



Australian Spine Registry



MONASH
University

Annual Report 2019



Enquires/Comments

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Australian Spine Registry (ASR)

Monash University
Level 3, 553 St Kilda Rd
Melbourne VIC 3004 Australia

Phone: 1800 998 722

Email: spineregistryAU@monash.edu

Website: spineregistry.org.au

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Foreword

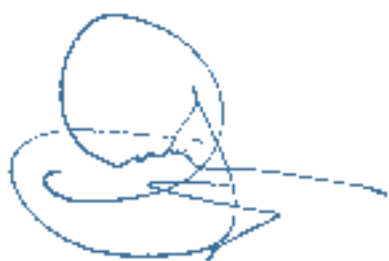
It is my pleasure to present the Australian Spine Registry 2019 Annual Report. We are very pleased that our pilot program has been able to obtain a level of patient and surgeon compliance that demonstrates that the Australian Spine Registry is a viable ongoing registry.

Since commencing data collection in January 2018, the registry has grown steadily with patient recruitment. The registry has been collecting data for over 24 months now and comprises over 1400 patients in the register. Patients remain overwhelmingly positive about the ASR as is evident by their participation and willingness to complete the registry specific questionnaires pre-operatively and post-operatively. Participating surgeons and their practice staff also continue to show enthusiasm and dedication, incorporating the registry data collection into their clinical practice. Without this engagement the ASR would not be possible. We are very proud of the continuing progress and growth of the registry in 2019.

This is the second annual report released by the ASR and this year's report examines additional patient cohorts which has only made possible by the increasing numbers of patients in the registry.

Key milestones of the ASR for 2019 include being awarded a 3-year HCF Foundation grant and presentations at the Royal Australian College of Surgeons Annual Scientific meeting in Bangkok and at the 2nd Combined Spine Society Meeting in Queenstown, New Zealand.

The ASR Pilot continues to be supported by generous donations from industry, health insurers and the Spine Society of Australia highlighting stakeholders' interest and commitment to what we believe will improve the full spectrum of spinal surgical care.



Mr Michael Johnson MBBS, FRACS (Orth)

Chairman, ASR Steering Committee
Clinical Lead, Australian Spine Registry
President, Spine Society of Australia



Acknowledgements

The ASR has continued to grow due to the efforts of a dedicated team.

The registry would not be possible without the ongoing efforts of the registry coordinator, Dr Esther Apos, Professor Susannah Ahern and her staff at the Registry Science and Research Unit, Monash University. In addition, the ASR thanks Mr Philippe Roussouly and his team for the support and continuous improvement of the registry web-based interface.

The ASR would also like to acknowledge the continuing assistance and advice of Mr Adrian Cosenza and Mr Jeff Clark from the Australian

Orthopaedic Association, and Mr Matthew Payne, HWL Ebsworth Lawyers concerning administrative, financial and legal matters.

The ASR gratefully acknowledges all the Steering Committee members, participating surgeons and their support staff for their time and commitment.

Most importantly, the ASR thanks all participating patients who generously share their information with the ASR to improve the quality of the management of spine surgery in Australia.

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 2020. 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
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
Deformity	A loss of the normal curvature of the spine
Discectomy	A type of surgery to decompress nerve compression secondary to disc herniation
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 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.
SSA	Spine Society of Australia
Thoracolumbar	Between T1 and the pelvis

Executive Summary

The Australian Spine Registry (ASR) is proud to present its second Annual Report. The ASR commenced recruiting patients and collecting data in January 2018 and now has in excess of 1300 patients. The data presented in this report was collected for all patients recruited between 15 January 2018 and 15 January 2020 and analyses the entire patient group and specific patient cohorts. Aggregated analyses are presented.

During 2019, the ASR streamlined its operations, data collection and data analysis. One of the ASR's strengths has been data acquisition. The ASR has successfully implemented processes which has resulted in 87% patient data completion and 91% surgeon data completion.

A quick glance at ASR patient data shows:

- 52% males and 48% females with a median age at the time of surgery of 62 years for males and 66 years for females
- 41.7% of patients presented with one or more comorbidity
- Discectomy and ACDF patients were generally younger (median age of 47 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 69.5 years of age

- 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 and 12-months post operatively.
- » EQ-5D-3L scores improved in the 6 and 12-month time period for the entire cohort
- » 84% of the patients in the discectomy cohort exceeded the MCID which indicates a significant improvement post-surgery.

Looking ahead, the ASR pilot will continue to refine the data collection process in order to make it simpler for surgeons to enter data. Communication with patients via SMS will also be trialled to enable faster questionnaire completion with minimal disruption.

In 2019, funding support for the registry pilot was through the following medical device companies, health insurers and the Spine Society of Australia (SSA).

The ASR was also awarded a HCF Foundation grant for the next 3 years which will enable further surgeon recruitment and allow the development and trial of the SMS communication platform.

Funding supporters



Snapshot of The Australian Spine Registry

872

Increase in the number of patients in the past 12 months from January 19 2019 to January 15 2020.

1563

Total number of procedures captured.

689

Male

10 icons

10 icons

10 icons

10 icons

10 icons

10 icons

52%

626

Female

10 icons

10 icons

10 icons

48%

PROMs completion

Pre-Op

6 Mth

12 Mth

24 Mth

Patients eligible (n)

1307

882

504

18

Complete with data (n)

1137

700

433

17

Complete with data (%)

87.0%

79.4%

85.9%

94.4%

(Patients recruited up to 15 January 2020)



Patients

1332



Surgeons

13



Sites

13

Key Milestones of the ASR in 2019



First Annual Report

January 2019



Stakeholders Update

April 2019



1000 Patients in the ASR

September 2019



HCF Foundation grant
awarded

November 2019

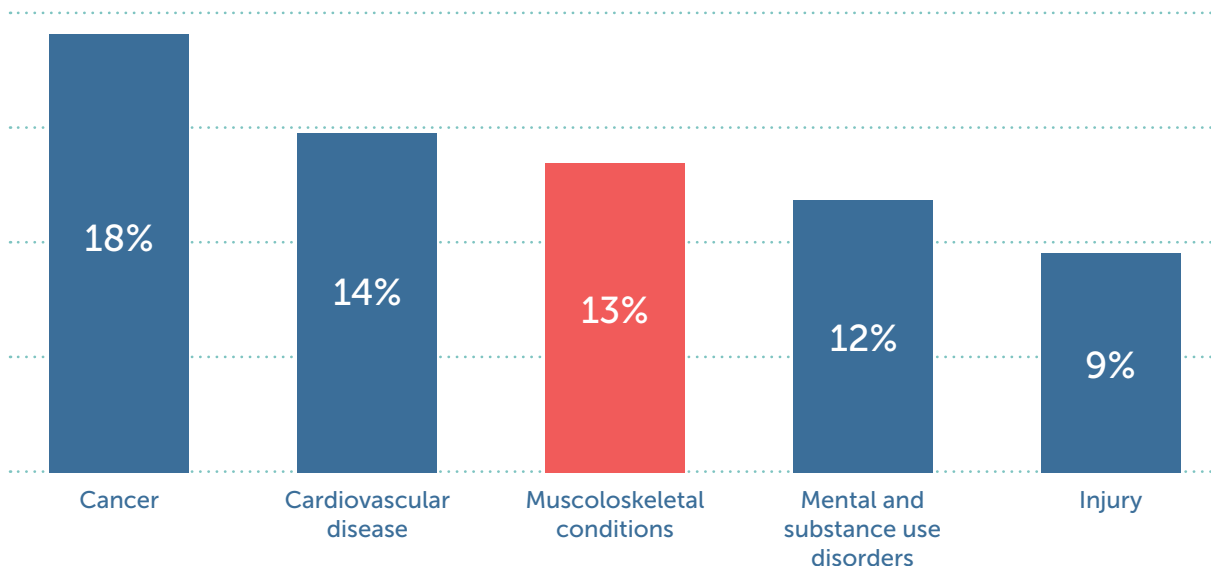


2 Year Patient Follow Up
Commenced

December 2019

Background

In Australia, there are 5 leading disease groups causing burden.



Musculoskeletal conditions are ranked third, with back pain and back related problems representing one of the leading diseases in this group to cause burden within the Australian population². It is estimated that one in six Australians (≈ 4 million) had back problems in 2017-18. Back problems are a range of conditions related to bones, joints, connective tissue, muscles and nerves of the back and are a significant cause of disability and lost productivity in Australia¹.

Back problems often lead to poorer quality of life, psychological distress, bodily pain and disability. Spine surgery is usually the last resort in the treatment of back problems and while surgery is not necessary or suitable for everyone with back problems, approximately 45,000 Australians undergo spine surgery every year³. In 2015-2016, back pain and problems cost the Australian health system an estimated 2.8 billion, representing 23% of disease expenditure on musculoskeletal conditions and 2.4% of total health expenditure⁴.

There is now recognition world-wide that unique clinical insights can be gained by large scale registries⁵. Where they have been introduced at a state or national level in Australia, they have become one of the most clinically valued tools for quality improvement⁶.

The Australian Spine Registry (ASR) aims to be an essential platform for spine surgery research in Australia. The pilot registry commenced patient recruitment and data collection on 15th of January 2018.

The registry has captured data from elective spine surgery patients from multiple geographic locations within Australia with a particular focus on patient reported outcomes. The registry is now into its second year of data collection and has recruited over 1200 patients and has collected data on over 1500 surgeries.

The 2019 Annual Report provides an overview of all patients and reports on patient reported outcome measures for the following patient cohorts:

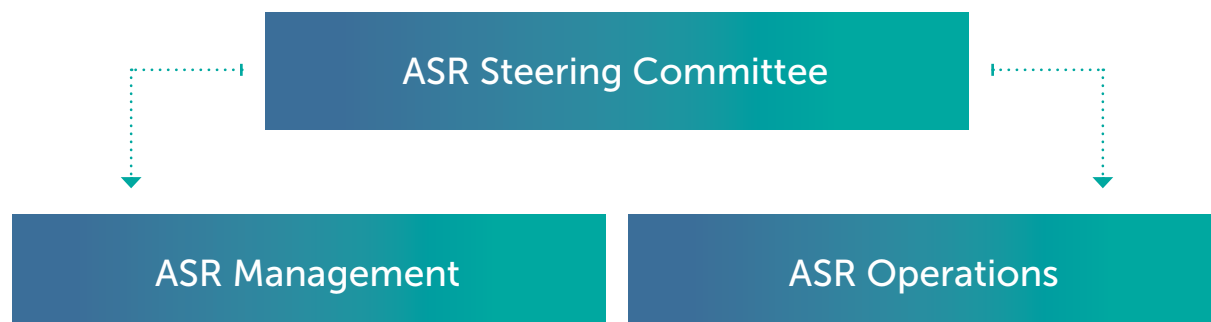
- Patients who have undergone single level discectomy
- Patients who have undergone single level anterior cervical discectomy and fusion
- Patients with L4-L5 degenerative spondylolisthesis

ⁱ <https://www.aihw.gov.au/reports/chronic-musculoskeletal-conditions/back-problems/contents/how-do-back-problems-affect-quality-of-life>

Governance

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.



Management Committee

The 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 and the Steering Committee Chair.

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

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.

Pilot Phase of Registry

The ASR has almost completed the pilot phase, where the dataset, methods and data tools are being tested at a sample of participating sites across Australia. The aim of the pilot registry is to test and evaluate current ASR processes and outcomes, and to make recommendations regarding the feasibility for a national rollout of the ASR.

Research Ethics and Governance

The ASR received ethics approval under the National Mutual Acceptance (NMA) scheme through Melbourne Health, Victoria, in August 2016. All participating public hospitals have governance authorisation. Depending on the private hospital, either ethics and/or governance authorisation has been granted.

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.

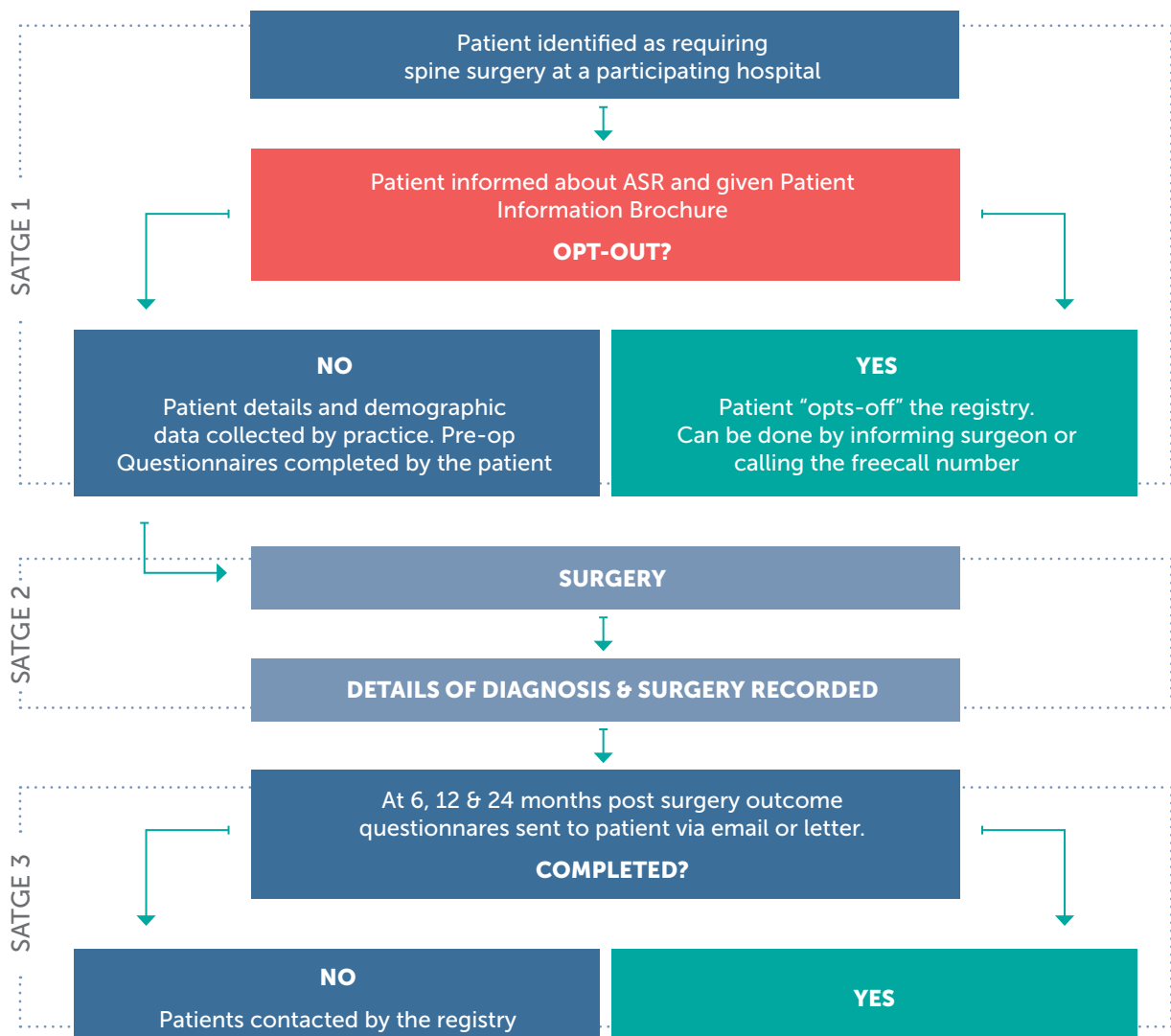
Inclusion Criteria

- 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, surgeons and Monash University registry staff and entered into the ASR KEOPS database. KEOPS is a data management tool designed and constructed specifically for spine specialists⁷.

The registry collects information about the patients before and after surgery in the form of self-completed questionnaires. Pre-operatively, these questionnaires are completed either on paper or electronically, directly through the KEOPS database web-based portal.

KEOPS is a fully customisable data collection tool which can track clinical outcomes and deliver and follow-up patient questionnaires at desired intervals. Data entry is achieved through click boxes and drop-down menus and minimises time spent by surgeons on surgery outcome reporting. The ability to customise KEOPS for Australian practices and its ease of use were key reasons for this software being selected for this pilot.

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 Classification⁸ in the diagnosis section which is a diagnostic coding matrix that codes three primary elements commonly used in clinical decision making:

- Symptoms
- Structural Pathology
- Compressive Pathology

The registry uses 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 Oswestry Disability Index (ODI) for lower back pain
- The Neck Disability Index (NDI) for acute or chronic disability of the neck⁹⁻¹²
- General quality of life (QoL) EuroQol five dimension (EQ-5D™-3L) questionnaire¹²

Summary of the ASR

Surgeon and Hospital Engagement

Spine surgery is performed by both orthopaedic surgeons and neurosurgeons. Currently the ASR has ten orthopaedic spine surgeon and three neurosurgeons actively participating (with one neurosurgeon changing practices and not continuing).

In 2019, the ASR did not increase the number of participating sites and recruited only one additional neurosurgeon (Figure 1). The objective of the ASR in 2019 was to consolidate registry operations for the purpose of future expansion.

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



Patient Uptake

Active recruitment of patients commenced on 15th January 2018. Patient recruitment over time has been consistent over the 12-month period as shown in Figure 2. Only 2% of patients had opted out of the registry (data not shown).

Figure 2: Accumulation rate of patients from registry launch on 15 January 2018 to 15 January 2020

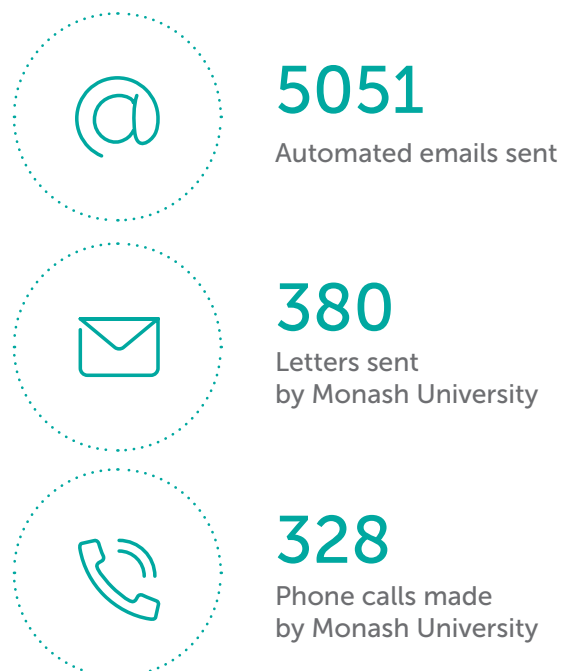


Registry Communications and Responses

Post-operatively, patients automatically receive the questionnaires either by email or mail at 6, 12 and 24 months after their surgery. At the time of this publication, 77.5% of patients provided an email address and 95.9% of patients provided a mobile number.

If the registry has not received completed questionnaires from patients within the required time frame, the registry follows up each patient with 1 phone call. Figure 3 outlines the total number of automated emails and contact attempts by the registry up to January 15, 2020. We have found that with patients with email addresses, it takes approximately 3.8 emails for the patient to respond. With patients with no email address, compliance from letters tends to high but at a considerably higher expense than email.

Figure 3: Post-operative communication methods to eligible patients



Surgeon reported data

The registry management consistently provides feedback and support to surgeons and their practice staff regarding patient recruitment and data completeness. Practices have also been audited to ensure

that all eligible patients are recruited into the registry and that surgeons are not “cherry picking” patients. The data entry completion rate by surgeons at 15 Jan 2020 is shown in Figure 4.

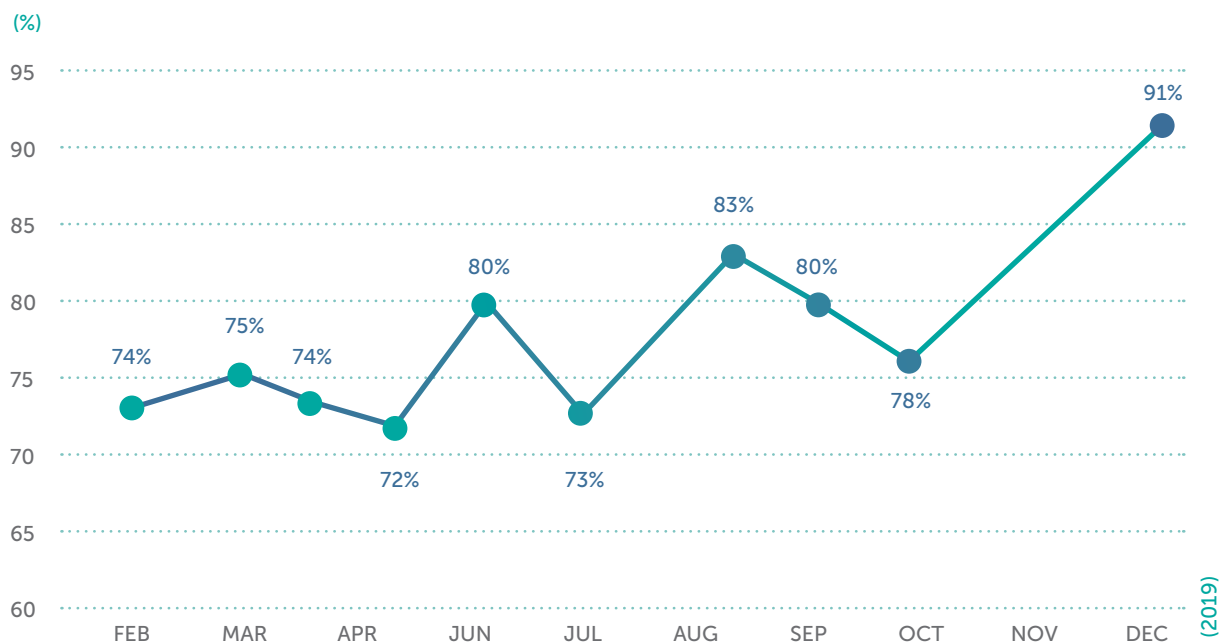
Figure 4: Surgeon data entry completion rate



The registry is very proactive in informing participating surgeons of their data entry and reports monthly data completion trends. Data completeness trending was instigated in February 2019. Every month, surgeons are sent an SMS with graphical information of their personal data compliance in comparison

to deidentified data completion of the other participating surgeons. The registry has set an 80% data completeness threshold. It can be seen that data entry by surgeons has progressively improved since data entry trend communication was started (Figure 5).

Figure 5: Surgeon data entry and completion trend (up to 31 December 2019)



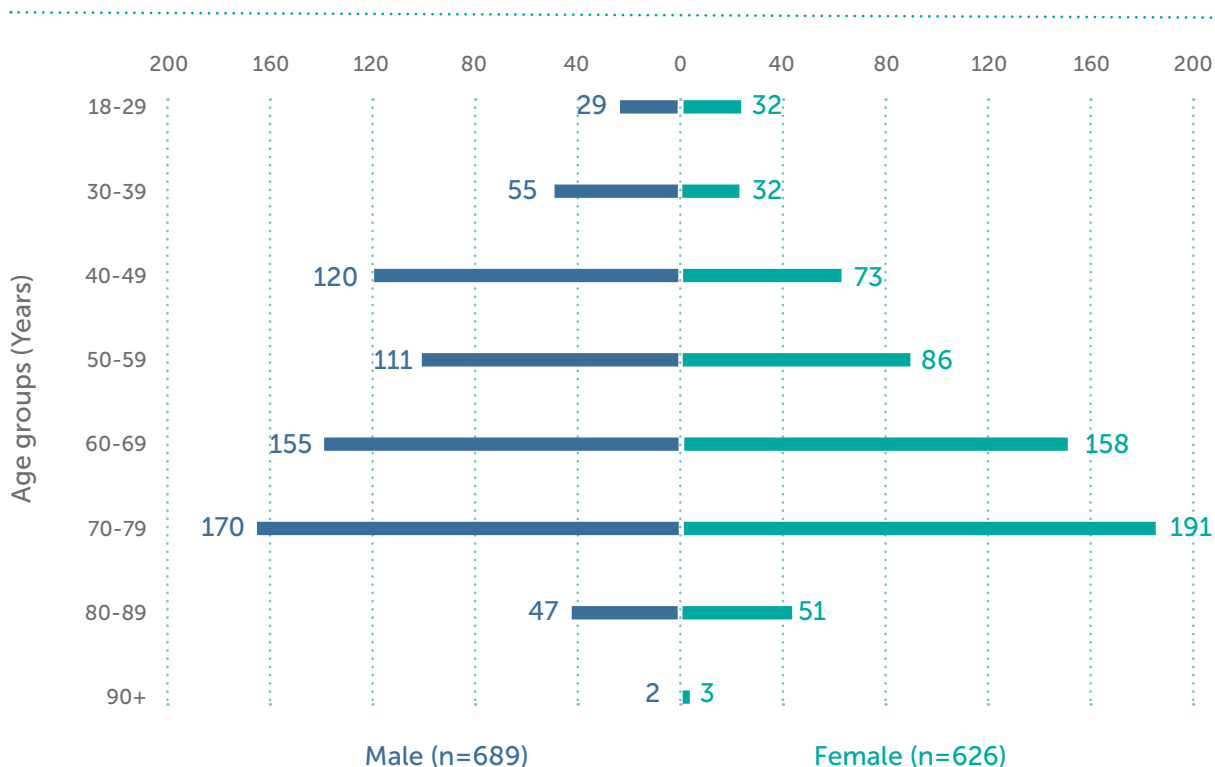
Overview of ASR Patients

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

Patient Demographics

As at 15 January 2020, there were 1315 patients participating in the registry. There were 689 (52%) males and 626 (48%) females. 70% of male and 78% of female patients were over the age of 50. (Figure 6). We note that the commonest decile having spine surgery is between 70-79 years of age.

Figure 6: Patient age distribution at the time of surgery



Treatment types

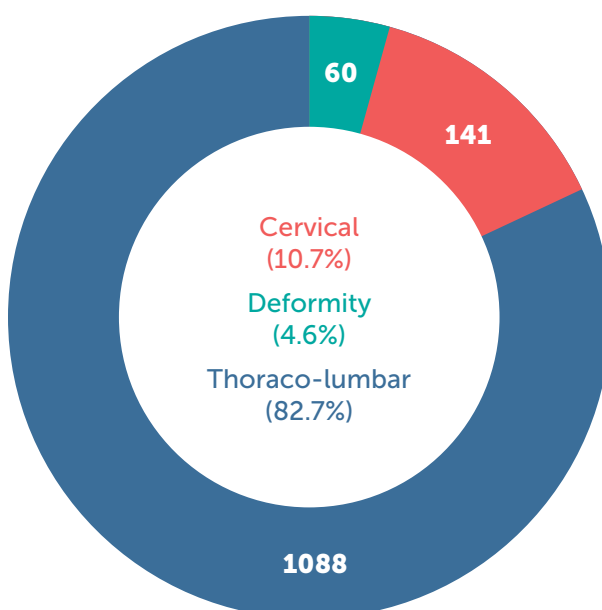
Patients were categorised into 3 groups based on the anatomical location of their surgery:

- Thoraco-lumbar
- Cervical
- Deformity

The breakdown of patients in each group is shown (Figure 7).

Given that the ASR is in a pilot phase, these figures are not indicative of the percentage of procedures that typically occur within Australia.

Figure 7: Percentage of patients by treatment types



Comorbidities

Current ASR data indicates that 37.7% of patients presented with one or more comorbidities (Figure 8). The frequency of patients having 1 or more comorbidities is shown in Figure 9.

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).

Figure 8: Percentage of patients with at least 1 comorbidity

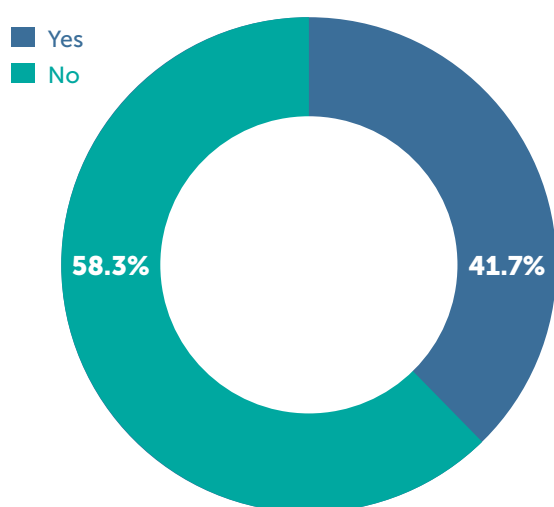
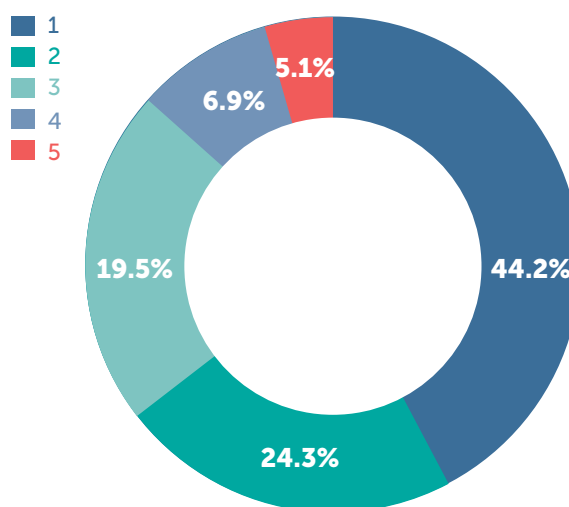


Figure 9: Percentage of patients by number of comorbidities reported



Patient Reported Outcome Measures

Patients are assessed before surgery and at 6, 12 and 24-months post-surgery for their level of disability and their general quality of life (QoL).

The completion rate for any of the PROMs at each time point is shown in Table 1. Overall,

patients participating in the registry and the follow up activities by the ASR has enabled almost a >80% PROMs completion rate at each time point. The registry is actively looking at new methods to improve the questionnaire completion especially at the pre-op time point to strive for a >90% completion rate.

Table 1: PROMs completion rate

PROMs completion (Any)	Pre-op	6 Mth	12 Mth	24 Mth
Patients eligible (n)	1307	882	504	18
Complete with data (n)	1137	700	433	17
Complete with data (%)	87.0%	79.4%	85.9%	94.4%

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

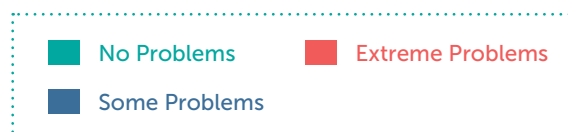
Figure 10 shows the EQ-5D-3L scores for all patients that have completed the EQ-5D-3L for each of the 5 dimensions up to 12 months. There were insufficient patient numbers for the 24-month time point.

For each of the dimensions, an improvement was observed. For pain/discomfort, 97.7% of patients reported some or extreme problems pre-operatively as compared to 67.1% at 6 months. For the mobility domain, 83.2% of patient reported some or extreme problems preoperatively; this reduced to 38.3% at 6 months. Interestingly, there was a slight increase at 12 months.

Self-care and anxiety/depression did not show a large change in the number of patients reporting problems between timepoints.

The data indicates that improvements are sustained at 12 months.

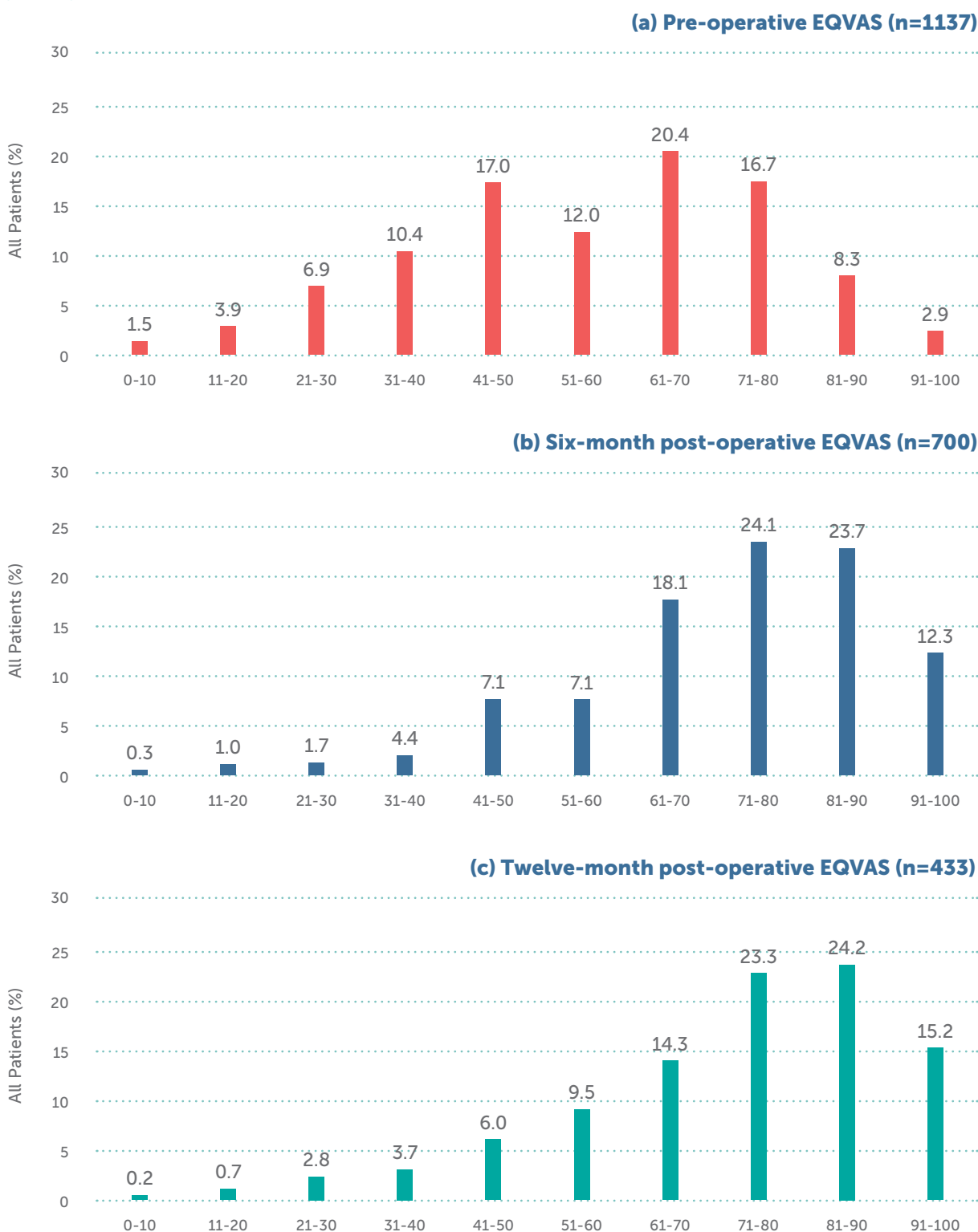
Figure 10: EQ-5D-3L score ranges for each domain for all patients at pre-op, 6 and 12-months post-op



Regarding EQ-VAS scores, a higher score indicates improved patient perception of general health. Analysis of the EQ-VAS scores at pre-op, 6 months and 12 months indicated that patients generally felt that the state of

their health had improved at the 6-month time point and this was maintained at the 12-month time point (Figure 11). This suggests a link between the patients' spinal condition and their perception of their overall general health.

Figure 11: EQ-VAS distribution for all patients who completed any EQ-VAS at pre-op, 6 and 12-months post-op



The higher the score, the better the perception of overall health.

Oswestry Disability Index - ODI

(All thoraco-lumbar and deformity surgery)

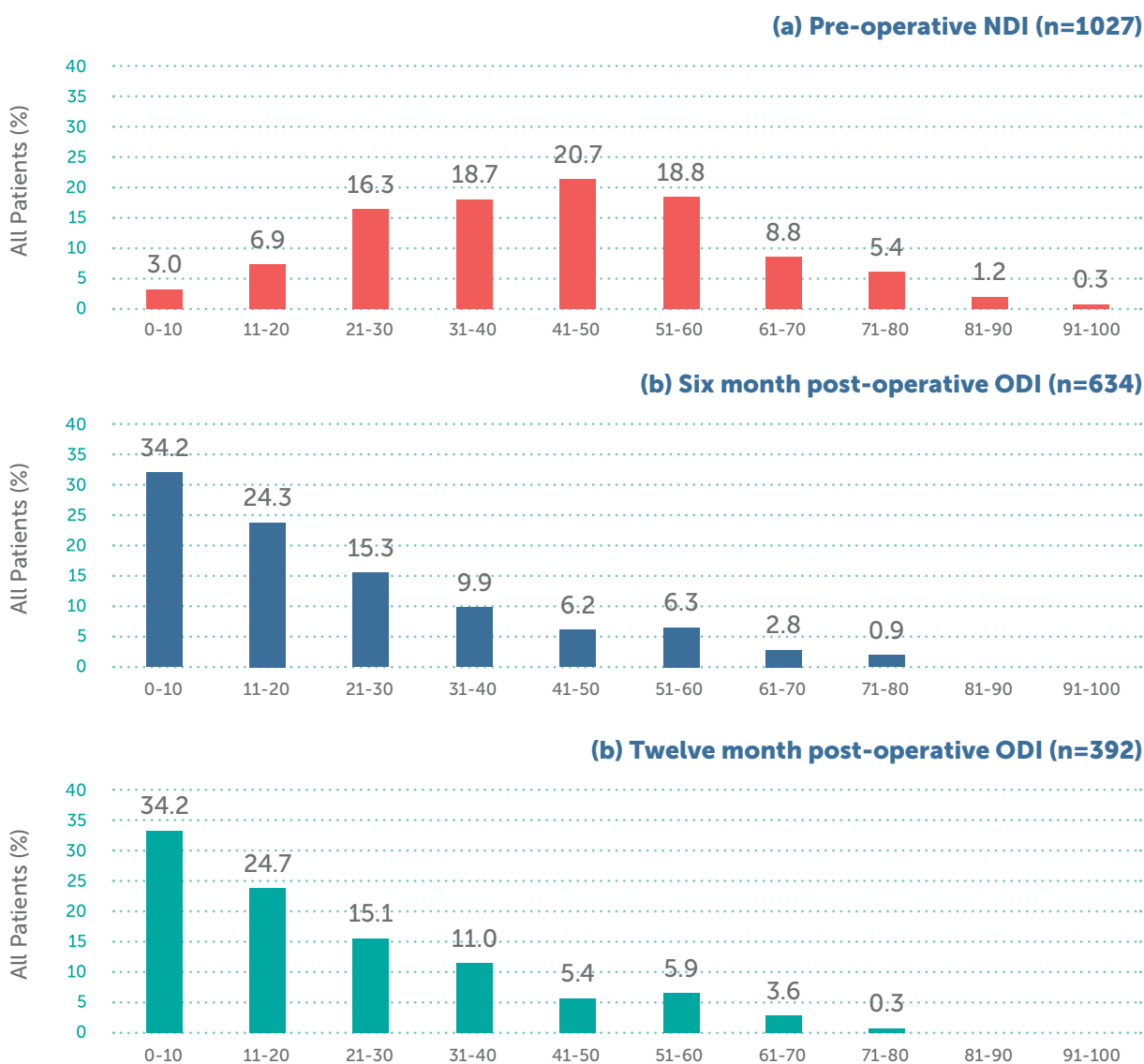
The ODI is only completed by patients that have undergone thoraco-lumbar surgery (84%) or who fall into the 'deformity' category of patients (4.7%) which is predominately scoliosis patients. There are 10 domains examined by the ODI which provide individual domain scores and an overall ODI score. The predefined levels of patient disability based on score is shown in Table 2¹³. As indicated in Table 2, a higher score indicates a higher level of disability.

Table 2: 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 thoraco-lumbar/deformity patients who completed PROMs at any time point (Figure 12). Preoperatively, 55.2% of patients had an ODI score of >41 indicating that patients considered themselves severely disabled or worse. At the 6-month time point, only 16.2% of patients considered themselves severely disabled or worse and, at the 12-month time point, 15.2% considered themselves severely disabled or worse.

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



Neck Disability Index - NDI

(All cervical surgery)

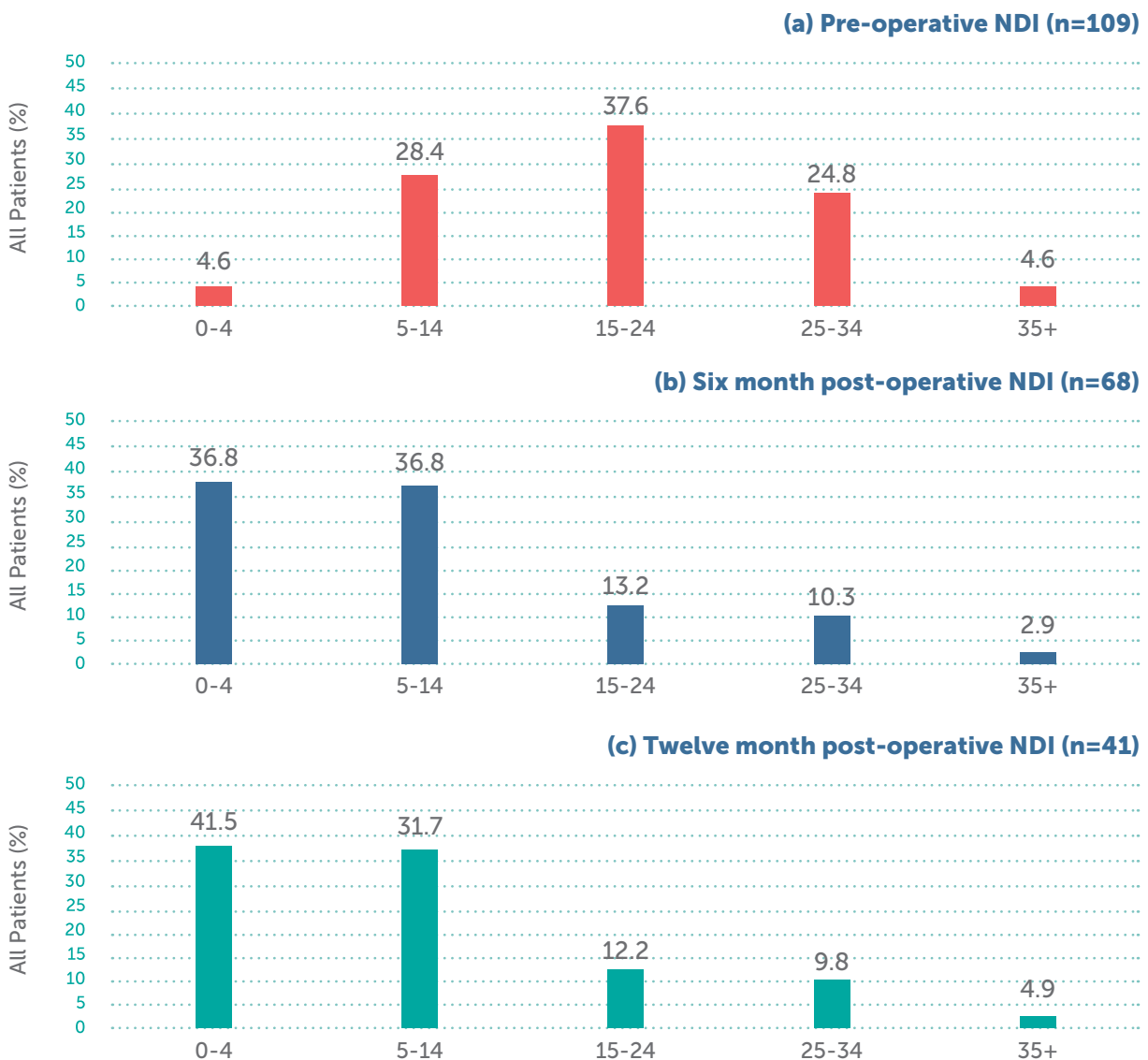
The NDI is only completed by patients who have undergone surgery in the cervical region of the spine. For the ASR cohort, this represents 10.7% of patients. As for the ODI, 10 domains are examined which provide individual domain scores and an overall NDI score. Each domain has a score up to 5 for a total score of 50⁴¹. The predefined levels of patient disability based on score is shown in Table 3 below. As indicated in Table 3, a higher score indicates a higher level of disability.

Table 3: 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 indicated in Figure 13, preoperatively, 67% of patients had an NDI score of >15 indicating that patients considered themselves to be moderately disabled or worse. At 6 months, only 26.4% of patients considered themselves to be moderately disabled or worse, and at 12 months, this figure was 26.9%. It is interesting to note that at 6 months, 36.8% of patients reported no disability.

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



Cohort Analysis

The ASR focussed on three patient cohorts for this annual report:

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

Lumbar Discectomy

Lumbar discectomy is a surgery to remove a herniated or degenerative disc in the lower spine. Discectomy literally means “cutting out the disc”. In this procedure, the surgeon relieves the nerve compression caused by the disc problem. The surgeon reaches the damaged disc from the back (posterior) of the spine—through the muscles and bone and accesses the disc by removing a small portion of the lamina. The lamina is the bone that forms the back of the spinal canal and makes a ‘roof’ over the spinal cord. Next, the spinal nerve is retracted to one side and depending on the particular case, one disc (single-level) or more (multi-level) may be removed. This surgery can be performed using an open or minimally invasive technique.

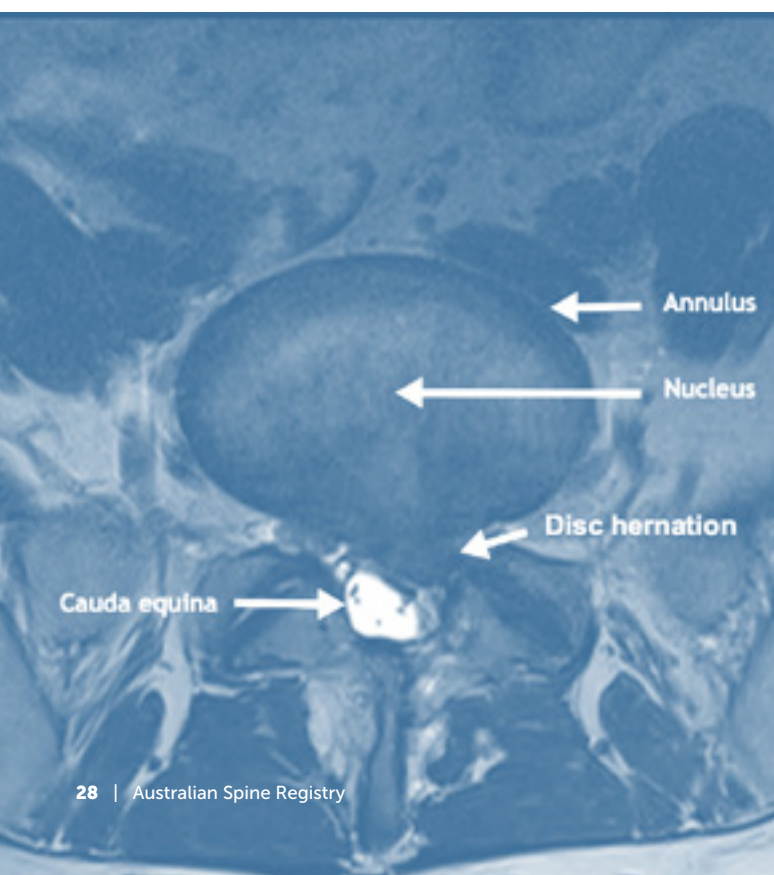
Discectomy patients were selected based on the following inclusion criteria:

- 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

(Images courtesy of Dr Rob Kuru)

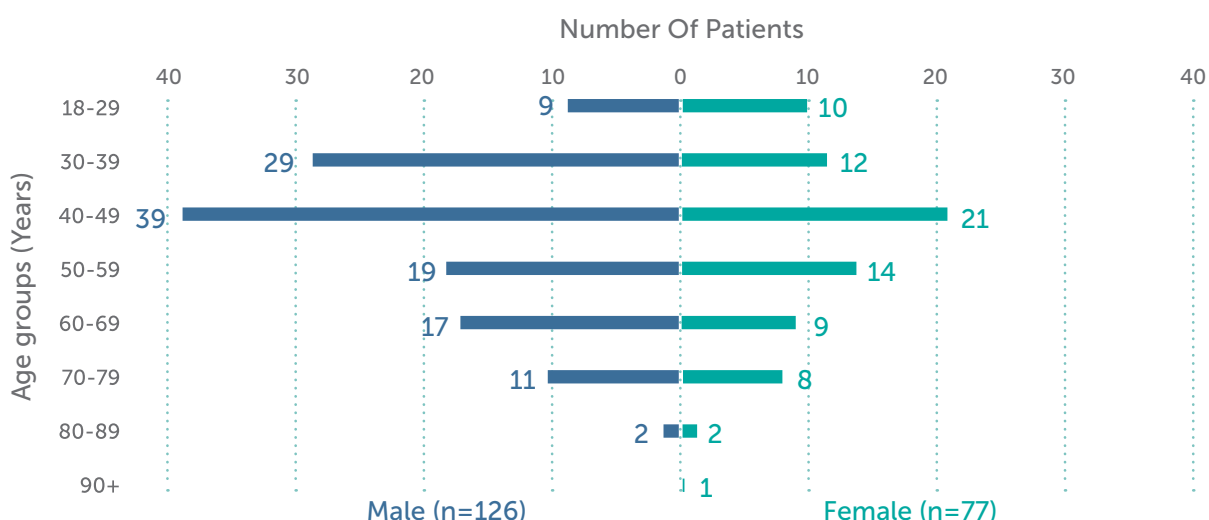


Demographics

203 patients met the discectomy cohort inclusion criteria which represent 15% of patients in the registry.

The 203 discectomy procedures were performed predominately on male patients. There were 126 males (62%) and 77 females (37%) in this group as shown in Figure 14. The median age of males was 45.5 years and females 47.0 years, which is younger than the median patient age from the total ASR patient cohort (62 years for males and 66 years for females respectively).

Figure 14: Patient age distribution of discectomy patients by 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 4 below; 16.7% of discectomy patients were reported to have at least one comorbidity; 41.7% of total patients were reported to have at least one comorbidity. Patients were further categorised into groups by the number of comorbidities reported (Table 5).

Table 4: Number of discectomy patients diagnosed with any comorbidity prior to surgery

Any comorbidity	All (n=1315) n (%)	Discectomy (n=203) n (%)
Yes	548 (41.7)	34 (16.7)
No	767 (58.3)	169 (83.3)

Table 5: Number of discectomy patients reported having ≥ 1 comorbidity

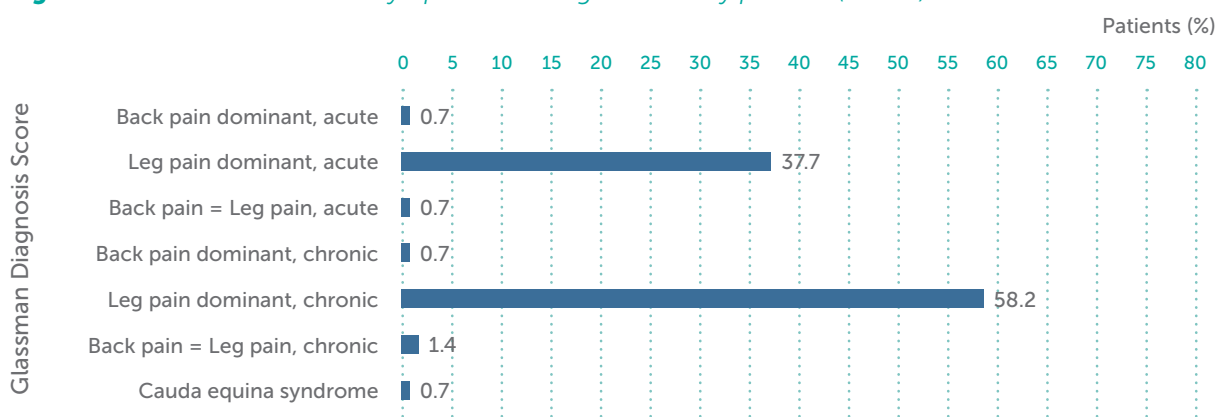
Number of comorbidities	All (n=548) n (%)	Discectomy (n=34) n (%)
1	242 (44.2)	16 (47.1)
2	133 (24.3)	7 (20.6)
3	107 (19.5)	8 (23.5)
4	38 (6.9)	1 (2.9)
5+	28 (5.1)	2 (5.9)

Glassman Classification Scores

The Glassman Classification Scores are only reported for patients who have had thoracolumbar procedures. Glassman scores were reported in only 67% of the discectomy cohort.

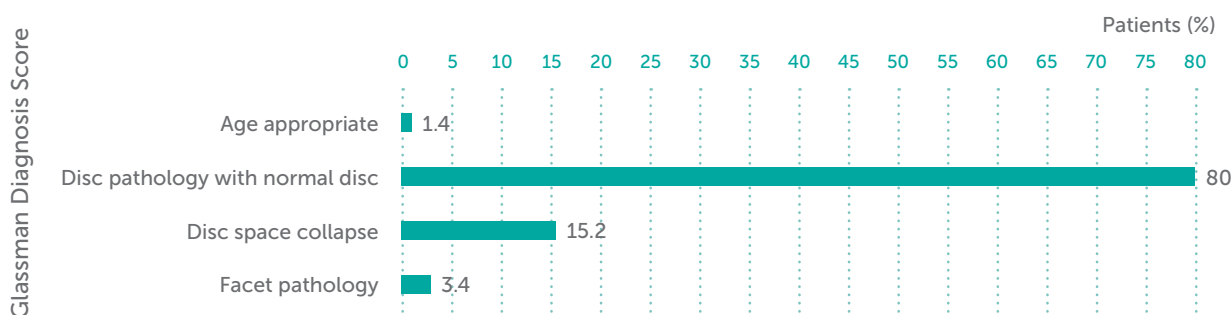
For 'Symptoms', acute and chronic leg pain was most commonly reported. Back pain was less commonly reported, as was neurogenic claudication. This is consistent with the commonly held clinical presentation of disc herniations (Figure 15). It can be concluded that the primary complaint for the majority of discectomy patients was leg pain.

Figure 15: Glassman Score for 'Symptoms' among discectomy patients (n=146)



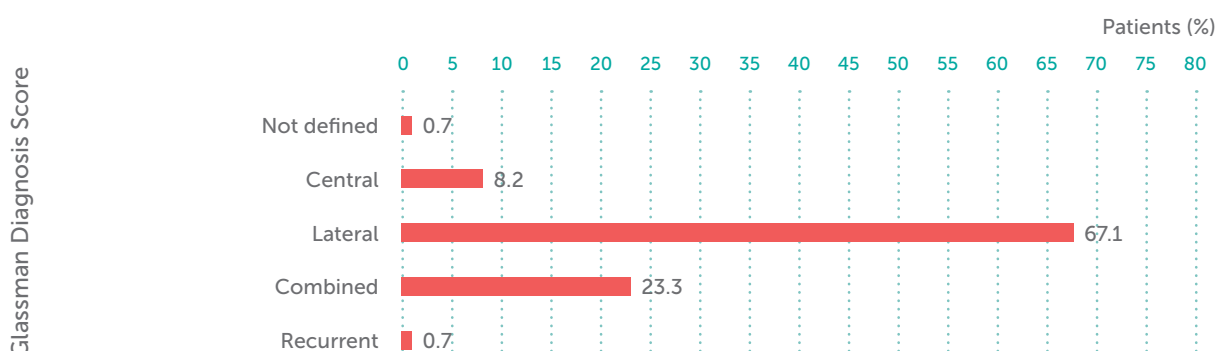
For 'Structural Pathology', surgeon comprehension and grading are consistent in describing the discectomy cohort (Figure 16).

Figure 16: Glassman Score for 'Structural Pathology' among discectomy patients (n=145)



For 'Compressive Pathology', the most common types of disc herniations are those compressing in the central and lateral recesses, as is typically reported by clinicians in discectomy patients (Figure 17).

Figure 17: Glassman Score for 'Compressive Pathology' among discectomy patients (n=146)



PROMs Analysis

The Oswestry Disability Index (ODI) and the EQ-5D-3L scores are presented for the discectomy cohort pre-operatively and at 6-months and 12-month 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 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)

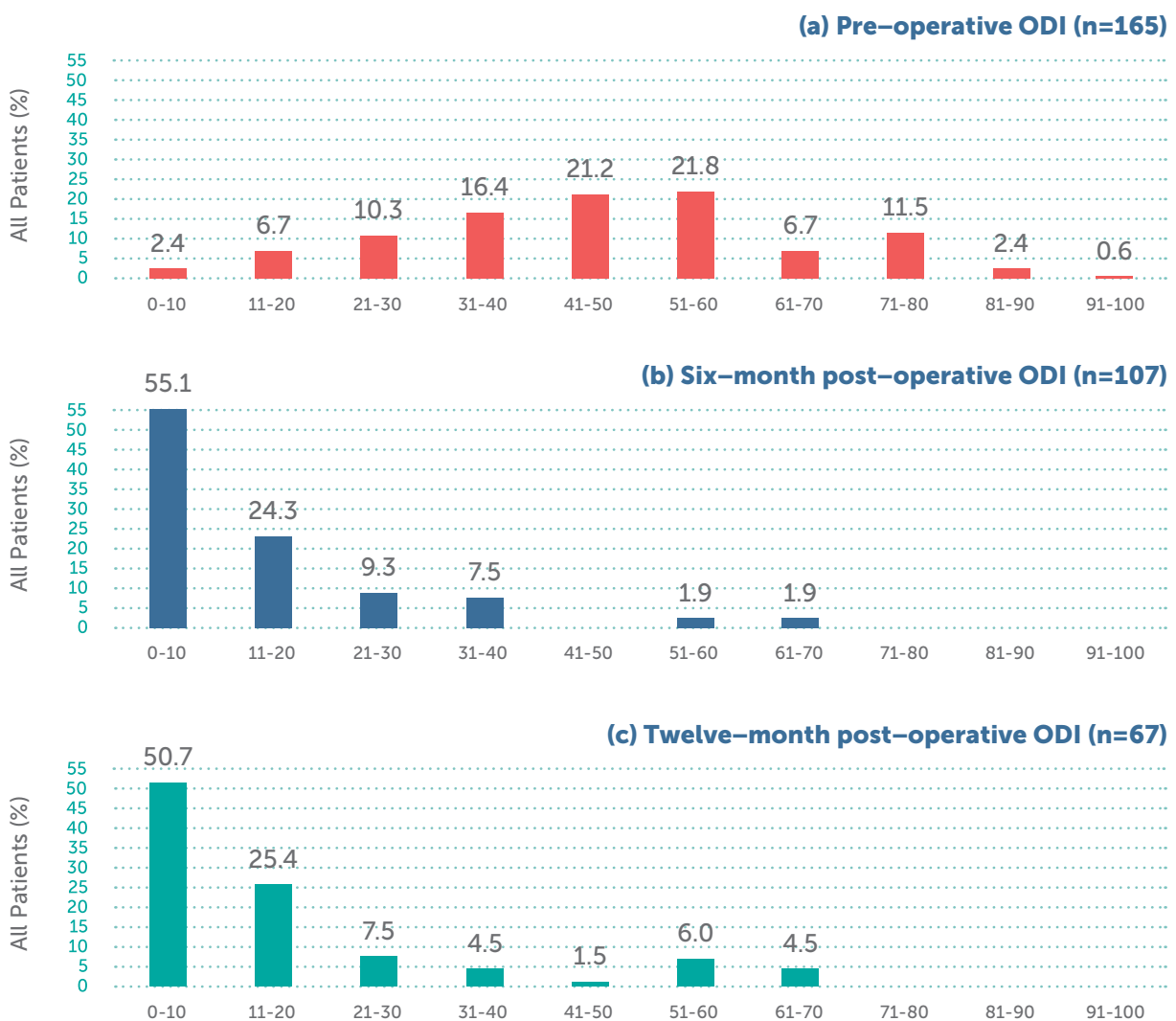
For the discectomy cohort, there were 203 patients of which 165 (81%) had completed their pre-operative questionnaires;

at 6 months, there were 139 patients of which 107 (77%) had completed their 6-month follow up and at 12 months there were 82 patients of which 68 (82%) had completed the 12-month follow up.

ODI scores for any questionnaires completed for each time point are shown (Figure 18). It can be seen that there is a shift to the left in the overall ODI scores for the discectomy cohort at the 6-month follow up time point which suggests an improvement over the 6-month period (where a lower ODI score indicates better relief from pain and disability). This was maintained at 12 months.

There were only 47 patients in this cohort that had complete data up to 12 months. Improvement trends in this group were similar to Figure 18 (data not shown).

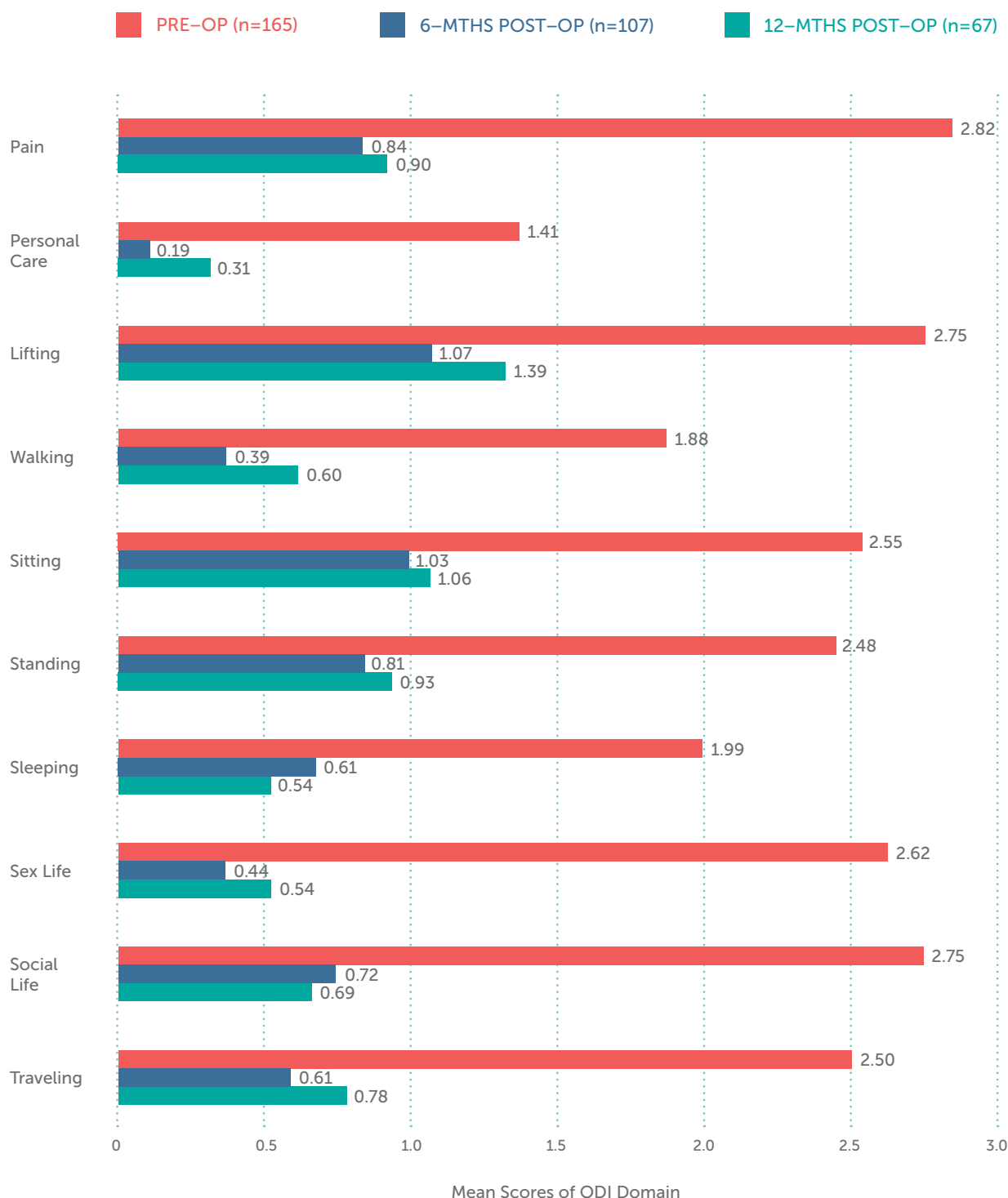
Figure 18: ODI distribution for discectomy patients who completed any ODI questionnaires at pre-op, 6 and 12-months post-op



Analysis of each of the ten ODI domains for the discectomy cohort is shown in Figure 19. 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-months and 12-months post-operatively than 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 affects all aspects of life and all aspects are improved by the surgery.

Figure 19: Mean ODI scores for each domain for discectomy patients who completed any ODI.



The Minimum Clinically Important Difference (MCID) is a threshold used to measure the effect of clinical treatments. MCID values, depending on the method used for calculation, can vary considerably. 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 using MDC¹⁴. This figure has been used to define MCID for this patient cohort. All discectomy patients fell within or exceeded this MCID on the ODI from pre-op to 6-months and 12-months post-operatively (Table 6 and Table 7).

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

ODI*	All (n=572) n (%)	Discectomy (n=92) n (%)
Exceeding the MCID (Improved)	376 (65.7)	77 (83.7)
Within the MCID (Unchanged)	185 (32.3)	15 (16.3)
Exceeding the MCID (Worsened)	11 (1.9)	0 (0)

Table 7: MCID for ODI from pre-op to 12-months post-op for discectomy patients

ODI*	All (n=321) n (%)	Discectomy (n=47) n (%)
Exceeding the MCID (Improved)	211 (65.7)	35 (74.5)
Within the MCID (Unchanged)	103 (32.1)	12 (25.5)
Exceeding the MCID (Worsened)	7 (2.2)	0 (0)

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

EQ-5D-3L

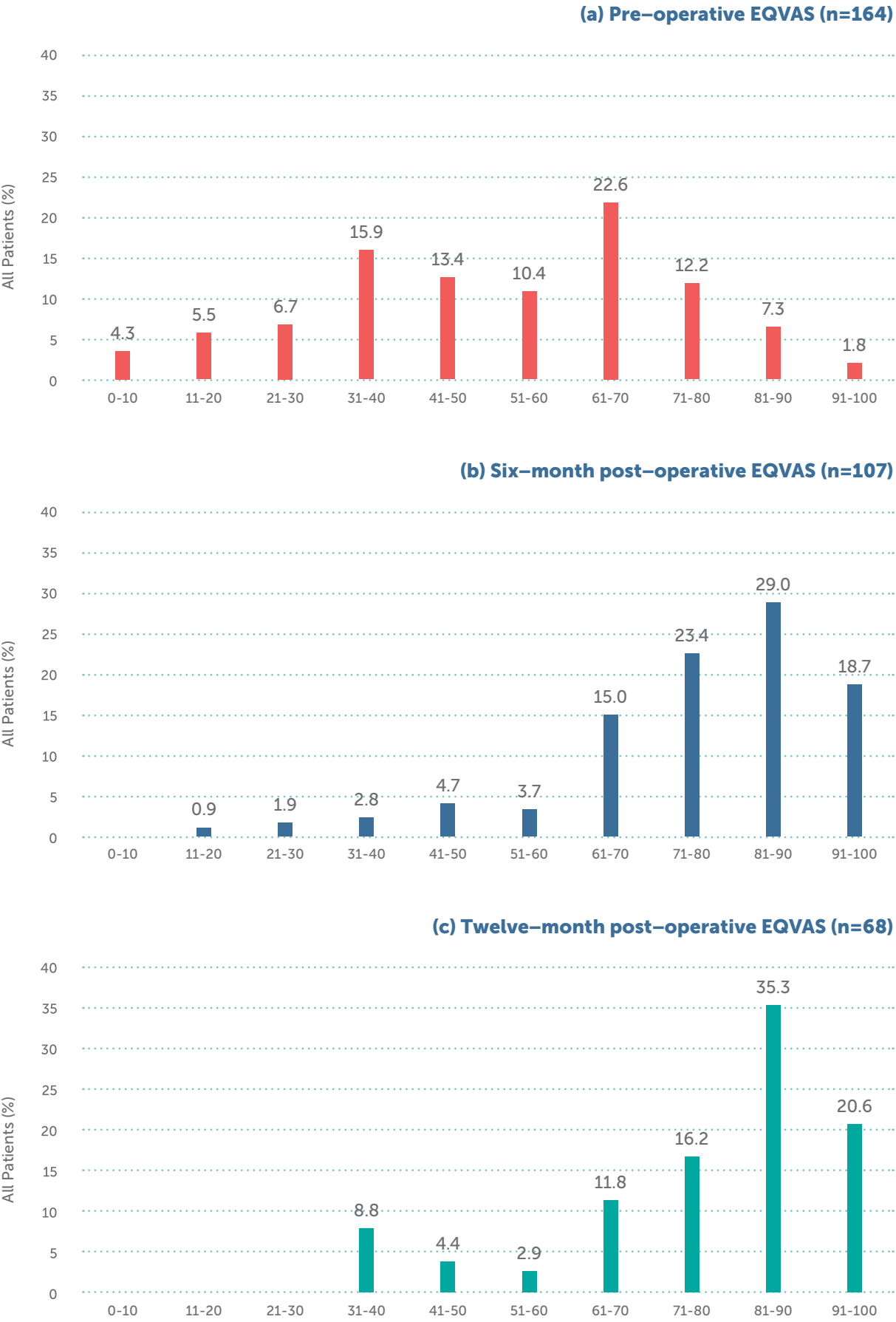
The discectomy cohort EQ-5D-3L dimension scores and the EQ-VAS were analysed and indicate general improvement of the discectomy patients across all domains (Table 8 and Figure 20). The mobility and pain/discomfort domain were the two domains which showed the most improvement over the 12-month period.

Table 8: EQ-5D-3L scores for each domain for discectomy patients at pre-op, 6 and 12-months post-op

EQ-5D-3L All Patients (n=48)				
Domain	Level of problem	Pre-op (%)	6 months (%)	12 months (%)
Mobility	1 – no problems	16.7	61.7	59.4
	2 – some problems	81.1	38	40.3
	3 – extreme problems	1.4	0.3	0.3
Self-care	1 – no problems	61.4	84.4	80.4
	2 – some problems	37.8	15.3	18.7
	3 – extreme problems	0.9	0.3	0.9
Usual activities	1 – no problems	12.4	43.5	47.6
	2 – some problems	64.8	51.6	47.3
	3 – extreme problems	22.8	4.9	5.2
Pain/discomfort	1 – no problems	2.3	32.9	35.4
	2 – some problems	54.5	60.8	58.2
	3 – extreme problems	43.2	6.3	6.3
Anxiety/depression	1 – no problems	50.4	71.5	68.3
	2 – some problems	44.7	24.5	27.7
	3 – extreme problems	4.9	4	4

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 Figure 20, discectomy patient's general perception of their health at 6 and 12 months post-operatively indicates an improvement post-surgery and appears to improve between 6 and 12-months.

Figure 20: EQ-VAS distribution for discectomy patients who completed any EQ-VAS at pre-op, 6 and 12-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 is then 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 Dr Rob Kuru)

The ACDF cohort was selected using the following criteria:

Inclusions:

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

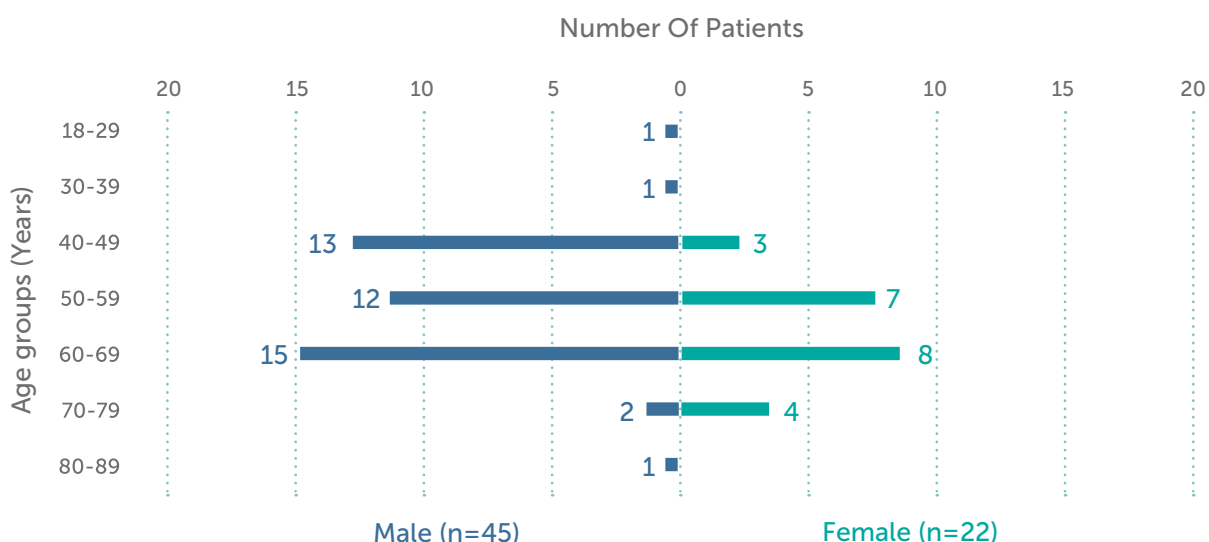
Exclusions:

- Scoliosis

Demographics

The 67 ACDF procedures were performed predominately on male patients. There were 45 males (67%) and 22 females (33%) in this cohort as shown in Figure 21. The median age for males was 54 years and for females it was 60.5 years, which is slightly younger than the median patient age from the total ASR patient cohort (62 years for males and 66 years for females).

Figure 21: Patient age distribution of ACDF patients by 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 Table 9 below; 40.3% of ACDF patients were reported to have at least one comorbidity; 41.7% of total patients were reported to have at least one comorbidity. Patients were further categorised into groups by the number of comorbidities reported (Table 10). Little difference was again observed between the two groups.

Table 9: Number of ACDF patients diagnosed with any comorbidity prior to surgery

Any comorbidity	All (n=1315) n (%)	ACDF (n=67) n (%)
Yes	548 (41.7)	27 (40.3)
No	767 (58.3)	40 (59.7)

Table 10: Number of ACDF patients reported having ≥ 1 comorbidity

Number of comorbidities	All (n=548) n (%)	ACDF (n=27) n (%)
1	242 (44.2)	12 (44.4)
2	133 (24.3)	7 (25.9)
3	107 (19.5)	5 (18.5)
4	38 (6.9)	2 (7.4)
5+	28 (5.1)	1 (3.7)

PROMs Analysis

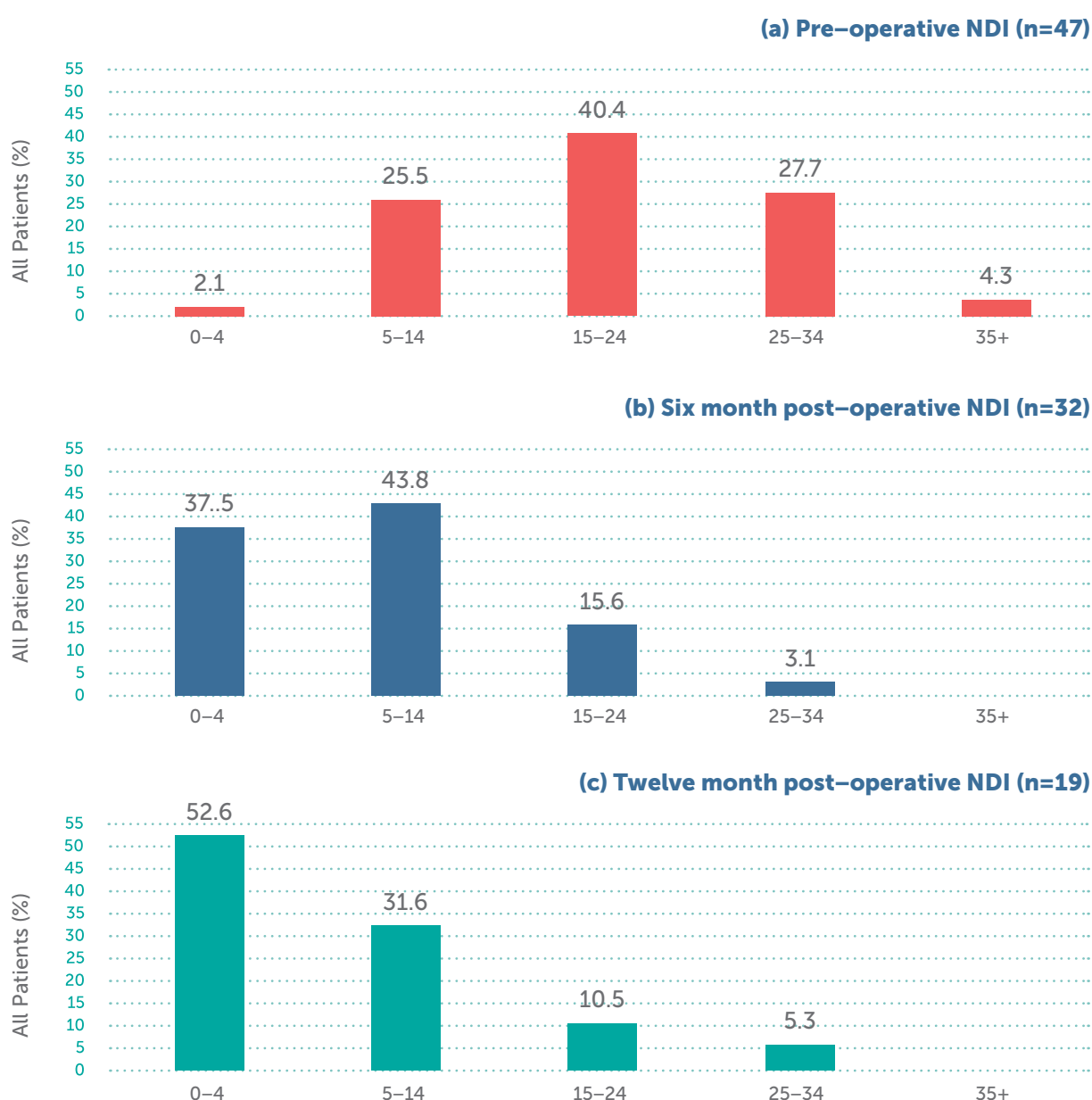
The Neck Disability Index (NDI) and the EQ-5D-3L scores are presented for the ACDF cohort pre-operatively and at 6 and 12-months post-operatively. It must be noted that these results show unadjusted outcomes and must be interpreted with caution as indicated previously for discectomy.

Neck Disability Index (NDI)

Of the 66 ACDF patients, 47 patients (71%) completed the pre-operative questionnaires. Of these patients who completed the pre-

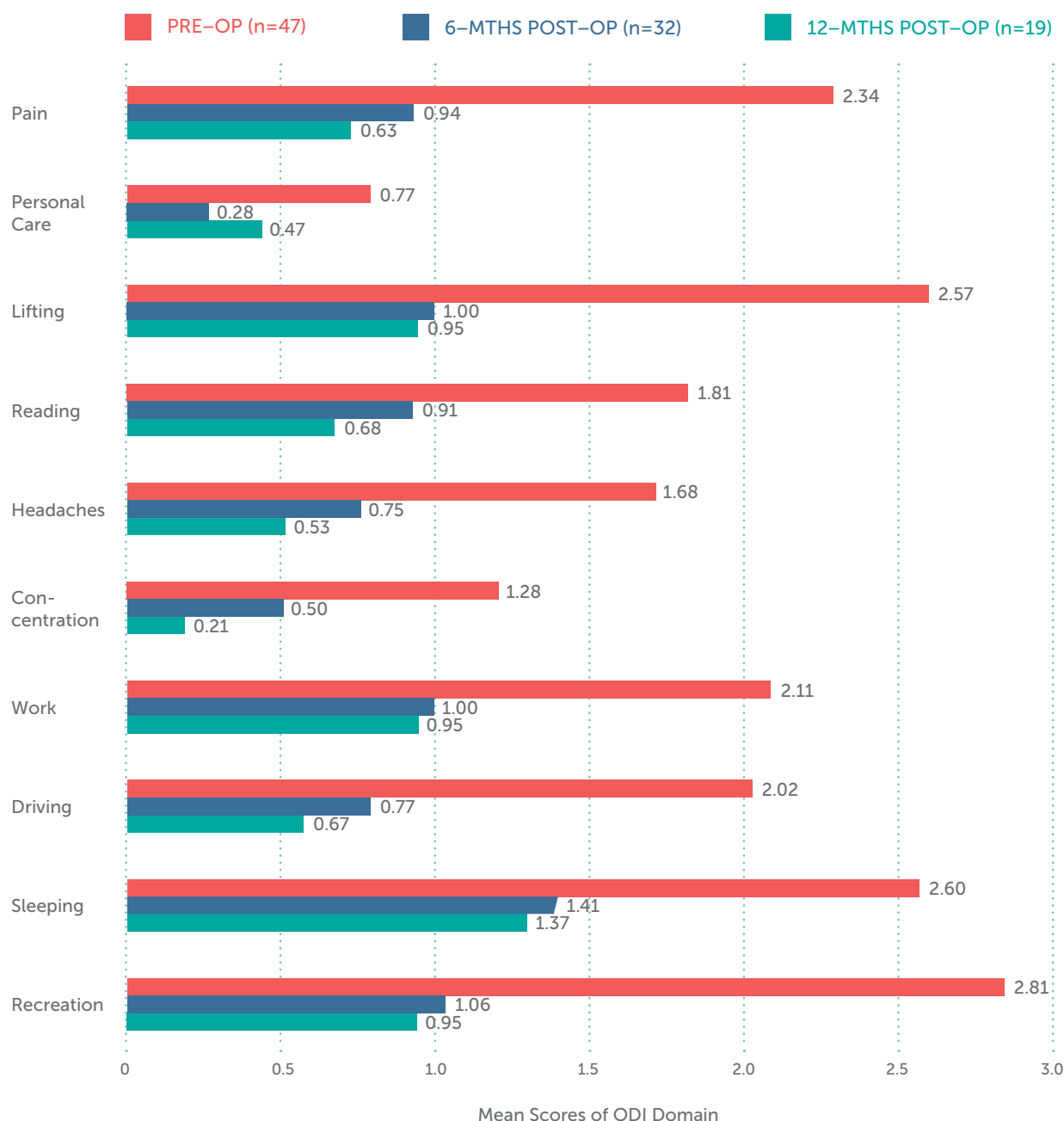
operative questionnaires, 31 patients reached and completed the 6-month post-operative time point and 19 patients completed their questionnaires at the 12-month time point. NDI scores for each time point are shown (Figure 22). A lower NDI score indicates better relief from pain and disability. It can be seen that there is a shift to the left in the overall NDI scores for the ACDF cohort at the 6 and 12-month follow up time points which suggests an improvement over the 6-month period. It would also appear that the improvement continues between 6 and 12 months.

Figure 22: NDI distribution for ACDF patients who completed any NDI questionnaires at pre-op, 6 and 12-months post-op



Analysis of each of the ten NDI domains for the ACDF cohort is shown in Figure 23. Figure 23 shows the mean number of NDI domain points at pre-operatively and at 6 and 12-months post-operatively. Average scores across all domains were lower at 6 and 12-months post-operatively. The domains of the NDI indicated that the pain caused by cervical nerve compression affects all aspects of life and all aspects are improved by the surgery.

Figure 23: Mean NDI scores for each domain for ACDF patients who completed any NDI at pre-op, 6 and 12-months post-op



The Minimum Clinically Important Difference (MCID) is a threshold used to measure the effect of clinical treatments. MCID can be defined as the smallest improvement in the PROMs needed to achieve a level of clinical improvement¹⁵. However, ACDF specific MCID is highly variable depending on the calculation

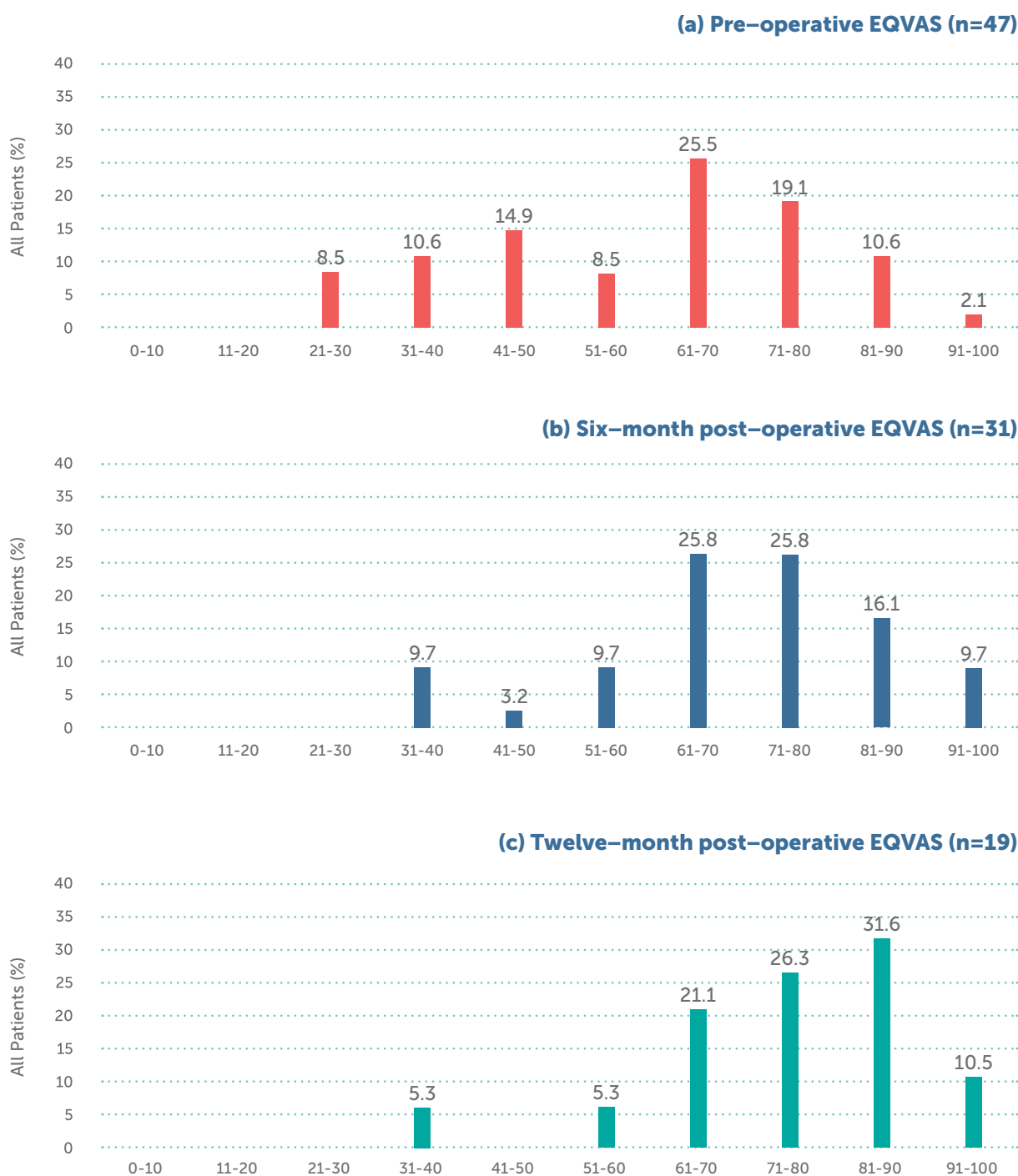
techniques used. The ASR has used the MCID thresholds as specified by Parker et al (2013) which have been reported to be 17.3 for the NDI16. There were only 21 patients in this group and the numbers were too low for a meaningful determination of MCID.

EQ-5D-3L

The ACDF cohort EQ-5D-3L dimension scores and the EQ-VAS, were examined. The number of patients that completed all three questionnaires for this patient cohort was very low (n=8). Analysis of the EQ-5D domains were not performed due to the low numbers.

However, examination of the EQ-VAS shows a shift to the right suggesting an improvement of patient perception of their general health status at 6 months and appears to continue to 12-months post-operatively (Figure 24).

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



The higher the score, the better the perception of overall health.

L4-L5 Degenerative Spondylolisthesis

Spondylolisthesis is defined as the displacement of a vertebral body in relation to the one below it. It can occur as an anterior displacement (anteriolisthesis), posterior displacement (retrolisthesis) or a lateral displacement (laterolisthesis).

Degenerative spondylolisthesis is a condition characterised by the forward slipping of one vertebra over the one below it. This condition generally occurs as part of the natural aging process where bones, joints and ligaments weaken and are less able to support the spinal column. Typically, degenerative spondylolisthesis occurs at the L3-L4 level and the L4-L5 level (most common). It is relatively rare in other levels of the spine¹⁷.



(Images courtesy of Mr Yi Yang)

The L4-L5 degenerative spondylolisthesis 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:

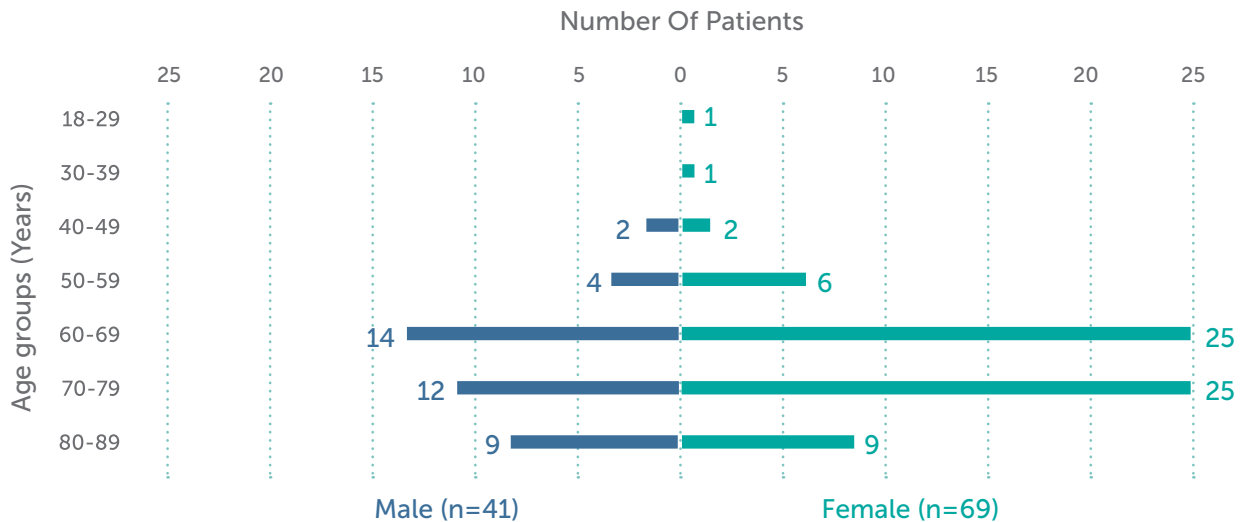
- Scoliosis

As of 15 January 2019, 110 patients met the L4-L5 Spondylolisthesis cohort inclusion criteria.

Demographics

There were 41 males (37%) and 69 females (62%) who were diagnosed with L4-L5 degenerative spondylolisthesis as shown in Figure 25. The median age for males was 70 years and 69 years for females, which is older than the median patient age from the total ASR patient cohort (62 years for males and 66 years for females).

Figure 25: Patient age distribution of L4-L5 Spondylolisthesis patients by gender



Comorbidities

The number of patients that were reported with a comorbidity is shown (Table 11); 61% of L4-L5 Spondylolisthesis patients were reported to have at least one comorbidity compared to 42% of the total patients. Patients were further categorised into groups by the number of comorbidities reported (Table 12).

Table 11: Number of L4-L5 spondylolisthesis patients with any comorbidity prior to surgery

Any comorbidity	All (n=1315) n (%)	L4-L5 Spondylolisthesis (n=110) n (%)
Yes	548 (41.7)	68 (61.8)
No	767 (58.3)	42 (38.2)

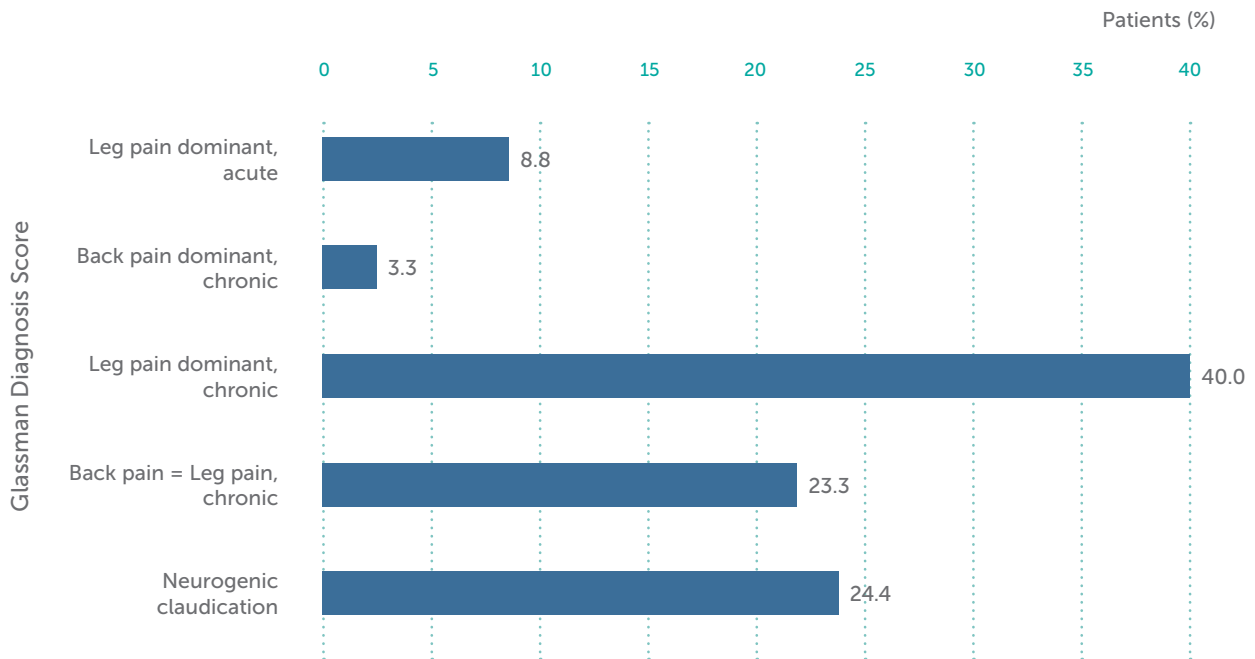
Table 12: Number of L4-L5 spondylolisthesis patients reported having ≥ 1 comorbidity

Number of comorbidities	All (n=548) n (%)	L4-L5 Spondylolisthesis (n=68) n (%)
1	242 (44.2)	29 (42.6)
2	133 (24.3)	17 (25)
3	107 (19.5)	15 (22.1)
4	38 (6.9)	3 (4.4)
5+	28 (5.1)	4 (5.9)

Glassman Classification Scores

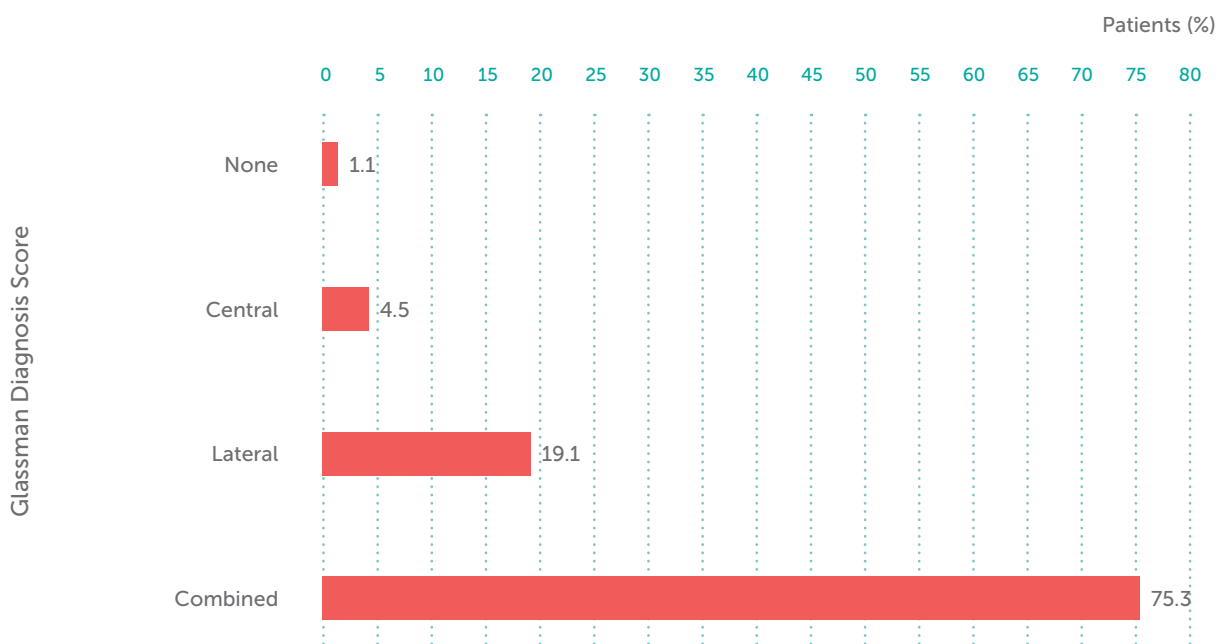
The Glassman classification scores for L4-L5 Spondylolisthesis cohort was examined. Analysis of the “Symptoms” category indicate that for the vast majority of these patients, surgery was performed for neurocompressive pain (Figure 26).

Figure 26: Glassman Score for ‘Symptoms’ among L4-L5 Spondylolisthesis patients (n=90)



Analysis of the ‘Compressive Pathology’ category, indicate that for the vast majority of these patients, surgery was performed for neurocompressive pathology (Figure 27).

Figure 27: Glassman Score for ‘Compressive Pathology’ among L4-L5 Spondylolisthesis patients (n=89)



PROMs Analysis

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

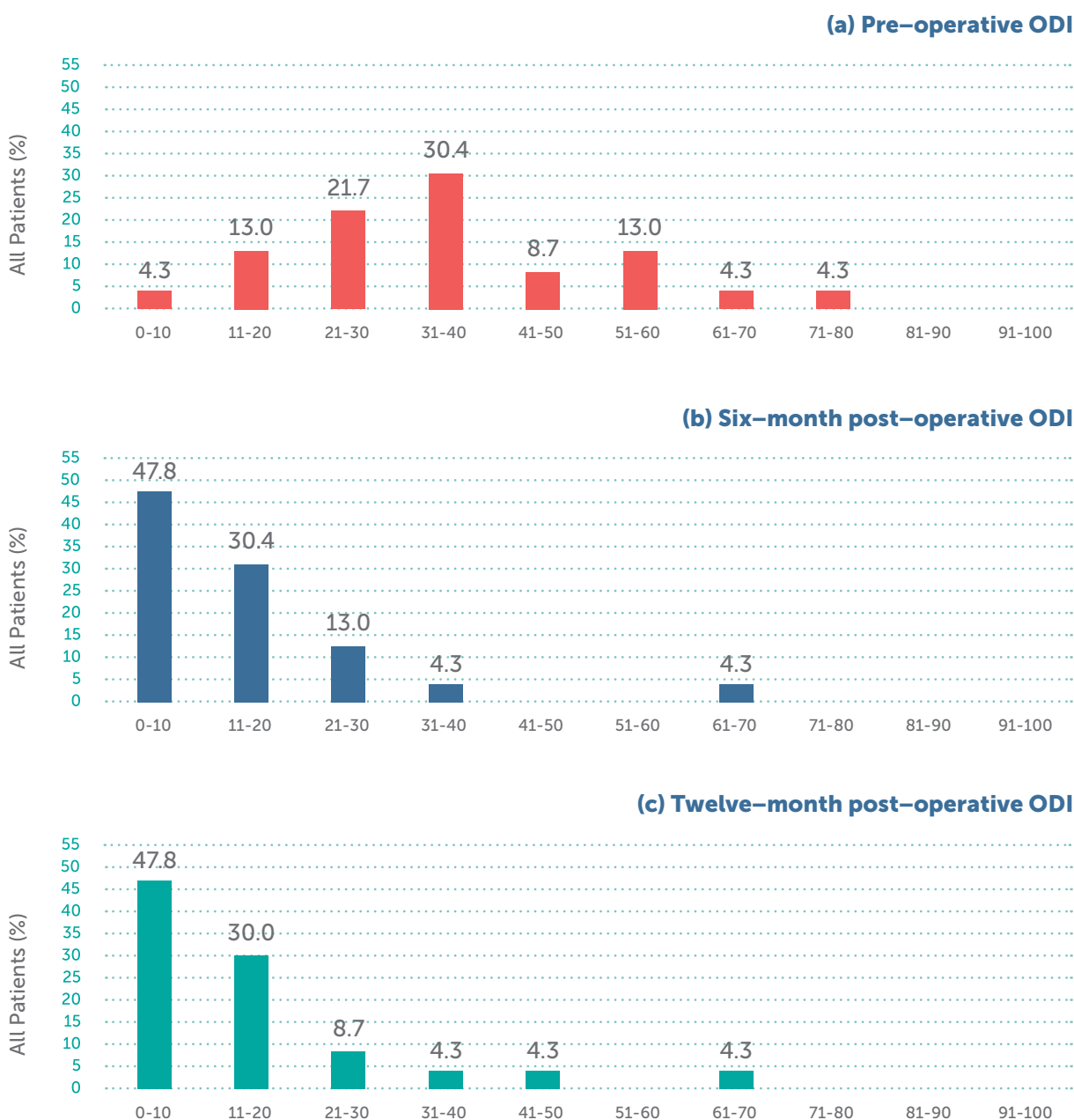
Oswestry Disability Index (ODI)

For this cohort, 96 (89%) patients completed their pre-operative questionnaires. Of those patients, 68 reached the 6-month time point

at the time of this publication of which 62 (91%) completed the 6-month follow-up. Only 28 patients had reached the 12-month time point of which 27 (96%) completed their 12-month follow-up.

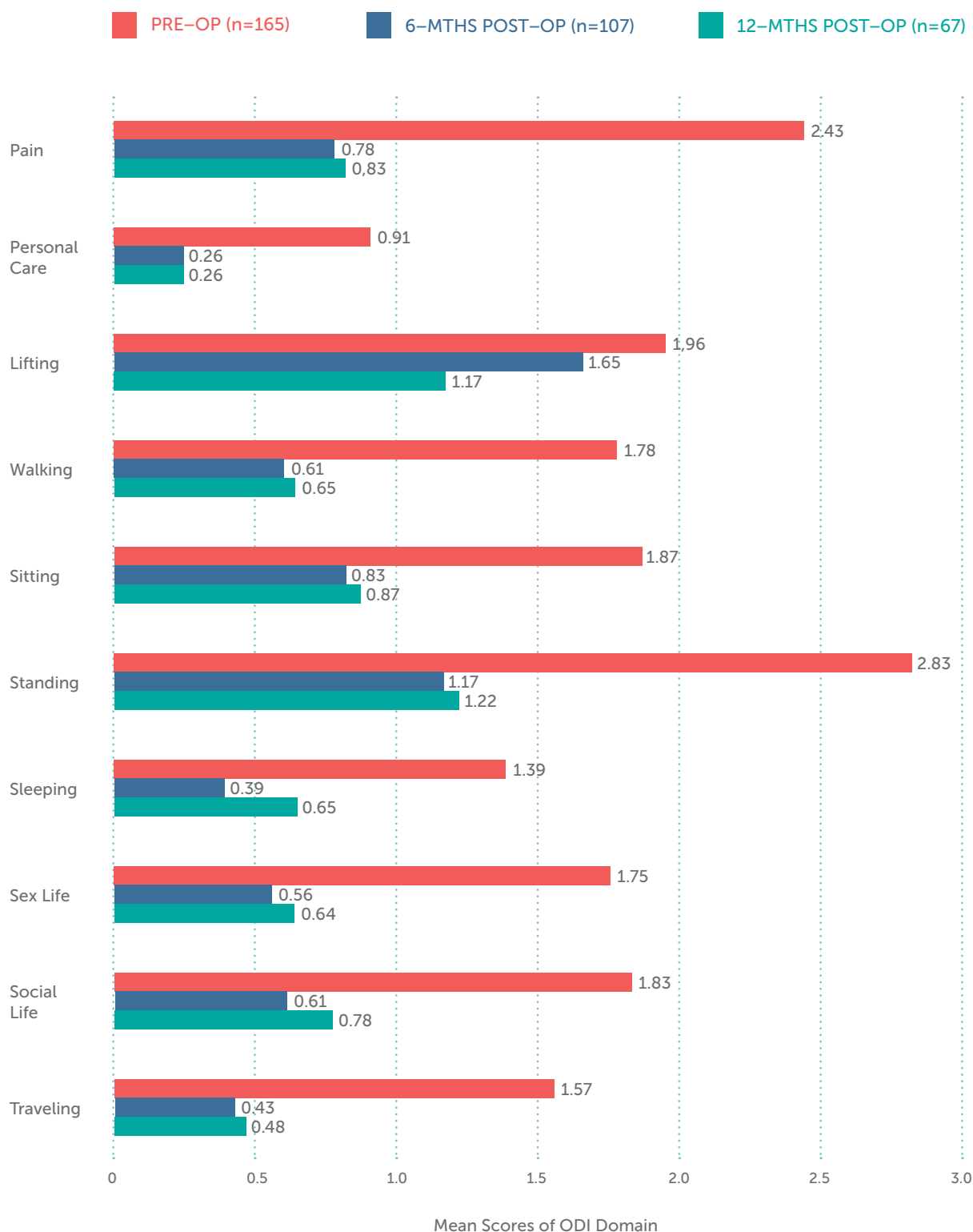
ODI scores for each time point are shown below (Figure 28). It can be seen that there is a shift to the left in the overall ODI scores for these patients at the 6-month follow up time point which indicates an improvement over the 6-month period (where a lower ODI score indicates better relief from pain and disability). This was maintained at 12 months.

Figure 28: ODI distribution for L4-L5 Spondylolisthesis patients who completed all ODIs at pre-op, 6 and 12-months post-op



Analysis of each of the ten ODI domains for the L4-L5 Spondylolisthesis patients that completed all questionnaires (n=23) is shown in Figure 29. Figure 29 shows the mean number of ODI domain points pre-operatively and at 6-months post-operatively. Average scores across all domains were lower at 6 and at 12 months post-operatively with pain and standing showing the largest improvement. The domains of the ODI indicated that the pain caused by L4-L5 degenerative spondylolisthesis effects all aspects of life and all aspects are improved by the surgery.

Figure 29: Mean ODI scores for each domain for L4-L5 Spondylolisthesis patients who completed all ODI questionnaires at pre-op, 6 and 12-months post-op (n=23)



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 ODI¹⁴. The number and proportion of spondylolisthesis patients undergoing surgery who improved, that is, exceeded the 12.8 threshold on the ODI from pre-op to 6-months post-operatively was 65% (Table 13). The total ASR patient population for whom a pre-op and post-op MCID was measured, 66% had a MCID exceeding 12.8. This data suggests that many patients recorded in the ASR have improved since their procedure. Table 14 shows the MCID for 12 months post-op; 74% of patients showed an improvement at this time point.

Table 13: MCID from pre-op to 6-months post-op for L4-L5 degenerative spondylolisthesis patients

MCID	All (n=572) n (%)	L4-L5 Spondylolisthesis (n=57) n (%)
Exceeding the MCID (Improved)	376 (65.7)	37 (64.9)
Within the MCID (Unchanged)	185 (32.3)	20 (35.1)
Exceeding the MCID (Worsened)	11 (1.9)	0 (0)

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

Table 14: MCID from pre-op to 12-months post-op for L4-L5 degenerative spondylolisthesis patients

MCID	All (n=321) n (%)	L4-L5 Spondylolisthesis (n=23) n (%)
Exceeding the MCID (Improved)	211 (65.7)	17 (73.9)
Within the MCID (Unchanged)	103 (32.1)	5 (21.7)
Exceeding the MCID (Worsened)	7 (2.2)	1 (4.3)

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

EQ-5D-3L

The L4-L5 Spondylolisthesis cohort EQ-5D-3L dimension scores and the EQ-VAS were analysed (Table 15 and Figure 30). 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.

Table 15: Percentage of patient responses, where all questionnaires have been completed, for EQ-5D-3L scores for each domain for L4-L5 Spondylolisthesis patients at pre-op, 6 and 12-months post-op

L4-L5 Degenerative Spondylolisthesis Patients (n=23)				
EQ-5D-3L				
Domain	Level	Pre-op (%)	6 months (%)	12 months (%)
Mobility	1 – no problems	8.7	73.9	87
	2 – some problems	91.3	26.1	13
	3 – extreme problems	0	0	0
Self-care	1 – no problems	60.9	91.3	95.7
	2 – some problems	39.1	8.7	4.3
	3 – extreme problems	0	0	0
Usual activities	1 – no problems	13	52.2	82.6
	2 – some problems	73.9	43.5	17.4
	3 – extreme problems	13	4.3	0
Pain/discomfort	1 – no problems	4.3	39.1	56.5
	2 – some problems	56.5	56.5	43.5
	3 – extreme problems	39.1	4.3	0
Anxiety/depression	1 – no problems	69.6	87	82.6
	2 – some problems	26.1	8.7	13
	3 – extreme problems	4.3	4.3	4.3

When examining EQ-VAS a shift to the right indicates an improvement of patient perception of their general health status. As shown in Figure 30, this cohort showed improvement in their general perception of their health 6-months post-operatively and was sustained at 12-months.

Figure 30: EQ-VAS distribution for L4-L5 Spondylolisthesis patients who completed any EQ-VAS at pre-op, 6 and 12-months post-op



Future Directions

Over the next 12 months the ASR will be evaluating new approaches for improving the database and communication with patients and surgeons. This includes:

- SMS communication with patients in relation to PROMs collection
- Development of a surgeon dashboard for real time reporting
- Improved comorbidity collection and identification of risk adjustment factors
- Ongoing refinement of ASR data elements to include new instrumentation, navigation, grafting materials and techniques

Furthermore, the registry will be looking at expanding the number of surgeons participating in the registry, analysing new patient groups as patient numbers in the registry increase and will begin to plan a staged roll out of the registry nationally. Most importantly, the ASR will be continuing to lobby industry and government to establish sustainable long-term funding.

Data Access

The ASR welcomes requests for access to data for data analyses from clinicians, researchers, governments, industry and others for the purposes related to health services and epidemiological research. Please contact the ASR for further information regarding the Data Access Policy and Procedure.

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

Appendix 1 - ASR Committees

ASR Steering Committee

Mr Michael Johnson	Committee Chair, Past President Spine Society of Australia
Professor Susannah Ahern	Head, Registry Science and Research Unit, Monash University
Mr John Cunningham	Orthopaedic Spine Surgeon
Dr Rob Kuru	Orthopaedic Spine Surgeon
Associate Professor Kevin Seex	Neurosurgical Spine Surgeon
Dr Andrew Hunn	Neurosurgeon
Professor John McNeil	Chief Investigator, ASPREE Clinical Trial, Epidemiology and Preventive Medicine
Associate Professor Ilana Ackerman	Associate Professor (Research), Clinical Epidemiology
Mr Chris Dalton	Medical Director, BUPA

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
Ms Jessy Hansen	Data Analyst

Appendix 2 - Participating Surgeons

State	Participating Surgeon	
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
	Kevin Seex	Neurosurgeon
	Ralph Stanford	Orthopaedic Spine Surgeon
	Mark Davies	Neurosurgeon
	Andrew Hunn	Neurosurgeon
Tasmania		
Western Australia	Peter Woodland	Orthopaedic Spine Surgeon

Appendix 3 - Approved Hospitals

Victoria

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

Tasmania

- Calvary Private Hospital – Lenah Valley

Western Australia

- St John of God Subiaco 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

Appendices

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 >35
- 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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