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Review Article

Perspective: Efficacy and outcomes for different lumbar interspinous devices (ISD) vs. open surgery to treat lumbar spinal stenosis (LSS)

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ABSTRACT

Background: Interspinous devices (ISD) constitute a minimally invasive (MI) alternative to open surgery (i.e., laminectomy/decompression with/without fusion (i.e., posterior lumbar interbody fusion (PLIF)/posterolateral instrumented fusion (PLF)) for treating lumbar spinal stenosis (LSS). Biomechanically, static and/or dynamic ISD "off-load" pressure on the disc space, increase intervertebral foraminal/disc space heights, reverse/preserve lordosis, limit range of motion (ROM)/stabilize the surgical level, and reduce adjacent segment disease (ASD). Other benefits reported in the literature included; reduced operative time (OR Time), length of hospital stay (LOS), estimated blood loss (EBL), and improved outcomes (i.e., ODI (Oswestry Disability Index), VAS (Visual Analog Scale), and/or SF-36 (Short-Form 36)).

Methods: Various studies documented the relative efficacy and outcomes of original (i.e., Wallis), current (i.e., X-STOP, Wallis, DIAM, Aperius PercLID), and new generation (i.e., Coflex, Superion Helifix, In-Space) ISD used to treat LSS vs. open surgery.

Results: Although ISD overall resulted in comparable or improved outcomes vs. open surgery, the newer generation ISD provided the greatest reductions in critical cost-saving parameters (i.e., OR time, LOS, and lower reoperation rates of 3.7% for Coflex vs. 11.1% for original/current ISD) vs. original/current ISD and open surgery. Further, the 5-year postoperative study showed the average cost of new generation Coflex ISD/decompressions was $15,182, or $11,681 lower than the average $26,863 amount for PLF.

Conclusion: Patients undergoing new generation ISD for LSS exhibited comparable or better outcomes, but greater reductions in OR times, EBL, LOS, ROM, and ASD vs. those receiving original/current ISD or undergoing open surgery.

Keywords: Interspinous Devices (ISD), Static, Dynamic, X-Stop, Coflex, Lumbar Spinal Stenosis (LSS), Decompression, Posterior Lumbar Interbody Fusion (PLIF), Posterolateral Fusion (PLF), Open Surgery, Laminectomy, Complications, Outcomes, Adverse Events

INTRODUCTION

For treating lumbar spinal stenosis, we compared the efficacy and outcomes of 3 different categories of interspinous devices (ISD) vs. open surgery (i.e., laminectomy/decompression, posterior lumbar interbody fusion (PLIF), posterolateral fusion (PLF/other) [Tables 1 and 2].[1-15] The three categories

Table 1: Utility of Coflex devices vs. decompressions vs. other fusions in dealing with lumbar spinal stenosis.

Author {ref number} Journal Year	Study Design	Data	Data	Data	Outcomes
Trautwein[14] **The Spine J 2010**	XR study IV Loading Load Bear Implants Coflex in 196 Pts Neutral Flex Ext X-rays	Measure Implant Load Function Size Elastic Def 12 Groups Force Data Indep Implant Size	Diagnosis F/O Time Median CF Coflex: 45.8N MLC Flex + Ext 140 N Max Overall Load Exceeded 239 N Ext	AvgL Coflex on SP 11.3%: and Lam + 7% of Static Failure Load	Implant Fatigue Strength Sig > Median Force Very Rare Coflex Fatigue Failure
Kabir[6] **Spine 2010**	ISD Review Biomech Eval Devices X-Stop Coflex Wallis DIAM "Further good quality trials needed to clearly outline the indications for their use"	Databases Medline CIINAHL PubMed Outcomes Clinical Question A Biomech Testing	Largest Number Studies X-STOP All Studies Showed Benefits of ISD X-Stop Imp Outcome vs. ConsRx	Select Pts Over 50 yrs Old Radiolog-ically Confirmed LSS/INC Studies Varied Results Other Devices	Small Number and Poor Design of Studies Diff Define Indications for Use in LDD
Schmier[13] **Clinicoecon Outcomes Res 2014**	Randomized Controlled Multicenter US FDA Investigational Device Exemption Clinical Trial Evaluation 5 Yr Costs Coflex vs. PLF	Outcomes Coflex ISD DecLam vs. PLF Used Medicare Rates And Typical Commercial Rates	5 Yr Costs Medicare 5 yr Data $15,182 Lower with Coflex DecLam $26,863 Fusion Difference $11,681 Coflex DecLam Higher QUALY 3.02 vs. PLF 2.97	Coflex DecLam Pts More Utility vs. Fusion Substantially Lower Costs Larger Cost Differences Commercial Insurance	Cost Savings Even Higher with 2 Level Procedures
Kumar[7] **Asian Spine J 2014**	Compare Outcome 22 Coflex vs 24 Dec LSS y X-ray Findings Eval Outcome/ X-rays Preop, F/O 6 mos, 1 yr, 2 yrs Postop	Outcomes ODI VAS-Back Pain VAS-Leg pain SF-36	X-ray FH Sag Angle Both Sig Imp All Outcome measures Sig > Imp Coflex vs. Dec	Changes in X-rays Note Correlate with > Imp Outcome	Add Coflex After LSS Dec Better Outcomes vs. Dec Alone (Short-Term)
Hirsch[5] **Orthop Traumatol Surg Res 2015**	Biomech Dynamics Changes L45 Foramen Surface Flex 4 ISD 6 Human Cadavers Marked L3-S1 foramina	3D Images In-Space=Synthes X-Stop=Medtronic Wallis=Zimmer Diam=Medtronic	Calculated Foraminal Surface Areas in Extension: All 4 Opened L45 Foramina L45 Wallis + Diam Foramen Opened Only Extension	X-Stop/In-Space L45 Foramen Opened in Extension and Flexion and Neutral No Device Opened L34 Foramen	X Stop and Diam Closed L5S1 Foramen on Extension Other 2 No Impact at This Level
Che[1] **Medical Science Monitor 2016**	Biomech IV Study Compare IDP (1) L45 PSRF Upper L34 Coflex vs. (2) L45 PSRF Only Aim: Biomech Coflex for Lumbar ASD Adjacent to Rigid Fixation	6 M Human Cadaver Biomech In Vitro Loads Flex Ext Lat Bend Axial Rot	First Eval Intact Level L45 PSRF Only vs. L45 PSRF + L34 Coflex PSRF alone vs. PSRF Sig > ROM Upper Level All Direction Loads IDP Change Slight	Upper Level Coflex > Stability All Direction vs. PSRF Only Esp Ext Coflex Not Sig<ICP vs. PSRF Alone	Result L45 PSRF with L34 Coflex > Stable vs. L45 PSRF Only Eval L45 PSRF + Coflex L34 Protect ASD

(Contd...)

Table 1: *(Continued).*

Author {ref number} Journal Year	Study Design	Data	Data	Data	Outcomes
Pintauro[11] **Curr Rev Musculoskelet Med 2017**	ISD: Are New Implants Better vs. Last Generation? ISD Treat LSS Compare 1st vs. Next Generation Devices/Comp Device Failure Reop Rates Sx Relief Outcomes	37 Studies 2011-2016 Device Fail Mean 3.7% <Failures Next Generation (Coflex, Superion Helifix, In-Space)	vs. More Failures Original (Wallis) Vs. Current Devices (X-STOP, Wallis, DIAM, Aperius PercLID) Reop Rate Mean F/0 24 mos	Lower Reop Rate Next Generation 3.7% vs. 11.1% Original Current ISD	Result: ISD Questioned Long-Term Function 2 Yr. Radiology + Sx Recurrence Rates?
Li[8] **Int Journal Surgery 2017**	Dec + Fus DSD Older Adults Reports Coflex Safe Option Rx-Ask Effect Dec + Coflex Fus 10 Studies	Review Database Web Science, PubMed, Embase, Cochrane Library	Dec + Coflex < Fus Greater Effect vs. Control Proc Outcomes: > ODI < LOS < EBL	Same VAS + Comp DecFus Control	Coflex Not Inferior to Dec +Fus Outcomes ODI/VAS **Coflex** <EBL <LOS Same Comp vs. Dec + Fus OR
Yuan[15] **J Clin NeuroScience 2017**	Clinical X-ray Outcome 42 Coflex vs. 45 PLIF LDD 5 Yr Data 87 Pts LDD Coflex < EBL < LOS < OR Time	Both Sig IMP ODI VAS-Leg+Back Pain	Coflex Sig Better Clinical Result Early F/O Coflex Final F/O Sup Inferior ASD Motion Same But Sig > > ASD For PLIF	OR Level ROM Sig Less with Coflex+PLIF at Final F/O But More <ROM Coflex and > Reop Not Sig PLIF	Both Sig Imp 5 Yr Outcome Coflex + PLIF Coflex More Early Efficacy vs. PLIF Coflex Safe Effective
Shen[12] **World Neurosurg 2019**	Biomech Analysis ISD Devices Measure IDP, FJF Use FE L1-L5 Levels 4 FE ISD Placed L34 Coflex-F, PSS, DIAM, Wallis	ISD<ROM Surgical Level Flex/Ext Not Lateral Bend or Torsion	Coflex-F vs. DIAM/ Wallis Better Stabilize OR Level (Flex/Ext) > FJF at Adjacent Level by 26-27%	DIAM Most Comparable ROM, IDP, FJP at Adjacent Levels vs. Intact Spine Wallis Device Between Coflex-F and DIAM	ISD Less Compensation Adjacent Levels re; ROM, IDP and FJD "may lower incidence of adjacent segment degeneration in the long-term"
Du[2] **J Clin Neuroscience 2020**	Retro Eval Long-Term Effect Coflex Rx LSS 73 Pts 2008-2012 Min 8 Yr F/O Clinical Effect X-rays Eval ASD	56 Pts F/O 107.6 Mos Sig Imp VAS, ODI and JOA Scores Postop	< ROM 6 Mos Postop ROM Sl > inc Last F/O ROM Adjacent Segment Sl. > 6 Mos and Last F/o	ISH and IFH > > 6 Mos Postop Last F/O < ISH/IFH Last F/O 11 (19.6%) Pts Comp 6 (10.7%) Reop	Coflex Effect Long-Term Rx LSS ISH/IFH Could > Short Period Time

(Contd...)

Table 1: *(Continued).*

Author {ref number} Journal Year	Study Design	Data	Data	Data	Outcomes
Fan[3] **Medicine 2020**	LDD Common Rx Include Dec, PLIF, Coflex ISD Meta-Anal Effect Coflex on LDD vs. PLIF	Databases PubMed WanFang 10 Studies 946 Pts All 10 RCT No Sig Diff ODI Dec Alone vs. Coflex vs. PLIF	Coflex and PLIF Better < VAS vs. Dec Only But Fewer Comp with Coflex Device	Coflex and PLIF Similar Effect IMP Lumbar Function Quality Life vs. Dec Alone	Both Devices Better Relieved Pain Coflex < Comp Rate Coflex Better for LSS
Guo[4] **Am J Transl Res 2022**	Compare Biomech Diff Coflex vs. X-Stop Nl CT Eval Healthy Volunteer 4 Lumbar Models Healthy, Mild DSD Coflex X-Stop	Simulate Flex/Ext Lat Bend Rot Compare ROM IDP Facet JF Stress Peak FJF Coflex vs. X-Stop	L45 Mild DLD Coflex < ROM 98.34%, X-STOP < ROM 95.86%, VMS: Dec IDP Coflex 59.4% X-Stop 66.17% Peak FJF Coflex 97.09% X-Stop 95.42%	Both No Sig Diff AL Von Mises Stress Coflex 637.56 MPA Flex 528.86 Ext X-Stop 476.65 MPA Ext	Peak FJF Coflex Ext 19.76 MPa vs. X-Stop 49.28 MPa Ext Both Coflex + X = Stop < ROM < IDP No Impact AL
Liu[10] **BMC Musculoskelet Disord 2022**	Biomech Eval Different ISD Rx LSS Devices BacFuse X-Stop Coflex	4 Finite Element Models L3-L5 Simulated 4 Motion Flex, Ext Lateral Bend Axial Rot ROM	Eval Stress Intact Spine vs. 3 Models with Diff ISD Devices All 3 < ROM/Disc/FJ with Motion > ROM/ Disc/FJ stress AS	> Effect Proximal Segment BacFuse > Distal AS Coflex X-STOP > Stress SP OR Level	All 3 Effectively Reduce Extension and Disc/FJ Stress Also > ROM and Disc/FJ Stress at AS
Li[9] **World Neurosurg 2023**	Rev Meta-Anal Comparing Lumbar Dynamic Fus Coflex vs. PLF LSS	Eval 26 Studies 2022-JOA VAS ODI Outcomes ASD Stat Eval for LSS	Coflex: Short OT 50.77 min <EBL 122.21cc <LOS 3.21 D > JOA, > ODI	Early F/O No Sig Diff Longer F/O Coflex<VAS vs. Fus-Coflex < Comp < ASD > ROM	Coflex: No Sig Diff Reop Fus Comp Coflex > Result PLF Early F/O

DecSF=Decompression/Spinal Fusion, DSD=Degenerative Spinal Disease, Rx=Treatment, Dec=Decompression, Fus=Fusion, Effect=Effective, Proc=Procedures, ODI=Oswestry Disability Index, LOS=Length of Hospital Stay, EBL=Estimated blood Loss, VAS=Visual Analog Scale, AE=Adverse Events, Comp=Complications, Rev=Review, Meta-Anal=Meta-Analysis, PLF=Posterior Lumbar Fusion, LSS=Lumbar Spinal Stenosis, Stat=Statistical Evaluation, ASD=Adjacent Segment Disease, JOA=Japanese Orthopedic Association Score, Short=Shorter, OT=Operating Time, D=Days, F/O=Follow-Up, Sig=Significant, ROM=Range of Motion, Reop=Reoperation Rate Diff=Rate Differences, Biomech=Biomechanical, Nl=Normal, CT=Cat Scan, Eval=Evaluations, Flex=Flexion, Ext=Extension, Lat=Lateral, Rot=Rotation, ROM=Range of Motion, IDP=Intradiscal Pressure, FJF=Facet Joint Force, AL=Adjacent Levels, IV=In Vivo, Def=Deformation, Indep=Independent, CF=Compressive Force, MLC=Maximum Load Change, N=Nuton (Measure Force), Max=Maximum AvgL=Average Loads, SP=Spinous Process, Lam=Lamina, PSRF=Pedicle Screw-Rod Fixation, M=Males, F=Females, Esp=Especially, Retro=Retrospective, Min=Minimum, Mos=Months, Imp=Improvement, Postop=Postoperatively, IFH=Intervertebral Foramen Height, ISH=Intervertebral Space height , IPD=Interspinous Process Devices, LBP=Low Back Pain, RLE=Right Lower Extremity Pain, Preop=Preoperatively, CEC=Cauda Equina Compression, LLam=Lumbar Laminectomy, Fac=Facetectomy, IBF=Interbody Fusion, LDD=Lumbar Degenerative Disease, PLIF=Posterior Lumbar Interbody Fusion, RCT=Randomized Controlled Studies, Sup=Superior, Inf=Inferior, SF-36=Short Form 36, FH=Foraminal Height, Sag Angle=Sagittal Angle, MPa=: MegaPascal: A basic unit of pressure or tension measurement in the International System of Weights and Measures Sx=Symptoms, X-STOP (Titanium/PEEK)=Medtronic, Lanx Aspen=Lanx Inc. Broomfield, CO, USA), DS=Grade I Degenerative Spondylolisthesis, SP=Spinous Process, yo=Year Old, mos=Months, DecFus=Decompression/Fusion, ASD=Adjacent Level Disease, PLF=Posterolateral Fusion, QUALY=Quality Adjusted Life Years

Table 2: List of interspinous and interlaminar stabilization and distraction devices.

Device name	Manufacturer
Aperius "PercLID" system	Medtronic (Minneapolis, MN, USA)
Coflex® Interlaminar stabilization device (Next Generation)	Xtant Medical (Belgrade, MT, USA)
DIAM Spine Stabilization System (Former Aperius PercLID Medtronic, Memphis, TN) (Current)	Medtronic Sofamor Danek (Minneapolis, MN, USA)
Falena® Interspinous Decompression Device	Mikai Spine (Genova, Italy)
Flexus	Globus Medical (Audubon, PA, USA)
Helifix® Interspinous Spacer System (Next Generation)	Alphatec Spine® (Carlsbad, CA, USA)
In-space (Next Generation)	Synthes® (DepuySynthes) (West Chester, PA, USA)
NL-Prow Interspinous Spacer	Non-Linear Technologies (North Andover, MA, USA)
Stenofix	Synthes® DepuySynthes (West Chester, PA, USA)
Superion® Indirect Decompression System (Next Generation)	Vertiflex, Inc. (San Clemente, CA, USA)
Wallis® System (Original/Current) (Formerly Abbott Spine Austin TX, USA 1986)	Zimmer Spine (Warsaw, Indiana, USA)
X-STOP® Titanium (Current) (Formerly Kyphon, Sunnyvale, CA)	Kyphon/Medtronic Spine Minneapolis, MN, USA
X-STOP® Peek (Polyetheretherketone) (Current)	Medtronic (Minneapolis, MN, USA)
BakFuse® Regeneration Technologies	RTI Surgical® (Alachua, FL, USA)
Lanx Aspen	Lanx Inc. (Broomfield, CO USA)

of ISD included; the original (i.e., Wallis), current (i.e., X-STOP, Wallis, DIAM, Aperius PercLID), and new generation (i.e., Coflex, Superion Helifix, In-Space) ISD. Biomechanically, ISD devices were designed to; "off-load" the pressure on the disc space, increase intervertebral foraminal/disc space height, reversed/preserve the lumbar lordosis, limit range of motion (ROM)/stabilize the index surgical level, and decrease the incidence of adjacent segment disease (ASD). We also reviewed the literature regarding additional reported benefits; reduced operative times (OR Time), shorter lengths of stay (LOS), decreased estimated blood loss (EBL), fewer reoperations, lesser perioperative/postoperative costs, and comparable vs. improved outcomes (i.e., ODI (Oswestry Disability Index), VAS (Visual Analog Scale), and/or SF-36 (Short Form-36).

Biomechanically, ISD Enhance Stability at the Index Surgical Level with Reduction of ASD

Five biomechanical studies using surgical fusion models documented the efficacy of different ISD devices in reducing ROM at the index and adjacent surgical levels [Tables 1 and 2].[1,4,5,10,12] In 6 human cadavers, Hirsch *et al.* (2015) evaluated foraminal surface areas in flexion/extension (i.e., using a spinal loading frame, testing flexion/extension from 0-10 Nm, marking L34, L45, and L5S1 foramina, employing Stereoscopic 3D images before/after implants) placed in In-space, X-STOP, DIAM, and Wallis ISD at L45; "All four devices significantly opened the L45 foramen in extension", but for the X-Stop(®) and In-space(®) devices the;"... L4-L5 foramen opened not only in extension but also in flexion and the neutral position."[5] Using six human male cadaver biomechanical models, Che *et al.* (2016) studied 1-level rigid fixation with kinematics/intradiscal pressure recordings with 3-dimensional motion/applied loads in flexion-extension, lateral bending, and axial rotation.[1] They found that L4-L5 pedicle screw-rod fixation (PSRF)/L3-L4 Coflex devices stabilized both levels, while the PSRF at L4-L5 stabilized L4-L5, but increased L3-L4 ROM; they concluded that future Coflex devices could fuse index surgical levels, and reduce the frequency of ASD [Tables 1 and 2].[1] In 2019, Shen *et al.* performed a "biomechanical analysis" (i.e., "finite element study") of "intradiscal pressure (IDP) and facet joint force (FJF)" using 4 ISD devices (i.e., Coflex-F, DIAM, Wallis, and Pedicle Screws) placed at L3-L4; all ISD significantly decreased ROM at the index surgical level in flexion/extension, but exhibited "little influence" in torsion/lateral bending.[12] Notably, the Coflex-F device; "...showed advantages in stabilizing the surgical level..." and demonstrated a greater reduction of ASD vs. Wallis and DIAM devices. Guo *et al.* in 2022 looked at 4 CT-derived radiographic studies (i.e., including "flexion, extension, lateral bending, and rotation for normal lumbar CT, mild degenerated lumbar segment, Coflex, and X-Stop fixed lumbar segments) to; ".compare ROM, intradiscal pressure, facet joint force, maximum Von Mises stress, and peak facet contact forces.[4] They found; "Coflex and X-STOP devices can effectively decrease the ROM and intradiscal pressure in extension, without affecting the adjacent levels" [Tables 1 and 2]. In the same year, Liu *et al.* (2022) performed a biomechanical analysis in flexion, extension, lateral bending/axial rotation, and ROM with CT images of LSS utilizing four finite element (FE) models from L3-S5 (i.e., including the intact lumbar spine, and BacFuse, X-Stop and Coflex ISD devices); although all 3 ISD decreased ROM in extension, the BacFuse ISD further increased cephalad stress, the Coflex ISD increased distal stress, and the X-STOP ISD placed maximal stress at the index/surgical levels.[10]

Treatment of LSS: Efficacy and Outcomes for Different ISD Devices vs. Open Surgery

For LSS, Efficacy and Outcomes of Different ISD Devices vs. No Surgery vs. Open Surgery

Multiple ISD devices used to treat LSS improved clinical outcomes [Tables 1 and 2].[6,8,14] Trautwein *et al*. (2010) assessed the neutral, flexion, and extension X-rays for 176 patients undergoing Coflex placement for LSS; they observed extremely rare Coflex "fatigue failure."[14] Kabir *et al*. (2010) found that X-STOP, Coflex, Wallis, and DIAM ISD devices improved clinical outcomes vs. poorer results seen for patients not undergoing any surgery.[6] In 10 studies, Li *et al*. (2017) found that new-generation Coflex ISD yielded better ODI but comparable VAS outcomes, shorter LOS, greater reductions in EBL, and fewer complications vs. patients having open decompressions and/or fusions.[8]

For LSS, Improved Efficacy and Outcomes of Decompressions/ Coflex ISD Alone or vs. Decompressions Alone

Two series focused on the improved efficacy and outcomes for patients undergoing decompressions/Coflex ISD placement for LSS alone or vs. decompressions only [Tables 1 and 2].[2,7] For a non-randomized series of LSS patients, Kumar *et al*. (2014) found better postoperative outcomes (ODI, VAS, SF-36) at six months, one year, and two years following decompressions/Coflex ISD (22 patients) placement vs. decompressions alone (24 patients; outcomes still improved but inferior to Coflex results). Further, outcomes in both patient groups did not directly correlate with improved radiological parameters (i.e., disc/foraminal height sagittal angle).[7] For 56 patients with LSS managed with decompression/Coflex ISD alone, Du *et al*. (2020) found postoperative outcomes at six months and nearly nine postoperative years (i.e., without intervening spinal/epidural injections or physical therapy) showed nearly comparable maintained improvement (i.e., VAS, ODI, JOA scores); over this interval there was just a slight increase in ROM at the index and adjacent levels, with only mild decreases in intervertebral disc space and foraminal height.[2] Additionally, there were only 11 overlapping complications ((19.6%): 1 surgery-related, one hematoma, one infection, one dural tear, two restenosis, one ectopic ossification, one osteolysis, one fracture, four loosening/shedding displacement, 6 ASD), with just 6 requiring reoperations (10.7%: 2 for recurrent stenosis, and 4 for ASD).

For LSS, Improved Efficacy and Outcomes of Decompressions/ Coflex ISD Alone or vs. Decompressions Alone

For LSS, four studies documented better or similar outcomes for decompressions/Coflex ISD procedures but greater reductions in perioperative factors vs. PLIF and vs. decompressions alone [Tables 1 and 2].[3,5,9,11,14] Yuan *et al*. (2017) evaluated the 5-year clinical/radiological outcomes for 87 consecutive non-randomized or "clinically segregated" (i.e., selected/chosen) LSS patients undergoing decompressions/Coflex ISD (42 patients) vs. PLIF (45 patients) procedures.[15] Although both groups demonstrated comparable improvement on ODI and VAS outcome scales, decompression/Coflex devices showed greater reductions in EBL, LOS, operative times, and ROM (more significantly reduced with Coflex vs. PLIF procedures) and no increase in ASD vs. PLIF (i.e., likely due to the Coflex ISD "softer and less stiff" biomechanical construct). Also in 2017, Pintauro *et al*. compared outcomes in 37 studies using original (i.e., Wallis), current (i.e., X-STOP, Wallis, DIAM, Aperius PercLID), and next generation (i.e., Coflex, Superion Helifix, In-Space) ISD devices; at two postoperative years clinical outcomes for all devices were comparable, but next-generation ISD required just a 3.7% incidence of reoperations vs. 11.1% for original/current devices.[11] In 2020, Fan and Zhu (2020) identified 946 patients in 10 LSS RCTs (Randomized Controlled Studies) who underwent decompressions/ Coflex ISD vs. PLIF vs. decompressions alone; although they all demonstrated improved outcomes, Coflex and PLIF patients had better VAS scores vs. decompressions alone, and Coflex patients alone sustained fewer complications vs. PLIF patients.[3] Li *et al*. (2023), in a meta-analysis of 26 LSS articles, showed decompressions/Coflex ISD reduced operative times, EBL, ASD, LOS, and complication rates but showed comparable long-term JOA, VAS, ODI outcomes vs. PLIF; these findings inferred potential cost-savings for utilizing Coflex ISD.[9]

Greater Cost Savings for Decompression/Coflex ISD vs. Instrumented Posterolateral Lumbar Fusions (PLF) for Treating LSS

The study by Schmier *et al*. focused on the cost savings for decompression/Coflex ISD vs. instrumented posterolateral lumbar fusions (PLF) for treating LSS [Tables 1 and 2].[13] "(*In a)*...randomized, controlled, multicenter US Food and Drug Administration Investigational Device Exemption clinical trial...", they documented the efficacy, outcomes (i.e., QALY: quality-adjusted life years), and reduced costs for performing decompression/Coflex procedures vs. instrumented posterolateral fusions (PLF). At five postoperative years, the average Medicare payments for decompression/Coflex ISD was $15,182 vs. a substantially higher $26,863 for those undergoing PLF (i.e., a cost savings of $11,681), and patients experienced higher "...mean quality-adjusted life years (i.e., 3.02 vs. 2.97)", which equated with greater "utility."

CONCLUSION

For treating LSS, different ISD devices (i.e., original, current, and new generation) resulted in comparable or better outcomes vs. open surgery (i.e., laminectomy/decompressions, PLIF, instrumented PLF) or no surgery, but newer generation devices often demonstrated greater reductions in EBL, LOS, OR time, index-level ROM, ASD, reoperation rates, and increased cost savings.

Ethical approval

Institutional Review Board approval is not required.

Declaration of patient consent

Patient's consent not required as there are no patients in this study.

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Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of Artificial Intelligence (AI)-Assisted Technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

REFERENCES

1. Che W, Chen Q, Ma YQ, Jiang YQ, Yuan W, Zhou XG, *et al.* Single-level rigid fixation combined with coflex: A biomechanical study. Med Sci Monit 2016;22:1022-7.
2. Du MR, Wei FL, Zhu KL, Song RM, Huan Y, Jia B, *et al.* Coflex interspinous process dynamic stabilization for lumbar spinal stenosis: Long-term follow-up. J Clin Neurosci 2020;81:462-8.
3. Fan Y, Zhu L. Decompression alone versus fusion and Coflex in the treatment of lumbar degenerative disease: A network meta-analysis. Medicine (Baltimore) 2020;99:e19457.
4. Guo Z, Liu G, Wang L, Zhao Y, Zhao Y, Lu S, *et al.* Biomechanical effect of Coflex and X-STOP spacers on the lumbar spine: A finite element analysis. Am J Transl Res 2022;14:5155-63.
5. Hirsch C, Breque C, Ragot S, Pascal-Mousselard H, Richer JP, Scepi M, *et al.* Biomechanical study of dynamic changes in L4-L5 foramen surface area in flexion and extension after implantation of four interspinous process devices. Orthop Traumatol Surg Res 2015;101:215-9.
6. Kabir SM, Gupta SR, Casey AT. Lumbar interspinous spacers: A systematic review of clinical and biomechanical evidence. Spine (Phila Pa 1976) 2010;35:E1499-506.
7. Kumar N, Shah SM, Ng YH, Pannierselvam VK, Dasde S, Shen L. Role of coflex as an adjunct to decompression for symptomatic lumbar spinal stenosis. Asian Spine J 2014;8:161-9.
8. Li AM, Li X, Yang Z. Decompression and coflex interlaminar stabilisation compared with conventional surgical procedures for lumbar spinal stenosis: A systematic review and meta-analysis. Int J Surg 2017;40:60-7.
9. Li T, Yan J, Ren Q, Hu J, Wang F, Liu X. Efficacy and safety of lumbar dynamic stabilization device coflex for lumbar spinal stenosis: A systematic review and meta-analysis. World Neurosurg 2023;170:7-20.
10. Liu Z, Zhang S, Li J, Tang H. Biomechanical comparison of different interspinous process devices in the treatment of lumbar spinal stenosis: A finite element analysis. BMC Musculoskelet Disord 2022;23:585.
11. Pintauro M, Duffy A, Vahedi P, Rymarczuk G, Heller J. Interspinous implants: Are the new implants better than the last generation? A review. Curr Rev Musculoskelet Med 2017;10:189-98.
12. Shen H, Fogel GR, Zhu J, Liao Z, Liu W. Biomechanical analysis of different lumbar interspinous process devices: A finite element study. World Neurosurg 2019;127:e1112-9.
13. Schmier JK, Halevi M, Maislin G, Ong K. Comparative cost effectiveness of Coflex® interlaminar stabilization versus instrumented posterolateral lumbar fusion for the treatment of lumbar spinal stenosis and spondylolisthesis. Clinicoecon Outcomes Res 2014;6:125-31.
14. Trautwein FT, Lowery GL, Wharton ND, Hipp JA, Chomiak RJ. Determination of the *in vivo* posterior loading environment of the Coflex interlaminar-interspinous implant. Spine J 2010;10:244-51.
15. Yuan W, Su QJ, Liu T, Yang JC, Kang N, Guan L, *et al.* Evaluation of Coflex interspinous stabilization following decompression compared with decompression and posterior lumbar interbody fusion for the treatment of lumbar degenerative disease: A minimum 5-year follow-up study. J Clin Neurosci 2017;35:24-9.

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