Medicare Claims Study:
mild vs. Benchmark LSS Procedures

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Background: Broad Foundation of Scientific Evidence

The *mild* Procedure

16 completed clinical studies & 30+ published articles

Level 1 Data

Two Level 1
Multi-Center RCT studies
One Single Site RCT Study

Significant Functional Improvement[1]

Clinically meaningful & statistically significant mobility & pain improvement

5-Year Durability[2]

88% of patients avoided surgical decompression while experiencing significant symptom relief

Safety Profile Equivalent to an ESI[3]

Clinically proven safety equivalence to epidural steroid injections (ESIs)

Nearly 50k patients treated to date

Source 1, 2, and 3: Refer to appendix for references

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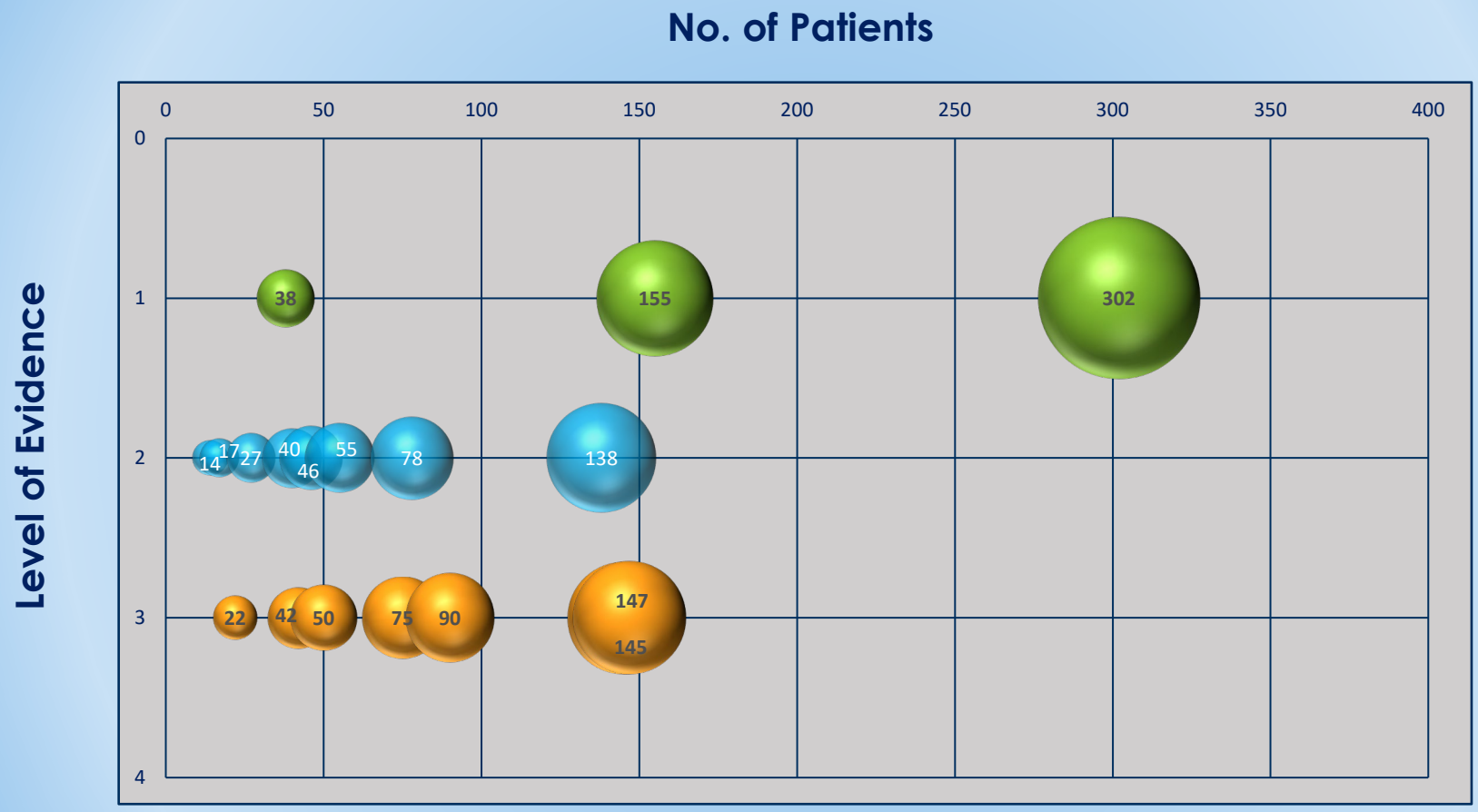
Evidence at a Glance

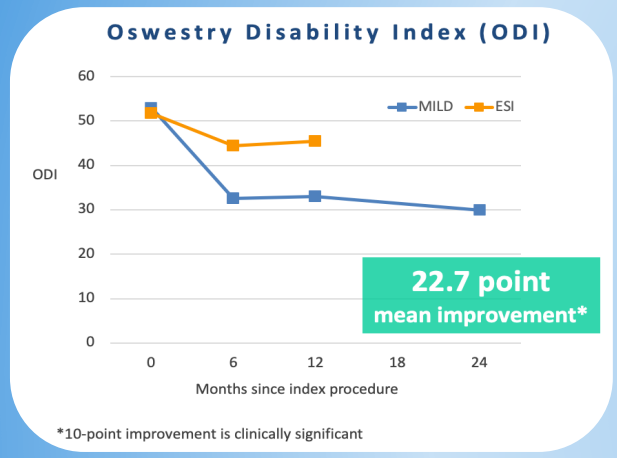
The *mild* Procedure

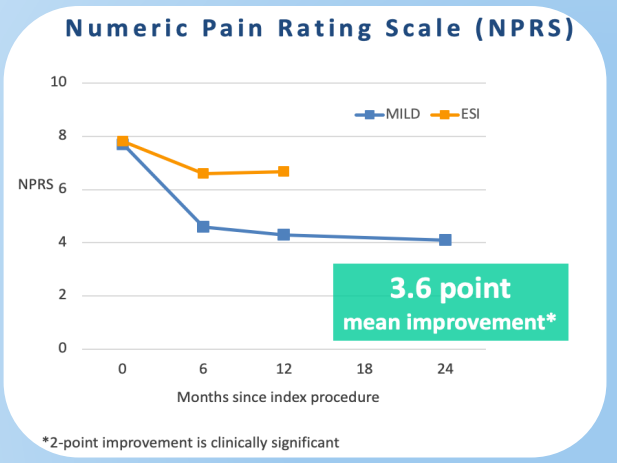


Clinical Efficacy Established

The *mild* Procedure

Durable, Proven Efficacy[1,3]

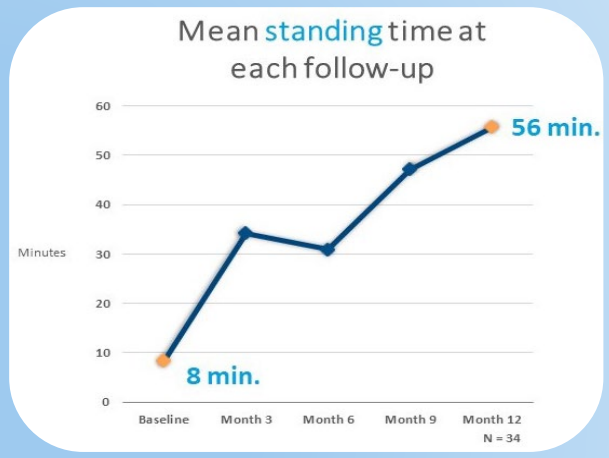




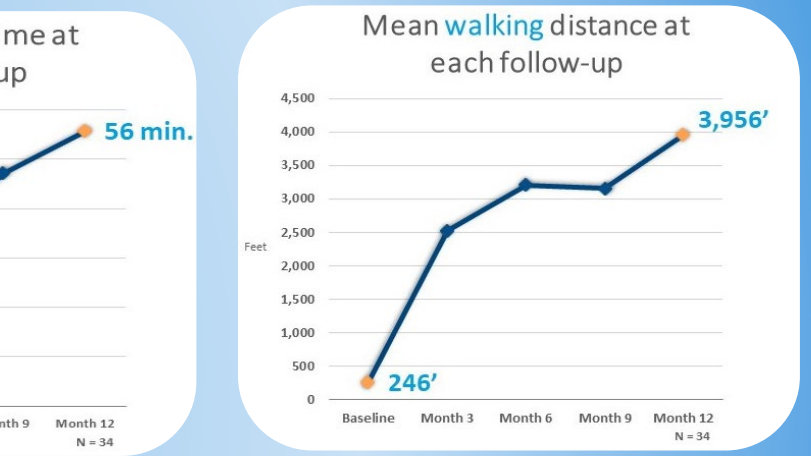
Level 1 Data
MiDAS ENCORE
300 Patient Study

Significant and sustained functional and pain improvements through 2-year follow-up

"Real World" Functional Improvement[4]



7X
Standing Time



16X
Walking Distance

MILD saved 88% of patients from open lumbar decompression surgery through 5 years[5]

Source 1, 3, 4, and 5: Refer to appendix for references

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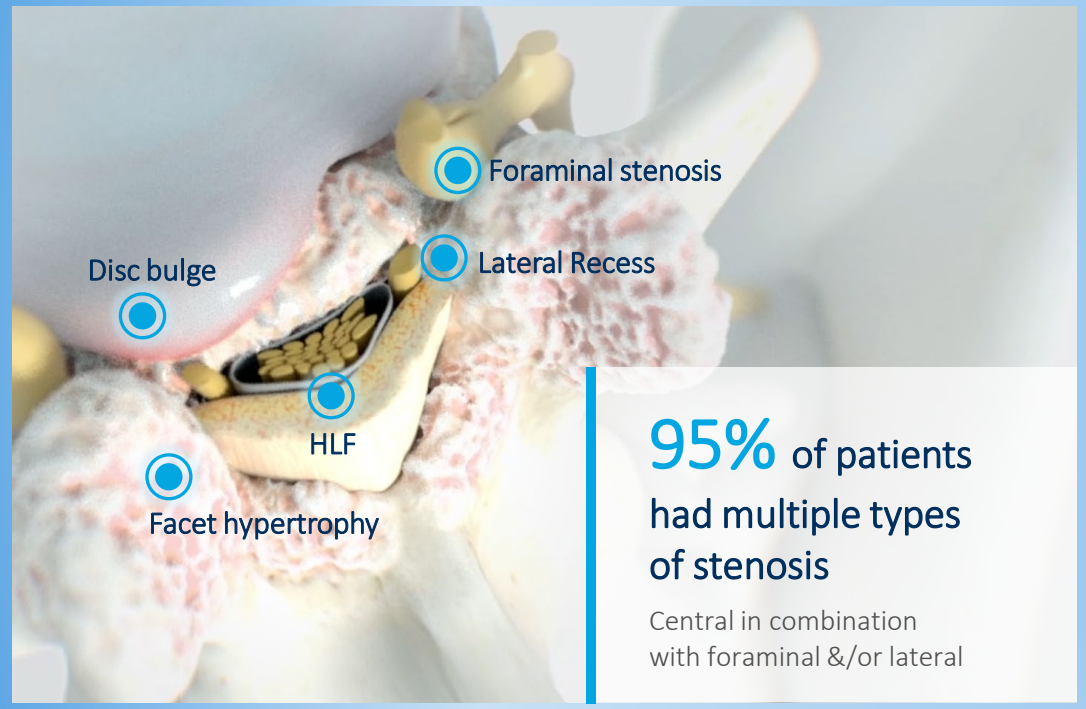
Effective for Patients with Comorbidities

Level 1 RCT: MiDAS ENCORE 2Y Follow-up

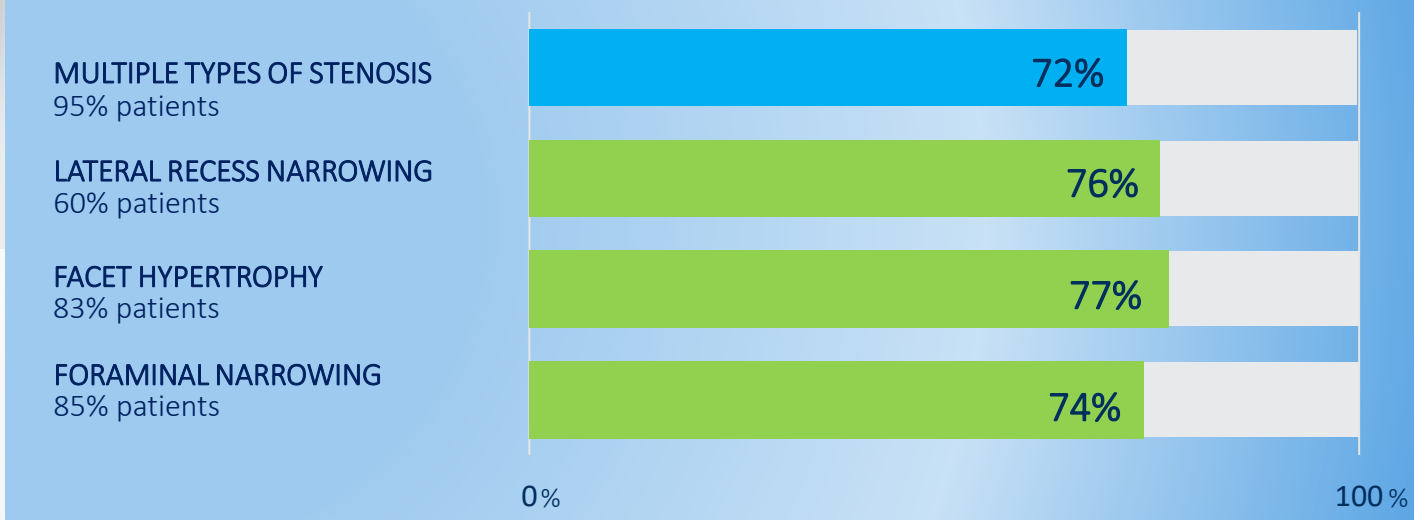
Significant Improvement in Patients with Comorbidities[1,6]



95% of patients had multiple types of stenosis

Central in combination with foraminal &/or lateral

ODI Response Rate*



*Percent of patients achieving ODI improvement of ≥ 10 points at 2-year follow-up.

Source 6: Refer to appendix for references

Safety Profile Equivalent to an ESI

Level 1 RCT: MiDAS ENCORE

Equivalent Safety Profile

Adverse Event (AE)	ESI	*mild*
Device-and Procedure-Related AEs	1.3%	1.3%
Device- and Procedure-Related Serious AEs	0%	0%

Removes the problem, leaves nothing behind

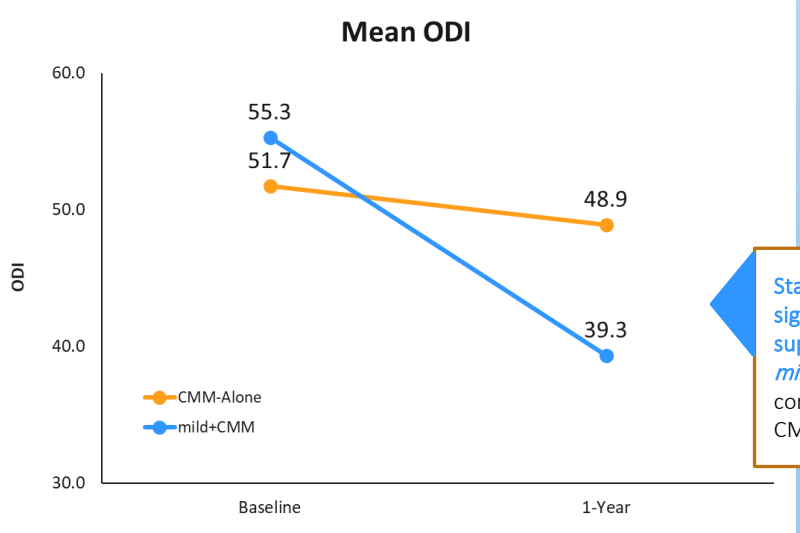
No Spinal Instability

No evidence of spinal instability through 2 years

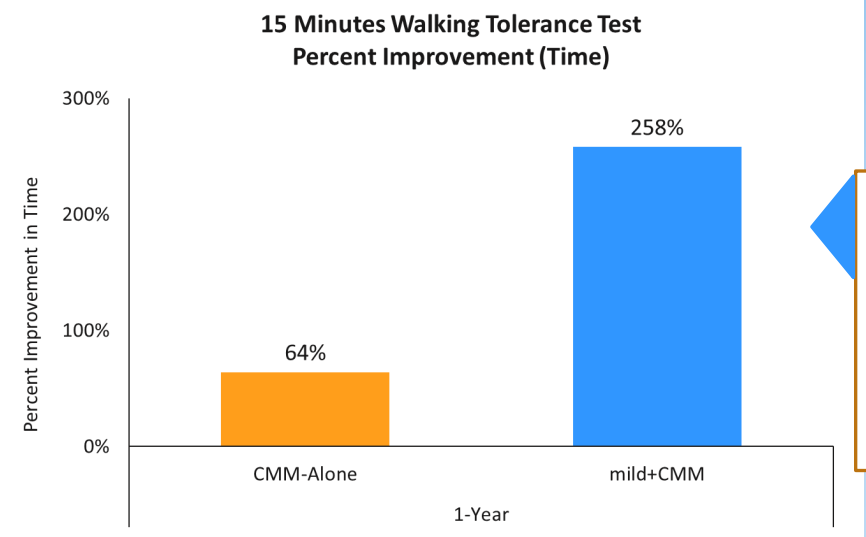
No Spine Fractures

No implants and no evidence of lumbar spine fractures through 2 years

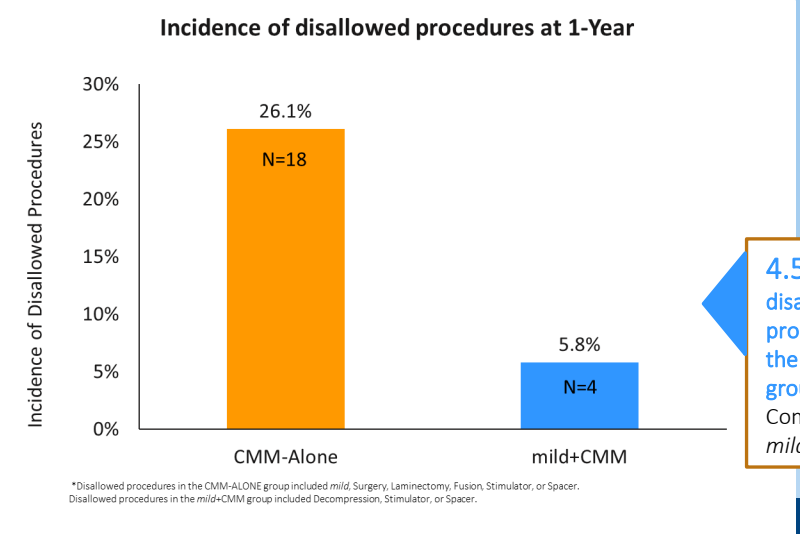
MOTION Study – 1 Year Outcomes of Level 1 RCT



Statistically-significant superiority of *mild*+CMM compared to CMM-ALONE



>200% improvement in the *mild*+CMM with statistically superiority over CMM-ALONE

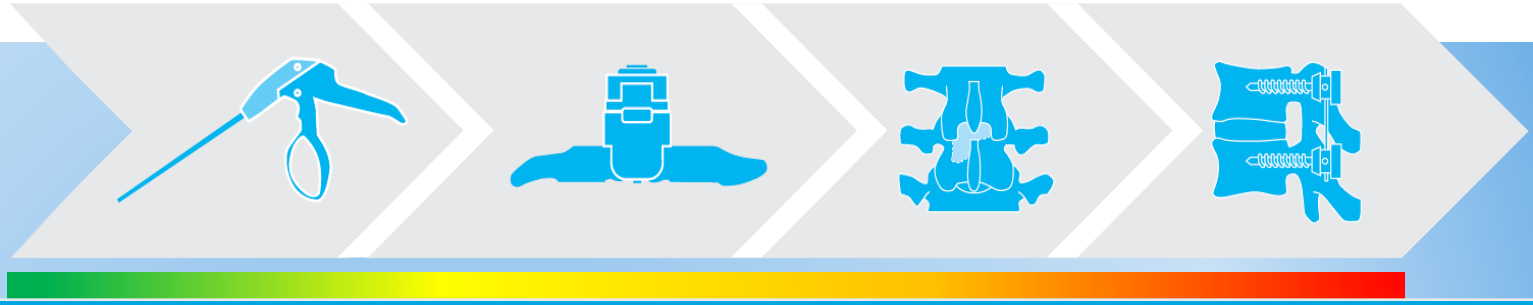


4.5x more disallowed procedures in the CMM-ALONE group Compared to *mild*+CMM

Adjunction Results	*CMM-Alone N=78 %(n) [events]*	*mild+CMM N=77 %(n) [events]*	*p-value*
Total AEs	11.5% (7) [8]	11.7% (8) [13]	0.7927
Related AEs	0.0% (0) [0]	0.0% (0) [0]	-
Related SAEs	0.0% (0) [0]	0.0% (0) [0]	-
Unrelated SAEs	11.5% (7) [8]	11.7% (8) [13]	0.7927

✓ *Safety between groups is statistically similar at 1Y*

Data Establishes *mild* as the 1st Option



Comparison of Complications Between Various Decompression Procedures[7]					
2-Year Outcomes	*mild*	Interspinous Process Distraction		Surgical Decompression	Fusion
		Superion™	X-Stop®		
Reoperation	5.6%	20%	14.4-26%	6-7.8%	12.5-16.9%
Device- and procedure-related AEs	1.3%	Device-related		Intraoperative: 9.9%	23.3%
		11.6%	7.5%		18% Early
		Procedure-related			
		14.2%	15.9%	Postoperative: 12.3%	6% Late
Device- and procedure-related serious AEs	0%	8.4%	9.5%		
Lumbar spine fractures	0%	16.3%	8.5%	-	4.2%
Removal of hardware	No Implants	16.3%	12.4%	No Implants	4.3%

mild Reduces Resource Utilization

Health Care Economics

Significant Reduction in Chronic Pain Management (CPM) Treatments After *mild*

VA Loma Linda[9]

45% Reduction in Patient Time Spent in CPM

55% of Patients Discharged From CPM

75% Reduction in # of Interventional Pain Management Procedures / Month

Significant LSS Treatment Cost Advantage

Two Year Average Cost
Cleveland Clinic Study[10]

	Average Cost
mild	$5,458
ESI	$7,888
Laminectomy Surgery	$13,771

Hospital Laminectomy Charges Reported as:

$23,724[11]

Includes any repeat or revision procedure, and the cost of any alternate treatment post-failure.

Excludes complications, rehabilitation, post-acute care, etc. costs.

Source 9, 10, and 11: Refer to appendix for references

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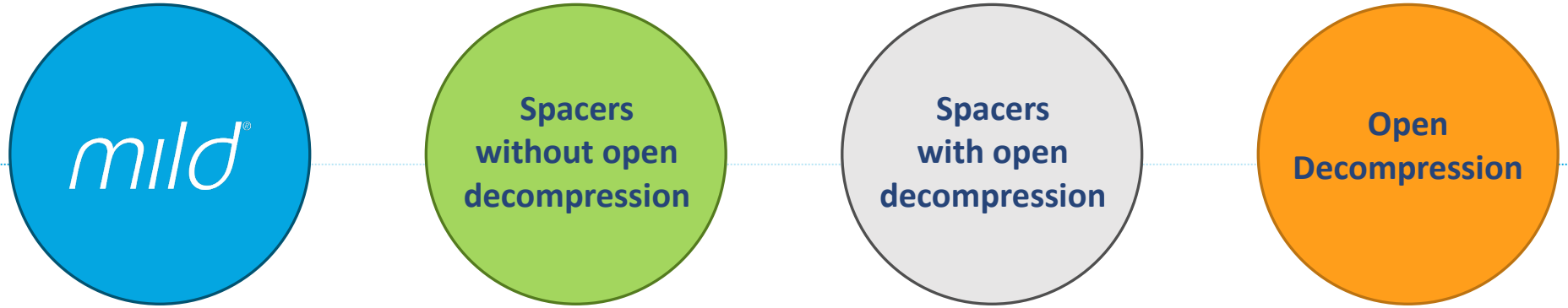
Real-World Study Design

Medicare Claims Study

Four Cohorts



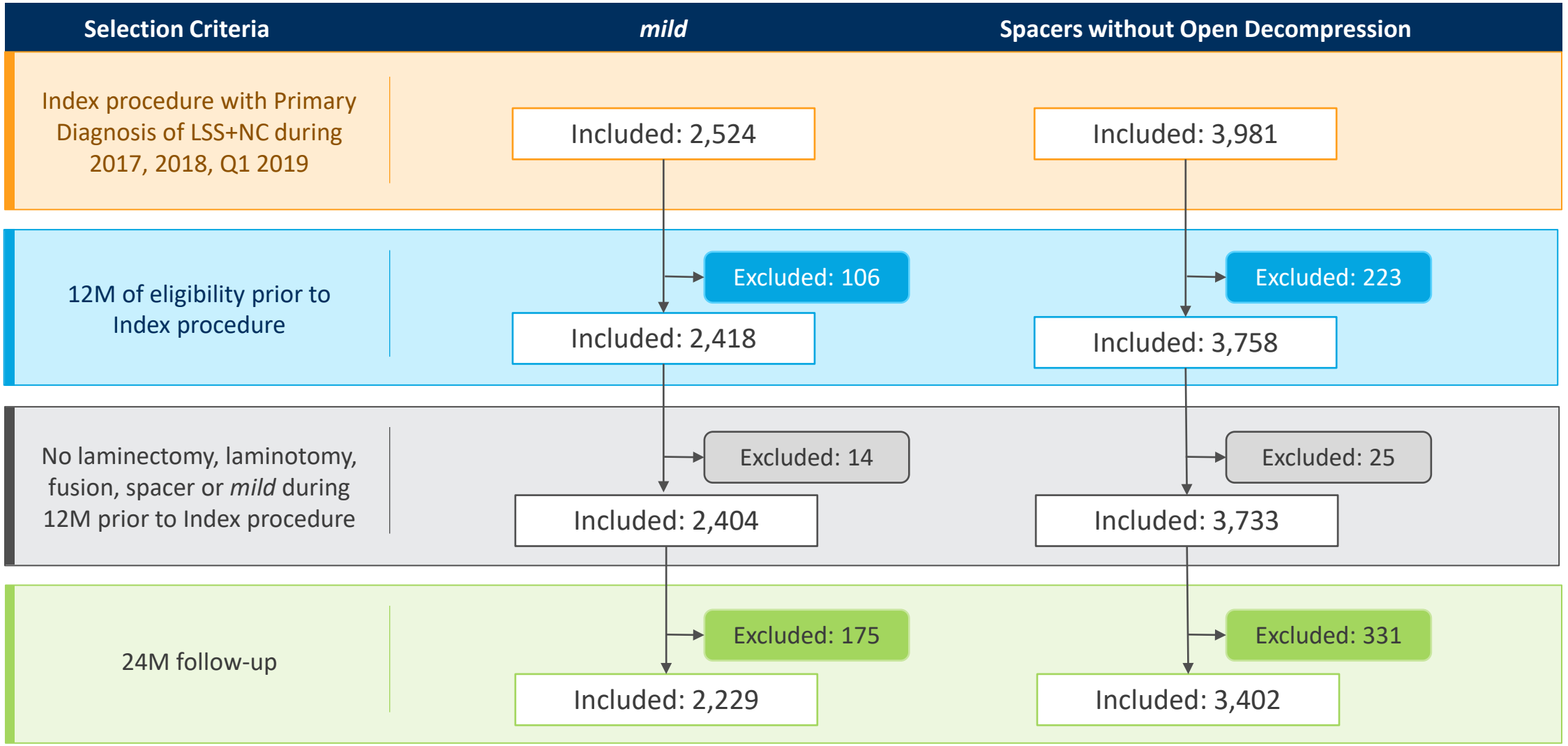
Objective	Evaluate *mild* vs benchmark LSS procedures using real-world claims data
Data Source	CMS Medicare Research Identifiable Files (RIFs) containing all claims for 100% of Medicare beneficiaries
Follow-up	24 Months
Outcome Measures	• Presence of Harms (Safety) • Subsequent Lumbar Spine Intervention (Efficacy) • Overall Rate of Harms and Subsequent Procedures

Medicare Claims Studies—Overview

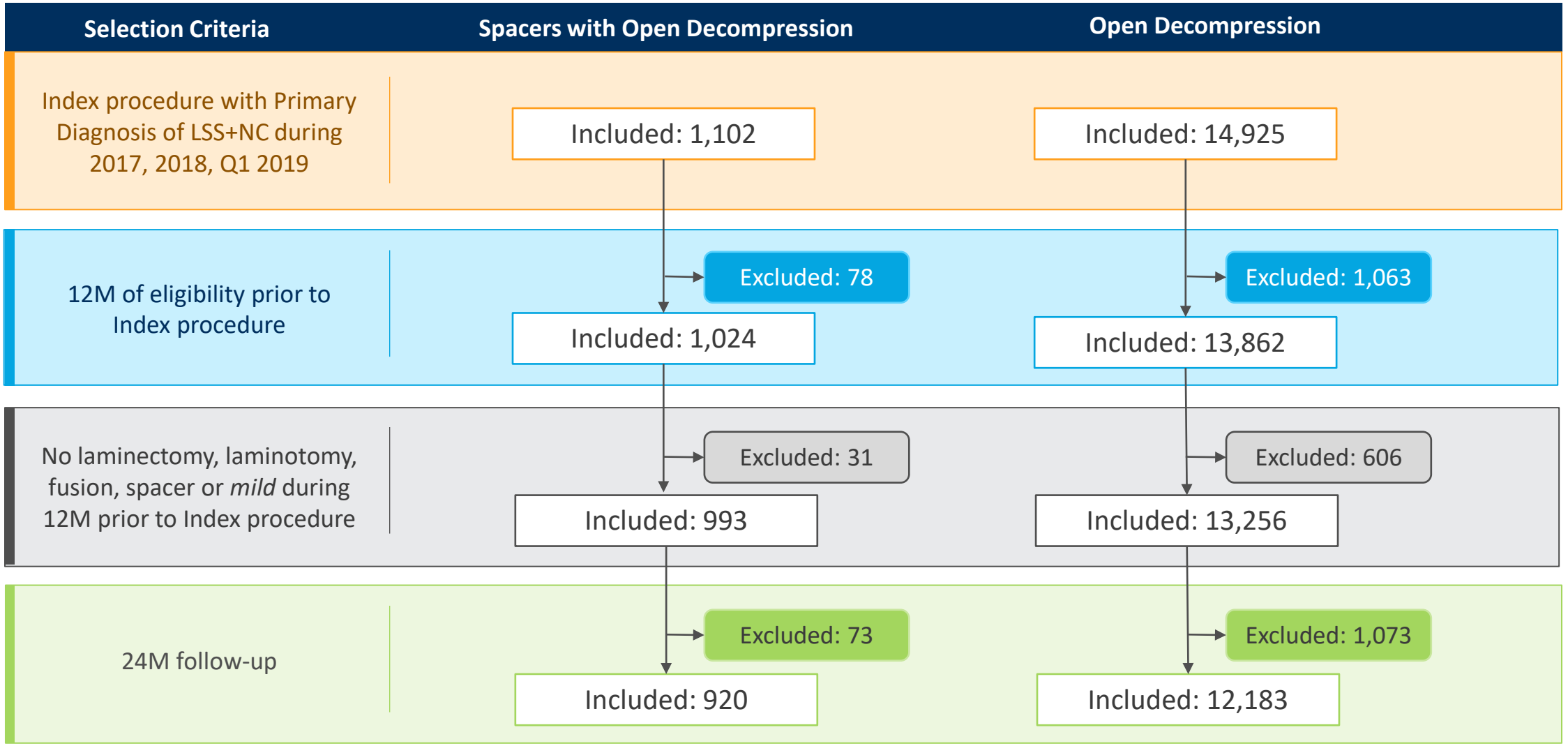
Medicare Claims: Data Available for Analysis	
Yes	**No**

• Longitudinal data (using encrypted beneficiary ID)
• Demographics
• Presenting comorbidities
• Harms
• Procedures
• Medication usage
• Timing
• Site of service
• Healthcare expenditures and utilization
	• Traditional Patient Reported Outcomes (PROs)
	  - ODI
	  - VAS / NPRS
	  - ZCQ
	• Ability to walk or stand
	• Ability to perform activities of daily living
	• Patient satisfaction
	• Pain levels
	• Sleep quality

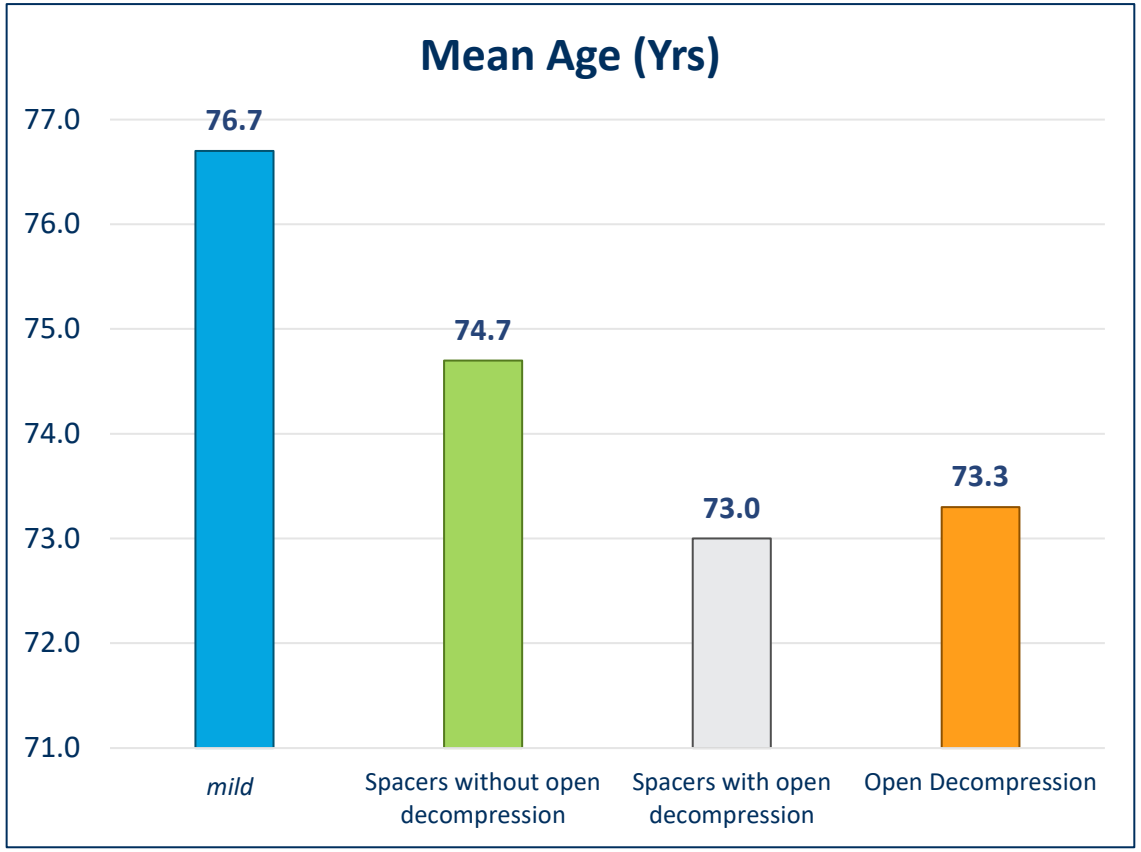
Populations for Analysis

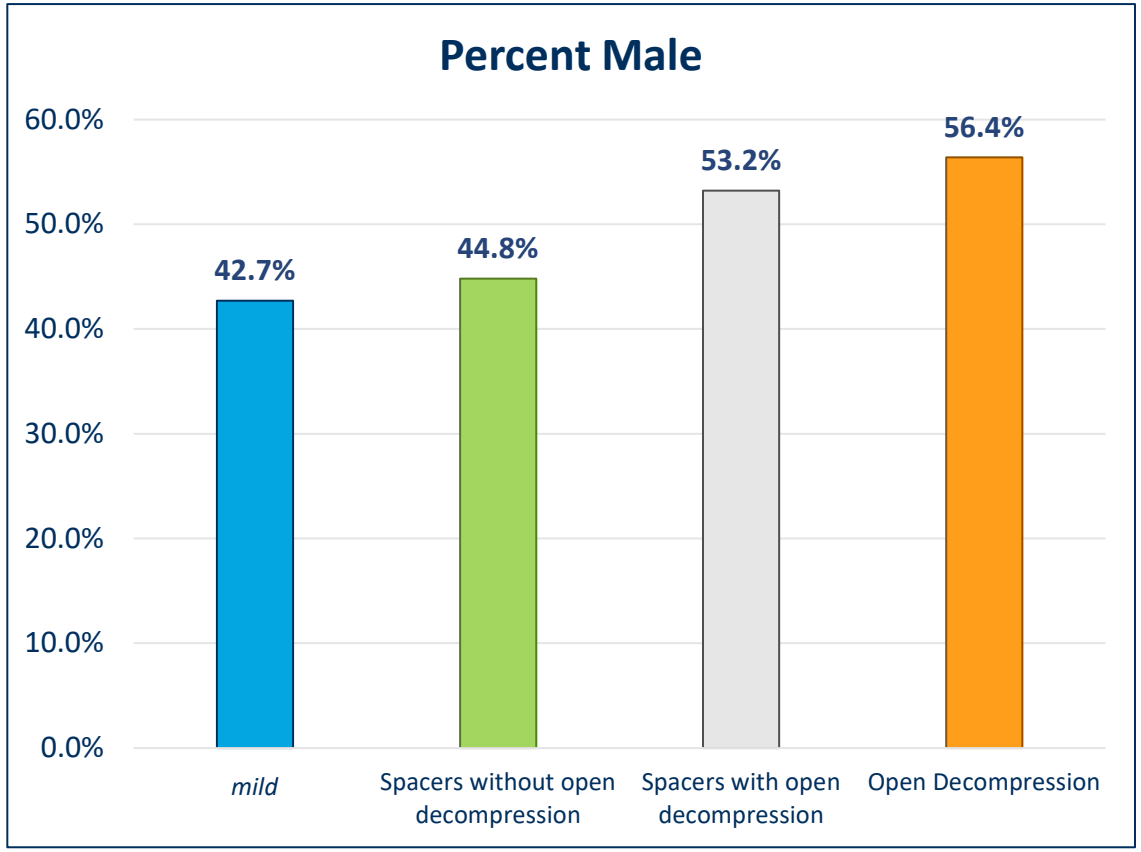


Populations for Analysis (Continued)

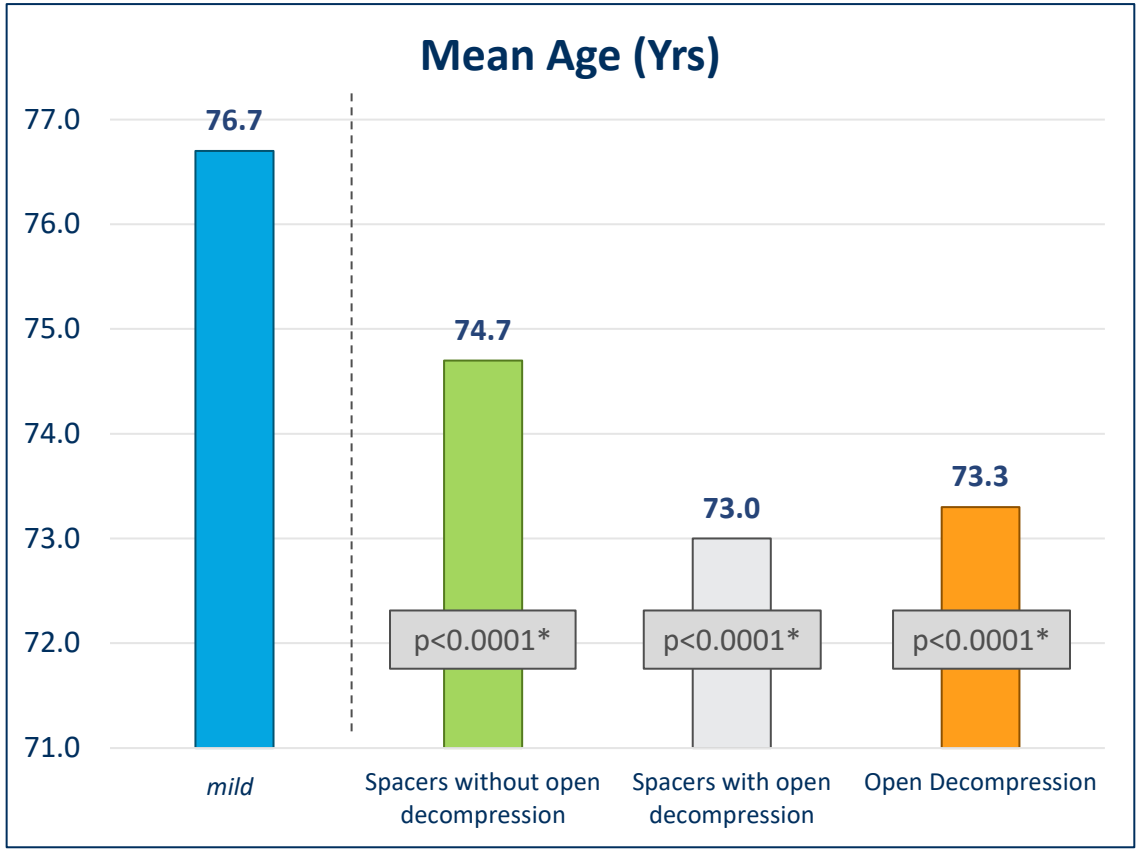


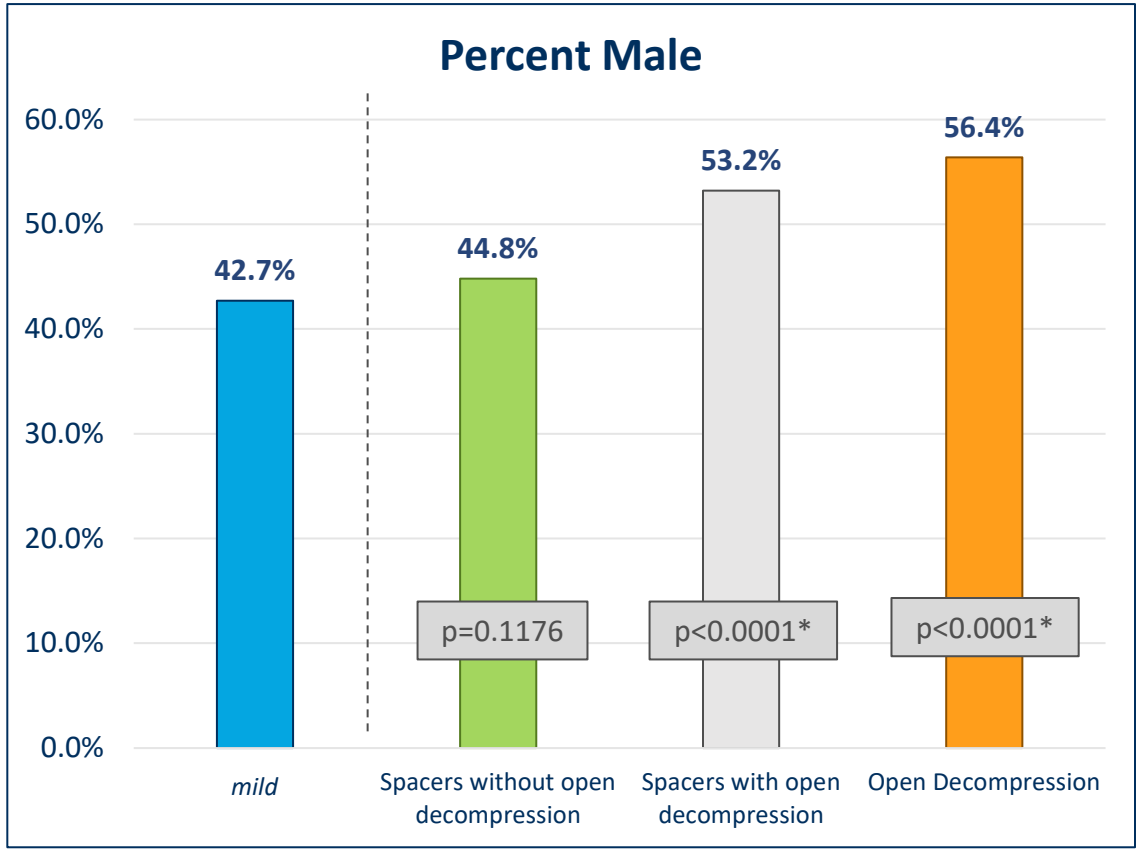
Demographics





Demographics





*Statistically-significantly different from the *mild* cohort.

Presence of Harms

Harm	*mild*		Spacers without open decompression		Spacers with open decompression		Open Decompression	
	N = 2,229		N = 3,402		N = 920		N = 12,183	
Presence of any Harm	**118**	**5.3%**	**401**	**11.8%**	**140**	**15.2%**	**1,368**	**11.2%**
Mechanical complications	86	3.9%	351	10.3%	84	9.1%	494	4.1%
Wound problems / infections / dehiscence	21	0.9%	36	1.1%	36	3.9%	472	3.9%
Life-threatening complications*	17	0.8%	22	0.6%	18	2.0%	314	2.6%
Lumbosacral spinal cord / nerve root injury / dural tear**	·	·	·	·	20	2.2%	270	2.2%
DVT	·	·	·	·	·	·	·	·
Heterotopic Ossification	·	·	·	·	·	·	·	·
Death	·	·	·	·	·	·	28	0.2%

* Includes acute MI, pneumonia, respiratory problems, pulmonary embolism and stroke within 30 days of Index procedure.
** Includes lumbosacral spinal cord or nerve root injury, and dural tear / puncture or laceration within 30 days of Index procedure.
· Less than 11 patients.

Presence of Harms—
Statistical Comparison versus *mild*

Harm	*mild*	Spacers without open decompression		Spacers with open decompression		Open Decompression	
	N = 2,229	N = 3,402		N = 920		N = 12,183	
			p-value		*p*-value		*p*-value
Presence of any Harm	**5.3%**	**11.8%**	**<0.0001***	**15.2%**	**<0.0001***	**11.2%**	**<0.0001***
Mechanical complications	3.9%	10.3%	<0.0001*	9.1%	<0.0001*	4.1%	0.6515
Wound problems / infections / dehiscence	0.9%	1.1%	0.4972	3.9%	<0.0001*	3.9%	<0.0001*
Life-threatening complications*	0.8%	0.6%	0.4900	2.0%	0.0003*	2.6%	<0.0001*
Lumbosacral spinal cord / nerve root injury / dural tear**	·	·	·	2.2%	·	2.2%	·
DVT	·	·	·	·	·	·	·
Heterotopic Ossification	·	·	·	·	·	·	·
Death	·	·	·	·	·	0.2%	·

* Includes acute MI, pneumonia, respiratory problems, pulmonary embolism and stroke within 30 days of Index procedure.
** Includes lumbosacral spinal cord or nerve root injury, and dural tear / puncture or laceration within 30 days of Index procedure.
* Indicates statistical superiority of *mild* versus this cohort value.
· Less than 11 patients.

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Statistical Comparison versus *mild*

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Lumbosacral spinal cord / nerve root injury / dural tear**	·	·	·	2.2%	·	2.2%	·
DVT	·	·	·	·	·	·	·
Heterotopic Ossification	·	·	·	·	·	·	·
Death	·	·	·	·	·	0.2%	·

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Statistical Comparison versus *mild*

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DVT	·	·	·	·	·	·	·
Heterotopic Ossification	·	·	·	·	·	·	·
Death	·	·	·	·	·	0.2%	·

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DVT	·	·	·	·	·	·	·
Heterotopic Ossification	·	·	·	·	·	·	·
Death	·	·	·	·	·	0.2%	·

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DVT	·	·	·	·	·	·	·
Heterotopic Ossification	·	·	·	·	·	·	·
Death	·	·	·	·	·	0.2%	·

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DVT	·	·	·	·	·	·	·
Heterotopic Ossification	·	·	·	·	·	·	·
Death	·	·	·	·	·	0.2%	·

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First Subsequent Lumbar Spine Intervention—
Interventional Cohorts

Procedure	*mild*		Spacers without open decompression	
	N = 2,229		N = 3,402	
Subsequent Lumbar Spine Intervention	**567**	**25.4%**	**895**	**26.3%**
Disc procedure	·	·	·	·
Drug delivery implant	19	0.9%	48	1.4%
Endoscopic decompression	·	·	·	·
Fusion	72	3.2%	92	2.7%
Laminectomy / laminotomy	129	5.8%	114	3.4%
mild	75	3.4%	30	0.9%
Neurostimulation	116	5.2%	276	8.1%
Removal of implant	13	0.6%	73	2.1%
Repair of dural / cerebrospinal fluid leak	·	·	·	·
Spacer (with open decompression)	20	0.9%	18	0.5%
Spacer (without open decompression)	158	7.1%	317	9.3%
Treatment of fracture / dislocation	·	·	·	·
Vertebral excision	·	·	·	·
Other lumbar spine procedure	·	·	11	0.3%

· Less than 11 patients.

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Fusion	72	3.2%	92	2.7%
Laminectomy / laminotomy	129	5.8%	114	3.4%
mild	75	3.4%	30	0.9%
Neurostimulation	116	5.2%	276	8.1%
Removal of implant	13	0.6%	73	2.1%
Repair of dural / cerebrospinal fluid leak	·	·	·	·
Spacer (with open decompression)	20	0.9%	18	0.5%
Spacer (without open decompression)	158	7.1%	317	9.3%
Treatment of fracture / dislocation	·	·	·	·
Vertebral excision	·	·	·	·
Other lumbar spine procedure	·	·	11	0.3%

· Less than 11 patients.

First Subsequent Lumbar Spine Intervention—
Interventional Cohorts

Procedure	*mild*		Spacers without open decompression	
	N = 2,229		N = 3,402	
Subsequent Lumbar Spine Intervention	**567**	**25.4%**	**895**	**26.3%**
Disc procedure	·	·	·	·
Drug delivery implant	19	0.9%	48	1.4%
Endoscopic decompression	·	·	·	·
Fusion	72	3.2%	92	2.7%
Laminectomy / laminotomy	129	5.8%	114	3.4%
mild	75	3.4%	30	0.9%
Neurostimulation	116	5.2%	276	8.1%
Removal of implant	13	0.6%	73	2.1%
Repair of dural / cerebrospinal fluid leak	·	·	·	·
Spacer (with open decompression)	20	0.9%	18	0.5%
Spacer (without open decompression)	158	7.1%	317	9.3%
Treatment of fracture / dislocation	·	·	·	·
Vertebral excision	·	·	·	·
Other lumbar spine procedure	·	·	11	0.3%

· Less than 11 patients.

Overall Rate of Harms and Subsequent Procedures
Interventional Cohorts

Procedure	*mild*		Spacers without open decompression	
	N = 2,229		N = 3,402	
Presence of any Harm	118	5.3%	401	11.8%
Subsequent Lumbar Spine Intervention	567	25.4%	895	26.3%
Overall Rate of Harms and Subsequent Procedures	651	29.2%	1,066	31.3%

Overall Rate of Harms and Subsequent Procedures
Interventional Cohorts

Procedure	*mild*		Spacers without open decompression	
	N = 2,229		N = 3,402	
Presence of any Harm	118	5.3%	401	11.8%
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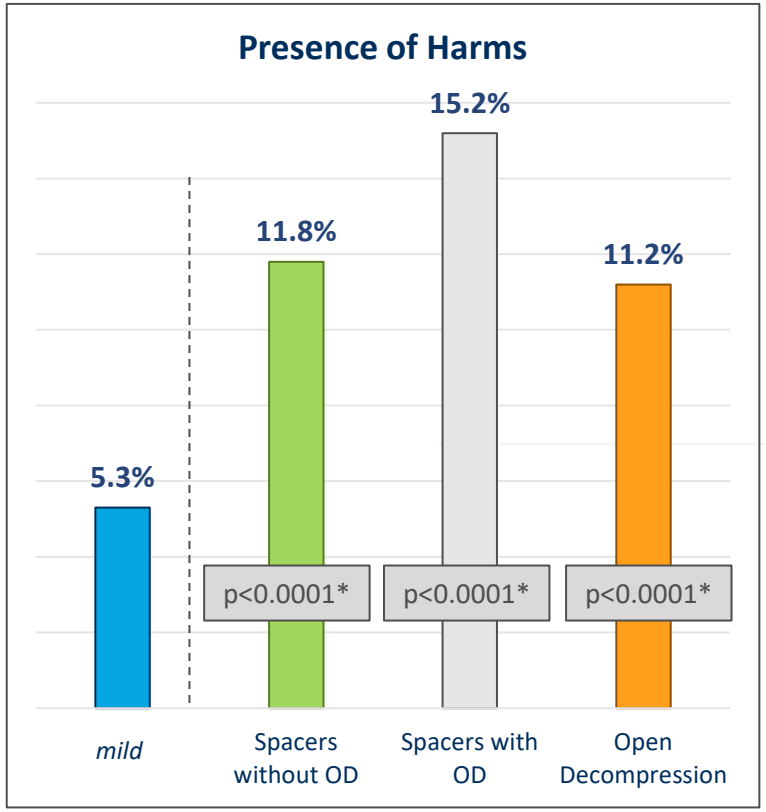
Overall Rate of Harms and Subsequent Procedures
Interventional Cohorts

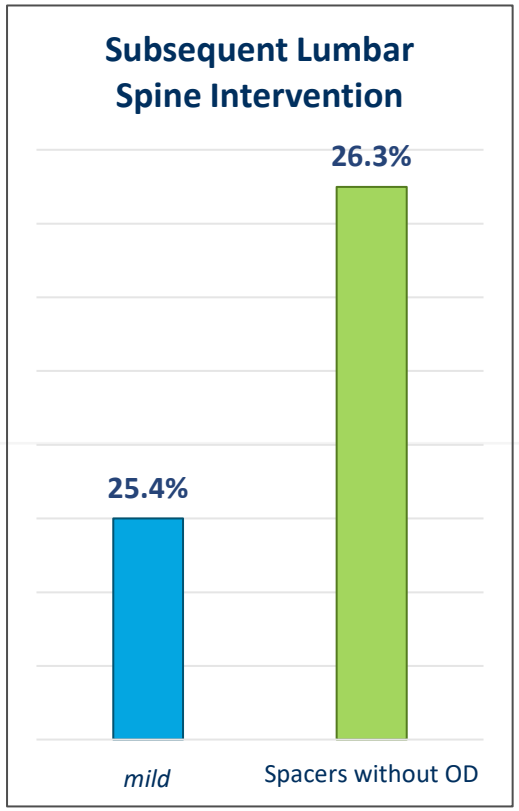
Procedure	*mild*		Spacers without open decompression	
	N = 2,229		N = 3,402	
Presence of any Harm	118	5.3%	401	11.8%
Subsequent Lumbar Spine Intervention	567	25.4%	895	26.3%
Overall Rate of Harms and Subsequent Procedures	651	29.2%	1,066	31.3%

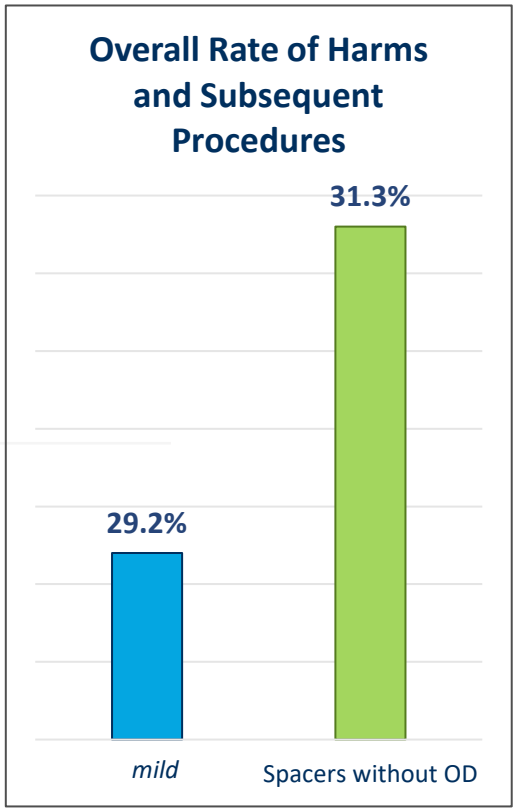
Medicare Claims Study
mild vs. Benchmark LSS Procedures

All Cohorts



Interventional Cohorts





*Statistically-significantly different from the *mild* cohort.

mild Real-World 2-year Safety and Efficacy

Versus all Benchmark LSS Cohorts:

- Lowest rate of harms
- Oldest patient population

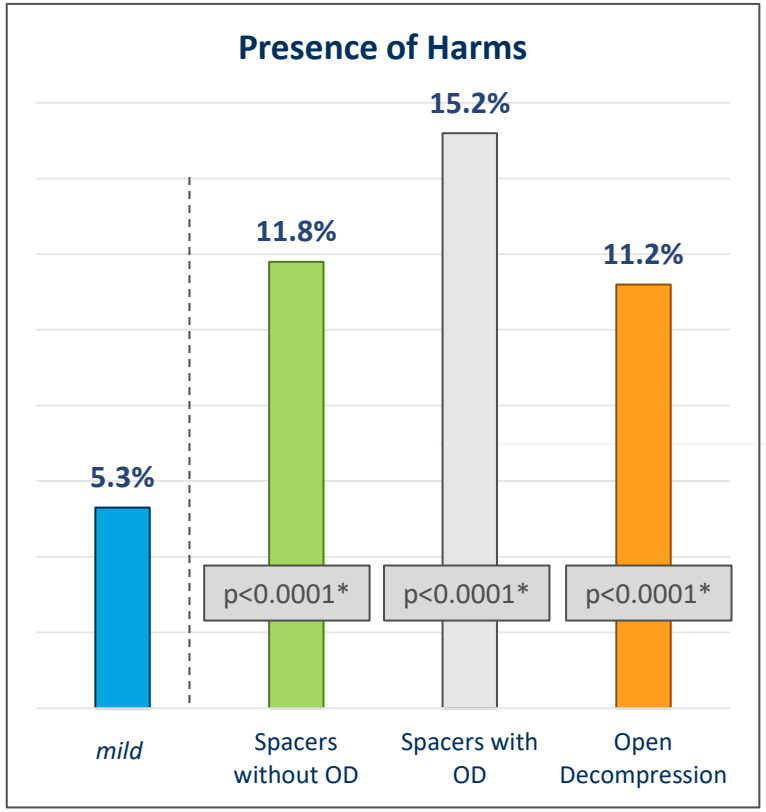
Versus Spacers without Open Decompression:

- Lower subsequent procedure rate
- Lower Overall Rate of Harms and Subsequent Procedures

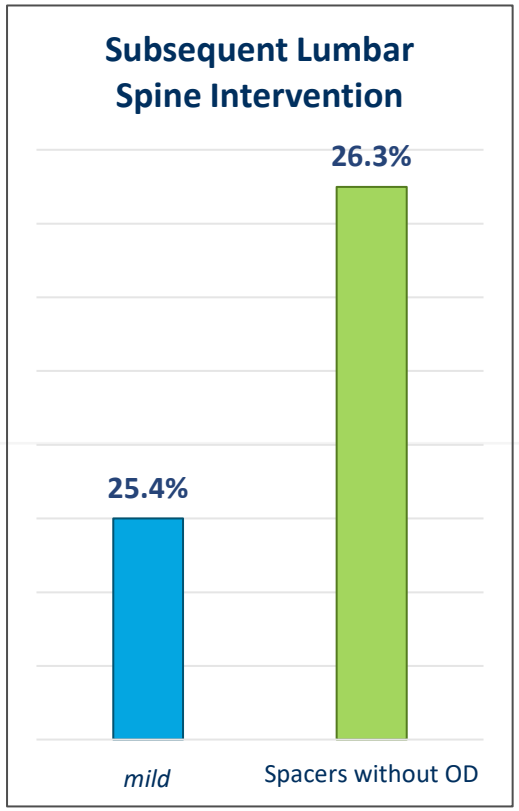
Established NON-INFERIORITY to Spacers without Open Decompression (p<0.0001)

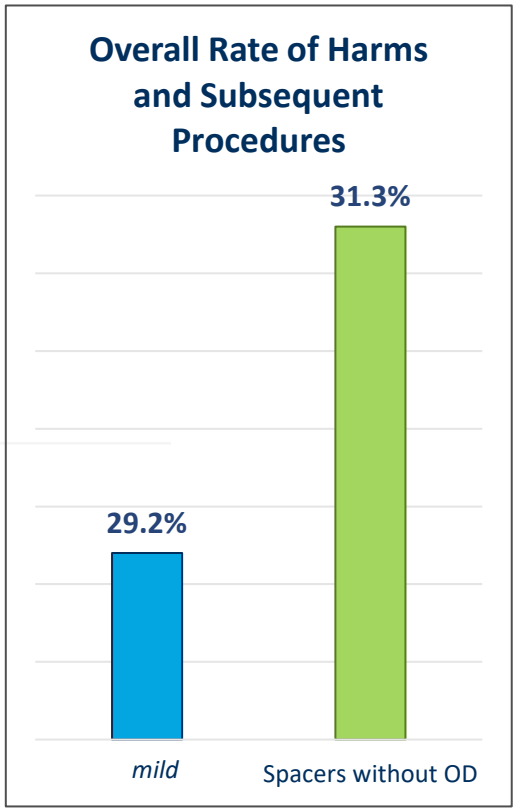
Medicare Claims Study
mild vs. Benchmark LSS Procedures

All Cohorts



Interventional Cohorts





*Statistically-significantly different from the *mild* cohort.

mild Real-World 2-year Safety and Efficacy

Versus all Benchmark LSS Cohorts:

- Lowest rate of harms
- Oldest patient population

Versus Spacers without Open Decompression:

- Lower subsequent procedure rate
- Lower Overall Rate of Harms and Subsequent Procedures

Established NON-INFERIORITY to Spacers without Open Decompression (p<0.0001)

Initial referral should be to the pain physician

			
Patient	**Chronic Angina**	**Cancer**	**Chronic Pain**
	Referral	Referral	Referral
Specialist	**Cardiologist**	**Oncologist**	**Pain Specialist**
	Referral	Referral	Referral
Surgeon	**Cardiothoracic Surgeon**	**Surgical Oncologist**	**Orthopedic Surgeon**