Australian Spine Registry

Australian Spine Society

MONASH University

Annual Report 2021

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

Enquiries/Comments

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Foreword

It is with great pleasure that I present the Australian Spine Registry 2021 Annual Report.

Whilst we thought that 2020 was a very trying and interesting year, 2021 was even more demanding. The normal way our community and health system function continued to be challenged by the need to manage the COVID-19 pandemic. Patients, surgeons, practice staff and hospitals continued to be affected. The impact on elective surgery during 2021 was especially significant due to the lockdowns and the surge of COVID-19 cases requiring hospital care.

Despite these challenges, our registry continued to maintain an excellent level of patient and surgeon compliance. Although our recruitment was affected due to the reduction of elective surgery during 2021, patient follow up and data collection continued, and compliance remained over 80% demonstrating that the ASR is a viable registry under the most trying circumstances.

Currently the registry has almost 3500 patients (almost 1000 more than last year). At the beginning of 2021, we welcomed 2 more public hospitals to the registry: The Royal Brisbane and Women's Hospital and Princess Alexandra Hospital, Brisbane. We are now planning a staged expansion of the registry nationally.

The ASR Pilot to this stage has been supported by generous donations from industry, health insurers and the Spine Society of Australia.

The next phase for the registry is to secure sustainable funding. The ASR developed a comprehensive business case which was presented to the federal government in October 2021 with the aim of securing adequate and stable funding which is essential to expand the registry in order to maximise its potential. The business case was warmly received with an offer of $900,000 over the next two years. We would like to thank the Minister, the Hon. MP Greg Hunt and the staff in the Department of Health for their advice and support.

We also need to thank Dr Esther Apos, our co-ordinator, Ms Trieu-Anh Truong, and all the staff at Monash for their tireless efforts.

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

- the patients, without whose willingness to be involved and to provide their time to complete the registry specific questionnaires pre-operatively and post-operatively, the registry would not be 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 registry coordinator, Dr Esther Apos and Trieu-Anh Truong, our research assistant.
- Professor Susannah Ahern and her staff at the Clinical Outcomes data Reporting and Research Program (CORRP), Monash University.
- Mr Philippe Roussouly and his team for the support and continuous improvement of the registry web-based interface.
- Ms Jane Macintosh for her valuable assistance in the preparation of the ASR business case.
- the SSA Board for their continuing support.
- Professor Stephen Graves and Mr Adrian Cosenza from the AOA, particularly for their advice concerning the business case.
- the members of the Steering Committee and the SSA Registry Committee, for their time and commitment.

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 2022. 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
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
CORRP	Clinical Outcomes data Reporting and Research Program
COVID-19	Coronavirus disease of 2019
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
EQ-VAS	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
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
PTED	Percutaneous Transforaminal Endoscopic Discectomy
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.
SSA	Spine Society of Australia
Thoracolumbar	Between T1 and the pelvis

Executive Summary

The Australian Spine Registry (ASR) is proud to present its fourth Annual Report. The ASR commenced recruiting patients and collecting data in January 2018 and at the time this annual report was published, there were over 3500 patients in the database.

The data presented in this report was collected for all patients recruited between 15 January 2018 and 15 January 2022 and analyses the entire patient group and specific patient cohorts. Aggregated analyses are presented.

We also have analysed the effect of COVID-19 lockdown on our data collection and on the patient reported outcome measures (PROMs). The COVID-19 pandemic restrictions did not seem to have an effect on the ASR patients' quality of life when compared to pre-pandemic years. Registry operations were not adversely affected, however surgeon and patient recruitment slowed due to the COVID-related travel restrictions and elective surgery restrictions in NSW and Victoria, where most of the current ASR participating surgeons practice.

One of the ASR's strengths has been data acquisition. The ASR has successfully implemented processes, such as automatic SMS reminders, which have allowed >80% of data collection from both patients and surgeons. Another key initiative of the registry was the addition of a surgeon specific dashboard. The dashboard will be launched to all surgeons mid-2022.

A quick glance at ASR patient data shows:

- Participants comprised 1358 (53%) males and 1196 (47%) 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
- 46.6% of patients presented with one or more comorbidities
- Discectomy and ACDF patients were generally younger (median age of 48 years and 57 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
- Patient reported outcome questionnaire analysis showed:
    - » Based on the ODI and NDI scores, 82% of patients of the entire cohort indicated an improvement at 6, 12 and 24-months post operatively.
        - » For thoracolumbar and deformity patients, the median ODI pre-op score was 44 compared to median follow up scores of 18 (6 months), 16 (12 months) and 16 (24 months).
        - » For cervical patients, the median NDI pre-op score was 40 compared to median follow up scores of 13 (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.
    - » 86%, 84% and 82% 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.
    - » 56% and 68% and 56% of the patients in the ACDF cohort exceeded the NDI MCID (17) at 6, 12 and 24-months respectively
    - » 68%, 70% and 77% of the patients in the L4-L5 spondylolisthesis cohort exceeded the ODI MCID (12.8) at 6,12 and 24 months.

In 2021, funding support for the registry pilot continued to be through medical device companies, health insurers and the Spine Society of Australia (SSA).

The ASR submitted a comprehensive business case to the federal government with the aim of securing sustainable long-term funding for the next phase of registry expansion. In February 2022, ASR received an offer of $900,000 from the Commonwealth government for the next two years.

Industry funding supporters

Snapshot of The Australian Spine Registry

850

Increase in the number of patients in the past 12 months from January 15 2021 to January 15 2022.

3198

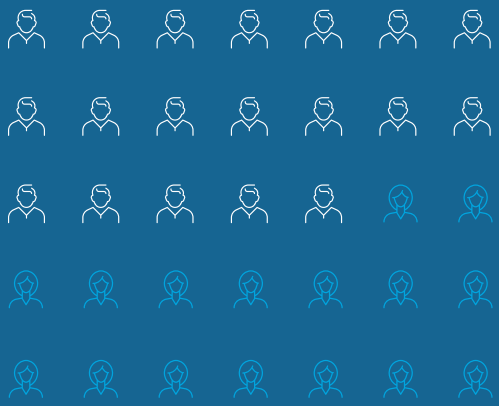
Total number of procedures captured.

1.8% opted-out

0.6% deceased*

1358 Male

1196 Female



PROMs completion	Pre-Op	6 Mth	12 Mth	24 Mth
Patients eligible (n)	2544	2319	1990	1277
Complete data (n)	2165	1897	1651	998
Complete data (%)	85.1%	81.8%	83.0%	78.2%

(Patients recruited up to 15 January 2022)

**Data collected directly from families or practices.*

Patients 3136

Surgeons 17 Actively Recruiting

Sites 18

Key Milestones of the ASR in 2021

SMS communication commenced

February 2021

3000 Patients in the ASR

September 2021

Third Annual Report Published

October 2021

ASR 5-year strategic plan & business case for federal funding submitted to the federal government

October 2021

KEOPs User Dashboard Pilot commenced

November 2021

Background

The Australian community spends over $1 billion on spine surgery every year. With an ageing population and other factors at play, this figure is projected to grow by more than 20% over the next decade[a]. However, there is limited oversight or measurement of the effectiveness of spine surgery, whether it delivers clinical efficacy and optimal patient outcomes, or the extent to which it delivers value to consumers and the healthcare system.

The Australian healthcare system, whilst collecting more data than ever before, lacks the essential information regarding clinical and patient outcomes which is necessary to monitor and evaluate clinical practice and patient care. Furthermore, it lacks proper linkage and integration in many areas. This gap hinders surgical activity and financial monitoring at a broad system-level.

The main reasons for the paucity of spine surgery data are threefold:

- Spine surgery is diverse, complex, and does not have readily obtained outcome metrics. It is heavily dependent on data from patient reported outcome measures (PROMs) questionnaires, which makes spine registry administration costly and burdensome if dependent on traditional paper and phone methods.
- To date there has been no single, independent, nationally collaborative entity with broad coverage and surgeon support which collects, analyses and reports on validated patient outcome measures to assess the extent to which spine surgery improves pain, disability, and quality of life.
- There has been no guaranteed long term, sustainable funding to establish an entity to do this work.

In the absence of accurate, reliable, real-world data on spine surgery interventions, it is impossible to accurately track, monitor and measure clinical practice and patient care, and identify opportunities for change and improvements.

Without the infrastructural capability to collect and analyse clinical and patient data, variations in clinical practice and patient outcomes will remain largely unscrutinised and unexplained. The effectiveness of spine surgery healthcare expenditure to deliver value-based care will therefore remain unexamined.

The ASR is aiming to fill this gap in patient outcome data. The ASR has completed its fourth year of data collection and has shown that it is a viable and sustainable entity. It is proud to present its fourth annual report.

a Estimate based on demographic projections (ABS Population Projections, Australia 2017-2066), historical hospital separations data (ACSQHC analysis. Data drawn from the Admitted Patient Care National Minimum Data Set (APC NMDS), 2011-12 to 2018-19, Australian Institute of Health and Welfare 2019.), and APRA data on growth in spine surgery prostheses (APRA Statistics. Private health insurance prostheses report. December 2020. Released 23 February 2021).

Governance

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, in accordance with the Australian Commission on Safety and Quality in Healthcare's Operating Principles (2008) and Framework for Clinical Quality Registries (2014). The Steering Committee's focus is on providing strategic direction and ensuring deliverables are met by the ASR.

ASR Management Committee

A management committee meets monthly and oversees the day to day operation of the registry and has been based at Monash University since February 2017. It comprises the registry secretariat, the Steering Committee Chair and the Monash University Data Custodian/ academic lead.

Registry Procedures and Policies

Key achievements of the Steering Committee have been the establishment of key policies and procedures including:

- ASR Protocol
- ASR Steering Committee Terms of Reference
- Conflict of interest Policy
- Communications Policy
- Data Access Policy

The registry has also published its strategic 10-year plan and has its first business case to put forward to the Australian Federal Government for ongoing sustainable funding of the registry in October 2021. In February 2022, the registry secured 2 years of funding from the Federal Government.

Data Custodian

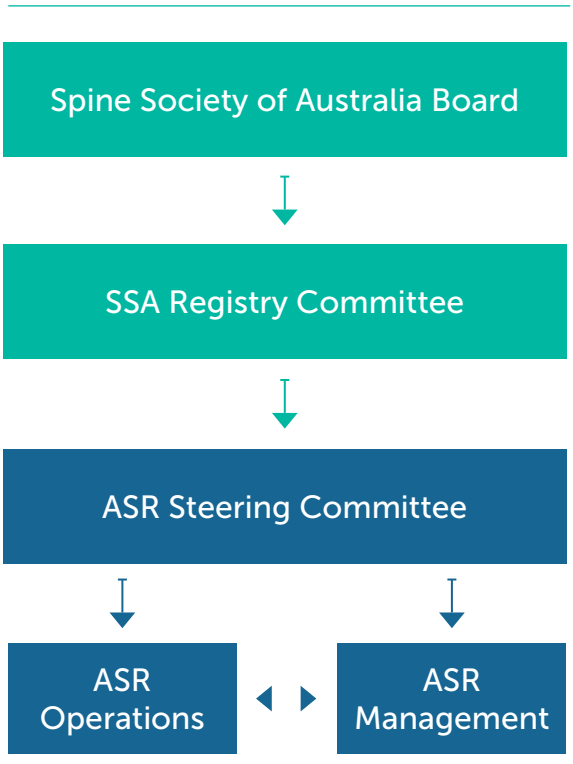
Monash University and the SSA have shared custodianship of the data, which includes accountability of the privacy, security and integrity of patient information held within the registry.

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.

Pilot Phase of Registry

The pilot's aim was to test and evaluate ASR processes and outcomes, and to make recommendations regarding the feasibility for a national rollout of the ASR. The ASR completed the pilot phase in October 2020. The ASR continued to work under the pilot framework due to limited funding.



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.

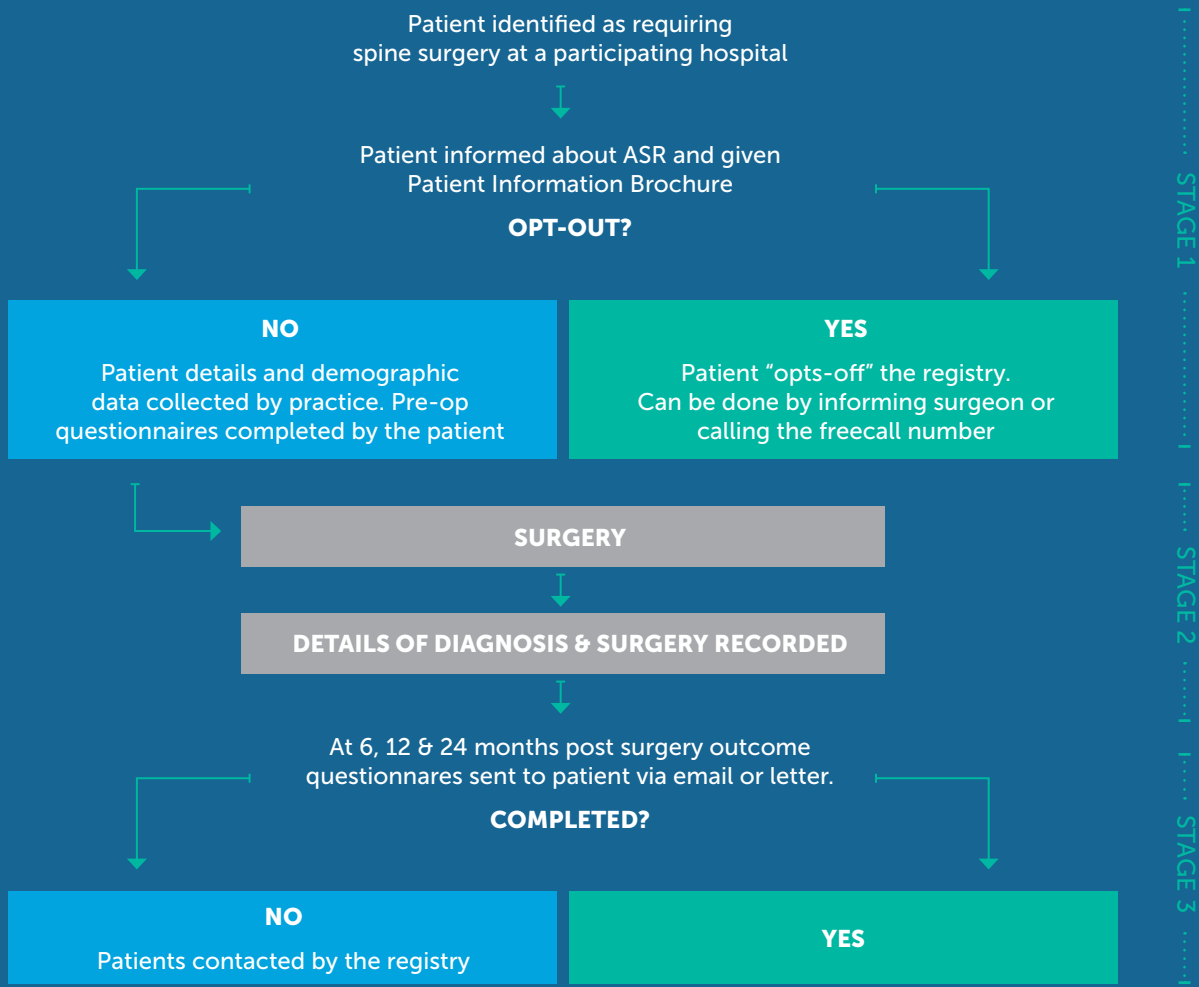
Inclusion Criteria

- 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



Data Collection Process

ASR Database

Data is collected by practices/hospitals, surgeons and Monash registry staff and entered into the ASR KEOPS database. KEOPS is a data management tool designed and constructed specifically for spine specialists.[2]

The registry collects information about the patients before and after surgery (6, 12 and 24 months) in the form of self-completed questionnaires. Pre-operatively, paper-based questionnaires are completed at the time of consultation with the surgeon. Some practices use iPads or an email link to enter responses directly into KEOPs. Post-operatively, patients are either emailed a link to complete the questionnaires or, for those patients who do not use email, paper-based questionnaires are sent to the patient which are returned and then entered by Monash registry staff.

KEOPS is a fully customisable data collection tool which can track clinical outcomes and deliver follow-up patient questionnaires at desired intervals. The ability to customise KEOPs for Australian practices and its ease of use were key reasons for selection and its continued use.

Data collected

Diagnoses (including comorbidities) and surgical information (including complications) are entered into the KEOPs database directly by surgeons. A list of the data collected is shown in Appendix 4.

Glassman Classification

The registry has customised the KEOPs database to include the Glassman Classification in the diagnosis section which is a diagnostic coding matrix that codes three primary elements commonly used in clinical decision making[3]:

- Symptoms
- Structural Pathology
- Compressive Pathology

The registry uses the symptoms category of the Glassman classification as a clinically relevant diagnostic scheme to analyse registry cohorts.

Patient Reported Outcome Measures

The ASR collects patient reported outcome measures (PROMs) which are key for following patient progress and to evaluate the quality of care.

The ASR uses the following validated questionnaires:

1. The Oswestry Disability Index (ODI) for lower back pain.[4]

The ODI is comprised of 10 items and assesses functional status and quality-of-life impairment in patients with acute or chronic low back pain. The index enquires about functional limitations in various activities of daily living with the index score ranging from 1 (best) to 100 (worst). Items include pain intensity, personal hygiene, walking, sleeping, social life, sexual life (optional) and travel are assessed by the patient. Each section has six possible responses, which are scored from 0 to 5.

2. The Neck Disability Index (NDI) for acute or chronic disability of the neck[5, 6-8]

The Neck Disability Index (NDI) has 10 items concerning pain and activities of daily living including personal care, lifting, reading, headaches, concentration, work status, driving, sleeping and recreation. The index is scored out of five (with the no disability response given a score of 0) giving a total score for the questionnaire out of 50. Higher scores represent greater disability.

3. General quality of life (QoL) EuroQol five dimension (EQ-5D™-3L) questionnaire[8]

The EQ-5D-3L consists of 5 descriptive questions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 3 levels: no problems, some problems, extreme problems. There is also a visual analogue scale (VAS) which patients are able to self-rate their health on a scale of 0 (worst imaginable health state) to 100 (best imaginable health state).

Summary of the ASR

Surgeon and Hospital Engagement

Spine surgery is performed by both orthopaedic surgeons and neurosurgeons. To date, 20 surgeons have participated in the ASR. There are currently 17 active users (15 orthopaedic spine surgeon and 2 neurosurgeons).

Due to the COVID-19 travel restrictions, surgeon data audits were not able to be conducted. The audits will recommence in 2022 with the easing of restrictions.

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.

In 2021, the ASR recruited its first Brisbane based public hospitals.

Figure 1: Number of hospital sites participating in the ASR across Australia

6 Public sites approved

12 Private sites approved

Patient Uptake

Active recruitment of patients commenced on 15th January 2018. Patient recruitment during 2021 remained steady despite COVID-19 lockdowns across the country (Figure 2). Elective surgeries were temporarily reduced in Victoria and New South Wales to urgent procedures to help hospitals respond to the increasing number of patients with coronavirus. The majority of elective spine surgery was not considered urgent and was postponed during this period resulting in fewer patients being entered into the registry.

Only 2% of patients had opted out of the registry and 0.6% were deceased. Reasons for opt-outs are shown in Figure 4. Cause of death is not currently collected by the registry (data not shown).

Figure 2: Accumulation rate of patients from registry launch on 15 January 2018 to 15 January 2022

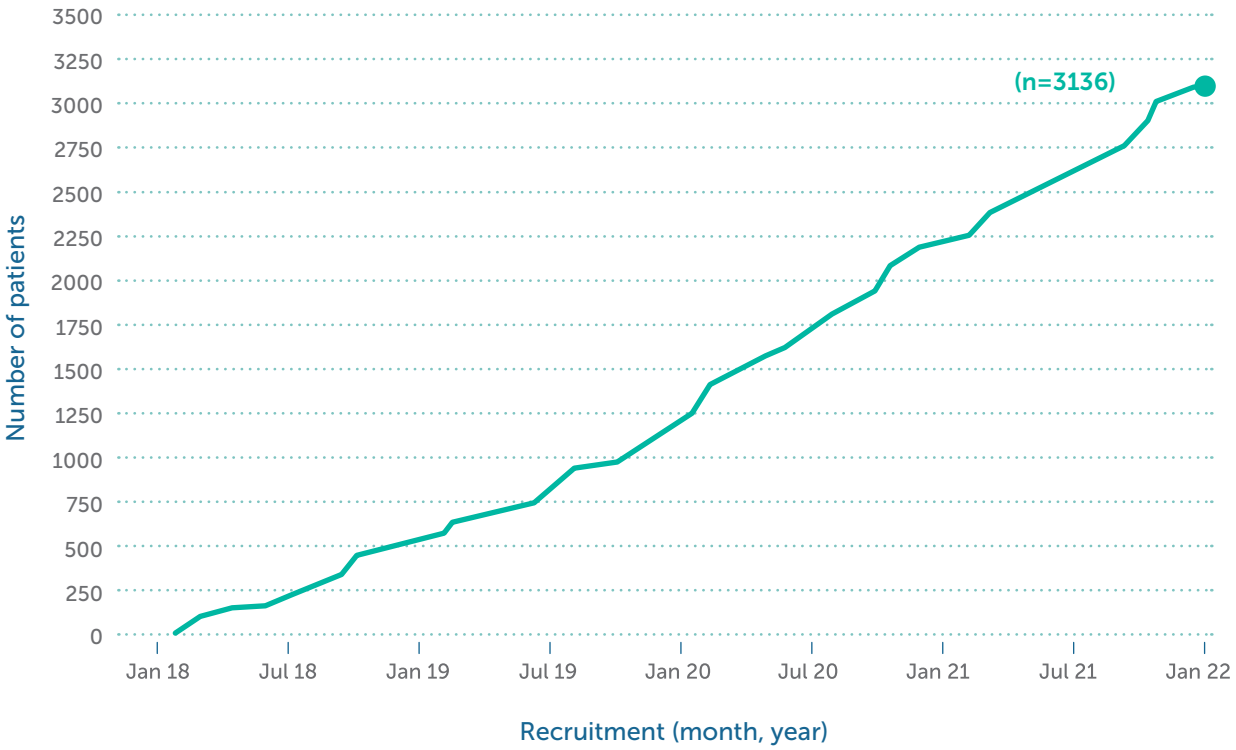


Figure 3: Patient recruitment by year

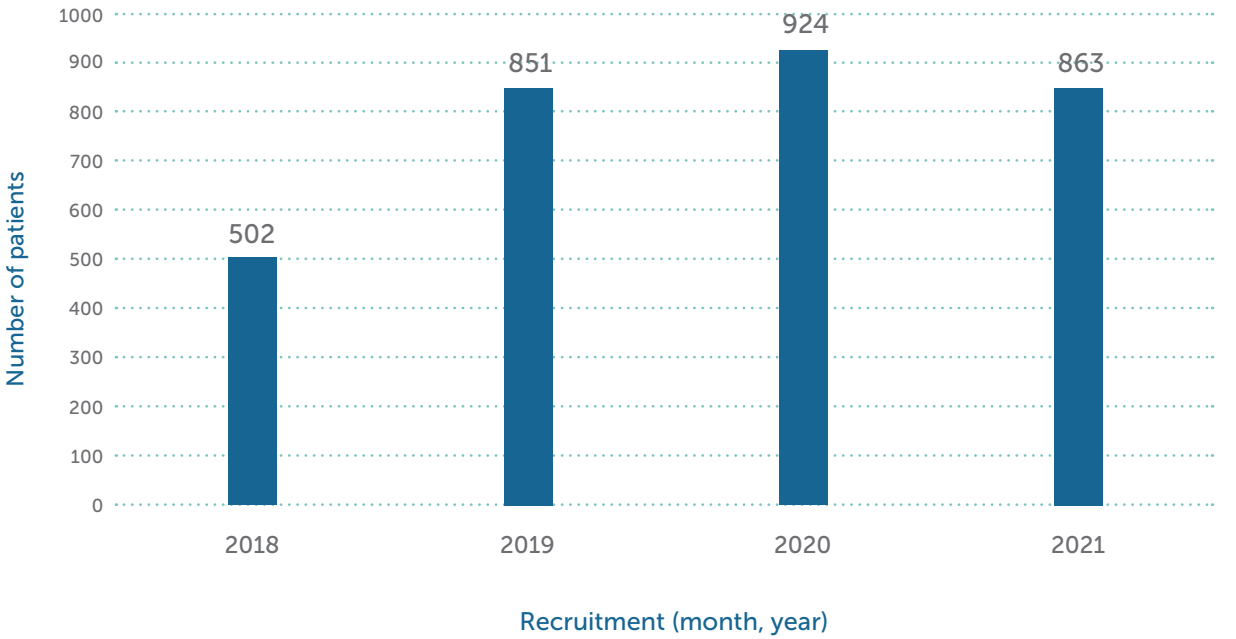
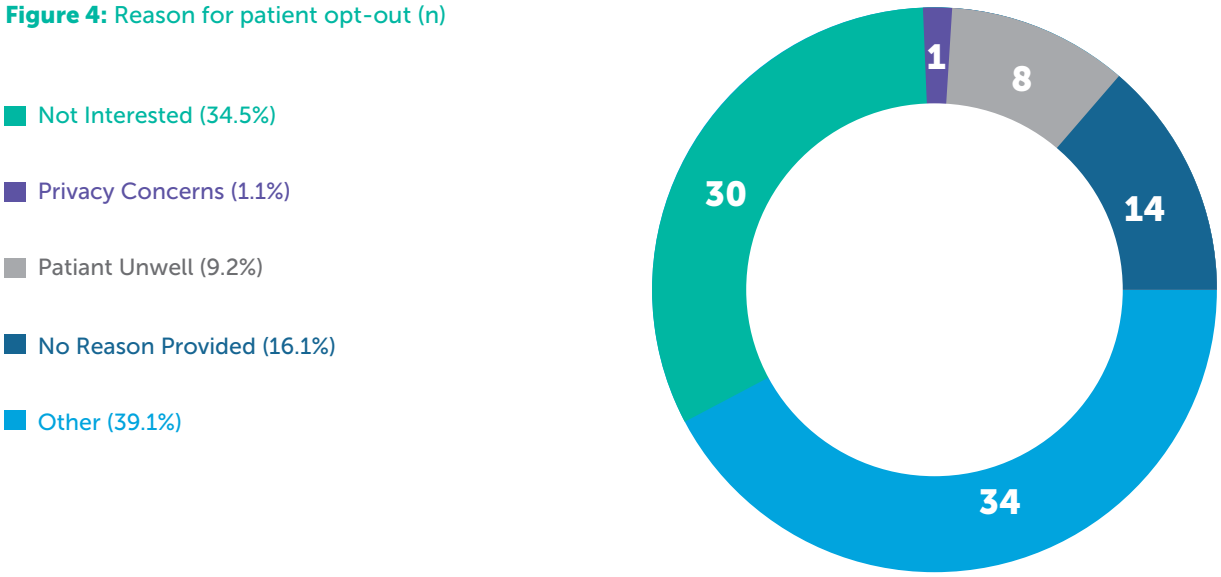


Figure 4: Reason for patient opt-out (n)



Registry Communications and Responses

Post-operatively, 87.5% of patients automatically received the questionnaires by email at 6, 12 and 24 months after their surgery.

Figure 5 outlines the total number of emails and contact attempts by the registry up to January 15, 2022. Patients with email addresses needed 6.23 emails to respond at any timepoint. For patients with no email address and where paper-based questionnaires are mailed out, patient compliance is high but at a considerable expense to the registry when compared to email. With the introduction of SMS reminders, the number of follow up attempts by Monash staff by phone has decreased.

Figure 5: Post-operative communication methods to eligible patients in the period between 15 January 2021 – 15 January 2022

8334
Emails sent

560
Phone calls made

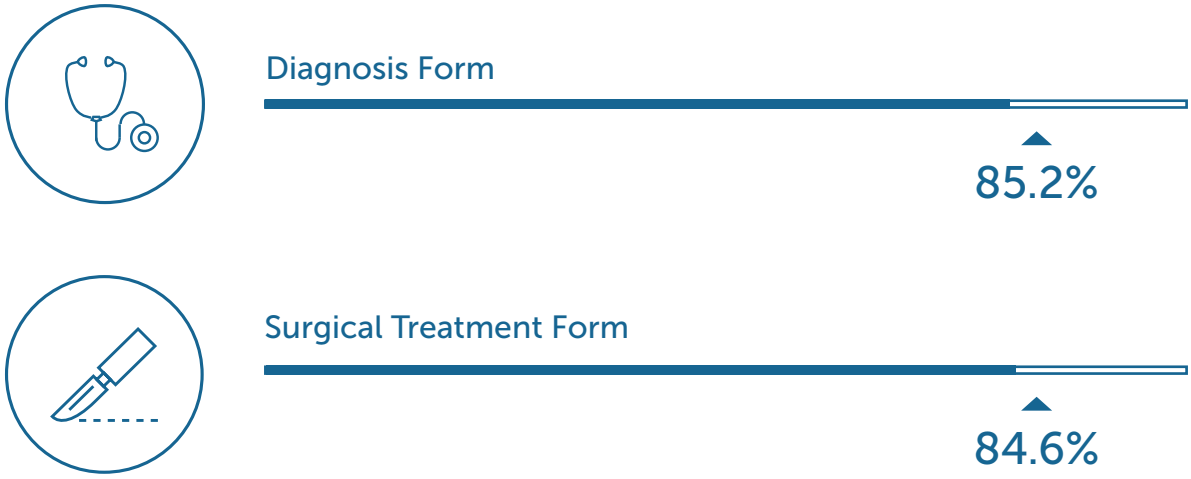
556
Letters sent

1792
SMS sent

Surgeon reported data

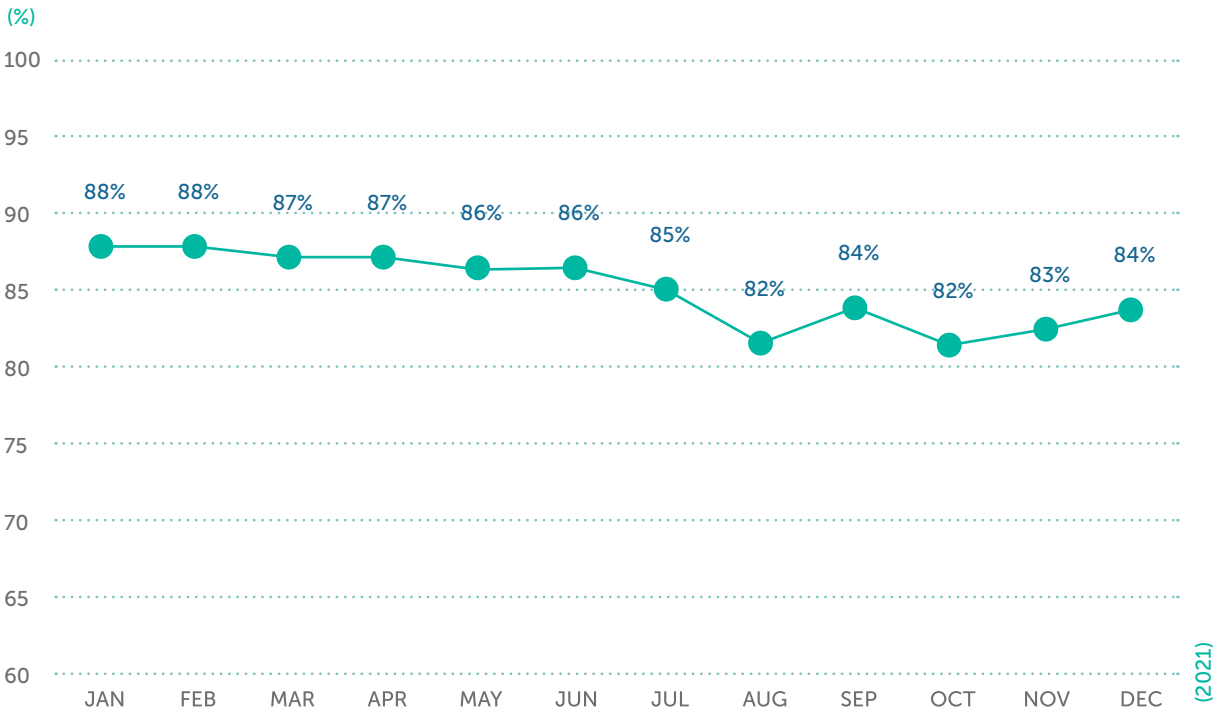
The registry management consistently provides feedback and support to surgeons and their practice staff regarding patient recruitment and data completeness. The data entry completion rate by surgeons at 15 January 2022 is shown in Figure 6.

Figure 6: 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 the majority of sites is excellent however there are a number of poor performing sites and the reasons for their poor performance are being investigated.

Figure 7: Surgeon data entry and completion trend (up to 31st Dec 2021)



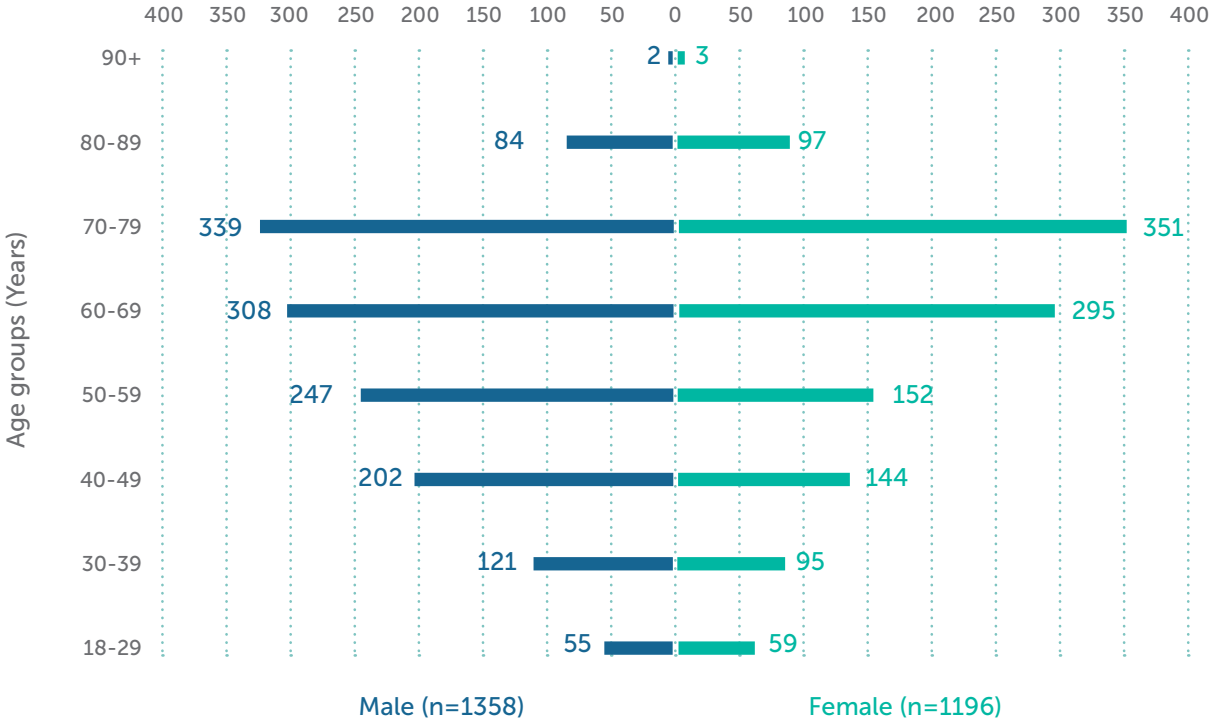
Overview of ASR Patients

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

Patient Demographics

As at 15 January 2022, of the 3136 patients in the registry, 2554 patients were eligible for analysis. There were 1358 (53%) males and 1196 (47%) females. 72% of male and 75% 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 27% of the patients undergoing spine surgery.

Figure 8: Patient age distribution at the time of surgery



Treatment types

Patients are categorised into 3 groups based on the anatomical location of their surgery or based on their deformity:

- Thoracolumbar
- Cervical
- Deformity

The breakdown of patients in each group is shown below (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=2554)
Thoracolumbar	2080 (81.4%)
Cervical	350 (13.7%)
Deformity	124 (4.9%)

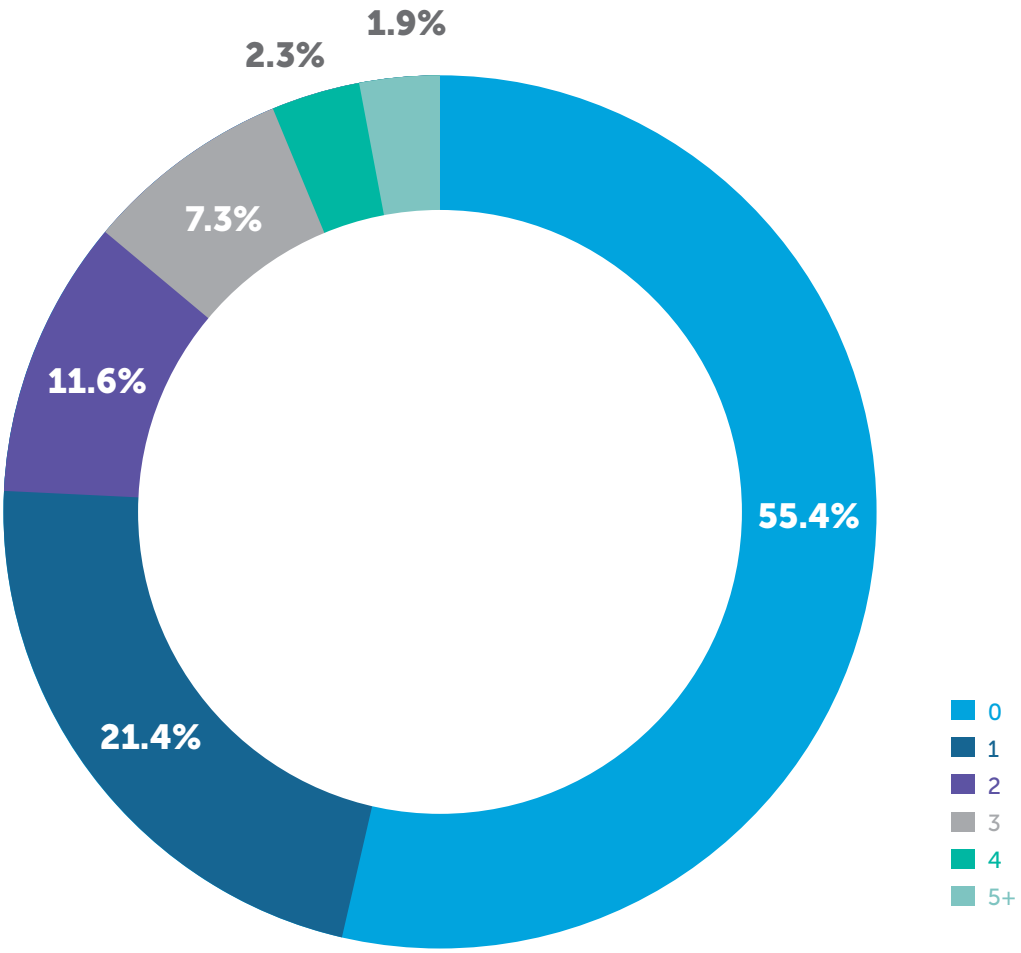
Given the small number of sites and surgeons currently participating in the registry, these figures are not indicative of the percentage breakdown of procedures that typically occur within Australia.

Comorbidities

Current ASR data indicates that 44.6% of patients presented with one or more comorbidities (Figure 9). Hypertension was the most common comorbidity reported (data not shown).

When comorbidities were broken down by surgeon, the rate of reporting varied suggesting that there may be an under reporting of comorbidities (data not shown). The ASR is currently undertaking a study regarding the collection methods and accuracy of comorbidities in spine registries.

Figure 9: Breakdown of number of comorbidities reported in all patients



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

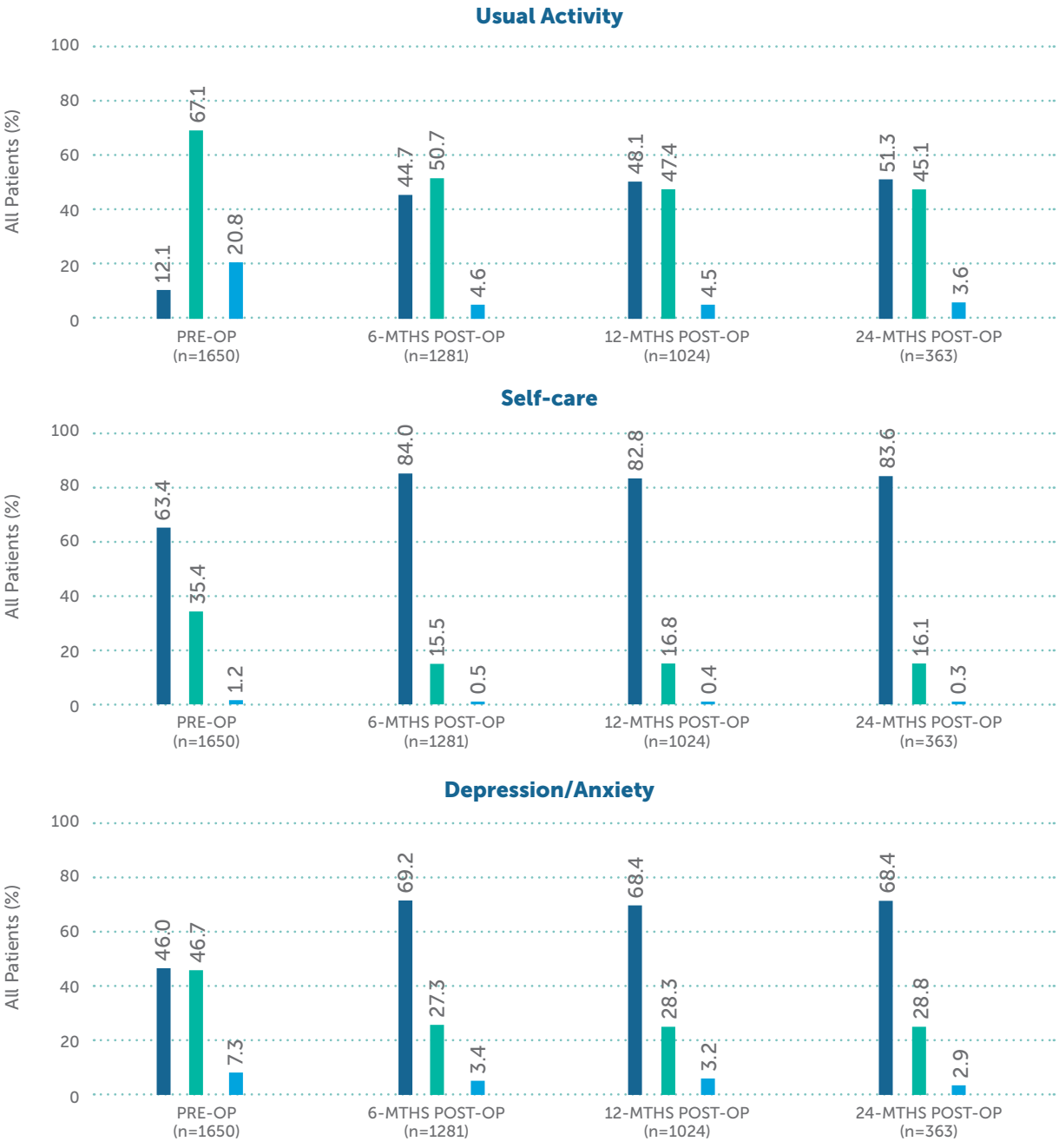
EQ-5D-3L Quality of Life (All Patients)

Figure 10 shows the EQ-5D-3L scores for any patient that has completed the EQ-5D-3L for each of the 5 domains (of mobility, pain/discomfort, usual activity, self-care and depression/anxiety) up to 24 months.

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

- **Mobility:** The key finding is that 78% experienced some/extreme mobility problems pre-operatively and this reduced by nearly 50% to approximately 38% at 6 month and remained stable. Given the age demographic distribution some of the persisting mobility problems may be non-spinal in origin.
- **Self-care:** There has been a reduction in self-care problems post-op compared with pre-op from about 37% to 16%, which is over a 50% reduction.
- **Usual activity:** Some/extreme problems were 88% pre-operatively, and reduced to 50% post–operatively, which is over a 40% reduction.
- **Pain/discomfort:** 98% of patients reported some or extreme problems pre-operatively as compared to 65% at 6 months, 63% at 12 months and 61% at 24 months.
- **Depression/anxiety:** Patients that experienced some/extreme anxiety/ depression decreased from 54% at pre-op to approximately 30% at all post-op timepoints - a reduction of over 40%.

Figure 10: 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



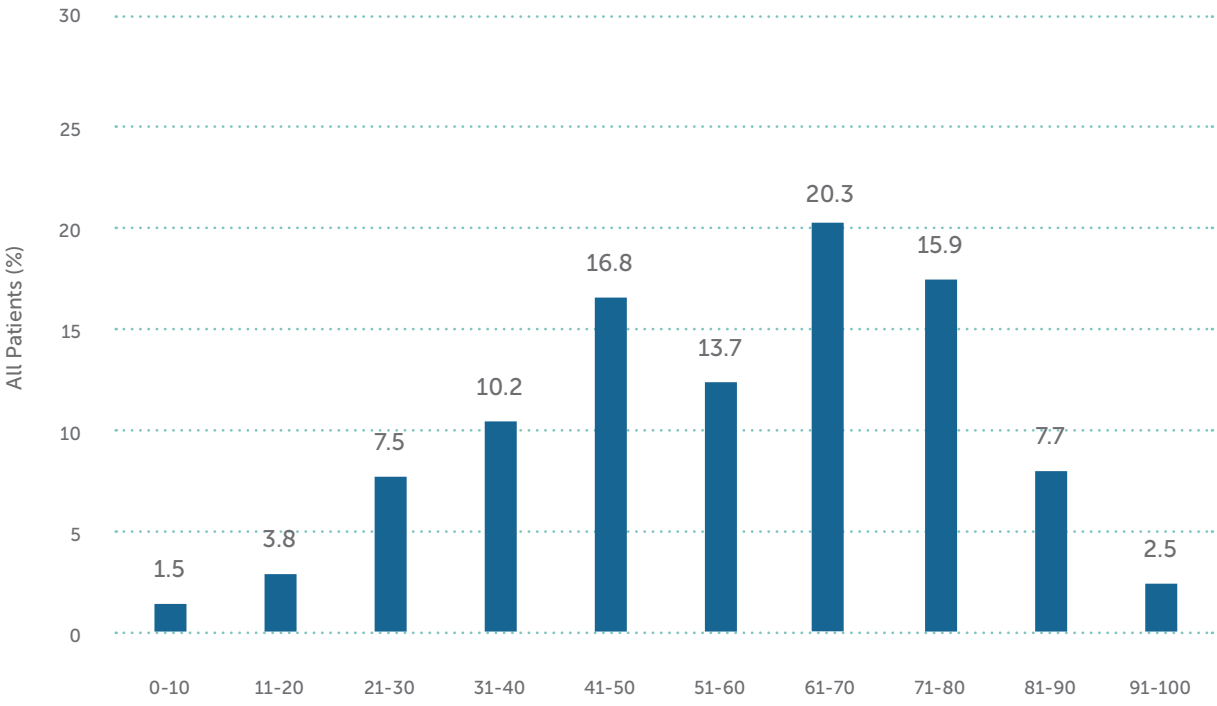
Regarding EQ-VAS scores, a higher score indicates improved patient perception of general health. The median EQ-VAS scores improved by 20 points from a median score of 60 pre-operatively, to a median score of 80 at 6 months post-operatively. This improved score of 80 was maintained for at the 12 and 24 months follow up (Table 2; Figure 11).

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

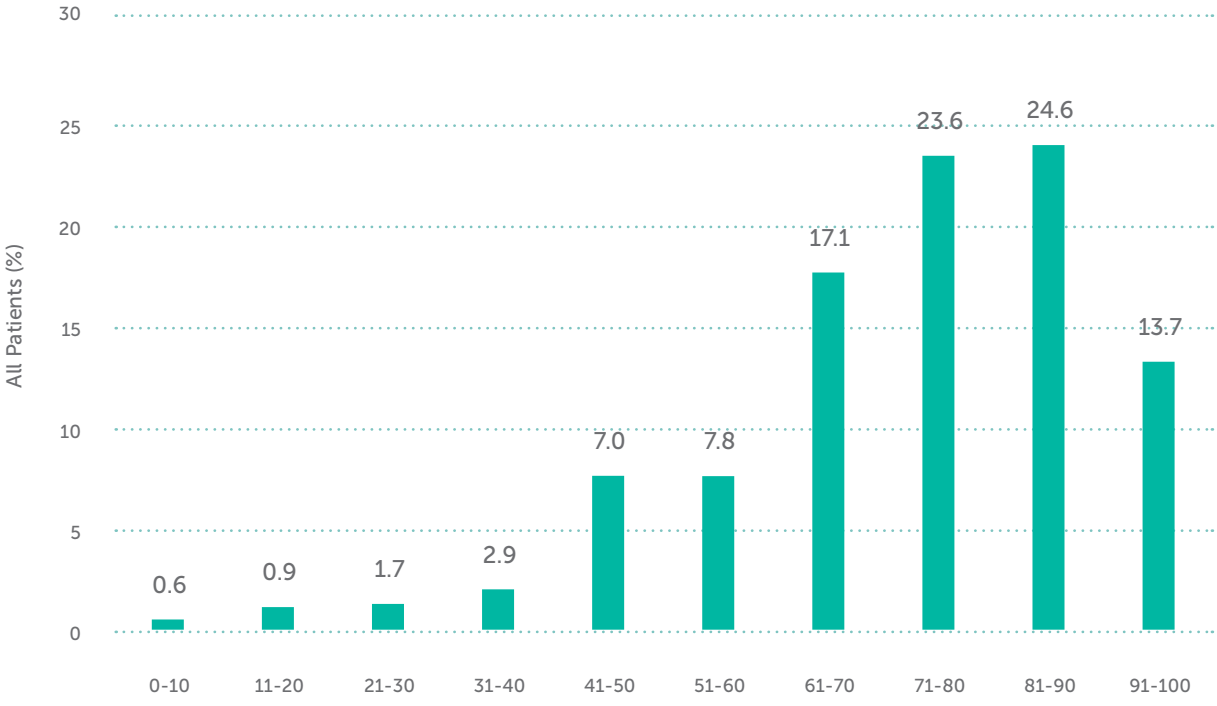
EQ-VAS	Pre-operative	6-Months	12-Months	24-Months
n	2161	1866	1609	970
Mean (SD)	58.5 (20.1)	74.1 (17.7)	74.7 (18.0)	74.9 (17.9)
Median (IQR)	60.0 (45.0, 74.0)	80.0 (65.0, 89.0)	80.0 (67.0, 90.0)	80.0 (65.0, 90.0)

Figure 11: EQ-VAS distribution for all patients who completed any EQ-VAS at pre-op, 6, 12 and 24-months post-op. *(Note, the higher the score, the better the perception of overall health)*

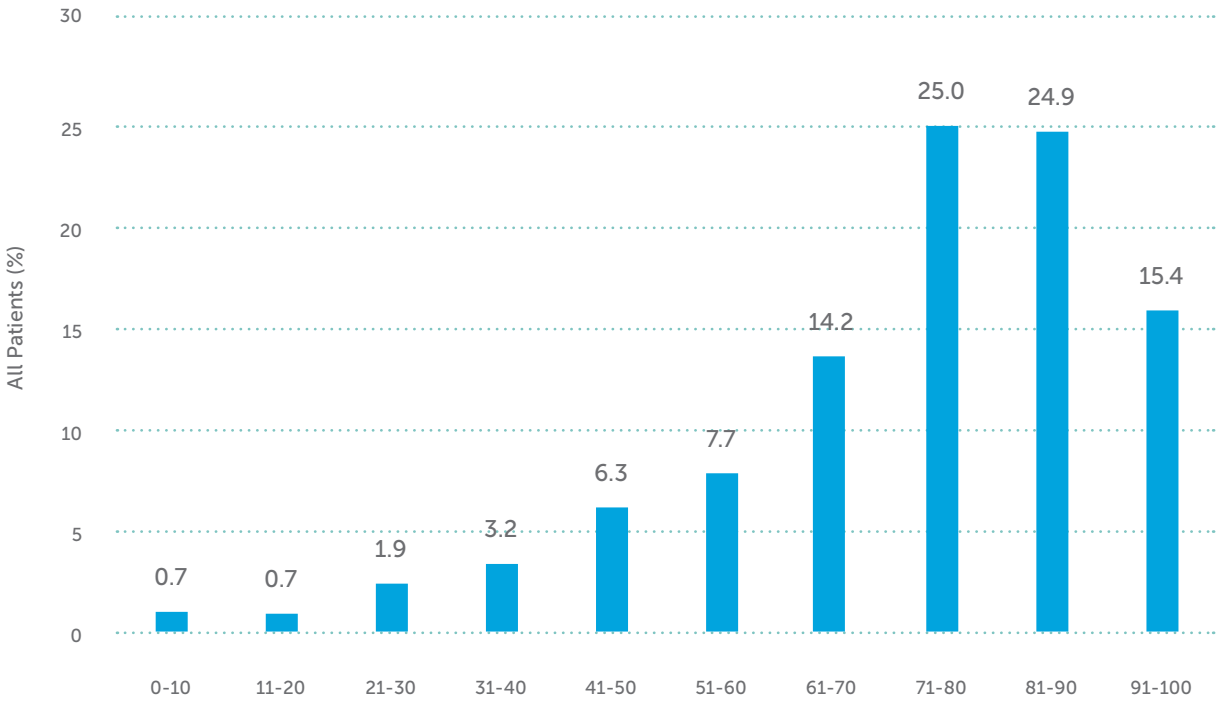
(a) Pre-operative EQ-VAS (n=2161)



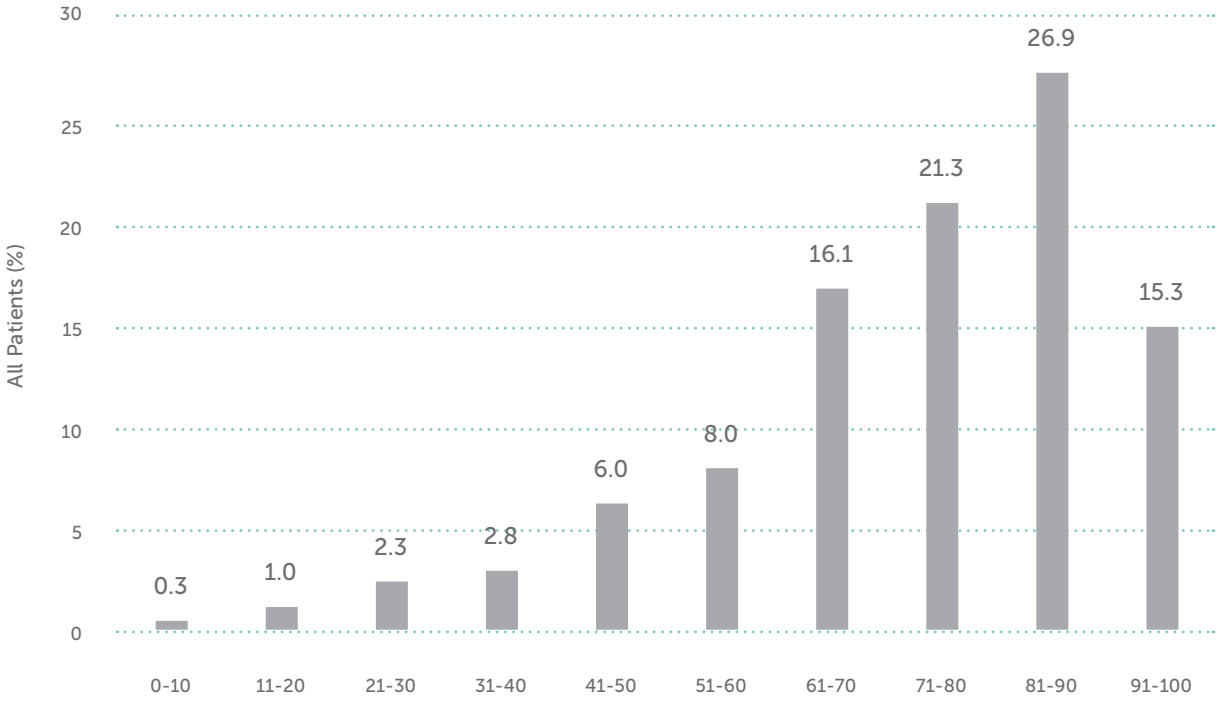
(b) Six-month post-operative EQ-VAS (n=1866)



(c) Twelve-month post-operative EQ-VAS (n=1609)



(d) Twenty-four-month post-operative EQ-VAS (n=970)



Oswestry Disability Index (ODI)

The ODI is completed by patients that undergo thoracolumbar surgery (81.4%) or who fall into the 'deformity' category of patients (4.9%) which is predominately scoliosis patients. 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[4]. As indicated in Table 3, a higher score indicates a higher level of disability.

Table 3: ODI Scoring

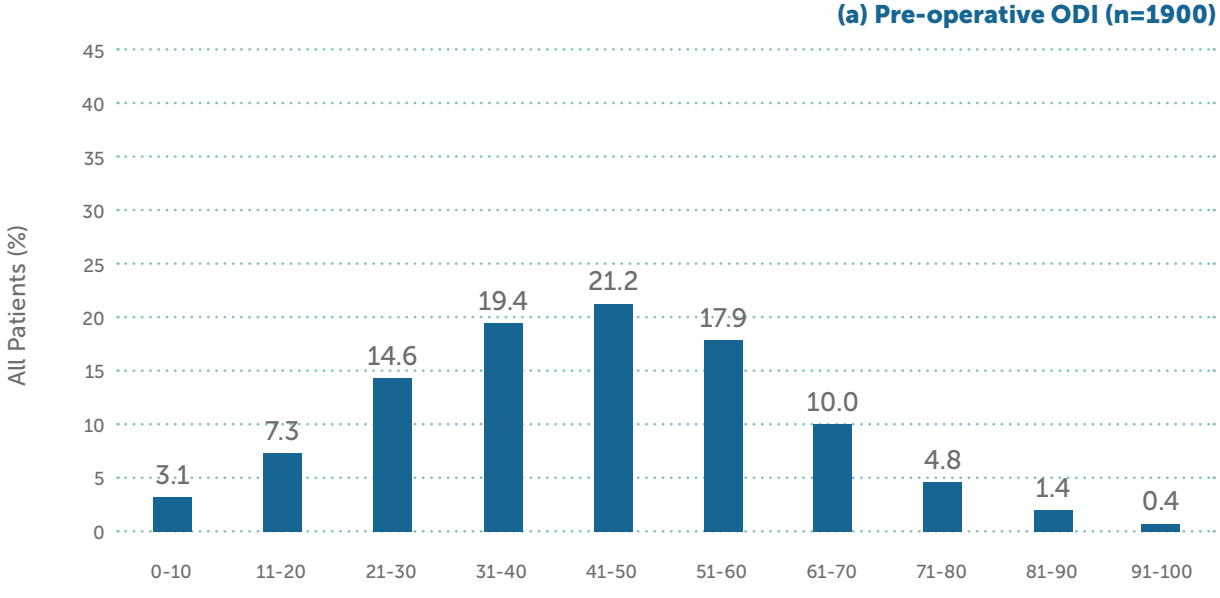
ODI Score	Level of Disability
0 - 20	Minimal disability
21 - 40	Moderate disability
41 - 60	Severe disability
61 - 80	Crippled
81 - 100	Bed bound

The overall ODI scores were analysed for all thoracolumbar/deformity patients who completed the 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 (within the minimal disability range). There was a small further reduction in median ODI score at 12 and 24 months. Figure 12 illustrates that the proportion of patients who considered themselves severely disabled or worse (ODI score > 41) reduced from 55.7% preoperatively to 15.6% at 6 and 12 months, and 15.3% at 24 months.

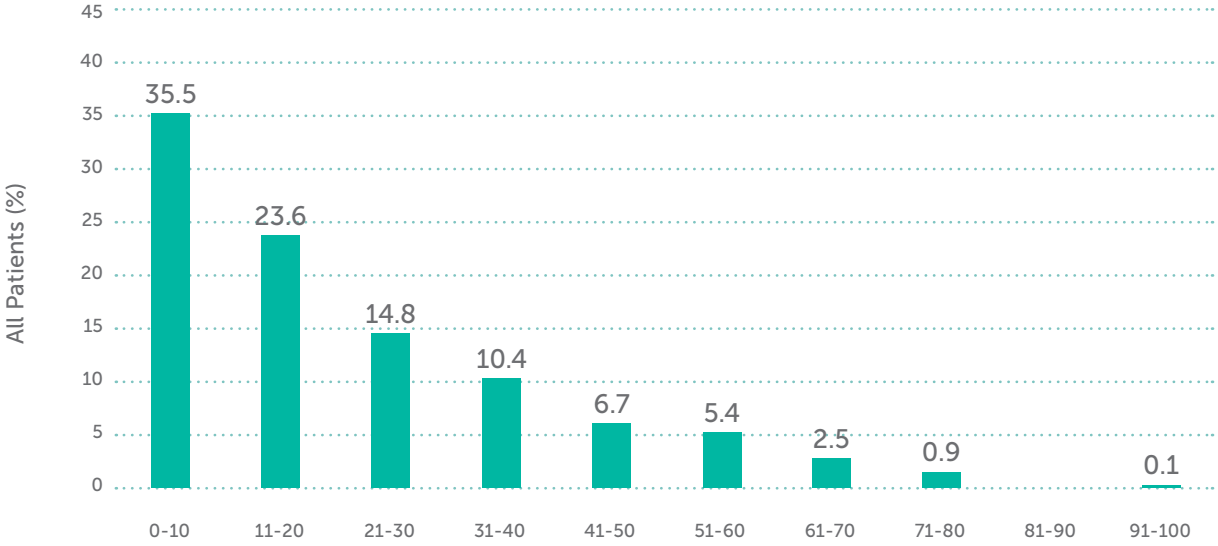
Table 4: ODI mean and median scores for all patients who completed any ODI at pre-op, 6, 12 and 24-months post-op

ODI	Pre-operative	6-Months	12-Months	24-Months
n	1900	1652	1453	898
Mean (SD)	43.3 (17.6)	21.2 (18.0)	20.5 (18.4)	20.0 (18.2)
Median (IQR)	44.0 (31.0, 56.0)	18.0 (7.0, 32.0)	16.0 (6.0, 31.0)	16.0 (4.0, 29.0)

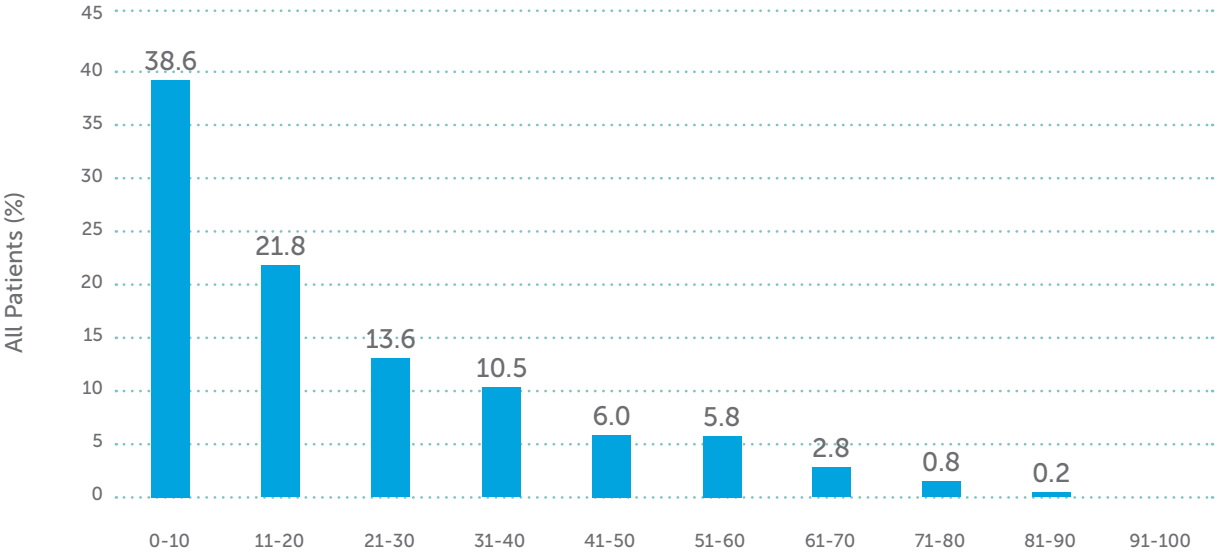
Figure 12: ODI distribution for all patients who completed any ODI at pre-op, 6, 12 and 24-months post-op



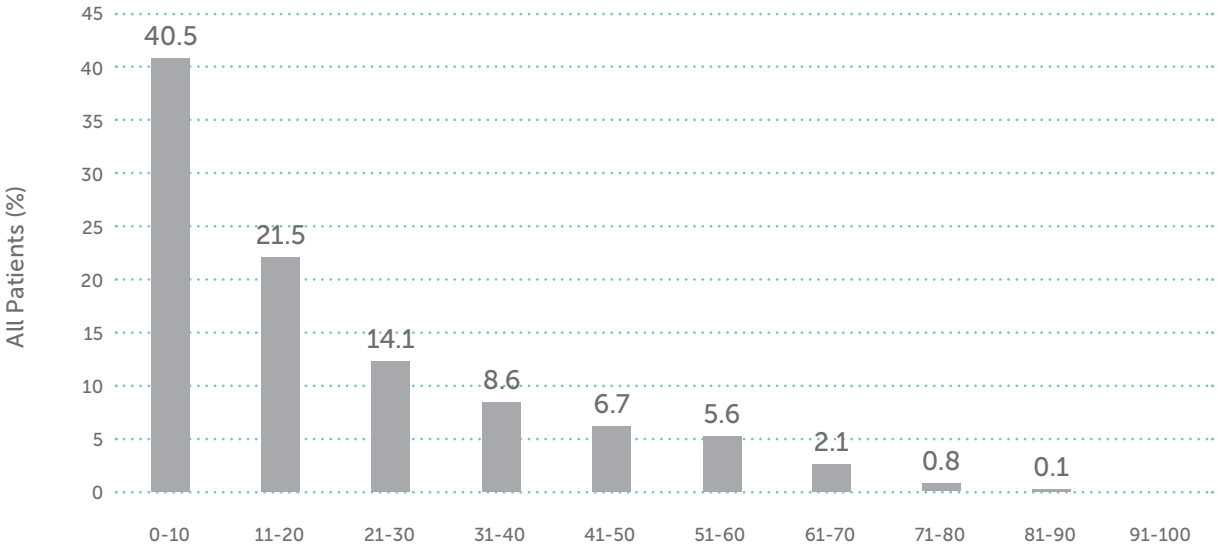
(b) Six-month post-operative ODI (n=1652)



(c) Twelve-month post-operative ODI (n=1453)



(d) Twenty-four-month post-operative ODI (n=898)



Neck Disability Index (NDI)

The NDI is completed by patients who have undergone surgery in the cervical region of the spine. This cohort represents 13.7% 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[7]. The classification of patient disability based on score is shown in Table 5[7] below, where a higher score indicates a higher level of disability.

Table 5: NDI Scoring

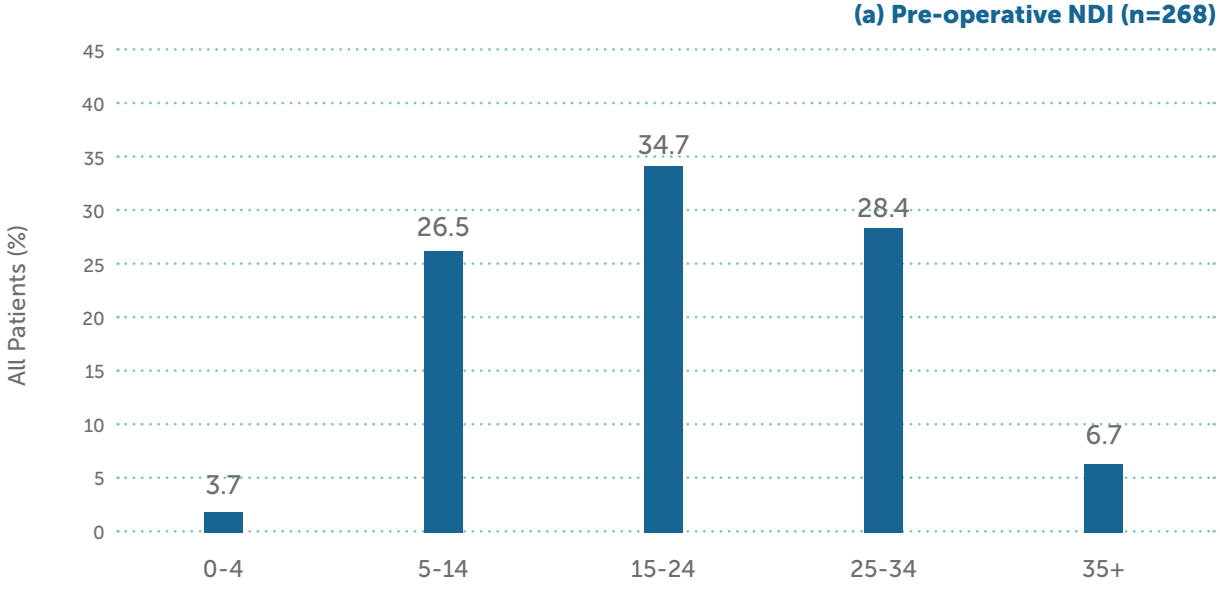
NDI Score	Level of Disability
0 – 4	No disability
5 – 14	Mild disability
15 – 24	Moderate disability
25 – 34	Severe disability
35 or over	Complete disability

As shown in Figure 13, median preoperative NDI scores reduced from 40 (complete disability) to 13 (mild disability) at 6 months post-operative, and this remained stable throughout 12 and 24 months' follow up. Preoperatively, 69.8% of patients had an NDI score of >15 indicating these patients considered themselves to be moderately disabled or worse. At 6 months, only 23.2% of patients considered themselves to be moderately disabled or worse, with improvement remaining stable until 12 and 24 months.

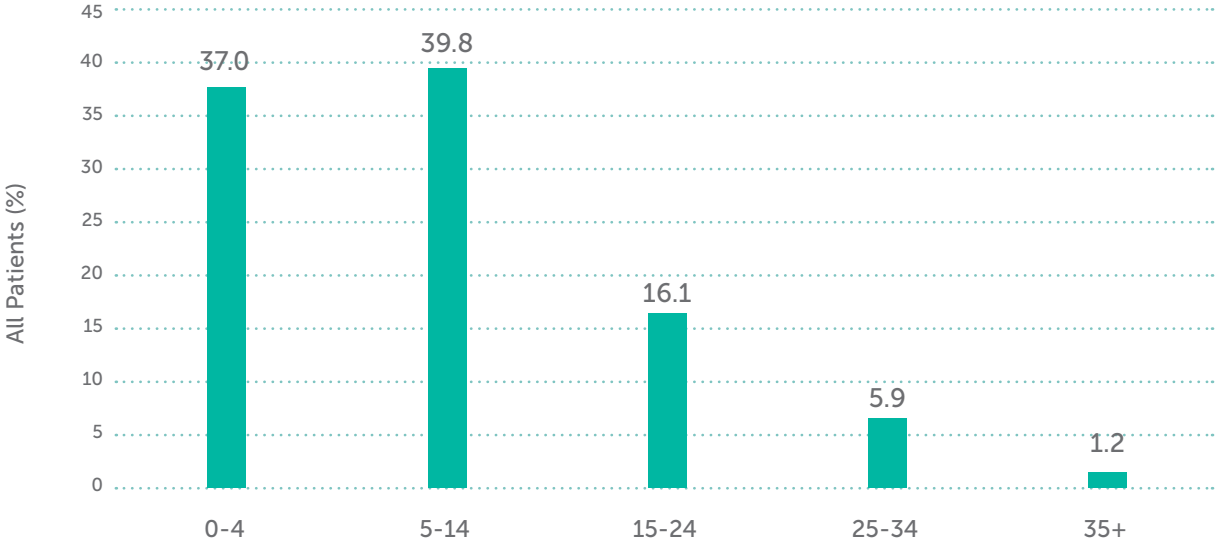
Table 6: NDI mean and median scores for all patients who completed any NDI at pre-op, 6, 12 and 24-months post-op

NDI	Pre-operative	6-Months	12-Months	24-Months
n	268	254	200	103
Mean (SD)	40.8 (18.6)	18.5 (17.0)	18.1 (17.5)	18.8 (18.2)
Median (IQR)	40.0 (28.0, 54.0)	13.0 (6.0, 28.0)	14.0 (4.0, 26.0)	12.0 (4.0, 28.0)

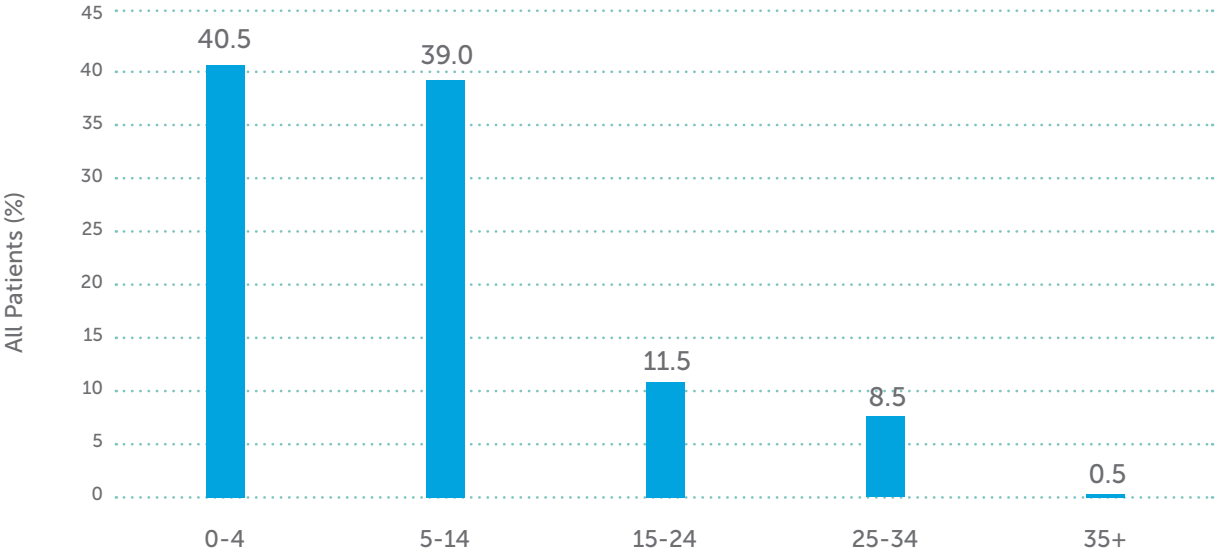
Figure 13: NDI distribution for all patients who completed any NDI at pre-op, 6, 12 and 24-months post-op



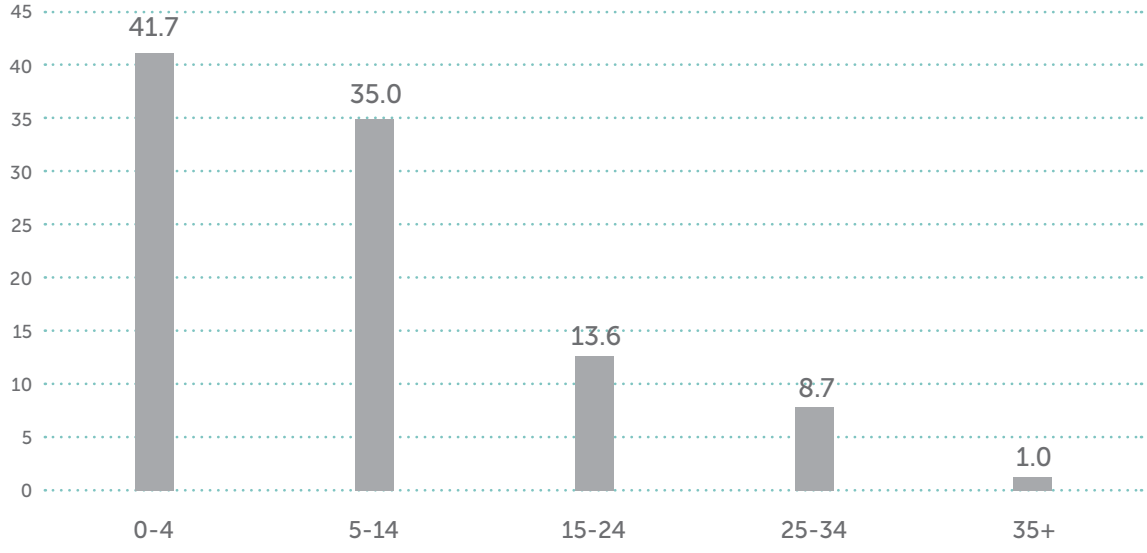
(b) Six-month post-operative NDI (n=254)



(c) Twelve-month post-operative NDI (n=200)



(d) Twenty-four-month post-operative NDI (n=103)



ASR and COVID-19

Did the pandemic and lockdowns make a difference to elective spine surgery patients?

The COVID-19 pandemic and the public health measures implemented across Australia to control community transmission impacted the provision of health services to the Australian community. For example, the Victorian government implemented some of the strictest public health measures in the world[b], where a Victorian living in Melbourne for the duration of the pandemic spent 245 days in lockdown. These and similar measures had significant and enduring effects on the volume, type and timing of elective surgery procedures undertaken at hospitals across Australia.

The ASR was able to continue functioning during these lockdowns. With the ability to work from home, general registry operations and data collection were not hampered. However, surgeon and site recruitment to the ASR decreased over 2020-21 due to the inability to travel and meet new sites and surgeons face-to-face.

The following section displays the COVID-19 period trends and compares general quality of life (EQ5D-3L mean scores) of patients by year. This includes 2018 (pre-COVID-19), and subsequent years (2019- 2021) which takes into consideration the various lockdowns and restrictions to elective surgery. As shown in Figure 2, the number of patients and rate of recruitment of ASR participants was largely unchanged during the pandemic.

The cumulation graph is now starting to show a plateau in patient recruitment which we believe will be transient as lock down and elective surgery restrictions ease.

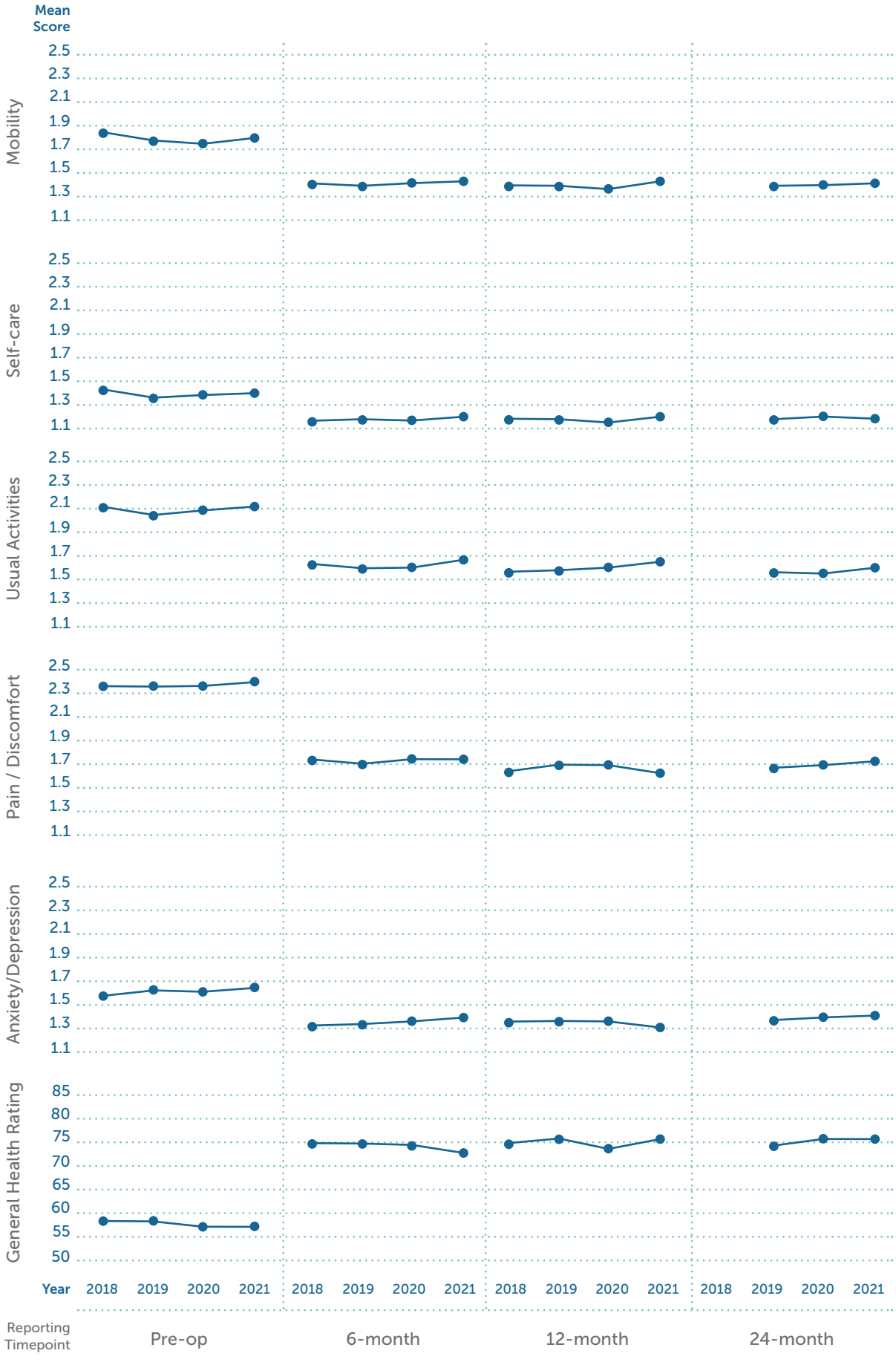
Surgeon data completion rate was also largely unchanged; pre-COVID mean of 89.0% per year to 87.7% for 2020 and 85.2% for 2021, with the drop in reporting percentage largely attributable to some newer surgeons and practices coming to grips with reporting procedures. In addition, registry operations and data collection were not significantly impacted by COVID-19 across all years reported.

Although COVID-19 restricted access to elective surgery due to hospitals' redirecting resources, ASR data collection remained stable. We used the EQ-5D-3L Quality of Life scores (Figure 14) to determine if COVID-19 had any impact on general patient well-being. There was no obvious change in any of the EQ-5D-3L domains (Figure 14). The prediction was that there may have been an impact to patients' quality of life during the pandemic lockdown periods. However, no obvious impact in any of the domains was identified.

Overall, the quality of life of ASR patients did not appear to be altered during the pandemic when compared to pre-pandemic.

b https://www.abc.net.au/news/2021-10-03/melbourne-longest-lockdown/100510710?utm_campaign=abc_news_web&utm_content=link&utm_medium=content_shared&utm_source=abc_news_web

Figure 14: Quality of life PROMs responses through COVID-19 pandemic by year of surgical treatment



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)

Lumbar Discectomy

Lumbar discectomy is one of the most common spinal procedures [9]. Discectomy literally means "cutting out the disc". The basic principle of the procedure is to relieve nerve compression caused by herniated or degenerative disc material in the lower spine. The surgeon reaches the damaged disc from the back (posterior) of the spine. The muscles along the spine are retracted and then small amounts of bone on the back or lamina of the spine are removed in order to access the spinal canal in which the nerves run. The lamina is the bone that forms the back of the spinal canal and makes a 'roof' over the spinal canal. The nerves are contained within a sausage of water called the thecal sac. Next, the spinal nerve is retracted to one side and depending on the particular case, the prominent portion of disc may be removed[c]. This surgery can be performed using an open or minimally invasive technique. There are various minimally invasive techniques now performed, including microdiscectomy, micro tubular discectomy, percutaneous transforaminal endoscopic discectomy (PTED)[d].

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

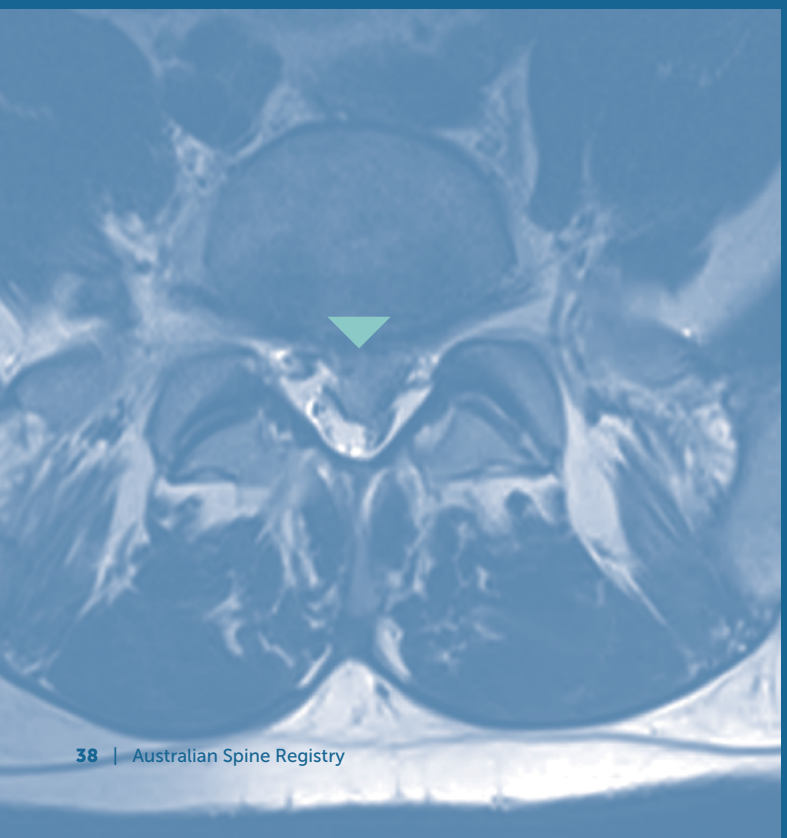
Patients from within this group were excluded if:

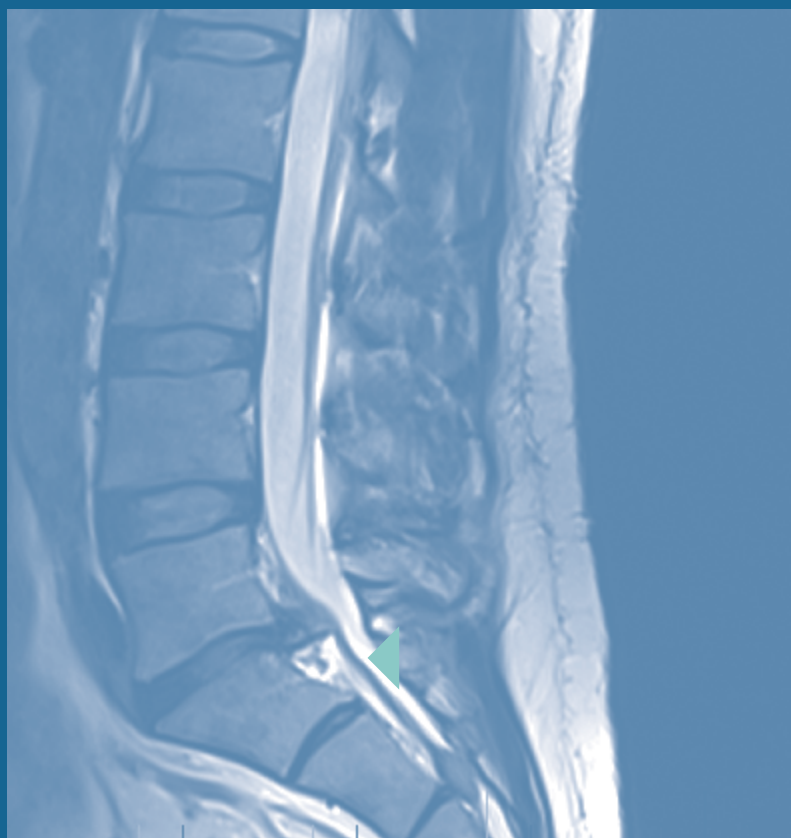
- Their discectomy surgery was revision surgery
- They had Scoliosis
- They also had a fusion

c https://www.mayfieldclinic.com/pe-lumdiscectomy.htm

d https://blog.barricaid.com/

(Images courtesy of Mr Michael Johnson)



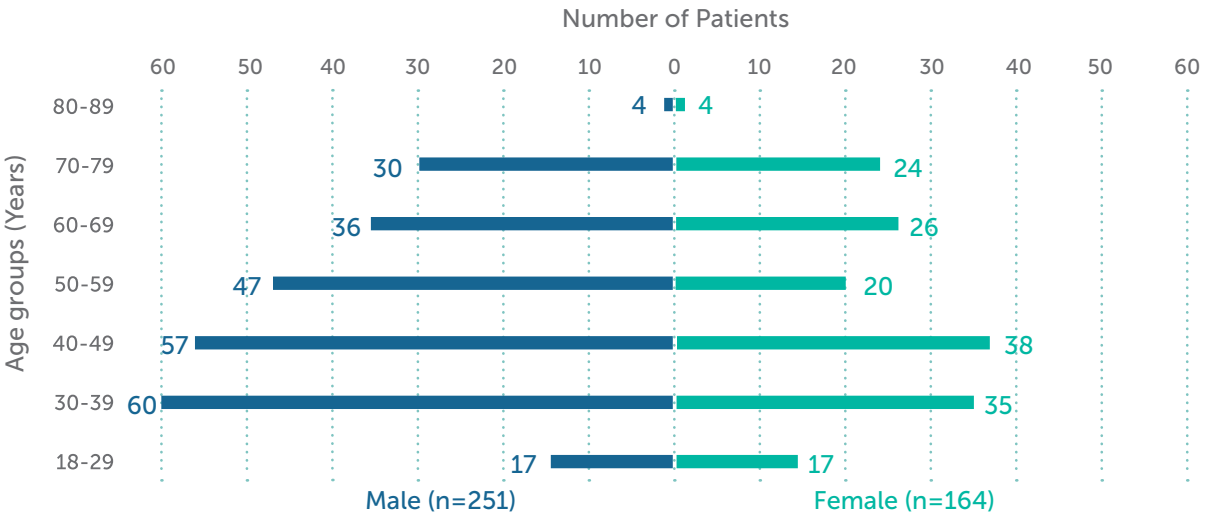


Demographics

415 patients met the discectomy cohort inclusion criteria which represents 20% of patients undergoing thoracolumbar procedures.

The single level lumbar discectomy procedures were performed predominately on male patients. There were 251 males (60%) and 164 females (40%) in this group as shown in Figure 15. The median age of both males and females were 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).

Figure 15: Discectomy procedures by patient age and gender



Comorbidities

Examination of the comorbidities in this group identified that discectomy patients had fewer comorbidities when compared to all patients in the registry. The number of patients that were reported with a comorbidity is shown in Table 7 below. 19% of discectomy patients were reported to have at least one comorbidity whereas 45% of the entire registry patient population were reported to have at least one comorbidity. Patients were further categorised into groups by the number of comorbidities reported (Table 8).

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

Any reported comorbidity	All (n=2554) n (%)	Discectomy (n=415) n (%)
Yes	1193 (46.7)	87 (21.0)
No	1361 (53.3)	328 (79.0)

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

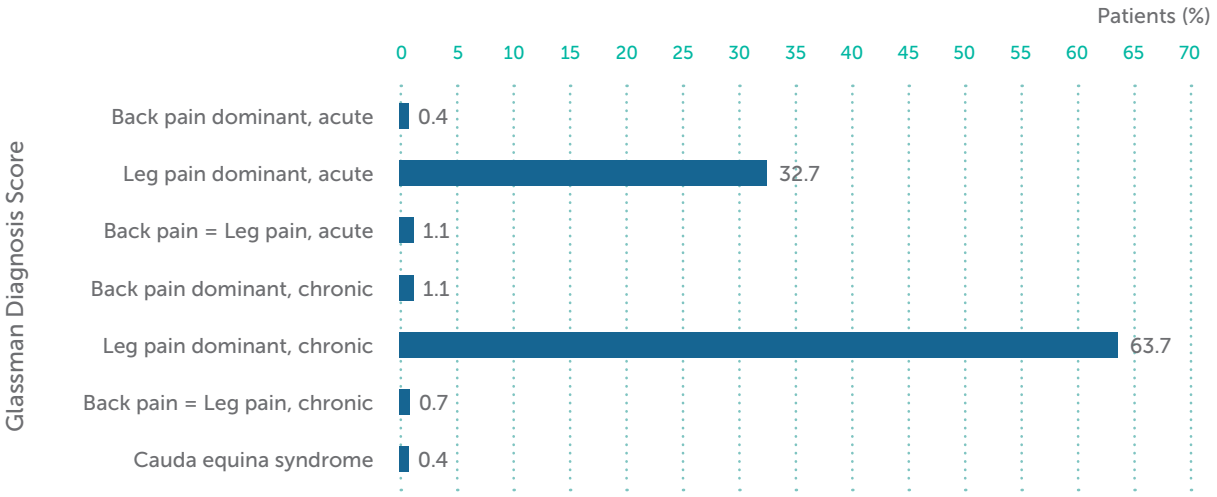
Number of reported comorbidities	All (n=2554) n (%)	Discectomy (n=415) n (%)
None	1416 (55.4)	335 (80.7)
1	547 (21.4)	45 (10.9)
2	296 (11.6)	18 (4.4)
3	186 (7.3)	13 (3.1)
4	60 (2.4)	1 (0.2)
5+	49 (1.9)	3 (0.7)

Glassman Classification Scores

The Glassman Classification Scores are a simple diagnostic classification scheme which categorises a patient's primary characteristics so that the treatment's impact can be linked to the recognised pathology[3]. Glassman scores are only reported for patients who have had thoracolumbar procedures. Glassman scores were reported in 67% of the discectomy cohort.

For 'Symptoms', acute and chronic leg pain were most commonly reported. Back pain was less commonly reported, as was neurogenic claudication. This is consistent with the commonly held clinical presentation of disc herniations (Figure 16).

Figure 16: Glassman Score for 'Symptoms' among discectomy patients (n=278)



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 difference seen in the figures presented below.

Oswestry Disability Index (ODI)

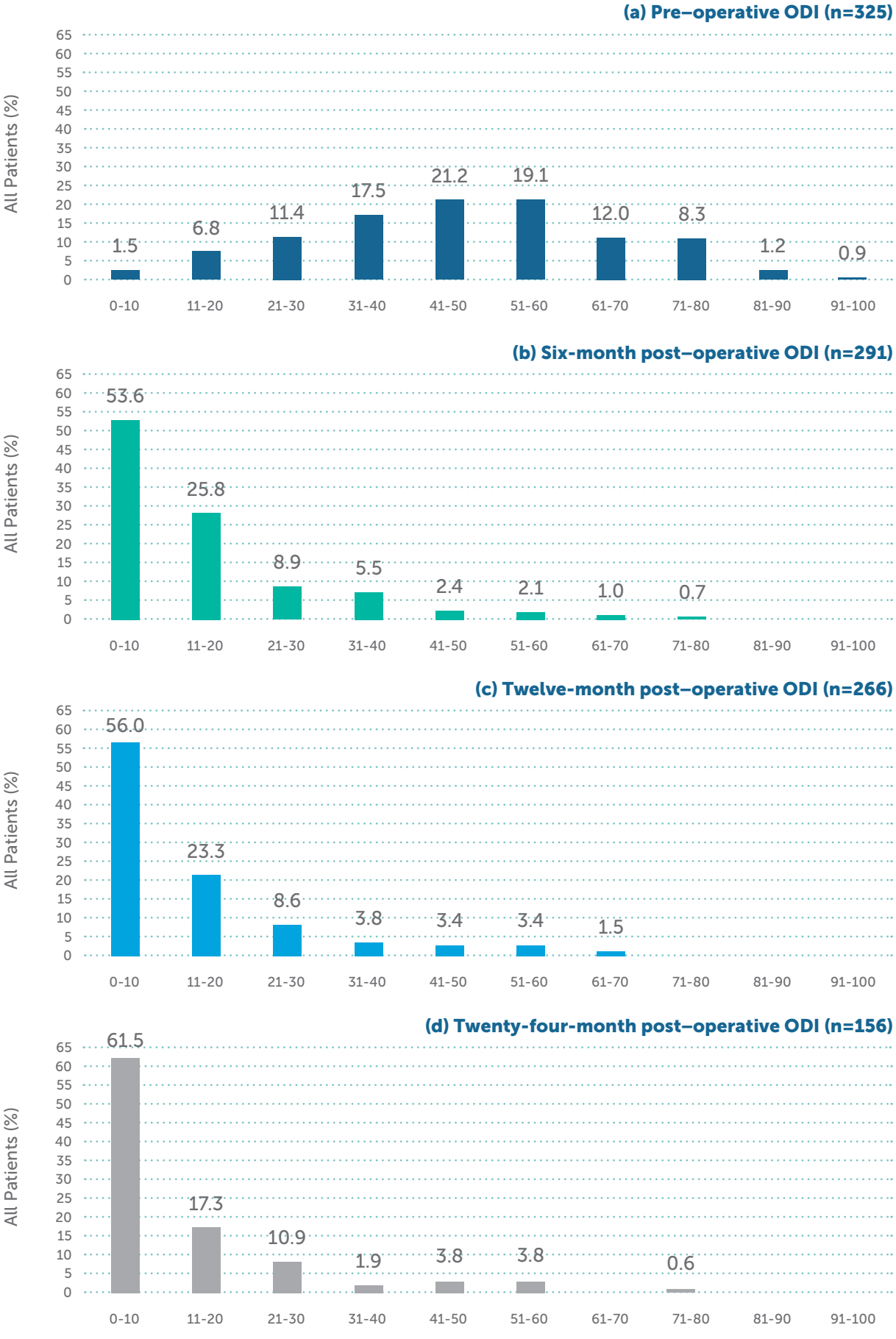
A lower ODI score indicates improved relief from pain and disability. ODI mean, median and overall scores for any questionnaires completed at each time point are shown in Table 9 and Figure 17 respectively. As shown in Table 9, median ODI scores improved from 46 pre-operatively to 13.7 at 6 months post-operatively, which was sustained until 24 months.

Table 9: 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	325	291	266	156
Mean (SD)	47.1 (18.0)	13.7 (14.6)	13.5 (15.1)	12.8 (15.4)
Median (IQR)	46.0 (34.0, 60.0)	8.0 (2.0, 20.0)	8.0 (2.0, 18.0)	8.0 (2.0, 20.0)

Figure 16 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 17: ODI distribution for discectomy patients who completed any ODI at pre-op, 6, 12 and 24-months post-op



Analysis of the ten ODI domains for the discectomy cohort is shown in Table 10. 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-operative compared to pre-operative. A lower ODI score indicates an improvement for that domain. The domains of the ODI indicated that the pain caused by disc prolapse effects all aspects of life and all aspects are improved by the surgery.

Table 10: 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	**325**	**291**	**266**	**156**
Pain, mean (SD)	2.51 (1.03)	1.09 (0.99)	1.08 (1.04)	1.07 (1.04)
Personal Care, mean (SD)	1.20 (1.14)	0.47 (0.96)	0.47 (0.93)	0.49 (0.96)
Lifting, mean (SD)	2.64 (1.30)	1.83 (1.50)	1.65 (1.46)	1.57 (1.44)
Walking, mean (SD)	1.93 (1.30)	0.80 (1.21)	0.80 (1.21)	0.77 (1.17)
Sitting, mean (SD)	2.03 (1.21)	1.14 (1.04)	1.10 (1.03)	1.05 (1.00)
Standing, mean (SD)	2.66 (1.33)	1.31 (1.31)	1.30 (1.33)	1.33 (1.34)
Sleeping, mean (SD)	1.78 (1.08)	0.83 (0.87)	0.85 (0.88)	0.82 (0.87)
Sex Life*, mean (SD)	2.38 (1.80)	0.99 (1.54)	0.93 (1.51)	0.94 (1.55)
Social Life, mean (SD)	2.48 (1.25)	1.10 (1.29)	1.02 (1.28)	1.01 (1.28)
Traveling, mean (SD)	2.12 (1.32)	0.94 (1.12)	0.92 (1.12)	0.83 (1.03)

* Note: Sex life question is optional; lower numbers of 281, 262, 233 and 140 (for each time-point, respectively).

The Minimum Clinically Important Difference (MCID) is a threshold used to measure the effect of clinical treatments. 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[10]. This figure has been used to define MCID for this patient cohort.

97.9% of discectomy patients were within or exceeded this MCID for the ODI at 6, 12-months and 24-months post-operatively (Table 11, Table 12 and Table 13).

Table 11: MCID for ODI from pre-op to 6-months post-op for discectomy patients

ODI*	All (n=1454) n (%)	Discectomy (n=242) n (%)
Exceeding the MCID (Improved)	954 (65.6)	207 (85.5)
Within the MCID (Unchanged)	455 (31.3)	30 (12.4)
Exceeding the MCID (Worsened)	45 (3.1)	5 (2.1)

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

ODI*	All (n=1278) n (%)	Discectomy (n=213) n (%)
Exceeding the MCID (Improved)	851 (66.6)	178 (83.6)
Within the MCID (Unchanged)	395 (30.9)	34 (16.0)
Exceeding the MCID (Worsened)	32 (2.5)	1 (0.5)

Table 13: MCID for ODI from pre-op to 24-months post-op for discectomy patients

ODI*	All (n=807) n (%)	Discectomy (n=130) n (%)
Exceeding the MCID (Improved)	546 (67.7)	106 (81.5)
Within the MCID (Unchanged)	232 (28.7)	23 (17.7)
Exceeding the MCID (Worsened)	29 (3.6)	1 (0.8)

*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 EQ-VAS were analysed and indicate improvement across all domains (Table 14 and Figure 18). The mobility and pain/discomfort domain were the two domains which showed the most improvement over the 12-month period, which was also maintained when measured at the 24-month time point.

Table 14: EQ-5D-3L scores for each domain for discectomy patients at pre-op, 6, 12 and 24-months post-op

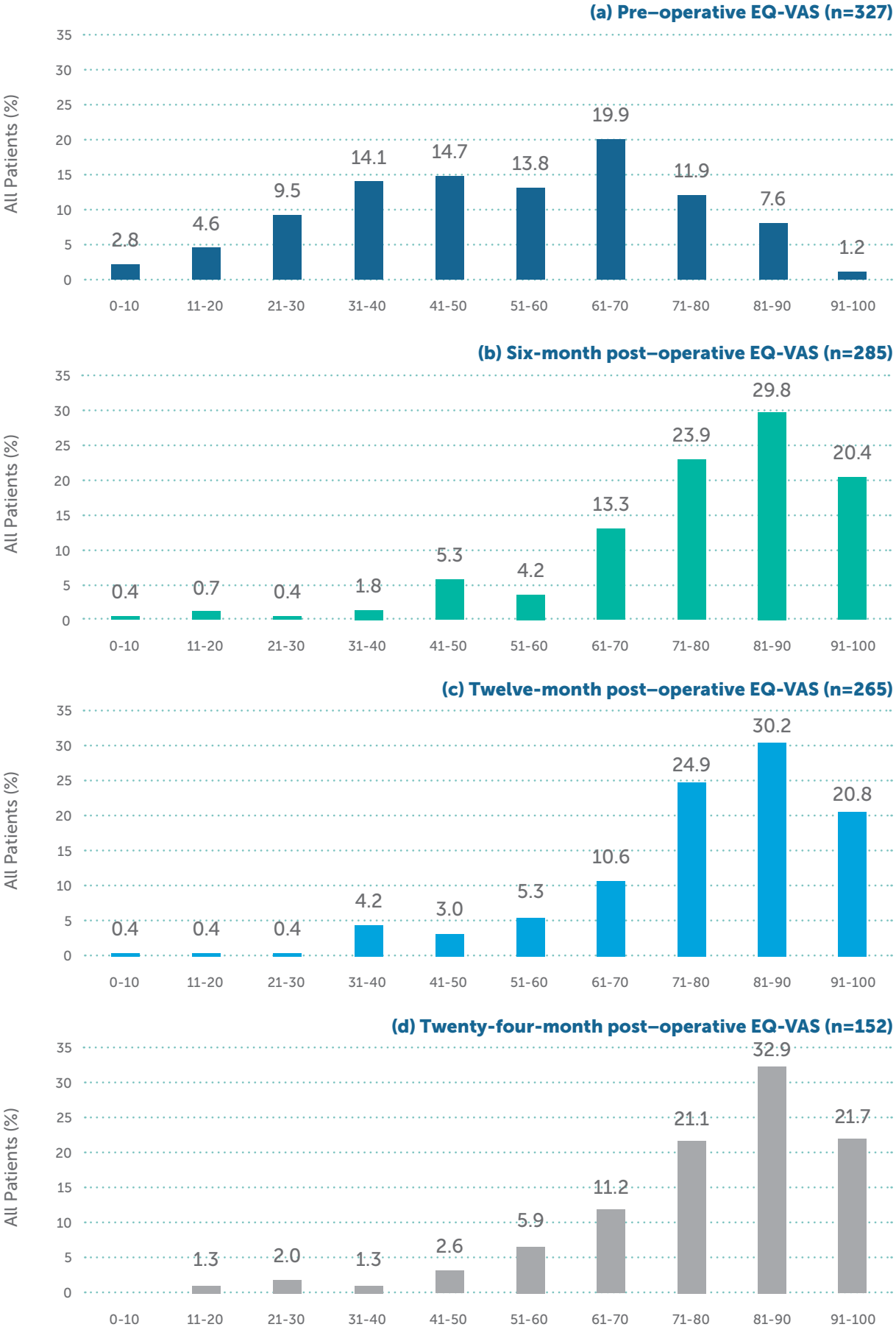
EQ-5D-3L All Patients					
Domain	**Level of problem**	**Pre-op (%) (n=327)**	**6 months (%) (n=285)**	**12 months (%) (n=265)**	**24 months (%) (n=152)**
Mobility	1 – no problems	13.8	73.7	74.3	77.6
	2 – some problems	83.5	26.3	25.3	22.4
	3 – extreme problems	2.8	0.0	0.4	0.0
Self-care	1 – no problems	52.6	91.6	90.6	88.8
	2 – some problems	45.6	8.4	9.1	10.5
	3 – extreme problems	1.8	0.0	0.4	0.7
Usual activities	1 – no problems	6.1	59.3	62.3	65.8
	2 – some problems	62.1	38.9	34.3	31.6
	3 – extreme problems	31.8	1.8	3.4	2.6
Pain/ discomfort	1 – no problems	1.2	45.3	45.7	48.0
	2 – some problems	52.0	51.9	49.1	47.4
	3 – extreme problems	46.8	2.8	5.3	4.6
Anxiety/ depression	1 – no problems	46.2	75.4	75.8	75.7
	2 – some problems	47.1	22.8	23.0	22.4
	3 – extreme problems	6.7	1.8	1.1	2.0

The EQ-VAS identifies the way in which patients perceive their general health at a given time point. A shift to the right in the EQ-VAS indicates an improvement of patient perception of their general health status. As shown in Table 15, median patient scores improved from 58 pre-operatively to 81 post-operatively, and were sustained until 24 months. Figure 18 highlights this in more detail.

Table 15: EQ-VAS mean and median scores for discectomy patients who completed any EQ-VAS at pre-op, 6, 12 and 24-months post-op

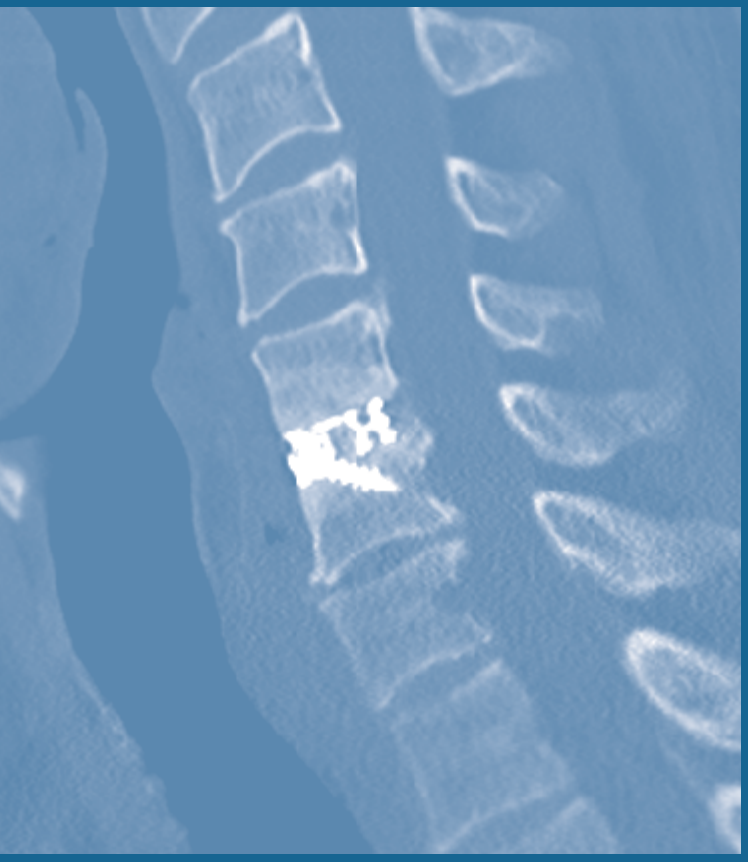
EQ-VAS	Pre-operative	6-Months	12-Months	24-Months
n	327	285	265	152
Mean (SD)	54.9 (20.7)	78.6 (16.0)	79.0 (16.0)	79.3 (16.9)
Median (IQR)	58.0 (40.0, 70.0)	81.0 (70.0, 90.0)	81.0 (72.0, 90.0)	83.0 (73.0, 90.0)

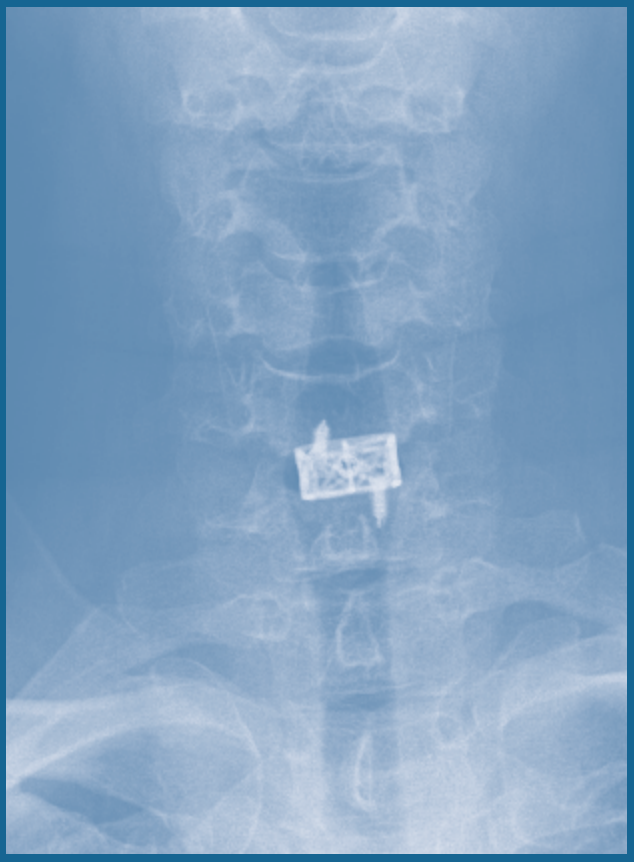
Figure 18: EQ-VAS distribution for discectomy patients who completed any EQ-VAS at pre-op, 6, 12 and 24-months post-op



Anterior Cervical Discectomy and Fusion (ACDF)

ACDF is a surgical procedure to treat nerve root or spinal cord compression by decompressing the spinal cord and nerve roots of the cervical spine with a discectomy, followed by inter-vertebral fusion to stabilise the corresponding vertebrae. The procedure is carried out from the front (anterior) of the spine through the throat area. Neck muscles, trachea and oesophagus are moved aside to expose the disc and bony area. The anterior approach is preferred as the disc can be accessed without disturbing the spinal cord, spinal nerves and strong neck muscles. Once the disc is removed, the space between the bony vertebra is prepared to receive a block of bone or a 'cage' to fill the space. Depending on the device used it may be filled with a bone graft. This spacer bone graft may be an autologous graft or an allograft (donor bone). A cervical plate may then be affixed to the front of the spine using bone screws. The cervical plate helps to stabilise the neck as the bone graft stimulates healing and solid fusion.





(Images courtesy of Mr John Cunningham)

The ACDF cohort was selected using the following criteria:

Inclusions:

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

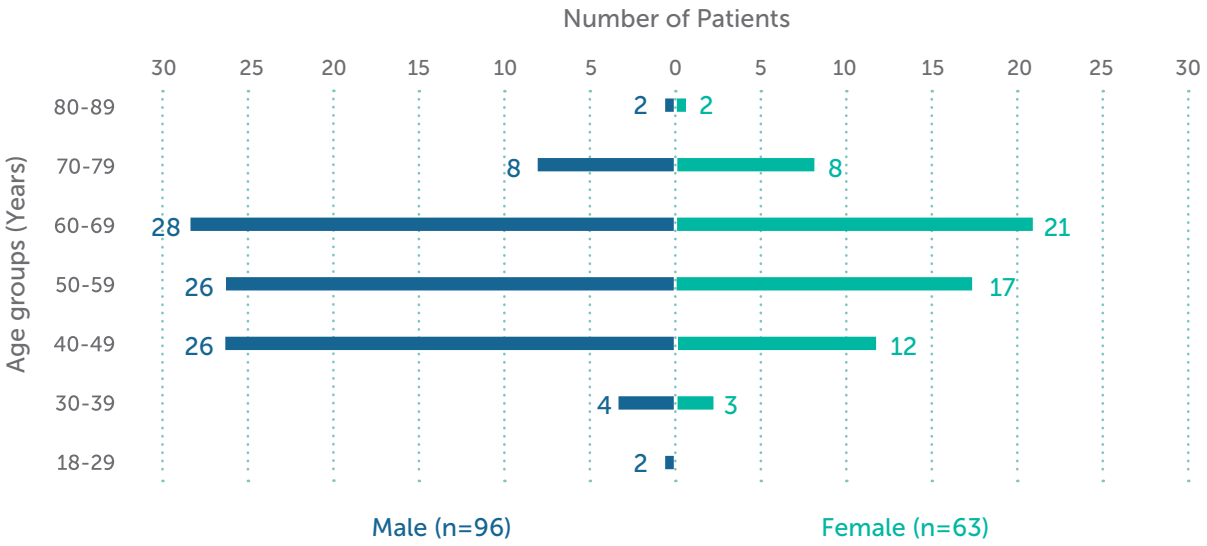
Exclusions:

- Scoliosis

Demographics

159 ACDF procedures were performed. These occurred more commonly on male patients. There were 96 males (60%) and 63 females (40%) in this cohort as shown in Figure 19. The median age for males was 55 years, with a median of 59 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 19: ACDF procedures by patient age and gender



Comorbidities

Examination of the comorbidities in this group identified that ACDF patients were not significantly different when compared to all patients in the registry. The number of patients that were reported with 'any' comorbidity is shown in Table 16. 45.3% of ACDF patients had at least one comorbidity, compared with 46.7% of the total cohort. Patients were further categorised into groups by the number of comorbidities reported (Table 17). Little difference was observed between the two groups.

Table 16: Number of ACDF patients diagnosed with any comorbidity prior to surgery

Any comorbidity	All (n=2554) n (%)	ACDF (n=159) n (%)
Yes	1193 (46.7)	72 (45.3)
No	1361 (53.3)	87 (54.7)

Table 17: Breakdown of number of reported comorbidities in ACDF patients

Number of reported comorbidities	All (n=2554) n (%)	ACDF (n=159) n (%)
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)

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. It must be noted that these results show unadjusted outcomes and must be interpreted with caution as indicated for discectomy.

Neck Disability Index (NDI)

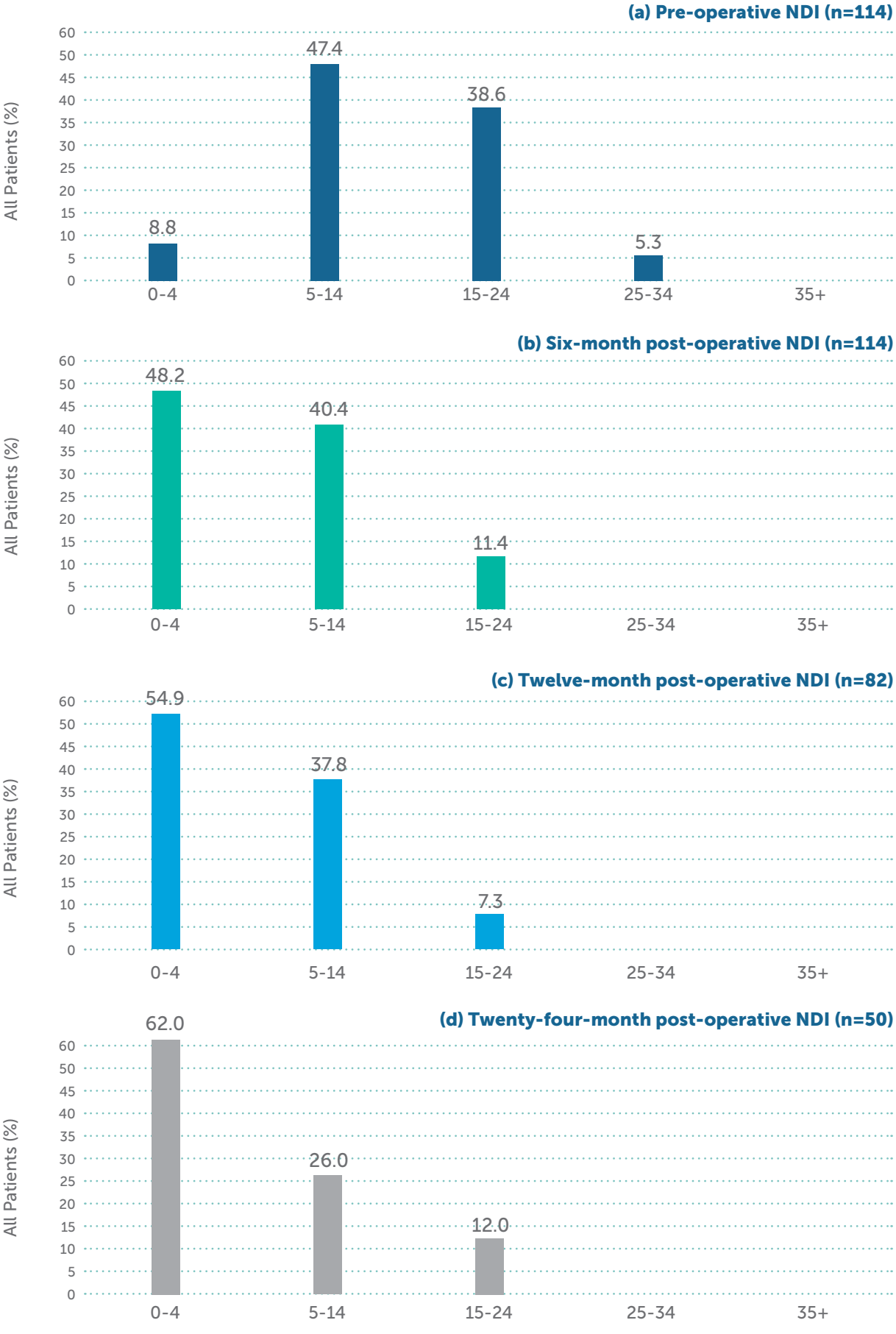
Of the 159 ACDF patients, 114 patients (72%) completed the pre-operative questionnaires. At 6 months, there were 144 patients of which 114 (79%) completed their 6-month follow-up. At 12 months, there were 112 patients, of which 82 (73%) completed their follow-up and at the 24-month time point of the 65 patients, 50 (77%) completed their follow-up questionnaires.

Median NDI scores reduced from 42 preoperatively, to 16 at 6-months post operatively, and continued to improve to 9 at 24 months postoperatively. These results are further detailed in Figure 20.

Table 18: NDI mean and median scores for ACDF patients who completed any NDI at pre-op, 6 and 12-months post-op

NDI	Pre-operative	6-Months	12-Months	24-Months
n	114	114	82	50
Mean (SD)	43.3 (19.3)	20.9 (17.7)	16.9 (15.7)	17.6 (19.1)
Median (IQR)	42.0 (30.0, 58.0)	16.0 (8.0, 30.0)	14.0 (4.0, 26.7)	9.0 (4.0, 28.0)

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



Analysis of each of the ten NDI domains for the ACDF cohort is shown in Table 19. Table 19 shows the mean number of NDI domain points at pre-operative and at 6, 12 and 24 months post-operatively. Average scores across all domains were lower at all post operative time points.

All the NDI domains indicated improvement by surgery. It is possible that there is further improvement between the 6 and 12-month post-operative time points.

Table 19: NDI mean scores for each domain for ACDF patients who completed any EQ-VAS at pre-op, 6, 12 and 24-months post-op

NDI	Pre-operative	6-Months	12-Months	24-Months
n	**114**	**113**	**78**	**48**
Pain, mean (SD)	2.45 (1.18)	1.06 (0.98)	0.72 (0.85)	0.75 (1.04)
Personal Care, mean (SD)	1.04 (1.08)	0.35 (0.70)	0.26 (0.67)	0.35 (0.76)
Lifting, mean (SD)	2.68 (1.43)	1.59 (1.49)	1.33 (1.54)	0.94 (1.33)
Reading, mean (SD)	2.00 (1.26)	1.04 (1.11)	0.78 (0.92)	0.98 (1.00)
Headaches, mean (SD)	1.76 (1.55)	0.97 (1.15)	0.81 (1.05)	0.92 (1.16)
Concentration, mean (SD)	1.30 (1.20)	0.67 (0.98)	0.42 (0.73)	0.48 (0.80)
Work, mean (SD)	2.38 (1.43)	1.20 (1.35)	0.95 (1.18)	1.08 (1.29)
Driving*, mean (SD)	2.27 (1.64)	0.92 (1.31)	0.63 (0.85)	0.74 (1.05)
Sleeping, mean (SD)	2.70 (1.39)	1.38 (1.18)	1.10 (1.16)	1.25 (1.39)
Recreation, mean (SD)	3.01 (1.43)	1.25 (1.34)	0.86 (1.08)	1.04 (1.43)

* Note: Driving question is optional; lower numbers of 110, 109, 75 & 47 (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[11]. 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[12].

Tables 20-22 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 (Tables 20-22).

Table 20: MCID for NDI from pre-op to 6-months post-op for ACDF patients

NDI*	All Cervical (n=114) n (%)	1-2 Level ACDF (n=46) n (%)
Exceeding the MCID (Improved)	66 (57.9)	27 (58.7)
Within the MCID (Unchanged)	48 (42.1)	19 (41.3)
Exceeding the MCID (Worsened)	0 (0.0)	0 (0.0)

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

Table 21: MCID for NDI from pre-op to 12-months post-op for ACDF patients

NDI*	All Cervical (n=80) n (%)	1-2 Level ACDF (n=34) n (%)
Exceeding the MCID (Improved)	49 (61.3)	23 (67.6)
Within the MCID (Unchanged)	31 (38.8)	11 (32.4)
Exceeding the MCID (Worsened)	0 (0.0)	0 (0.0)

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

Table 22: MCID for NDI from pre-op to 24-months post-op for ACDF patients

NDI*	All Cervical (n=79) n (%)	1-2 Level ACDF (n=36) n (%)
Exceeding the MCID (Improved)	45 (57.0)	20 (55.6)
Within the MCID (Unchanged)	34 (43.0)	16 (44.4)
Exceeding the MCID (Worsened)	0 (0.0)	0 (0.0)

EQ-5D-3L Quality of Life

The ACDF cohort EQ-5D-3L dimension scores and the EQ-VAS were examined. Review of the domain scores at each time point showed marked improvement for all domains (Table 23). The pain/discomfort domain showed the most improvement at 6 months followed by the 'usual activities' domain. For the pain/discomfort domain, 99.2% of patients reporting some or extreme pain/discomfort pre-operatively which reduced to 67% at 6-months post-surgery and to 43.8% at 24-months post-surgery. For the 'usual activities' domain, 79.8% of patients reports some or extreme problems with carrying out their usual activities. This was reduced to 48.3% 6-months post-surgery and 33.4% at 24 months post-surgery.

Table 23: EQ-5D-3L scores for each domain for ACDF patients at pre-op, 6, 12 and 24-months post-op

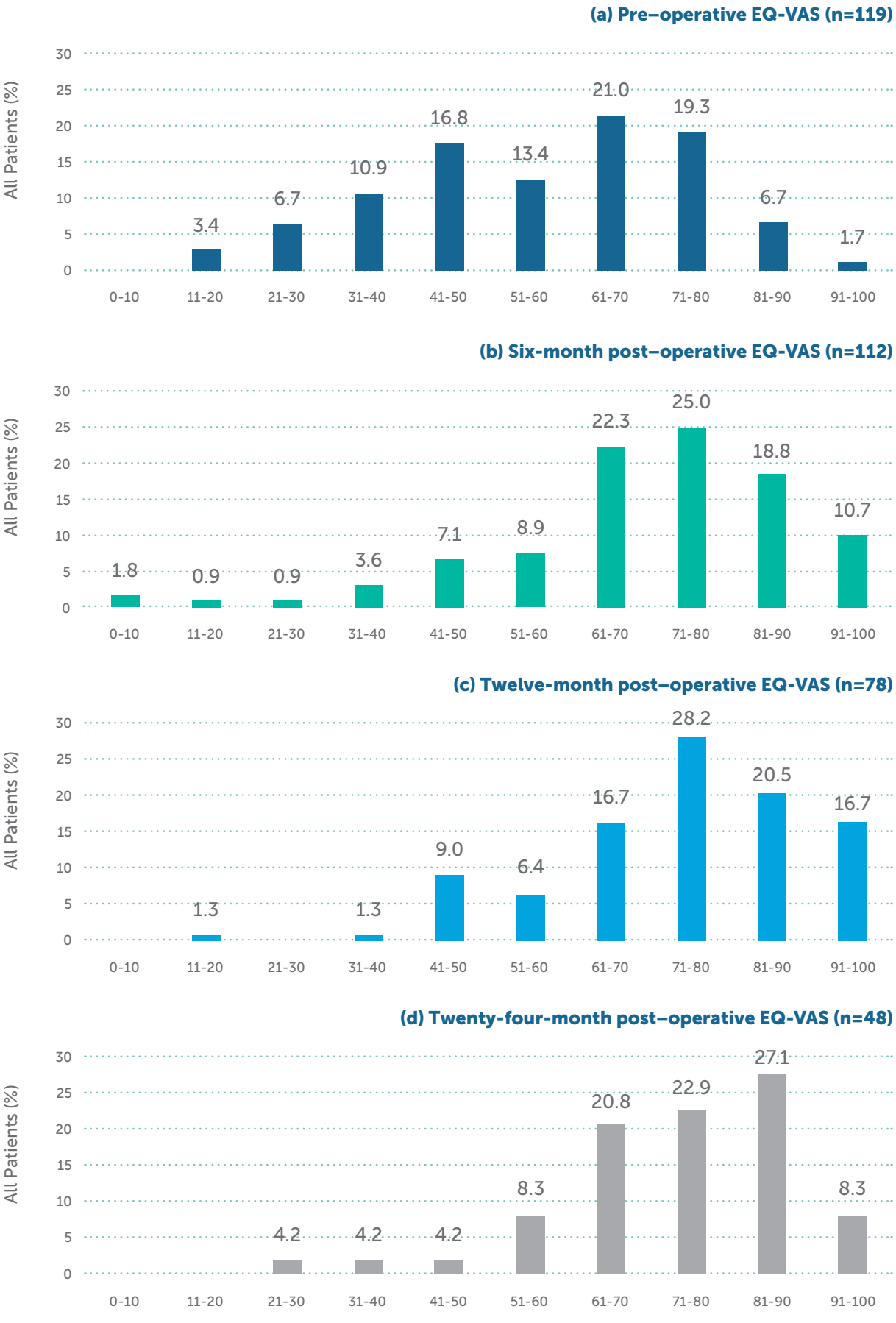
		ACDF Patients EQ-5D-3L			
Domain	**Level of problem**	**Pre-op (%) (n=119)**	**6 months (%) (n=112)**	**12 months (%) (n=78)**	**24 months (%) (n=48)**
Mobility	1 – no problems	57.1	75.9	83.3	83.3
	2 – some problems	42.0	24.1	16.7	16.7
	3 – extreme problems	0.8	0.0	0.0	0.0
Self-care	1 – no problems	68.1	89.3	88.5	83.3
	2 – some problems	31.1	10.7	11.5	16.7
	3 – extreme problems	0.8	0.0	0.0	0.0
Usual activities	1 – no problems	20.2	51.8	59.0	66.7
	2 – some problems	56.3	43.8	37.2	27.1
	3 – extreme problems	23.5	4.5	3.8	6.3
Pain/ discomfort	1 – no problems	0.8	33.0	50.0	56.3
	2 – some problems	68.9	61.6	46.2	39.6
	3 – extreme problems	30.3	5.4	3.8	4.2
Anxiety/ depression	1 – no problems	45.4	59.8	73.1	64.6
	2 – some problems	43.7	34.8	26.9	27.1
	3 – extreme problems	10.9	5.4	0.0	8.3

The EQ-VAS median scores improved from 60 pre-operatively to 75 at 6 months, and was sustained until 24 months (Table 23). These are further detailed in Figure 21.

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

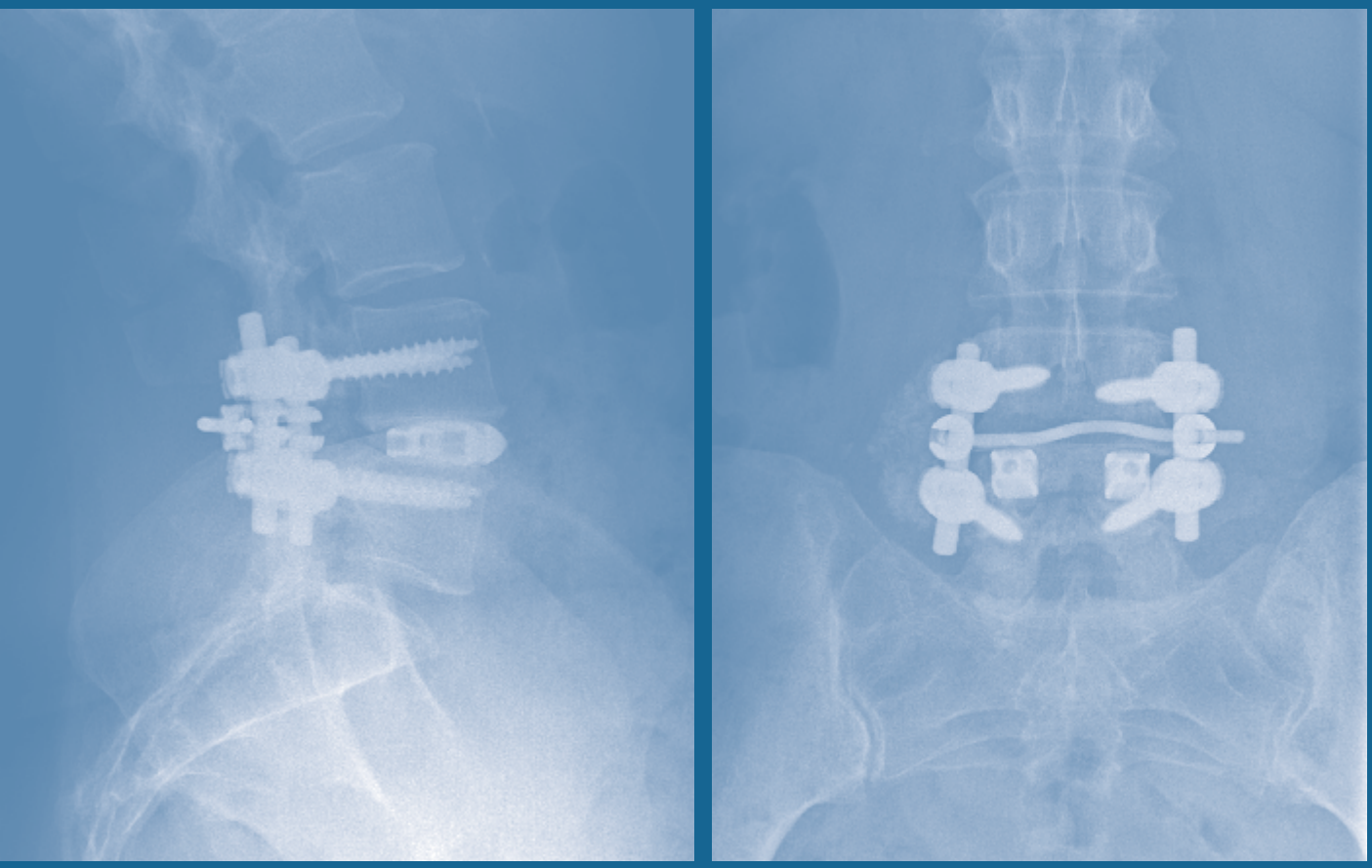
EQ-VAS	**Pre-operative**	**6-Months**	**12-Months**	**24-Months**
n	119	112	78	48
Mean (SD)	59.5 (18.3)	71.6 (18.5)	75.2 (16.2)	73.0 (17.8)
Median (IQR)	60.0 (50.0, 75.0)	75.0 (65.0, 85.0)	79.0 (70.0, 89.0)	77.0 (65.0, 86.5)

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



L4-L5 Degenerative Spondylolisthesis (L4-L5 DS)

Degenerative spondylolisthesis (DS) is a condition in which a vertebra slips forward over the vertebra below. This condition 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 at the L3-L4 level and the L4-L5 level (most common). It is less common at other levels of the spine[13].
It is reported that DS is strongly age and gender specific[14] and is uncommon under the age of 50[15].



(Images courtesy of Mr Michael Johnson)

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

Inclusions:

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

Exclusions:

- Scoliosis

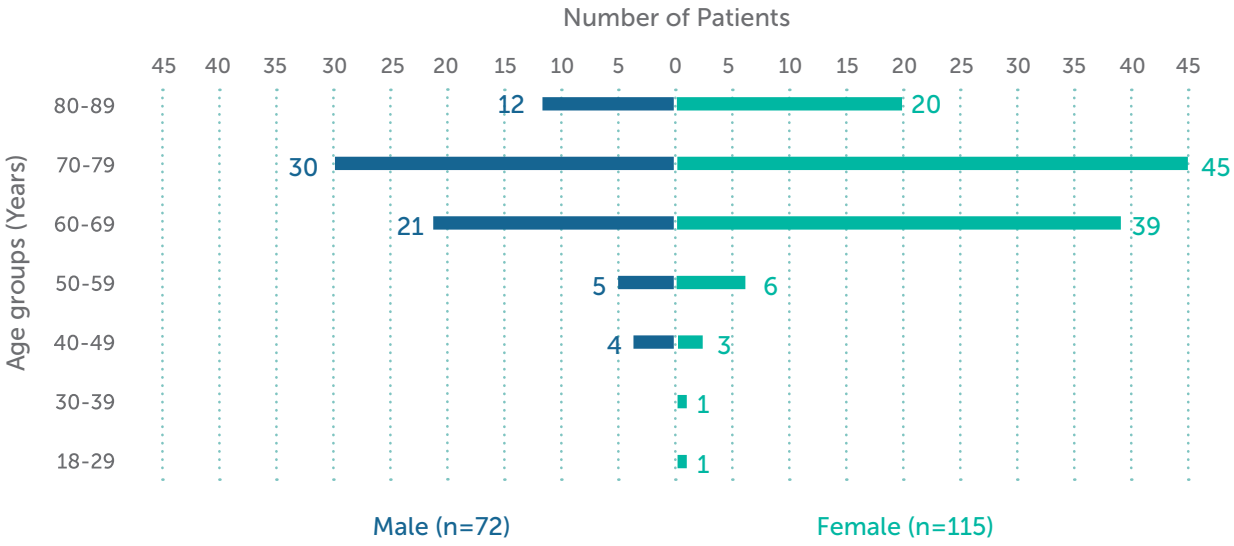
As of 15 January 2022, 187 patients met the L4-L5 DS cohort inclusion criteria.

Demographics

There were 72 males (39%) and 115 females (61%) who were diagnosed with L4-L5 DS as shown in Figure 22. This is a male:female ratio of 1:1.5.

The median age for males was 72 years and 71 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 22: L4-L5 Spondylolisthesis procedures by patient age and gender



Comorbidities

The number of patients that were reported with a comorbidity is shown (Table 25); 66% of L4-L5 DS patients were reported to have at least one comorbidity compared to 44% of the total patients. Patients were further categorised into groups by the number of comorbidities reported (Table 26). The patients have a greater number of comorbidities than seen in the discectomy group. This is consistent with the age profile.

Table 25: Number of L4-L5 DS patients with any comorbidity prior to surgery

Any comorbidity	All (n=2554) n (%)	L4-L5 DS (n=187) n (%)
Yes	1193 (46.7)	123 (65.8)
No	1361 (53.3)	64 (34.2)

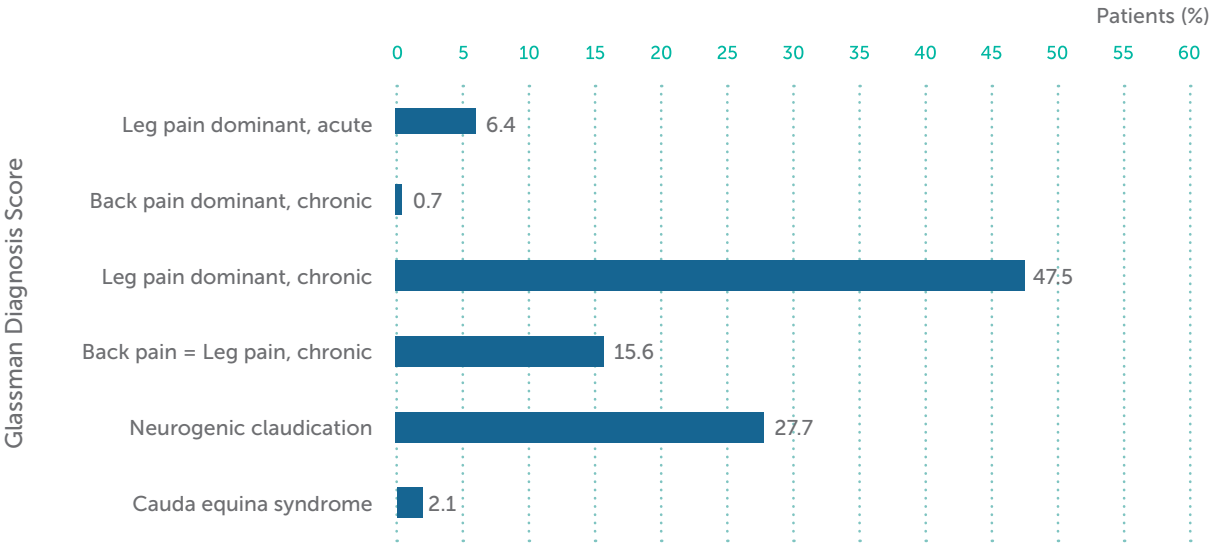
Table 26: Breakdown of number of comorbidities reported in L4-L5 DS patients

Number of reported comorbidities	All (n=2254) n (%)	L4-L5 DS (n=187) n (%)
None	1416 (55.4)	66 (35.3)
1	547 (21.4)	52 (27.8)
2	296 (11.6)	36 (19.3)
3	186 (7.3)	24 (12.8)
4	60 (2.4)	4 (2.1)
5+	49 (1.9)	5 (2.7)

Glassman Classification Scores

The Glassman classifcaition scores for the L4-L5 DS cohort were examined. Analysis of the "Symptoms" category indicate that for most of these patients, surgery was performed for neurocompressive pain (Figure 23).

Figure 23: Glassman Score for 'Symptoms' among L4-L5 DS patients (n=141)



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)

For this cohort, there were 187 eligible patients at pre-op of which 160 (86%) completed their pre-operative questionnaires. At 6-months there were 170 eligible patients of which 142 (83%) completed their 6-month post-operative questionnaire. At 12 months, there were 158 patients, of which 129 (82%) completed their post-operative questionnaire. At 24 months, there were 107 patients, of which 91 (85%) completed their post-operative questionnaire.

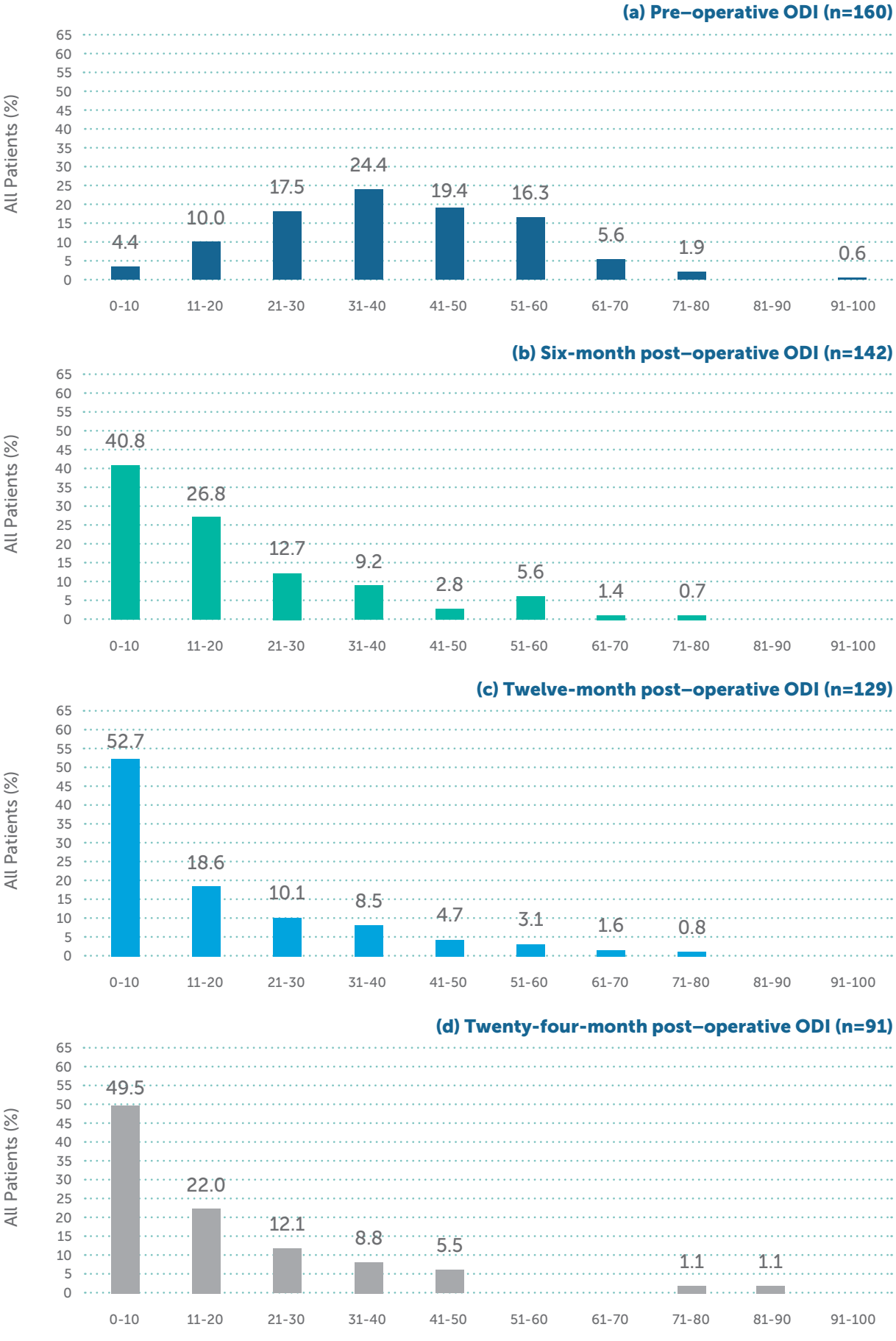
ODI median scores improved from 38 pre-operatively to 14 at 6-months post-operatively, which was sustained until 24 months (Table 27).

Table 27: 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	160	142	129	91
Mean (SD)	38.4 (16.4)	17.6 (17.3)	16.2 (16.9)	15.2 (16.5)
Median (IQR)	38.0 (26.0, 50.0)	14.0 (4.0, 27.0)	10.0 (4.0, 26.0)	11.0 (2.0, 27.0)

Figure 24 describes this in further detail.

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



Analysis of each of the ten ODI domains for the L4-L5 DS patients that completed any questionnaires is shown in Table 28. Table 28 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 28: ODI mean scores for each domain 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	**160**	**142**	**125**	**88**
Pain, mean (SD)	2.30 (1.04)	0.93 (0.99)	0.80 (1.00)	0.78 (0.99)
Personal Care, mean (SD)	0.95 (1.04)	0.42 (0.90)	0.30 (0.76)	0.26 (0.78)
Lifting, mean (SD)	2.33 (1.27)	1.52 (1.51)	1.34 (1.41)	1.26 (1.43)
Walking, mean (SD)	2.06 (1.26)	0.75 (1.13)	0.66 (1.14)	0.66 (1.06)
Sitting, mean (SD)	1.60 (1.14)	0.88 (0.92)	0.78 (0.91)	0.68 (0.85)
Standing, mean (SD)	2.67 (1.33)	1.16 (1.32)	1.17 (1.36)	1.23 (1.40)
Sleeping, mean (SD)	1.41 (0.95)	0.63 (0.76)	0.60 (0.70)	0.52 (0.83)
Sex Life*, mean (SD)	1.87 (1.94)	0.62 (1.32)	0.64 (1.37)	0.47 (1.21)
Social Life, mean (SD)	2.23 (1.22)	0.96 (1.34)	0.83 (1.25)	0.75 (1.07)
Travelling, mean (SD)	1.75 (1.22)	0.75 (1.16)	0.68 (1.05)	0.56 (0.95)

* Note: Sex life question is optional; lower numbers of 97, 87, 76 and 60 (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[10].

For the L4-L5 DS patients, 96.9% **exceeded or were within** the MCID for ODI. This was sustained at 12 and 24 months (Tables 30 and 31).

Table 30 shows the MCID for 12 months post-operatively; 71% of patients showed an improvement at this time point. Table 30 shows the MCID for 24 months post-operative, where 77% 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. This indicates that although DS patients are older, they are benefiting from their procedure(s).

Table 29: 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)	954 (65.6)	85 (67.5)
Within the MCID (Unchanged)	455 (31.3)	39 (31.0)
Exceeding the MCID (Worsened)	45 (3.1)	2 (1.6)

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

Table 30: MCID for ODI from pre-op to 12-months post-op for L4-L5 DS patients

MCID	All (n=835) n (%)	L4-L5 DS (n=83) n (%)
Exceeding the MCID (Improved)	851 (66.6)	80 (70.2)
Within the MCID (Unchanged)	395 (30.9)	32 (28.1)
Exceeding the MCID (Worsened)	32 (2.5)	2 (1.8)

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

Table 31: MCID for ODI from pre-op to 24-months post-op for L4-L5 DS patients

MCID	All (n=807) n (%)	L4-L5 DS (n=81) n (%)
Exceeding the MCID (Improved)	546 (67.7)	62 (76.5)
Within the MCID (Unchanged)	232 (28.7)	15 (18.5)
Exceeding the MCID (Worsened)	29 (3.6)	4 (4.9)

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

EQ-5D-3L Quality of Life

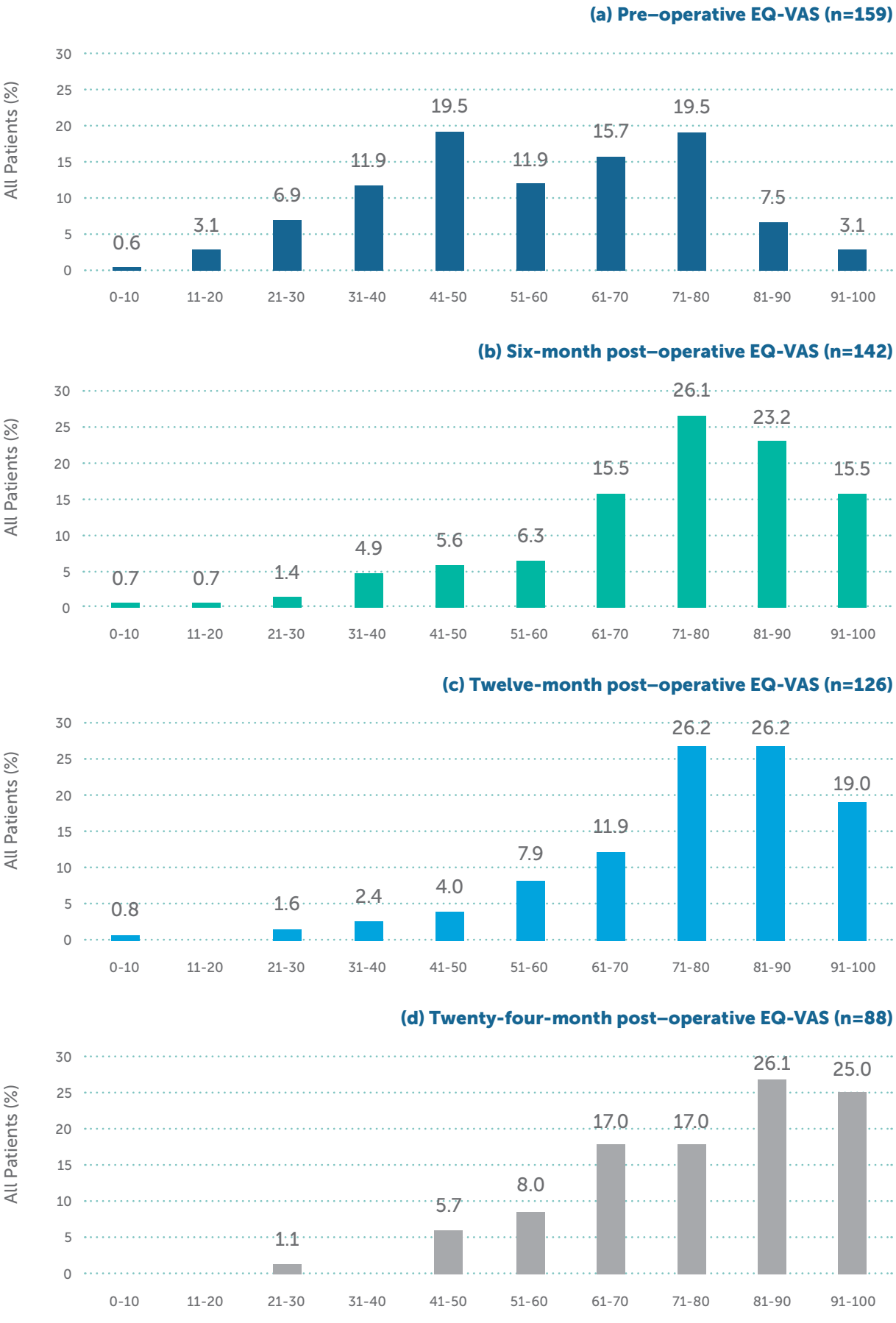
The L4-L5 DS cohort EQ-5D-3L dimension scores and the EQ-VAS were analysed (Table 32 and Figure 25). It is important to note that this group of patients have multifactorial health issues, and it is not unexpected that these patients have residual pain. In addition, this questionnaire asks about any pain, 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 35.9% at 6-months post-surgery; a reduction of 44.6%. For the pain/discomfort domain, 98.1% of patients reported some or extreme pain/discomfort pre-operatively which reduced to 56.3% at 6-months post-surgery; a reduction of 41.8%. For the usual activities' domain, 86.2% of patients reported some or extreme problems with carrying out their usual activities. This was reduced to 47.9% 6-months post-surgery; a reduction of 38.3%.

Table 32: EQ-5D-3L scores for each domain for L4-L5 DS patients at pre-op, 6, 12 and 24-months post-op

		L4-L5 DS Patients EQ-5D-3L			
Domain	**Level of problem**	**Pre-op (%) (n=159)**	**6 months (%) (n=142)**	**12 months (%) (n=126)**	**24 months (%) (n=88)**
Mobility	1 – no problems	19.5	64.1	69.8	61.4
	2 – some problems	79.2	35.9	30.2	38.6
	3 – extreme problems	1.3	0.0	0.0	0.0
Self-care	1 – no problems	74.2	86.6	88.1	92.0
	2 – some problems	25.2	13.4	11.9	8.0
	3 – extreme problems	0.6	0.0	0.0	0.0
Usual activities	1 – no problems	13.8	52.1	60.3	68.2
	2 – some problems	75.5	44.4	38.1	29.5
	3 – extreme problems	10.7	3.5	1.6	2.3
Pain/ discomfort	1 – no problems	1.9	43.7	51.6	47.7
	2 – some problems	61.0	51.4	44.4	48.9
	3 – extreme problems	37.1	4.9	4.0	3.4
Anxiety/ depression	1 – no problems	52.2	71.8	72.2	76.1
	2 – some problems	42.1	26.1	24.6	21.6
	3 – extreme problems	5.7	2.1	3.2	2.3

When examining EQ-VAS a shift to the right indicates an improvement of patient perception of their general health status. As shown in Figure 25, this cohort showed improvement in their general perception of their health 6, 12 and 24-months post-operatively.

Figure 25: EQ-VAS distribution for L4-L5 DS patients who completed any EQ-VAS at pre-op, 6, 12 and 24-months post-op



Future Directions

The registry has over the last 3 years consistently demonstrated that the ASR is feasible. COVID-19 did not significantly impact registry operations although patient and surgeon recruitment was reduced. The ongoing expansion and success of the ASR hinges on funding and promotion.

The ASR through the support of the SSA, was able to put together an insightful and thorough business case which it presented to the Federal Government in October 2021. At the time of publishing this annual report, the Federal Government recognised the importance of the ASR and the work that has been done to date, providing 2 years of very significant funding assistance. This is a major achievement for the registry as it demonstrates the importance of the ASR in the eyes of the Australian Federal Government.

From an operational perspective, the ASR will continue to improve the user experience by evaluating new approaches for improving the database and communication with patients and surgeons. This will include:

- Launching the surgeon dashboard for real time statistical reporting,
- Launching an improved comorbidity collection and identification of risk adjustment factors,
- Ongoing refinement of ASR data elements to improve and update the instrumentation, navigation, grafting materials and technique menus,
- Refinement of the collection of complications.

The ASR is also formally evaluating the addition of a paediatric arm to the registry. This has been discussed with the Queensland Children's Hospital and Queensland University of Technology and work is underway to define the minimal dataset and the KEOPs infrastructure.

The ASR is now entering a new and exciting phase of expansion and further development, and we look forward to reporting new milestones and achievements in future annual reports.

Registry Publications

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.

Appendices & References

Appendices

Appendix 1 - ASR Committees

SSA Registry Committee

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

ASR Steering Committee

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
Mr John Cunningham	Orthopaedic Spine Surgeon
Dr Rob Kuru	Orthopaedic Spine Surgeon
Professor John McNeil	Chief Investigator, ASPREE Clinical Trial, Epidemiology and Preventive Medicine
Professor Ilana Ackerman	Associate Professor (Research), Clinical Epidemiology

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 and Coordinator
Ms Trieu-Anh Truong	Research Assistant
Mr Sean Bulmer	Research Assistant
Mr Craig Pickett	Data Analyst

Appendix 2 - Participating Surgeons in 2021

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
Queensland	Dihan Aponso	Orthopaedic Spine Surgeon
	Steven Yang	Orthopaedic Spine Surgeon
	Peter McCombe	Orthopaedic Spine Surgeon
	Denis Hartig	Specialist Spine Surgeon
	Leo Zeller	Orthopaedic Surgeon
	Adam Parr	Orthopaedic Spine Surgeon
	John Albietz	Orthopaedic Spine Surgeon
	Antonio Tsahtsarlis	Neurosurgeon
	Kate Campbell	Orthopaedic Spine Surgeon
Tasmania	Andrew Hunn	Neurosurgeon

Appendices

Appendix 3 - Approved Hospitals

Victoria

- Epworth Richmond
- Royal Melbourne Hospital
- Epworth Eastern
- Warringal Private Hospital

Tasmania

- Calvary Private Hospital – Lenah Valley

Western Australia

- St John of God Subiaco Hospital

Queensland

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

New South Wales

- John Hunter Hospital
- Newcastle Private Hospital
- Nepean Public Hospital
- Lake Macquarie Private Hospital
- Macquarie University Hospital
- Nepean Private Hospital
- Prince of Wales Hospital
- Prince of Wales Private Hospital
- St George Private Hospital
- St George Public Hospital

Appendix 4 - Patient diagnosis 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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