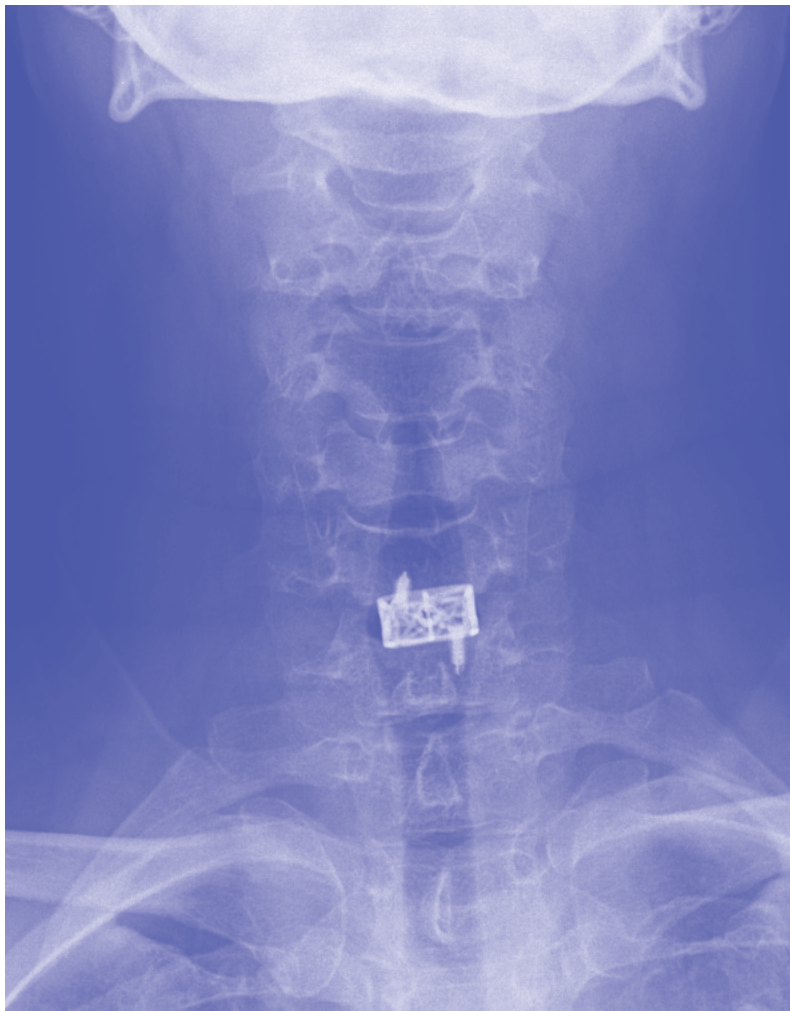
- Surgery Type – Cervical Discectomy only
- Number of levels ≤2
- Number of stages =1

Exclusions:

- Scoliosis

Images courtesy of Assoc. Prof John Cunningham

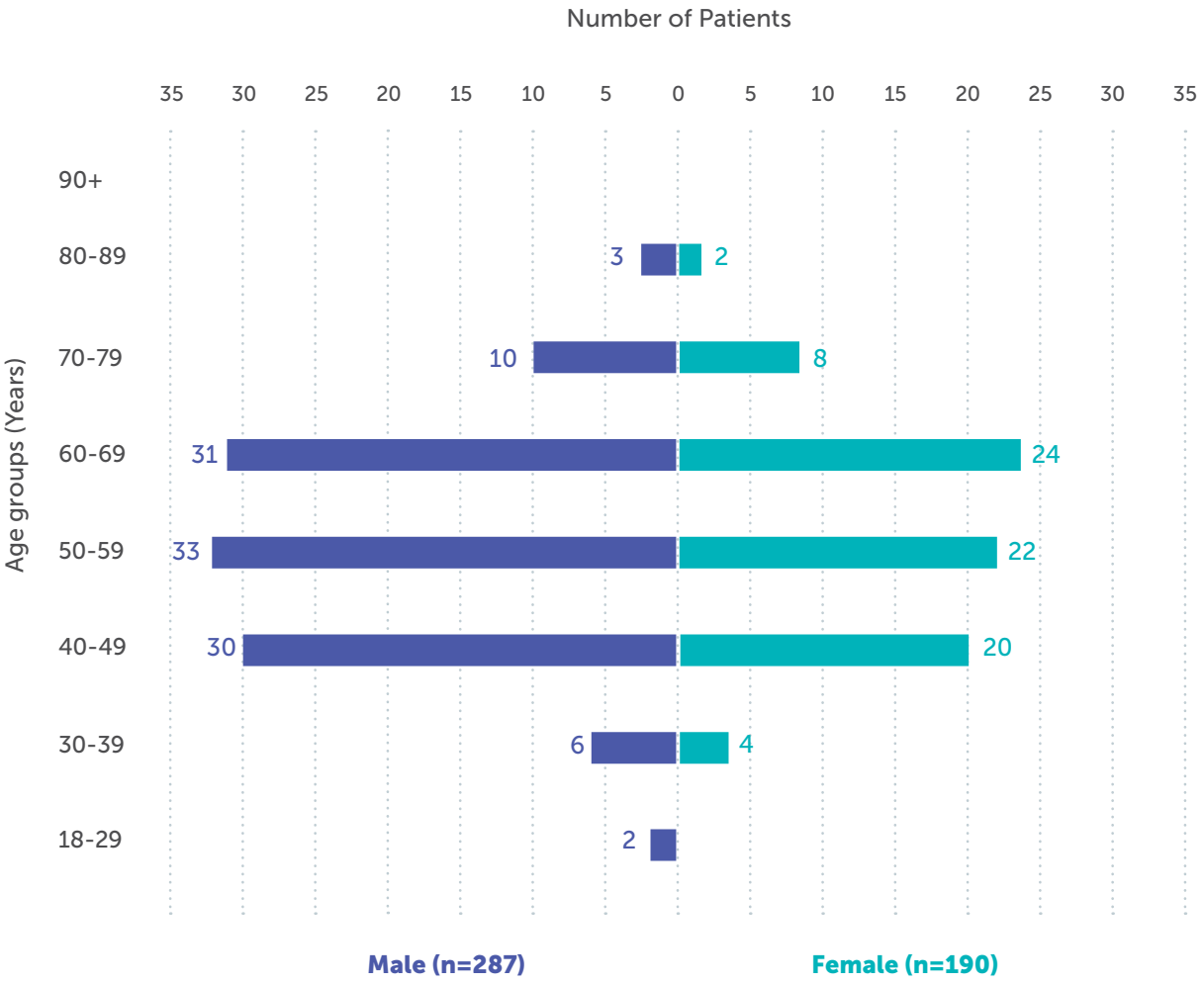




Demographics

195 ACDF procedures that met the eligibility criteria were analysed. These occurred more commonly on male patients. There were 115 males (59%) and 80 females (41%) in this cohort as shown in Figure 22. The median age for males was 54 years, with a median of 56 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).

Figure 22: ACDF procedures by patient age and gender



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 17, Table 18). Examination of the ASA scores for this cohort revealed that only 50% of the ACDF procedures had listed an ASA score (Table 19). Of the data collected, 29.6% of the patients were considered "normal" healthy patients with 49% with mild disease and 20.4% with severe disease which correlates with the ASA for the total ASR patient cohort.

Table 17: Number of ACDF patients diagnosed with any comorbidity prior to surgery

Any reported comorbidity	All (n=3735) n (%)	ACDF (n=195) n (%)
Yes	1,424 (38.1)	79 (40.5)
No	2,311 (61.9)	116 (59.5)

Table 18: Breakdown of number of comorbidities reported in ACDF patients

Number of reported comorbidities	All patients (n=2554)	ACDF patients (n=159)
None	1416 (55.4)	92 (57.9)
1	547 (21.4)	37 (23.3)
2	296 (11.6)	13 (8.2)
3	186 (7.3)	11 (6.9)
4	60 (2.4)	5 (3.1)
5+	49 (1.9)	1 (0.6)

Table 19: ASA scores for ACDF patients compared to all ASR patients

ASA Classification	All (n=2072) n (%)	ACDF (n=98) n (%)
1	497 (24)	29 (29.6)
2	949 (45.8)	48 (49)
3	602 (29.1)	20 (20.4)
4	24 (1.2)	1 (1)

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.

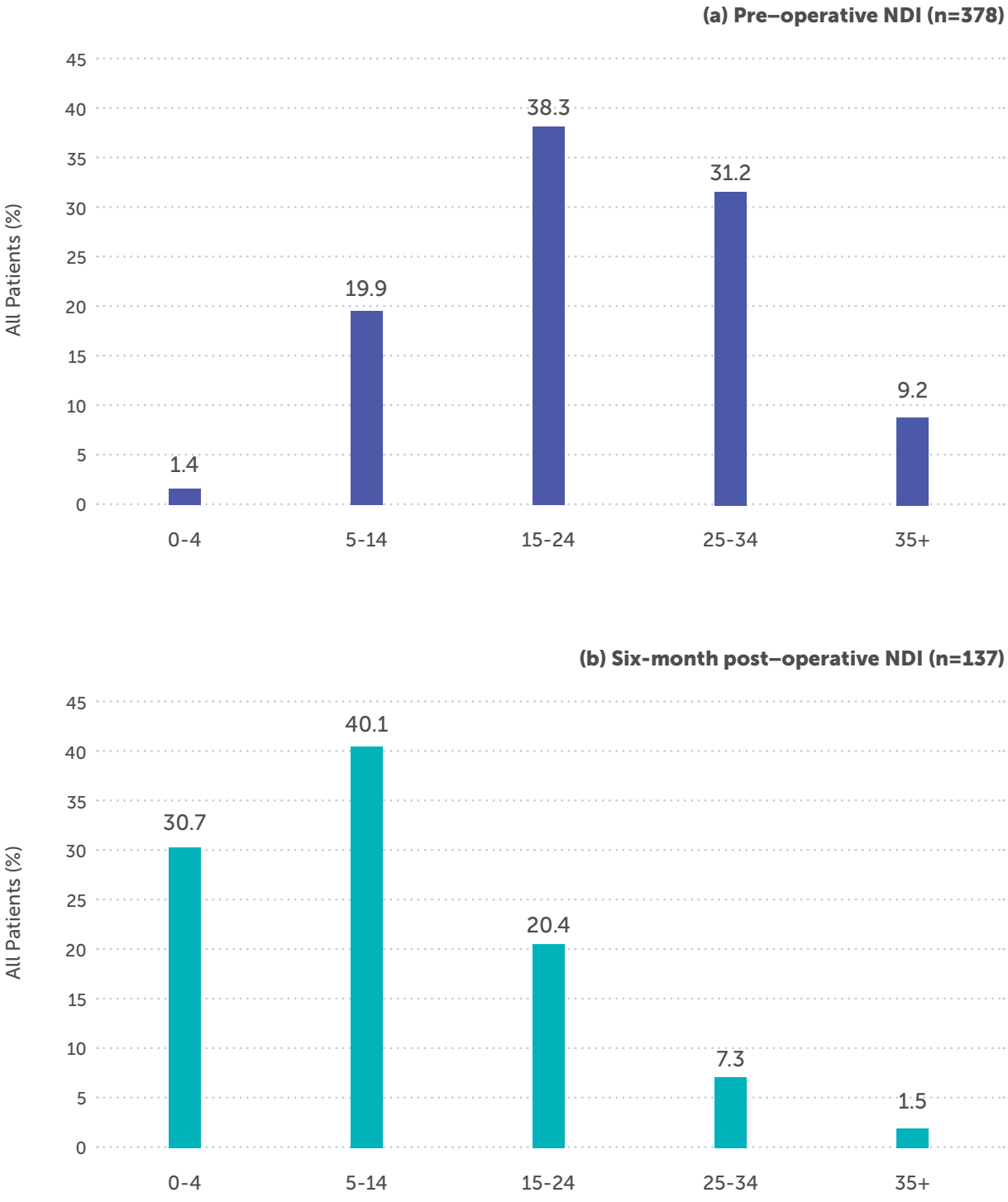
Neck Disability Index (NDI)

Median NDI scores (Table 20) reduced from 42 preoperatively, to 16 at 6-months post operatively, and continued to improve to 10.6 at 24-months postoperatively. These results are further detailed in Figure 23.

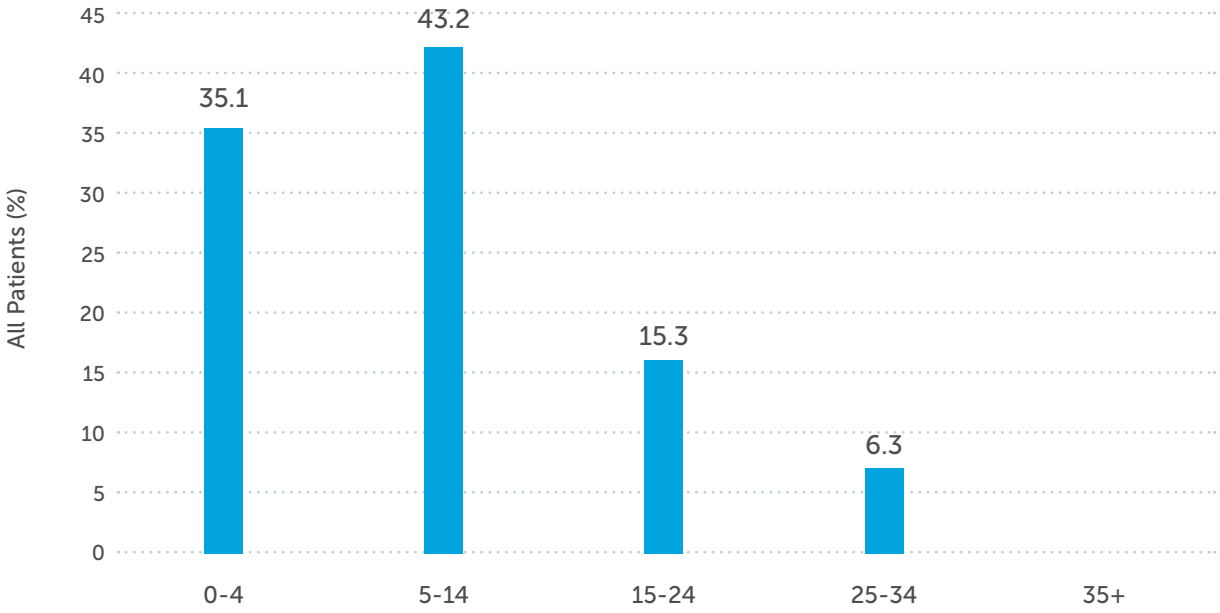
Table 20: NDI mean and median scores for ACDF patients who completed any NDI at pre-op, 6, 12 and 24-months post-op

NDI	Pre-operative	6-months	12-months	24-months
n	141	137	111	80
Mean (SD)	43.8 (18.4)	20.9 (17.4)	18.4 (16.2)	18.5 (19.1)
Median (IQR)	42.0 (32.0, 56.0)	16.0 (8.0, 30.0)	16.0 (6.0, 28.0)	10.6 (4.0, 29.0)

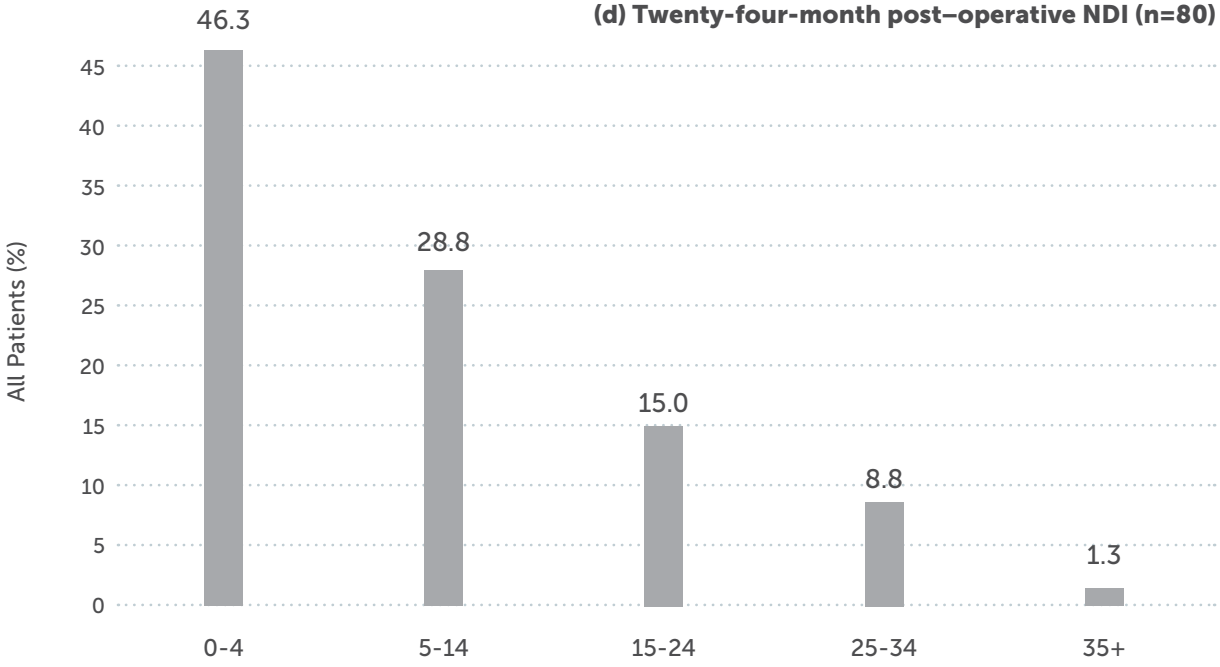
Figure 23: NDI distribution for ACDF patients who completed any NDI questionnaires at pre-op, 6,12 and 24-months post-op



(c) Twelve-month post–operative NDI (n=111)



(d) Twenty-four-month post–operative NDI (n=80)



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 21: NDI mean scores for each domain for ACDF patients who completed any EQVAS at pre-op, 6, 12 and 24-months post-op

NDI	Pre-operative	6-Months	12-Months	24-Months
n	**141**	**137**	**111**	**80**
Recreation, mean (SD)	3.03 (1.37)	1.24 (1.29)	1.03 (1.14)	1.24 (1.54)
Sleeping, mean (SD)	2.81 (1.36)	1.40 (1.23)	1.25 (1.23)	1.35 (1.43)
Lifting, mean (SD)	2.73 (1.43)	1.62 (1.48)	1.46 (1.54)	1.15 (1.47)
Pain, mean (SD)	2.45 (1.22)	1.07 (0.95)	0.82 (0.87)	0.82 (1.02)
Work, mean (SD)	2.45 (1.40)	1.25 (1.32)	1.09 (1.26)	1.13 (1.37)
Reading, mean (SD)	1.99 (1.26)	0.99 (1.10)	0.97 (1.12)	0.94 (1.01)
Driving*, mean (SD)	2.22 (1.59)	0.91 (1.28)	0.78 (1.03)	0.77 (1.07)
Headaches, mean (SD)	1.81 (1.56)	0.95 (1.15)	0.92 (1.13)	0.95 (1.19)
Concentration, mean (SD)	1.33 (1.18)	0.67 (0.96)	0.54 (0.86)	0.50 (0.84)
Personal Care, mean (SD)	1.04 (1.05)	0.32 (0.70)	0.28 (0.65)	0.40 (0.82)

* Note: Driving question is optional; lower numbers of 137, 133, 106 and 78 (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 improvement[14]. 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 NDI[15]. We note that in the literature there is considerable variation in the MCIDs reported for cervical surgery.

Table 22-24 shows patient data for all patients and ACDF patients who completed the NDI.

All patients were within or exceeded this MCID for NDI from pre-op to 6-months, 12-months and 24-months post-operatively (Table 20 -22).

Table 22: MCID for NDI from pre-op to 6-months post-op for ACDF patients

NDI*	All Cervical (n=275) n (%)	1-2 Level ACDF (n=103) n (%)
Exceeding the MCID (Improved)	151 (54.9)	56 (54.4)
Within the MCID (Unchanged)	124 (45.1)	47 (45.6)
Exceeding the MCID (Worsened)	0 (0.0)	0 (0.0)

Table 23: MCID for NDI from pre-op to 12-months post-op for ACDF patients

NDI*	All Cervical (n=248) n (%)	1-2 Level ACDF (n=84) n (%)
Exceeding the MCID (Improved)	144 (58.1)	53 (63.1)
Within the MCID (Unchanged)	103 (41.5)	31 (36.9)
Exceeding the MCID (Worsened)	0 (0.0)	0 (0.0)

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

NDI*	All Cervical (n=166) n (%)	1-2 Level ACDF (n=62) n (%)
Exceeding the MCID (Improved)	89 (53.6)	37 (59.7)
Within the MCID (Unchanged)	74 (44.6)	24 (38.7)
Exceeding the MCID (Worsened)	3 (1.8)	1 (1.6)

*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 25). The pain/discomfort domain showed the most improvement at 6 months followed by the 'usual activities' domain. For the pain/discomfort domain, 98.6% of patients reporting some or extreme pain/discomfort pre-operatively which reduced to 67% at 6-months post-surgery and to 47.6% at 24-months post-surgery. For the usual activities' domain, 80.9% of patients report some or extreme problems with carrying out their usual activities which reduced to 48.9% 6-months post-surgery and 36.3% at 24-months post-surgery.

Table 25: EQ-5D-3L scores for each domain for ACDF patients at pre-op, 6, 12 and 24-months post-op

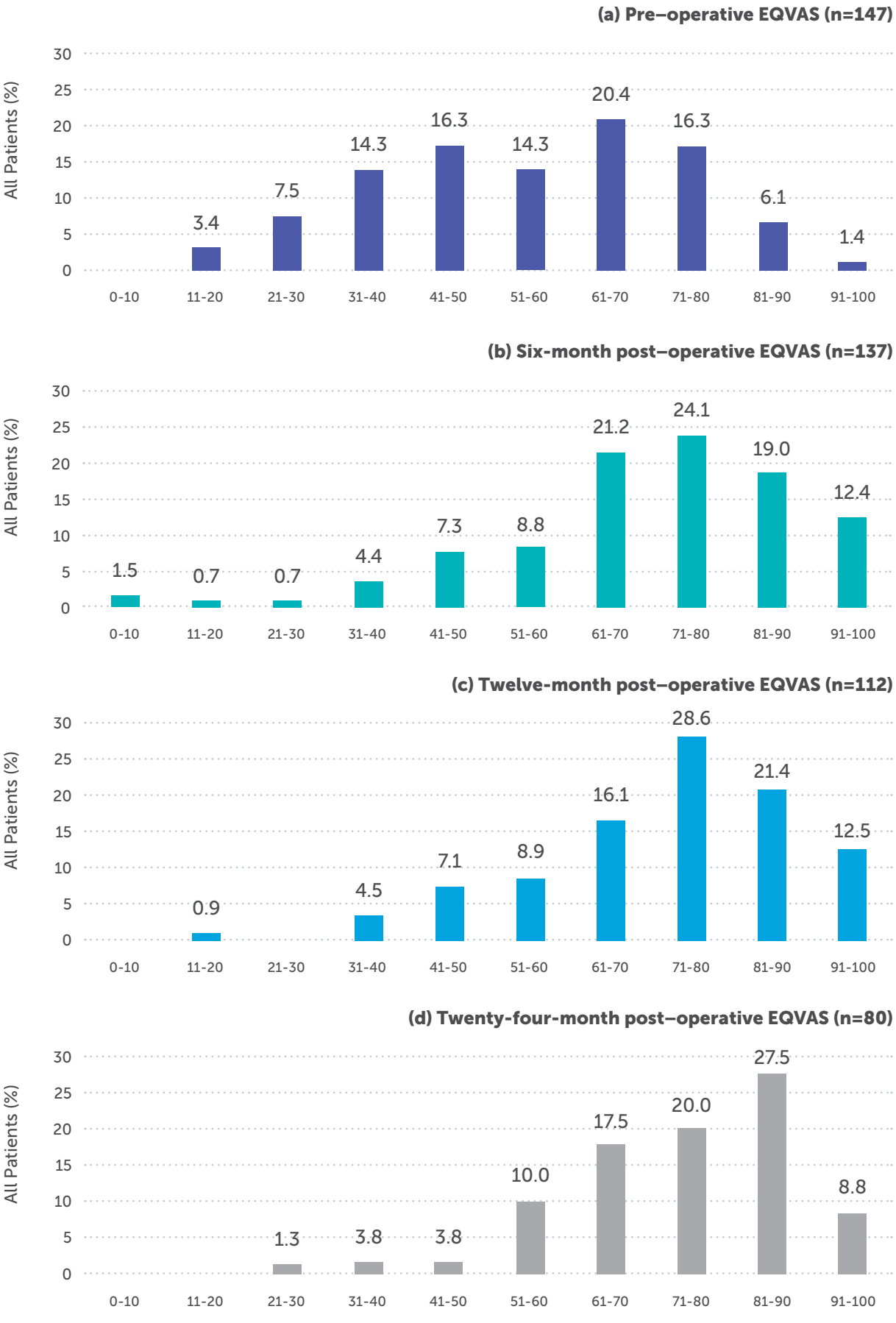
		EQ-5D-3L All Patients			
Domain	**Level of problem**	**Pre-op (%) (n=147)**	**6-months (%) (n=137)**	**12-months (%) (n=112)**	**24-months (%) n=80**
Pain/ Discomfort	1 – no problems	1.4	32.8	40.2	52.5
	2 – some problems	68.7	61.3	54.5	41.3
	3 – extreme problems	29.9	5.8	5.4	6.3
Usual Activities	1 – no problems	19.0	51.1	55.4	63.8
	2 – some problems	57.8	45.3	39.3	31.3
	3 – extreme problems	23.1	3.6	5.4	5.0
Anxiety/ Depression	1 – no problems	40.8	61.3	69.6	62.5
	2 – some problems	50.3	34.3	27.7	31.3
	3 – extreme problems	8.8	4.4	2.7	6.3
Mobility	1 – no problems	56.5	78.8	82.1	76.3
	2 – some problems	42.9	21.2	17.9	23.8
	3 – extreme problems	0.7	0.0	0.0	0.0
Self-Care	1 – no problems	68.7	87.6	83.9	81.3
	2 – some problems	30.6	12.4	16.1	18.8
	3 – extreme problems	0.7	0.0	0.0	0.0

The EQVAS median scores improved from 60 pre-operatively to 75 at 6 months, and was sustained until 24 months (Table 26). These are further detailed in Figure 24.

Table 26: EQVAS mean and median scores for ACDF patients who completed any EQVAS at pre-op, 6, 12 and 24-months post-op

EQVAS	**Pre-operative**	**6-Months**	**12-Months**	**24-Months**
n	147	137	112	80
Mean (SD)	57.8 (18.2)	72.1 (18.5)	73.5 (16.1)	71.7 (18.9)
Median (IQR)	60.0 (40.0, 70.0)	75.0 (65.0, 85.0)	76.0 (63.5, 85.0)	75.0 (60.0, 85.0)

Figure 24: EQVAS distribution for ACDF patients who completed any EQVAS at pre-op, 6, 12 and 24-months post-op



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 spondylolisthesis (DS) usually develops because of the natural ageing process, when bones, joints, and ligaments deteriorate and become less capable of supporting the spine. As a result of the vertebral slippage, the central canal narrows and the nerves become compressed. Typically, DS occurs most commonly at L4-L5. It most commonly presents as leg pain restricting walking and standing but can be associated with other symptoms such leg weakness, sensory abnormality or, rarely, bladder and bowel incontinence. It is reported that DS is strongly age and gender specific[16] and is uncommon under the age of 50[17].

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

Inclusions:

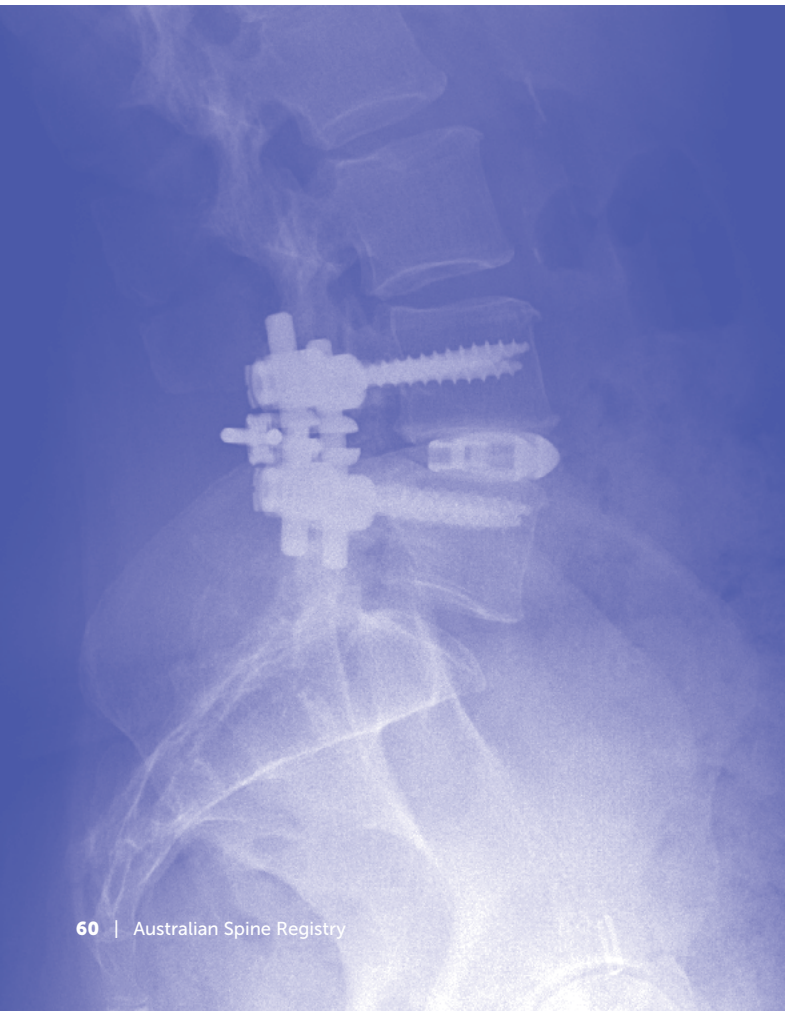
- Type of spondylolisthesis - degenerative
- Only at the L4-L5 level
- All grades (1-4) including spondyloptosis or retrolisthesis

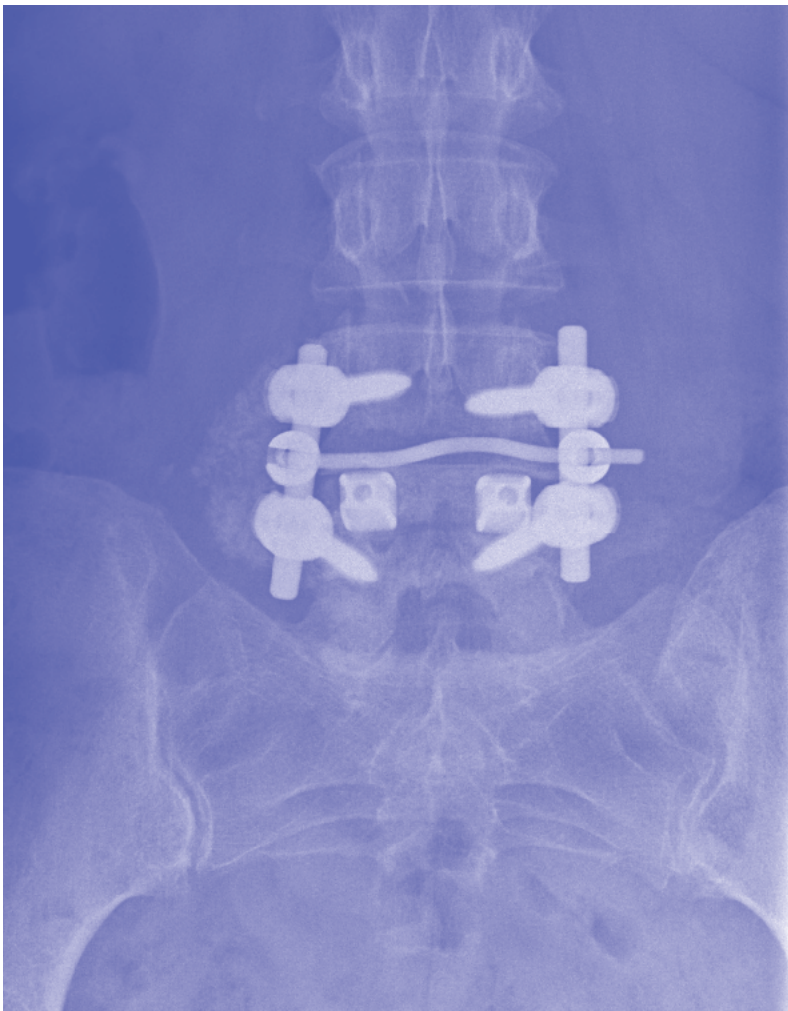
Exclusions:

- Scoliosis
- Revision surgery

As of 15 January 2023, 216 patients met the L4-L5 DS cohort inclusion criteria.

Images courtesy of Mr Michael Johnson



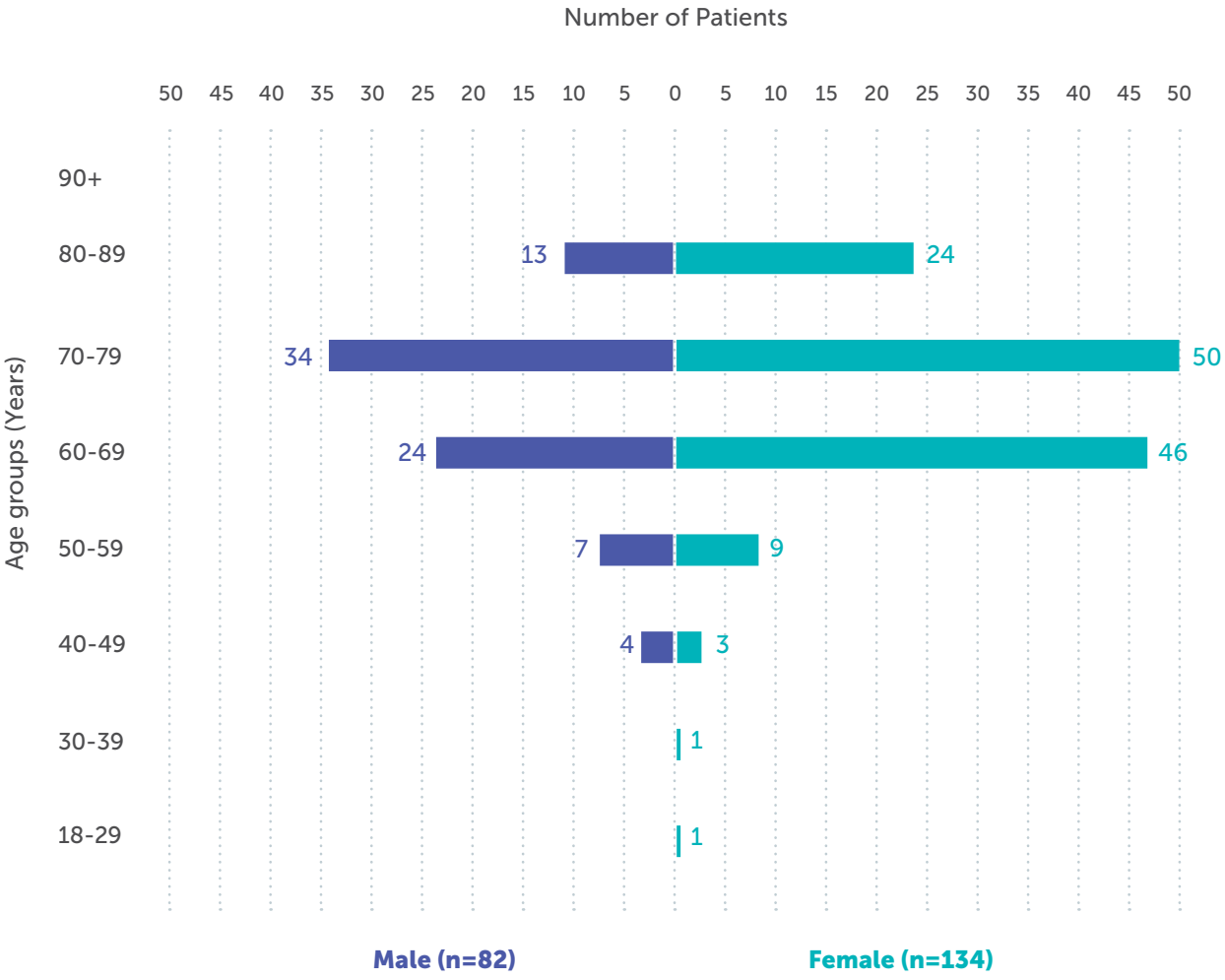


Demographics

There were 82 males (38%) and 134 females (62%) who were diagnosed with L4-L5 DS as shown in Figure 25.

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).

Figure 25: L4-L5 Spondylolisthesis procedures by patient age and gender



Surgeon Reported Comorbidities and ASA

The number of patients who were reported to have a comorbidity is shown (Table 27); 67% of L4-L5 DS patients were reported to have at least one comorbidity compared to 38.1% of the total patients. Patients were further categorised by their ASA score (Table 28). For the patient who had an ASA score recorded, 88% had mild to severe disease which consistent with their age profile.

Table 27: Number of "L4-L5 DS" patients diagnosed with any comorbidity prior to surgery

Any reported comorbidity	All (n=3,735) n (%)	L4-L5 DS (n=216) n (%)
Yes	1,424 (38.1)	145 (67.1)
No	2,311 (61.9)	71 (32.9)

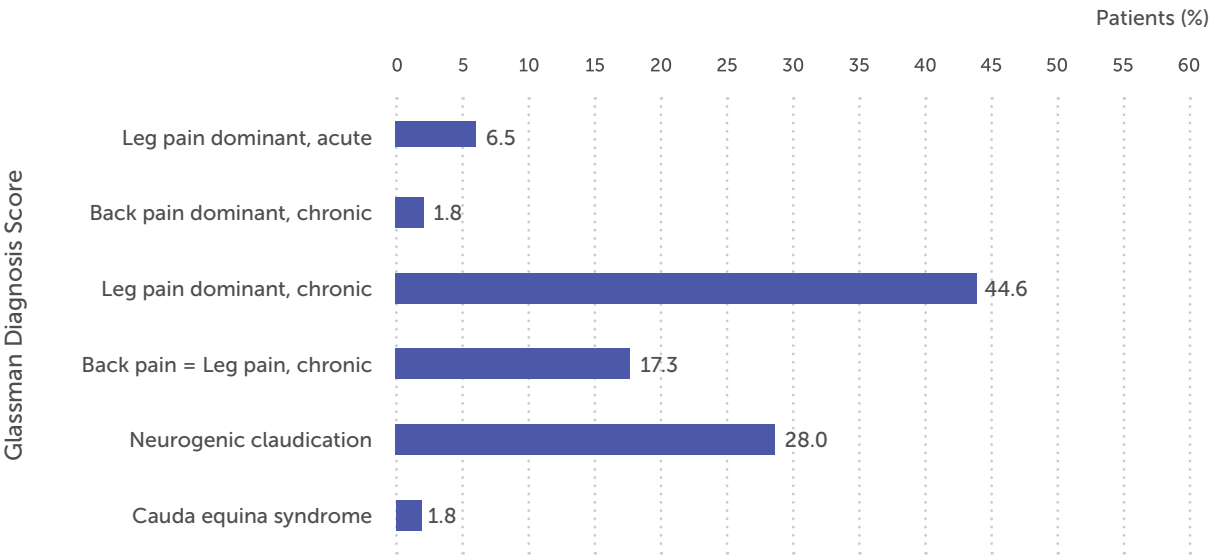
Table 28: ASA score reported for "L4-L5 DS" patients compared to all ASR patients

ASA Classification	All (n=2072) n (%)	L4-L5 DS (n=158) n (%)
1	497 (24)	17 (10.8)
2	949 (45.8)	79 (50)
3	602 (29.1)	60 (38)
4	24 (1.2)	2 (1.3)

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 26).

Figure 26: Glassman Score for 'Symptoms' among L4-L5 DS patients (n=168)



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.

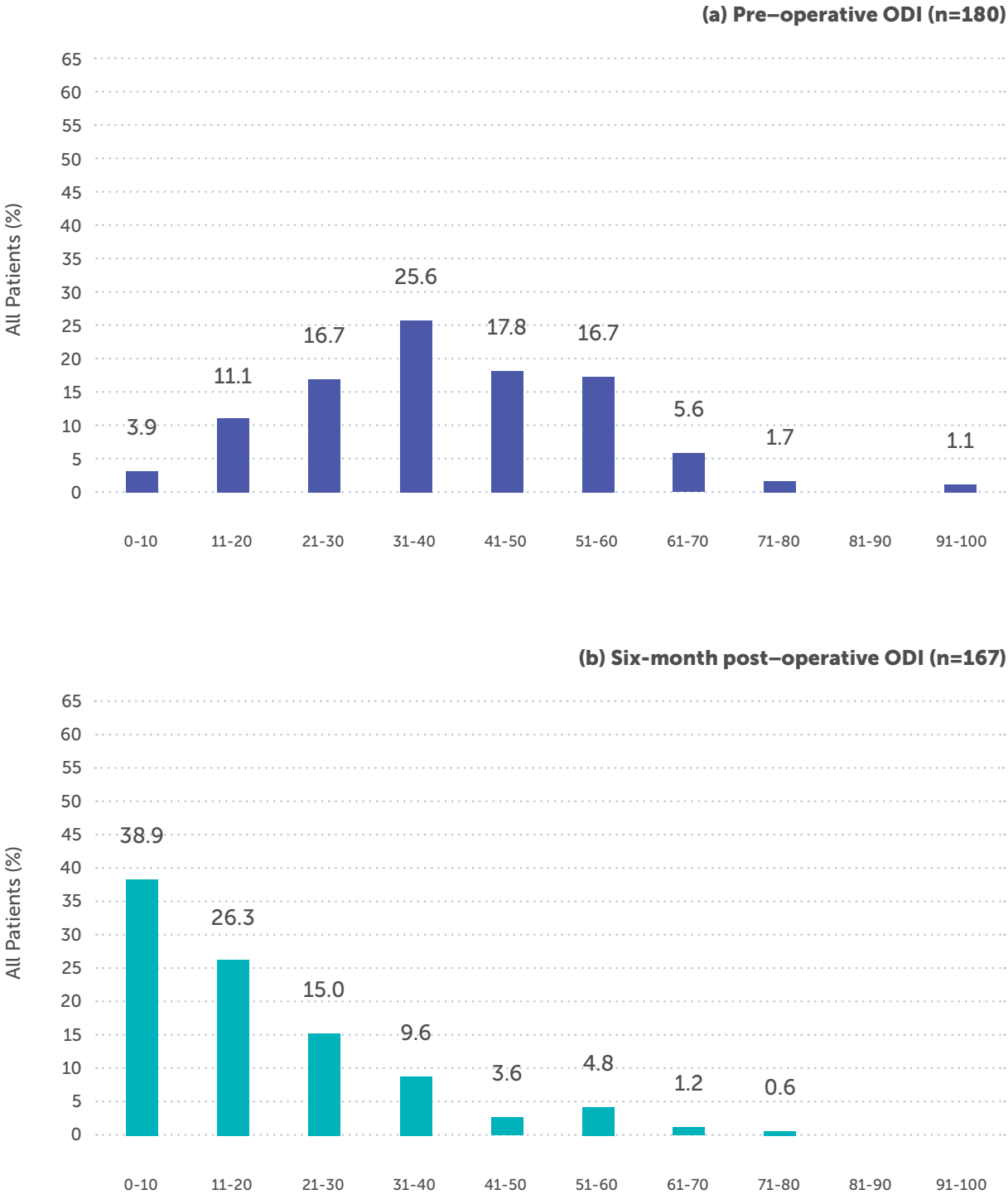
Oswestry Disability Index (ODI)

ODI median scores improved from 38.0 pre-operatively to 14 at 6-months post-operatively with further slight improvement at 12 and 24 months (Table 29). Figure 27 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.

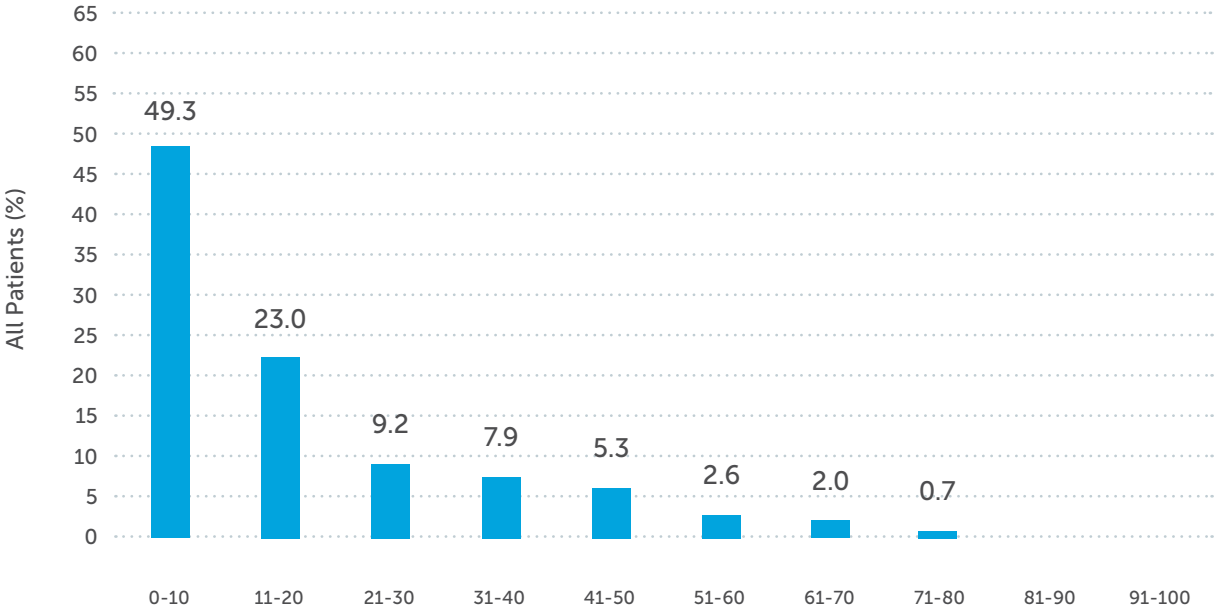
Table 29: ODI mean and median scores for L4-L5 DS patients who completed any ODI at pre-op, 6, 12 and 24-months post-op

ODI	Pre-operative	6-Months	12-Months	24-Months
n	180	167	152	130
Mean (SD)	38.6 (16.8)	18.0 (16.8)	16.3 (16.6)	16.6 (16.6)
Median (IQR)	38.0 (25.0, 50.5)	14.0 (4.0, 27.0)	11.5 (4.0, 25.0)	12.0 (2.0, 27.0)

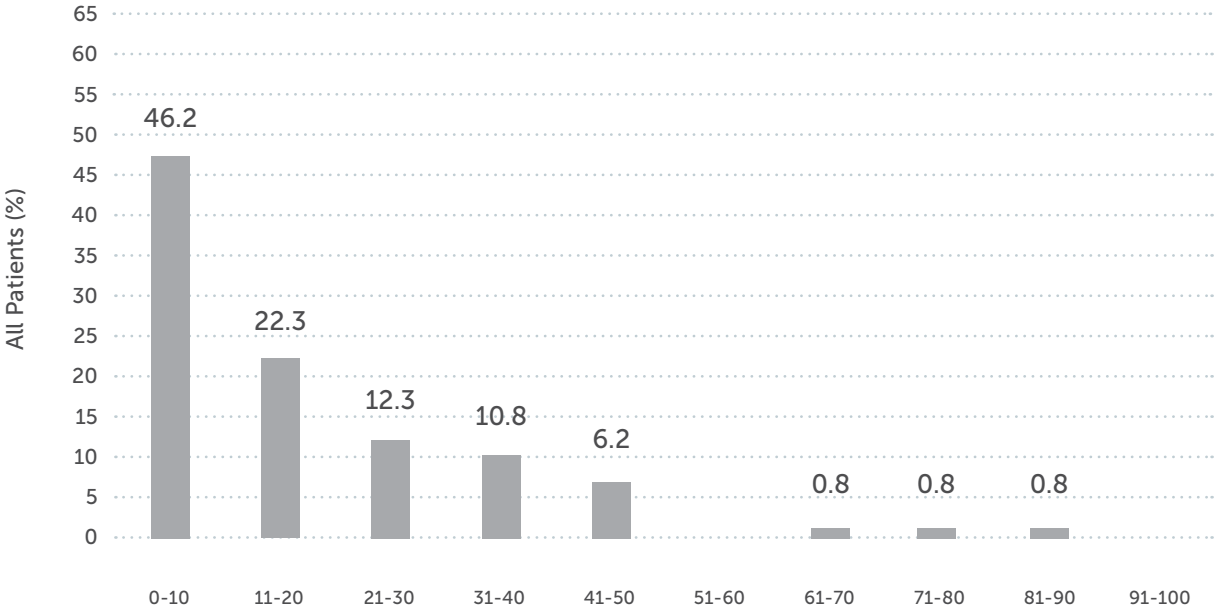
Figure 27: ODI distribution for "L4-L5 DS" patients who completed any ODI at pre-op, 6, 12 and 24-months post-op



(c) Twelve-month post–operative ODI (n=152)



(d) Twenty-four-month post–operative ODI (n=130)



The ten ODI domains for the L4-L5 DS patients that completed any questionnaires were analysed. Table 30 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 pain and standing showing the largest improvement.

Table 30: ODI mean scores for each domain for "L4-L5 DS" patients who completed any EQVAS at pre-op, 6, 12 and 24-months post-op

ODI	Pre-operative	6-Months	12-Months	24-Months
n	**180**	**167**	**152**	**130**
Standing, mean (SD)	2.73 (1.32)	1.24 (1.33)	1.20 (1.31)	1.24 (1.39)
Pain, mean (SD)	2.30 (1.05)	0.95 (0.98)	0.80 (0.98)	0.90 (1.07)
Lifting, mean (SD)	2.32 (1.25)	1.59 (1.51)	1.45 (1.44)	1.41 (1.49)
Social Life, mean (SD)	2.25 (1.24)	0.98 (1.31)	0.82 (1.24)	0.84 (1.14)
Walking, mean (SD)	2.11 (1.25)	0.80 (1.14)	0.74 (1.16)	0.72 (1.09)
Traveling, mean (SD)	1.79 (1.24)	0.75 (1.12)	0.66 (1.04)	0.68 (1.00)
Sex Life*, mean (SD)	1.78 (1.90)	0.69 (1.41)	0.64 (1.43)	0.49 (1.22)
Sleeping, mean (SD)	1.42 (0.99)	0.60 (0.74)	0.64 (0.79)	0.65 (0.87)
Sitting, mean (SD)	1.58 (1.18)	0.87 (0.92)	0.78 (0.93)	0.82 (0.90)
Personal Care, mean (SD)	0.94 (1.03)	0.39 (0.87)	0.32 (0.81)	0.37 (0.92)

* Note: Sex life question is optional; lower numbers of 110, 105, 95, 90 (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 ODI[13].

For the L4L5 DS patients, 98.6% **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 32 shows the MCID for 12-months post-operatively; 69.7% of patients showed an improvement at this time point. Table 33 shows the MCID for 24-months post-operatively, where 75.7% 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 71 for females. In spite of this age profile, these patients are still benefitting from their procedures.

Table 31: MCID for ODI from pre-op to 6-months post-op for "L4-L5 DS" patients

MCID*	All (n=1454) n (%)	L4-L5 DS (n=126) n (%)
Exceeding the MCID	(Improved)	97 (68.3)
Within the MCID	(Unchanged)	43 (30.3)
Exceeding the MCID	(Worsened)	2 (1.4)

Table 32: MCID for ODI from pre-op to 12-months post-op for "L4-L5 DS" patients

MCID*	All (n=1,778) n (%)	L4-L5 DS (n=92) n (%)
Exceeding the MCID	(Improved)	92 (69.7)
Within the MCID	(Unchanged)	38 (28.8)
Exceeding the MCID	(Worsened)	2 (1.5)

Table 33: MCID for ODI from pre-op to 24-months post-op for "L4-L5 DS" patients

MCID*	All (n=1,240) n (%)	L4-L5 DS (n=115) n (%)
Exceeding the MCID	(Improved)	87 (75.7)
Within the MCID	(Unchanged)	23 (20)
Exceeding the MCID	(Worsened)	5 (4.3)

*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 34 and Figure 28). 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.

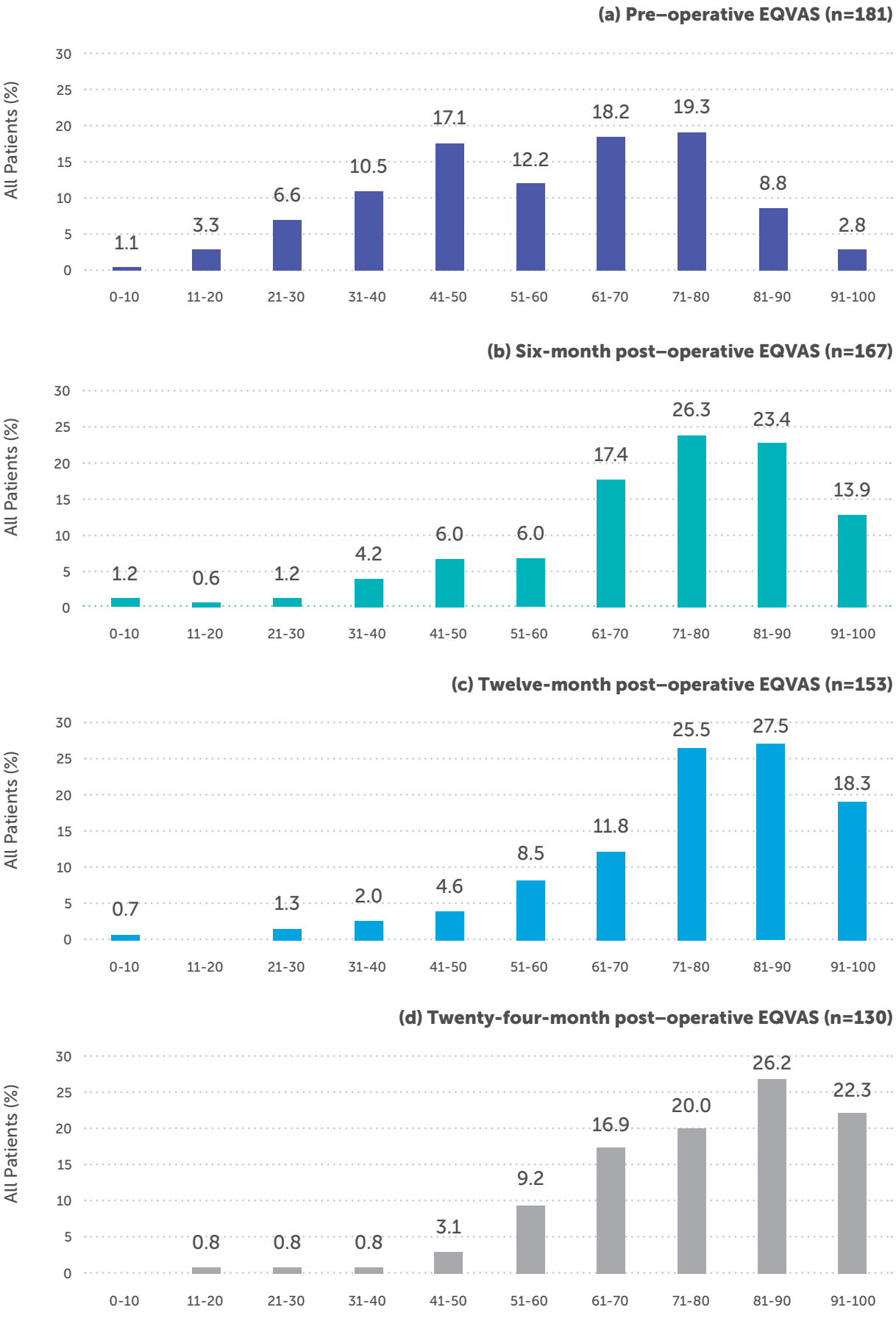
Examination of the EQ-5D responses indicate general patient improvement across all domains. The mobility domain showed the highest improvement. 80.5% of patients reported some or extreme problems with mobility pre-operatively. This was reduced to 37.7% at 6-months post-surgery; a reduction of 45.2%. For the pain/discomfort domain, 98.1% of patients reported some or extreme pain/discomfort pre-operatively which reduced to 58.1% at 6-months post-surgery; a reduction of 39.7%. For the usual activities' domain, 86.2% of patients reported some or extreme problems with carrying out their usual activities. This was reduced to 50.3% 6-months post-surgery; a reduction of 36.2%.

Table 34: EQ-5D-3L scores for each domain for "L4-L5 DS" patients at pre-op, 6, 12 and 24-months post-op

		EQ-5D-3L All Patients			
Domain	**Level of problem**	**Pre-op (%) (n=181)**	**6-months (%) (n=167)**	**12-months (%) (n=153)**	**24-months (%) (n=130)**
Mobility	1 – no problems	17.1	62.3	67.3	60.0
	2 – some problems	81.2	37.7	32.7	40.0
	3 – extreme problems	1.7	0.0	0.0	0.0
Usual Activities	1 – no problems	13.8	49.7	58.2	59.2
	2 – some problems	74.6	47.3	40.5	38.5
	3 – extreme problems	11.6	3.0	1.3	2.3
Pain/ Discomfort	1 – no problems	2.2	41.9	51.6	42.3
	2 – some problems	61.3	53.9	45.1	52.3
	3 – extreme problems	36.5	4.2	3.3	5.4
Self-Care	1 – no problems	74.0	87.4	88.9	92.3
	2 – some problems	25.4	12.6	11.1	7.7
	3 – extreme problems	0.6	0.0	0.0	0.0
Anxiety/ Depression	1 – no problems	52.5	72.5	76.5	76.2
	2 – some problems	42.5	25.7	20.9	20.8
	3 – extreme problems	5.0	1.8	2.6	3.1

When examining EQVAS a shift to the right indicates an improvement of patient perception of their general health status. As shown in Figure 28, this cohort showed improvement in their general perception of their health 6, 12 and 24-months post-operatively.

Figure 28: EQVAS distribution for L4-L5 DS patients who completed any EQVAS at pre-op, 6, 12 and 24-months post-op



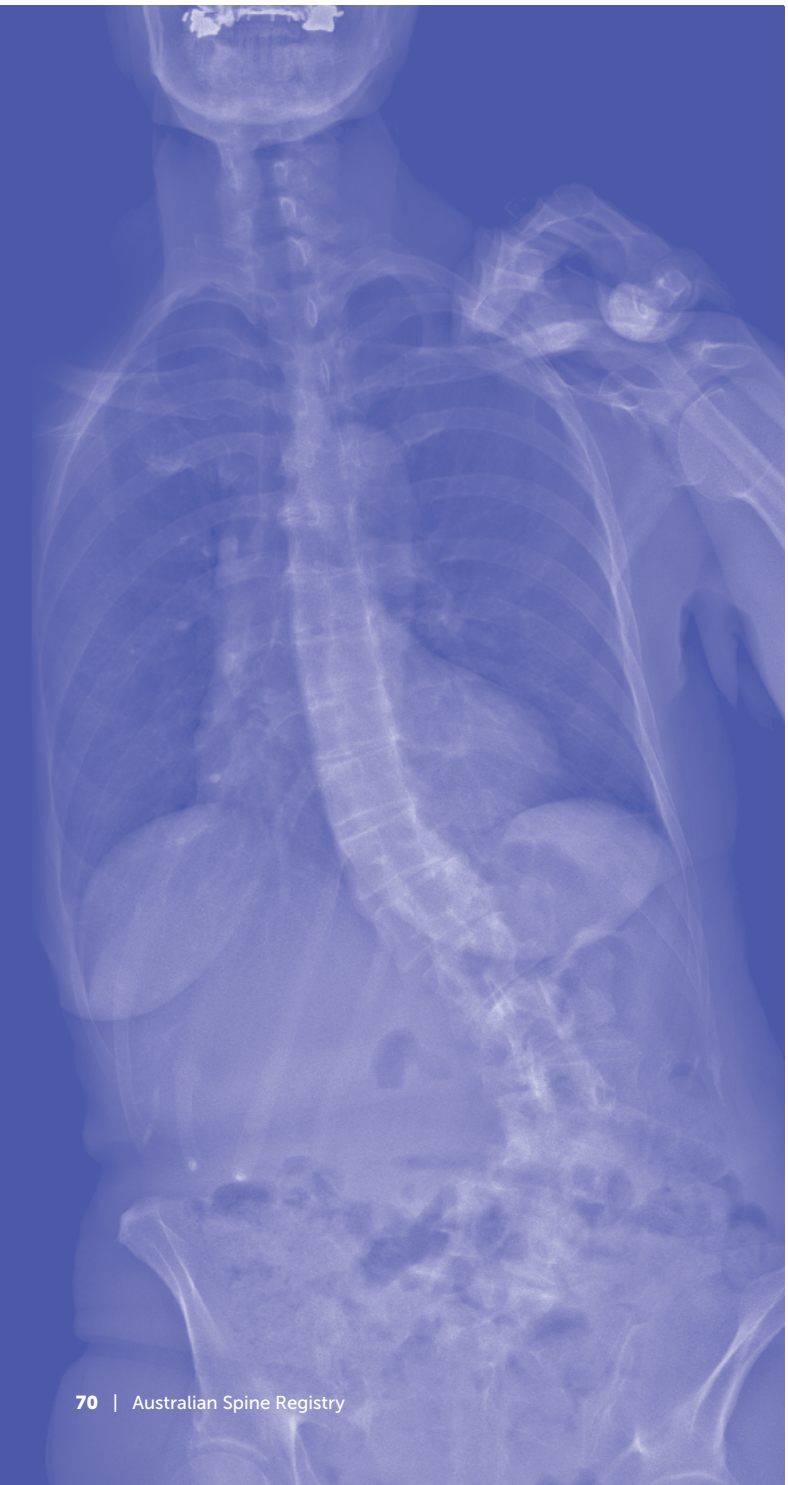
Complex Surgery

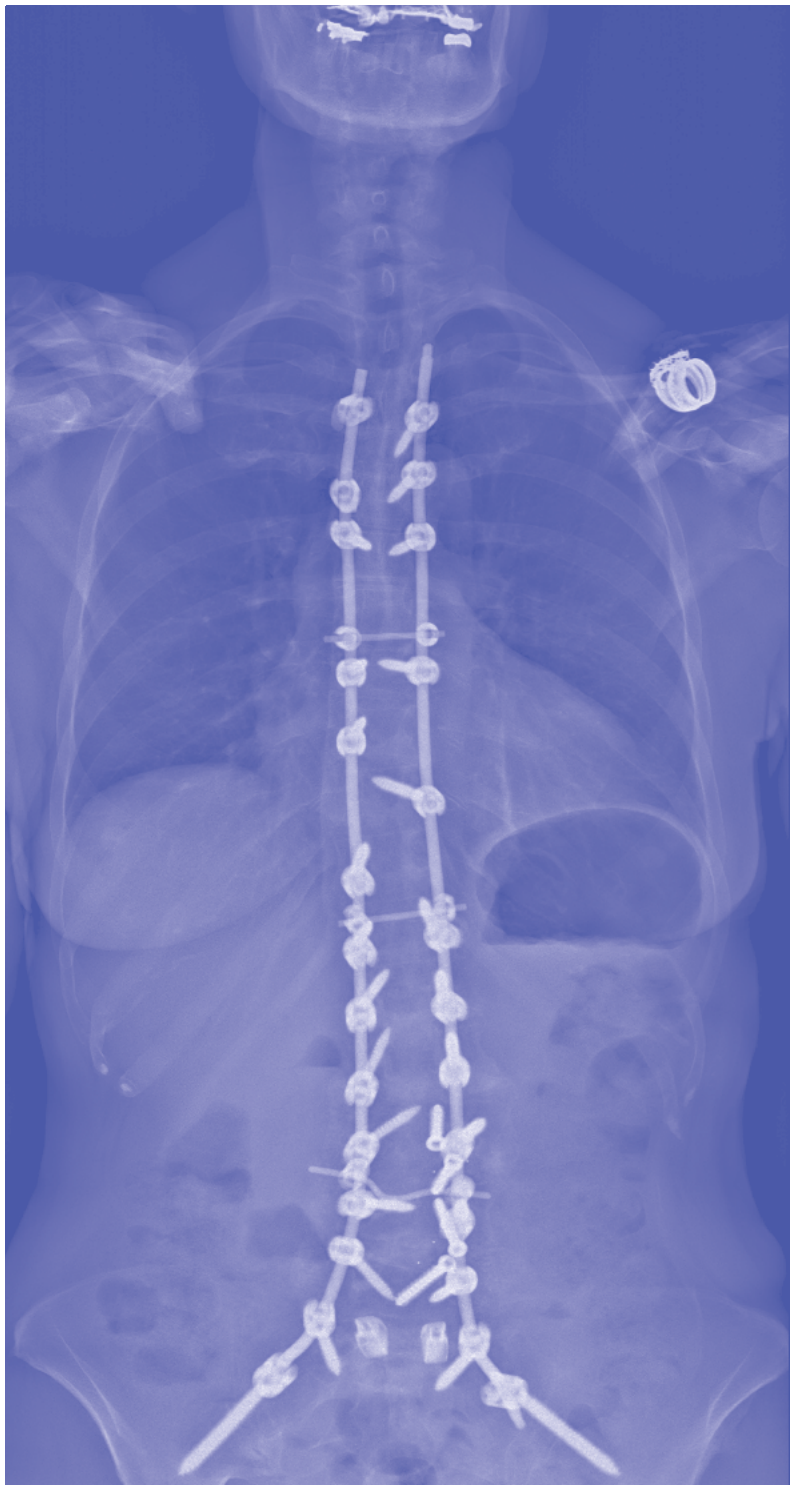
This cohort of patients has been selected using all the following inclusion criteria:

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.

Images courtesy of Assoc. Prof John Cunningham





Demographics

145 patients met the inclusion criteria which represents 4.5% of patients undergoing thoracolumbar procedures. As indicated in Figure 29, 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 30).
- Greater than 50% of the patients had had previous spine surgery (Figure 31).

Figure 29: Complex Surgery patients by age and gender

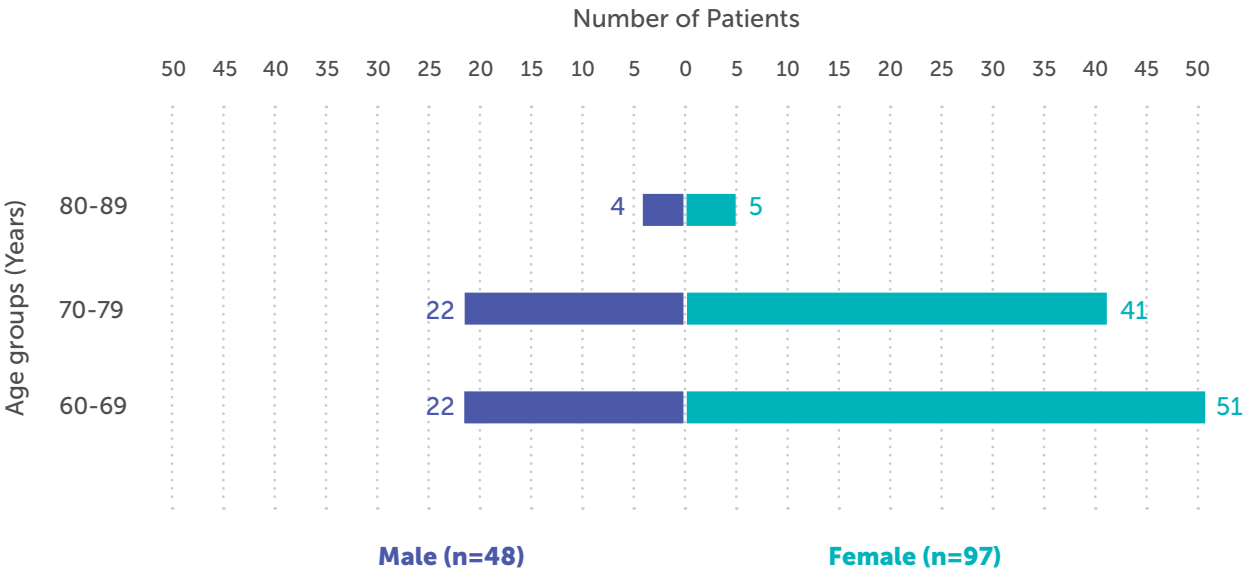


Figure 30: Number of patients who underwent multi-staged procedures for the "complex surgery" patients cohort

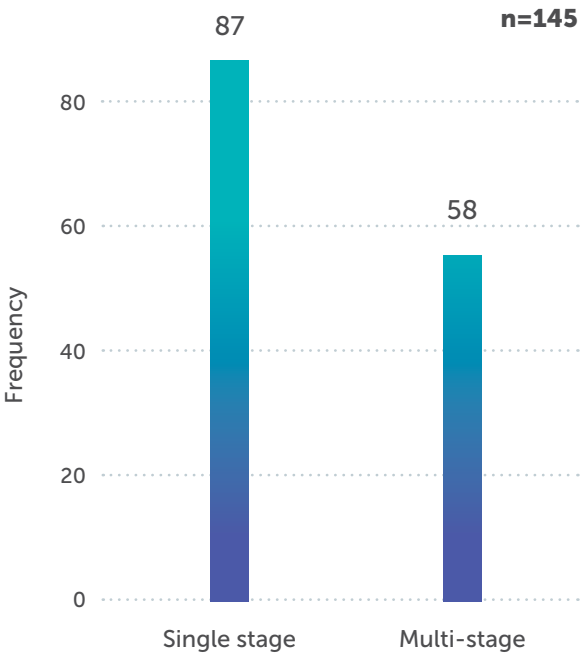
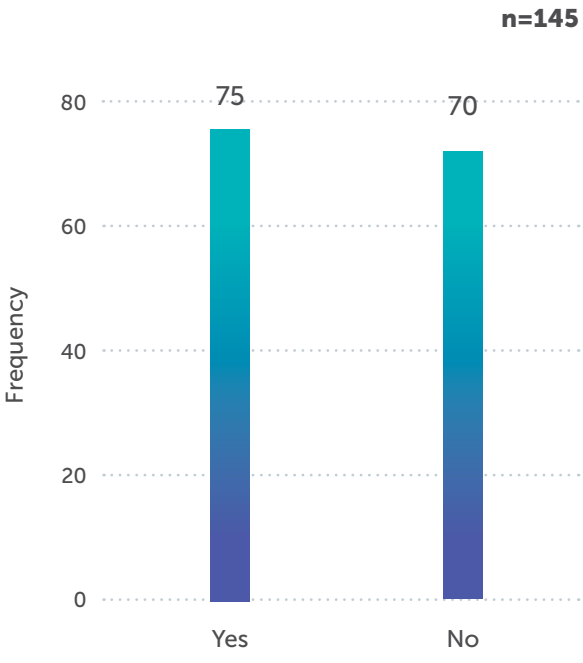


Figure 31: Number of patients of "complex surgery" patients that had had previous spine surgery



Surgeon Reported Comorbidities and ASA

This surgical cohort would appear to have a high level of associated SRCs in comparison to the overall spine surgery population (Table 35, Table 36). Whilst there was a variability between SRCs and ASA score, this trend was consistent (Table 37).

Table 35: Number of Complex Surgery patients with any comorbidity prior to surgery

Comorbidity Diagnosis	All (n=3735) n (%)	Complex Surgery (n=145) n (%)
No	2,311 (61.9)	41 (28.3)
Yes	1,424 (38.1)	104 (71.7)

Table 36: Breakdown of number of SRCs reported in Complex Surgery patients

Number of comorbidities	All (n=3735) n (%)	Complex Surgery (n=145) n (%)
None	2,311 (61.9)	41 (28.3)
1	656 (17.6)	51 35.2)
2	389 (10.4)	32 (22.1)
3	240 (6.4)	12 (8.3)
4	81 2.2)	4 (2.8)
5+	58 (1.6)	5 (3.4)

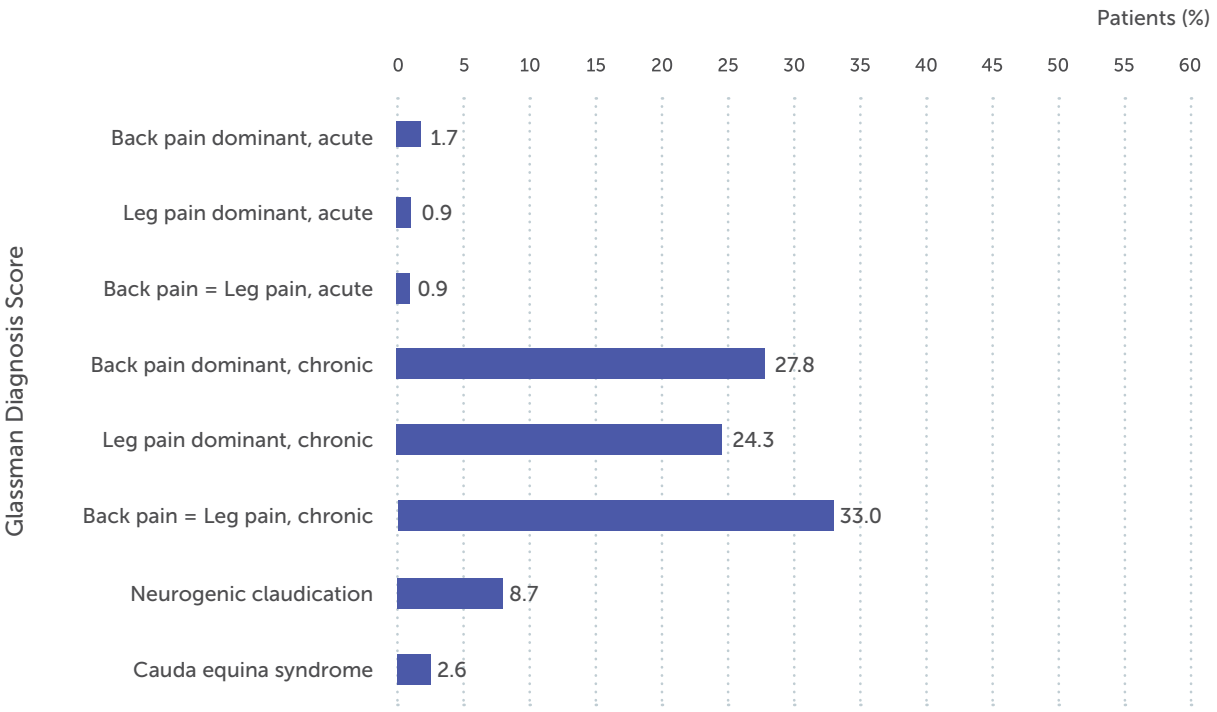
Table 37: ASA score reported for "Complex Surgery" patients compared to all ASR patients

ASA Classification	All (n=2072) n (%)	Complex Surgery (n=142) n (%)
1	497 (24)	3 (2.1)
2	949 (45.8)	54 (38)
3	602 (29.1)	83 (58.5)
4	24 (1.2)	2 (1.4)

Glassman Score for 'Symptoms' among Complex Surgery patients

As indicated in Figure 32, 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 32: Glassman Score for 'Symptoms' among complex surgery patients (n=115)



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.

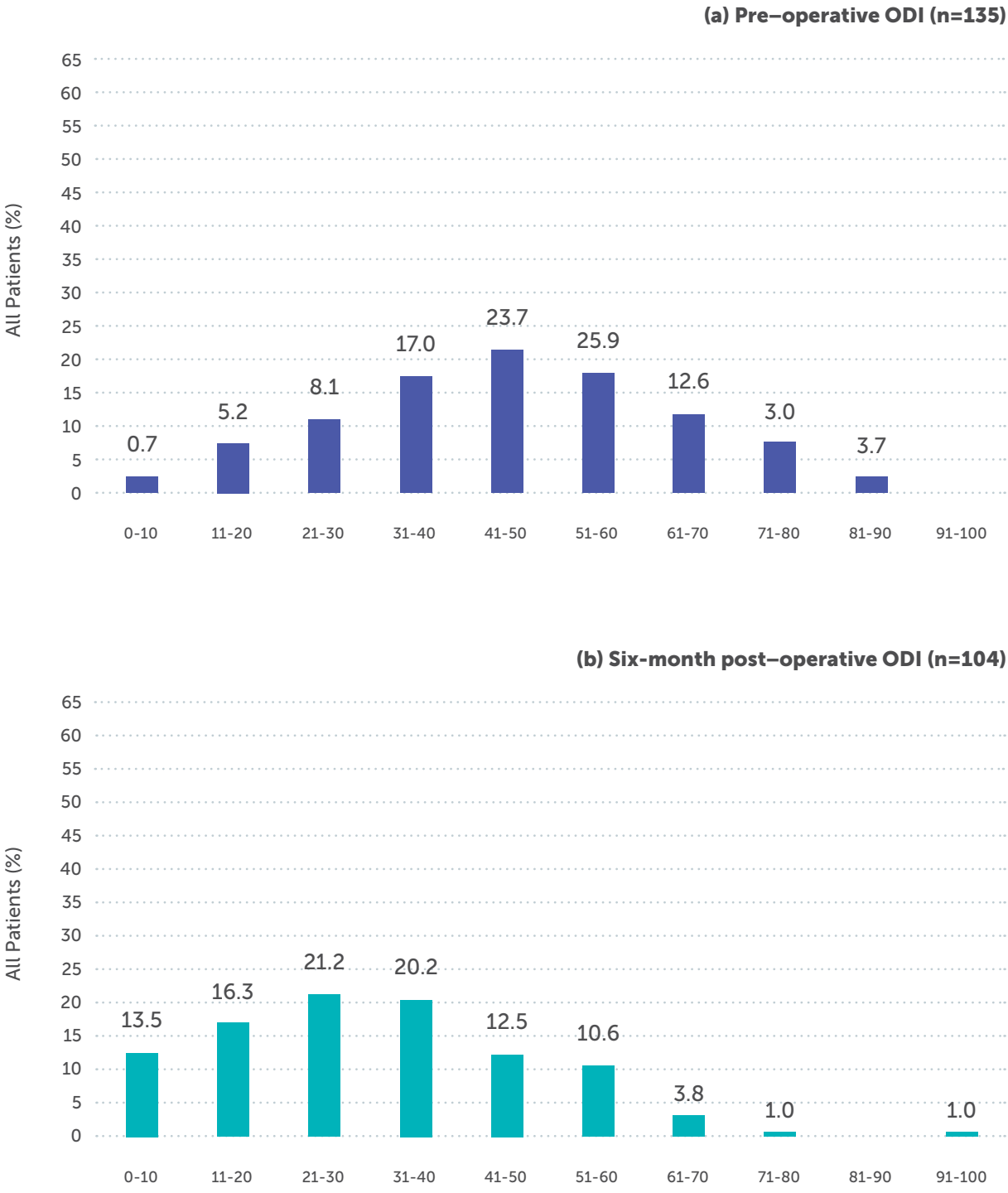
ODI median scores improved from 48 pre-operatively to 30 6-months post-operatively. There was a gradual improvement over the following 18 months (Table 38).

Table 38: ODI mean and median scores for Complex Surgery patients who completed any ODI at pre-op, 6, 12 and 24-months post-op

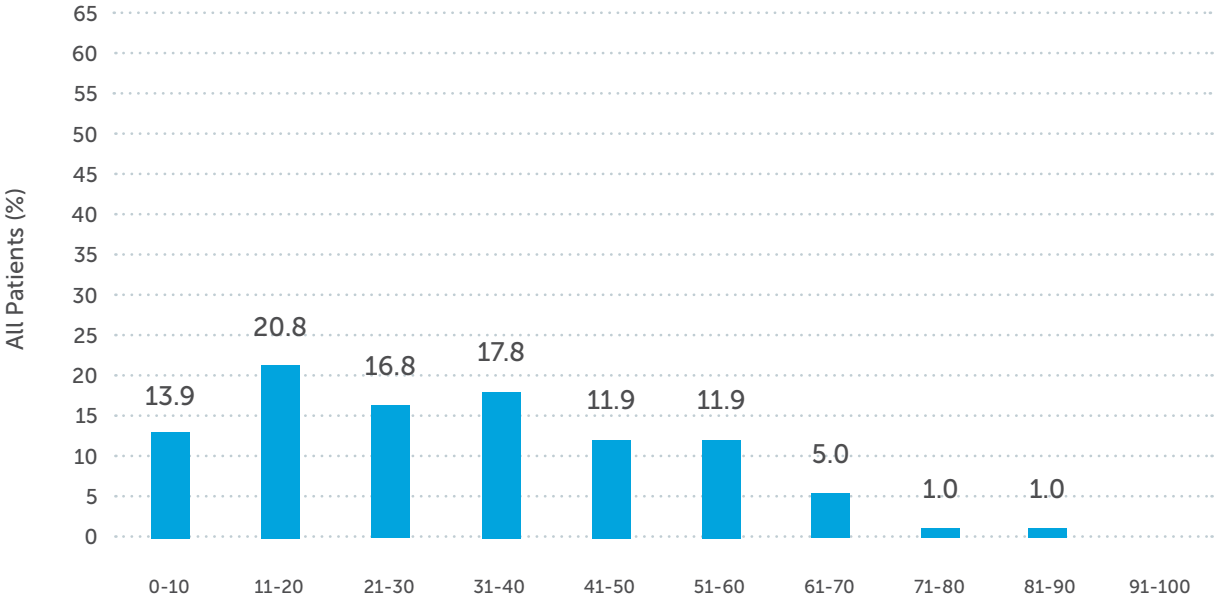
ODI	Pre-operative	6-months	12-months	24-months
n	135	104	101	68
Mean (SD)	47.9 (15.8)	31.9 (18.4)	31.1 (18.4)	27.6 (19.9)
Median (IQR)	48.0 (38.0, 60.0)	30.0 (18.0, 46.0)	30.0 (16.0, 44.0)	27.5 (10.5, 38.0)

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 33).

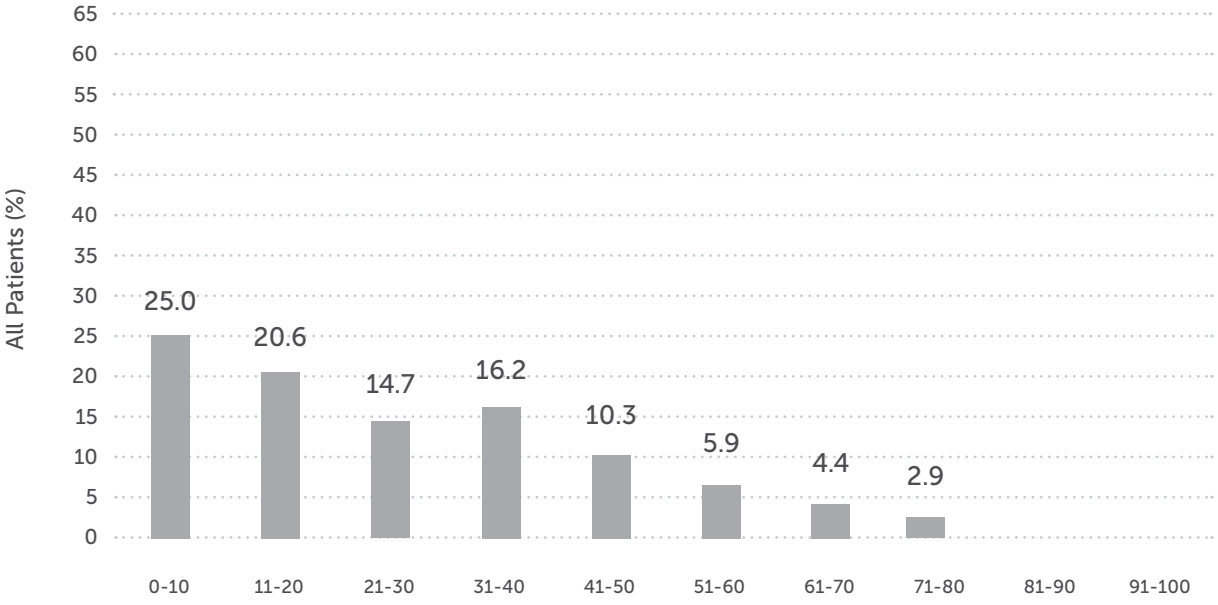
Figure 33: ODI distribution for Complex Surgery patients who completed any ODI at pre-op, 6, 12 and 24-months post-op



(c) Twelve-month post–operative ODI (n=101)



(d) Twenty-four-month post–operative ODI (n=68)



Using the ODI MCID of 12.8 for degenerative adult scoliosis [18,19], 52% of patients undergoing complex spine surgery have a clinically meaningful improvement (Table 39). Unlike the other cohorts where improvements are stable at 12 months and 24 months, in this cohort, recovery appears to be more prolonged (Tables 40 and 41).

There is a significant group where the benefit is limited. Approximately 20%, remain with an ODI greater than 40 at the 2 year time point (Figure 33). Further analysis of this cohort is required to establish factors associated with prognosis.

Table 39: MCID for ODI from pre-op to 6-months post-op for Complex Surgery patients

MCID*	All Thoracolumbar Patients (n=1969) n (%)	Complex Surgery (n=100) n (%)
Improved	1,277 (64.9)	52 (52)
Unchanged	624 (31.7)	45 (45)
Worsened	68 (3.5)	3 (3)

Table 40: MCID for ODI from pre-op to 12-months post-op for Complex Surgery patients

MCID*	All Thoracolumbar Patients (n=1,778) n (%)	Complex Surgery (n=97) n (%)
Improved	1,172 (65.9)	52 (53.6)
Unchanged	562 (31.6)	43 (44.3)
Worsened	44 (2.5)	2 (2.1)

Table 41: MCID for ODI from pre-op to 24-months post-op for Complex Surgery patients

MCID*	All Thoracolumbar Patients (n=1,240) n (%)	Complex Surgery (n=65) n (%)
Improved	830 (66.9)	43 (66.2)
Unchanged	365 (29.4)	19 (29.2)
Worsened	45 (3.6)	3 (4.6)

EQ-5D-3L Quality of Life

All domains of the EQ5D showed an improvement from pre-op up to 24 months (Table 42 and Table 43).

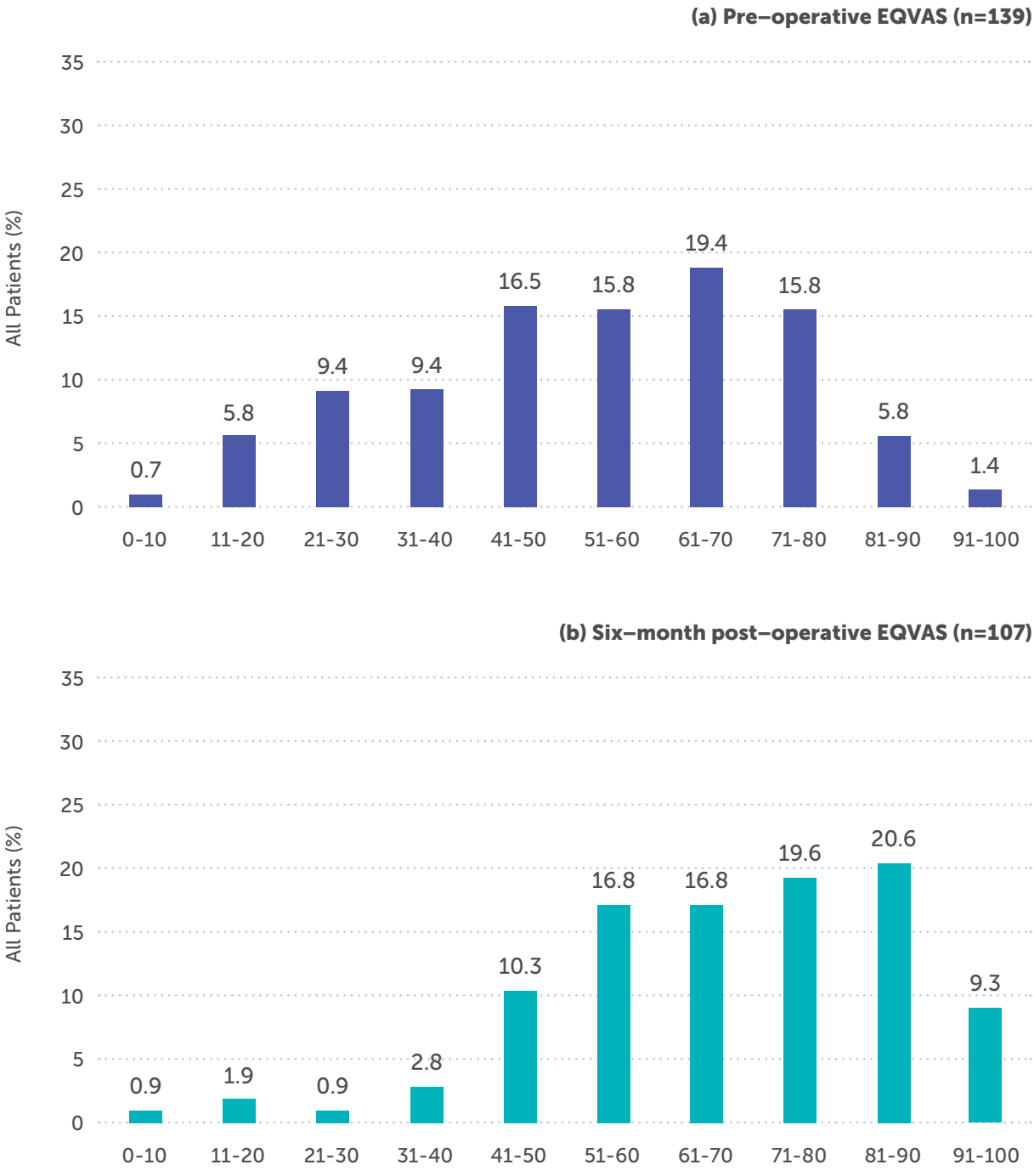
Table 42: EQ-5D-3L scores for each domain for Complex Surgery patients from pre-op, to 24-months post-op

EQ-5D-3L All Patients					
Domain	**Level of problem**	**Pre-Op (%) n=139**	**6-months (%) n=107**	**12-months (%) n=105**	**24-months (%) n=70**
Pain/ Discomfort	1 – no problems	0.7	19.6	21.0	22.9
	2 – some problems	49.6	74.8	74.3	68.6
	3 – extreme problems	49.6	5.6	4.8	8.6
Usual Activities	1 – no problems	8.6	18.7	27.6	32.9
	2 – some problems	68.3	72.9	64.8	60.0
	3 – extreme problems	23.0	8.4	7.6	7.1
Anxiety/ Depression	1 – no problems	42.4	52.3	64.8	62.9
	2 – some problems	49.6	45.8	31.4	32.9
	3 – extreme problems	7.9	1.9	3.8	4.3
Mobility	1 – no problems	6.5	31.8	34.3	38.6
	2 – some problems	89.9	66.4	64.8	61.4
	3 – extreme problems	3.6	1.9	1.0	0.0
Self-Care	1 – no problems	53.2	63.6	56.2	62.9
	2 – some problems	45.3	35.5	42.9	37.1
	3 – extreme problems	1.4	0.9	1.0	0.0

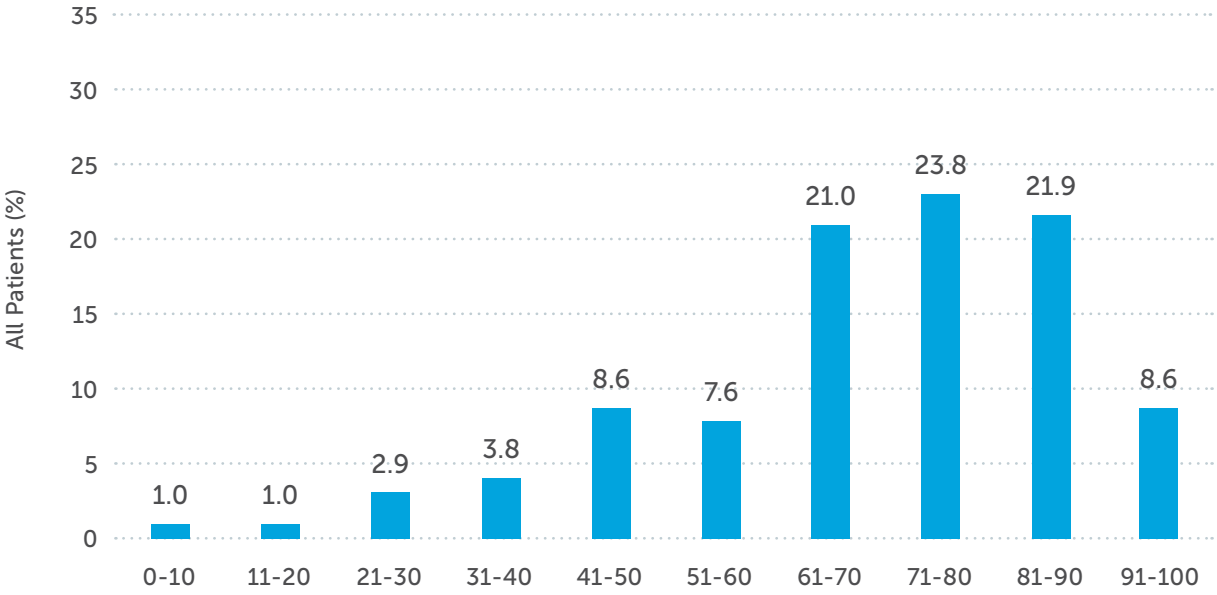
Table 43: EQVAS mean and median scores for Complex Surgery patients who completed any EQVAS at pre-op, 6, 12 and 24-months post-op

Factor	**Pre-operative**	**6-months**	**12-months**	**24-months**
N	**139**	**107**	**105**	**70**
mean (SD)	56.7 (19.9)	69.9 (18.7)	70.7 (18.9)	72.5 (18.9)
median (IQR)	60.0 (40.0, 70.0)	70.0 (60.0, 85.0)	74.0 (61.0, 85.0)	79.5 (65.0, 87.0)

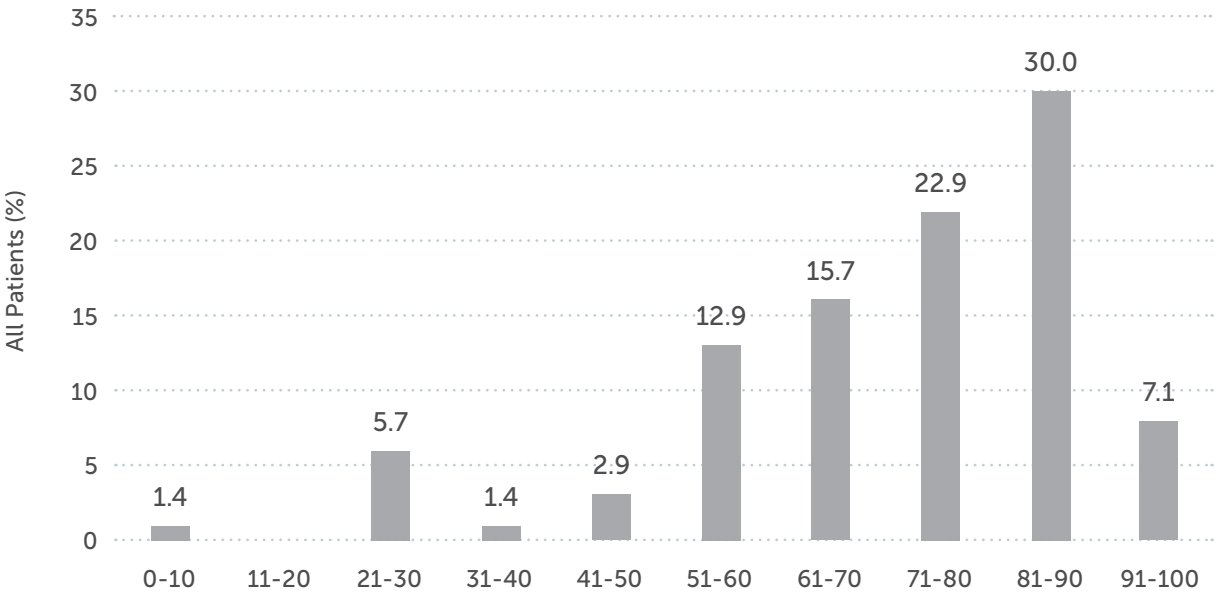
Figure 34: EQVAS distribution for Complex Surgery patients who completed any EQVAS at pre-op, 6, 12 and 24-months post-op



(c) Twelve–month post–operative EQVAS (n=105)



(d) Twenty–four–month post–operative EQVAS (n=70)



Future Directions

The ASR remains excited by the continued growth of the registry. New operational staff recruitment made possible through Federal Government funding, allows for a more targeted and streamlined recruitment approach for surgeons and private and public hospitals.

The ASR continues to benefit from the support of Monash University which allows for state-of-the-art IT security systems for our registry data in a world challenged by privacy issues on a regular basis.

The ASR aims to provide data and insight that is not only helpful for surgeons but also for patients. This includes understanding the impact of comorbidities on spine surgery outcomes. By understanding this relationship more closely, patients can be better informed when undergoing surgery. Our analysis of our data indicates the need for further research into an optimal method of comorbidity collection. Considering this, the registry will be trialling 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 surgery[20].

The ASR will also continue with refinement of complications data collection through our data entry program utilised by our registry users.

The ASR is working towards data linkage with the National Death Index. The ASR currently relies on notification from family members when an ASR patient dies. This is an inefficient mechanism and may be distressing for family to receive registry follow up letters. Therefore, the ASR believes that linkage is an ethically more suitable process. In addition, linkage to the National Death Index will allow the registry to explore associations between surgery and death, if within a certain timeframe. This has not been previously explored in an Australian context.

The ASR is now at a point where it can grow from a research perspective. It is forming a research committee in order to stimulate use of the database for research activities.

The ASR, together with the Queensland Children's Hospital, is currently developing a paediatric arm of the ASR specifically for paediatric spine surgery. The pilot program will commence in 2023. A user test site is currently being trialled and governance is underway in preparation for the project to commence in mid-2023.

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 2023 and beyond. The national roll out is key to the ASRs' ongoing success, to provide a greater understanding of patient and treatment factors that enhace patient outcomes.

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

Registry 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 2022

Darwin, 26 - 27 May 2022
Presentations at the SSA Annual Scientific Meeting May 2022 - Title of papers:

- Spinal Registries and adverse events: How well do we monitor outcomes?
- Society Session: Update on the Australian Spine Registry
- Registries; the need, challenges, and future
- Australian spine registry stakeholder presentation

Cairns, 23 June 2022
AOA Knowledge Summit
Title of paper: Analysing a clinical problem with data, what to consider

Adelaide, 7 Nov 2022
2022 ACTA ASM including the Australian Registry ASM
Title of paper: Comorbidity data collection across different spine registries; An evidence map

Appendices & References

Appendices

Appendix 1 - ASR Committees

SSA Registry Committee

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

ASR Steering Committee 2022

Mr Michael Johnson	Committee Chair, Past President Spine Society of Australia
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
Mr Sean Bulmer	Research Assistant
Mr Patrick Garduce	Data Analyst

Appendix 2 - Participating Surgeons in 2022

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
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
	Denis Hartig	Specialist Spine Surgeon
	Leo Zeller	Orthopaedic Surgeon
	Adam Parr	Orthopaedic Spine Surgeon
Tasmania	Imogen Ibbet	Orthopaedic Spine Surgeon
	Andrew Hunn	Neurosurgeon

Appendix 3 - Approved Hospitals

Victoria

- Epworth Richmond
- Royal Melbourne Hospital
- Epworth Eastern
- Warringal Private Hospital
- Epworth Geelong
- The Avenue Hospital

Western Australia

- St John of God Subiaco Hospital

Queensland

- Princess Alexandra Hospital
- Royal Brisbane and Women's Hospital

Tasmania

- Calvary Private Hospital – Lenah Valley

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 Public and Private Hospital

Appendices

Appendix 4 – 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

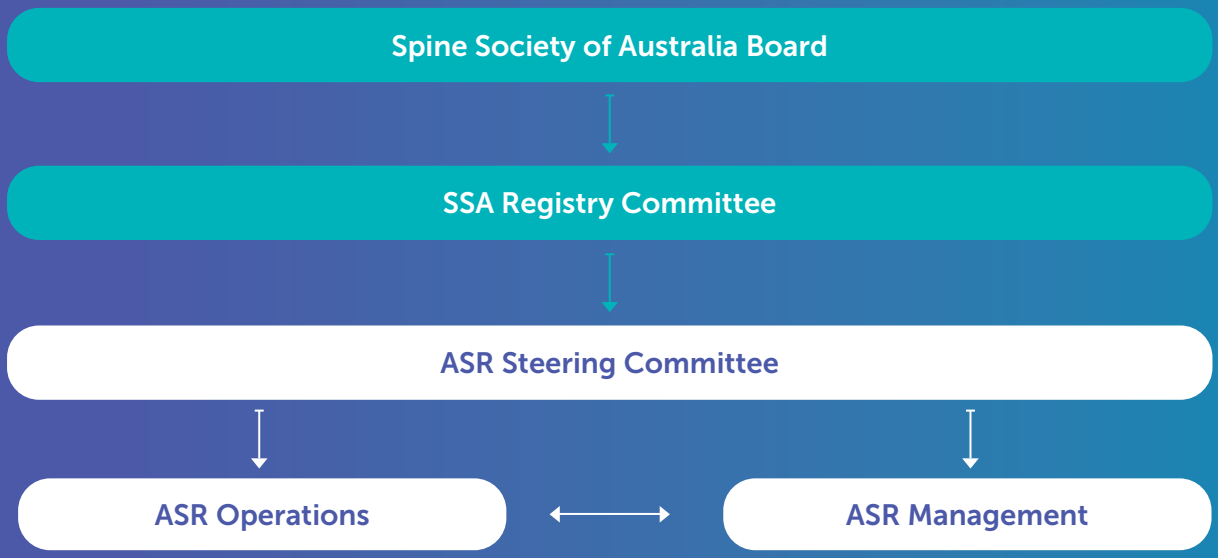
The ASR Steering Committee Membership comprises a multidisciplinary group of experts that are responsible for the governance of the ASR whose focus is on providing strategic direction and ensuring deliverables are met by the ASR.

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.



Appendix 5 – 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.

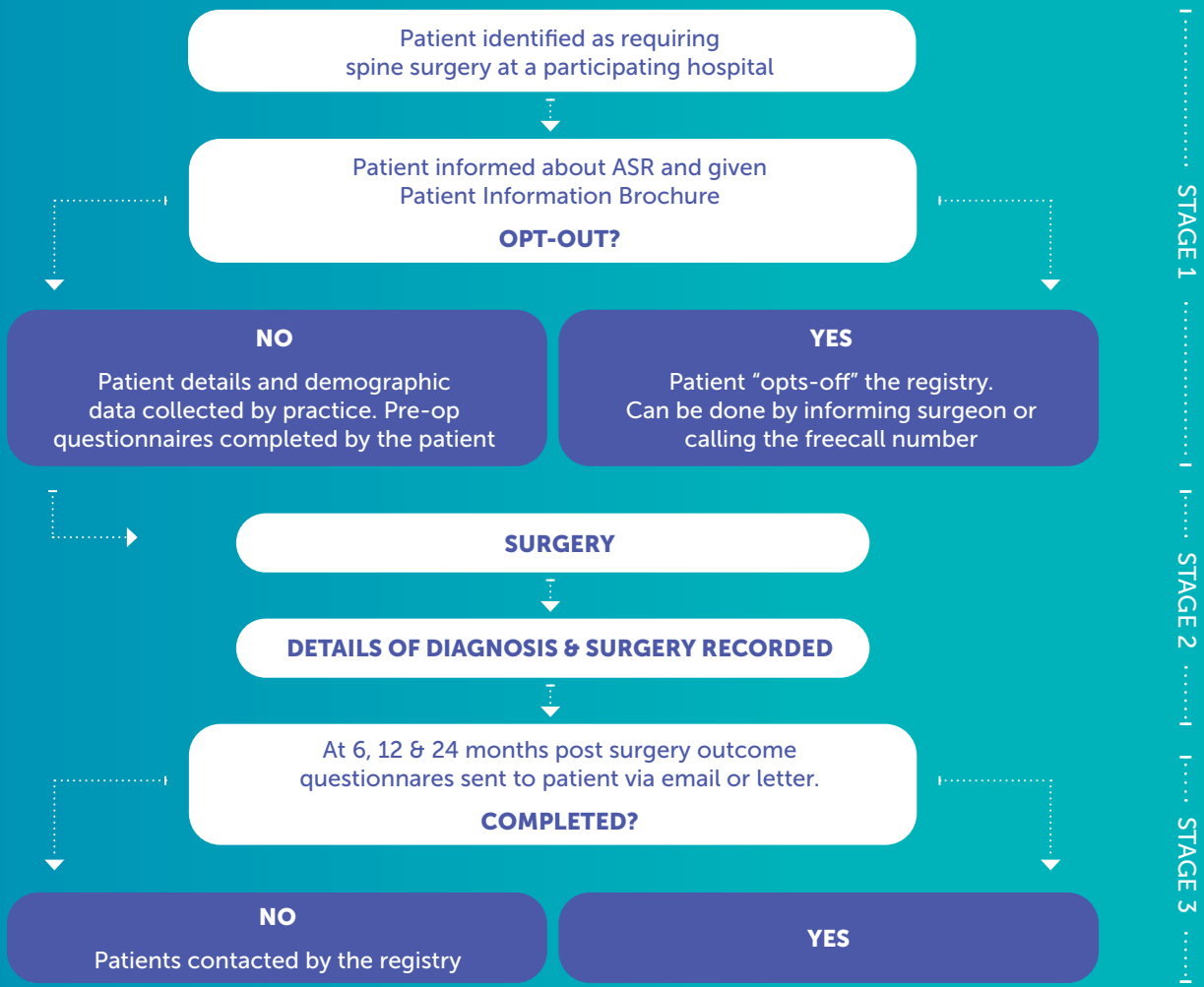
Inclusion Criteria

- 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

Registry Process



Appendices

Appendix 6 – 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 making[12]:

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 neck[21,10,22,23]

3. General quality of life (QoL) EuroQol five dimension (EQ-5D™-3L) questionnaire[13]

Appendix 7 - 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/m^2
- 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

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Australian Spine Registry

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