APPENDIXES

APPENDIX A – MEDLINE Search Strategy

Database: Ovid MEDLINE(R) <1966 to August Week 1 2006>
Search Strategy:
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1 exp spinal fusion/ (9927)
2 exp laminectomy/ (5593)
3 ((spine$ or spinal) adj4 decompres$).mp. (1222)
4 laminotomy.mp. (231)
5 laminoplasty.mp. (370)
6 (pedicle adj4 screw).mp. (892)
7 intervertebral.mp. (18324)
8 (lumbar adj4 vertebra$).mp. (26722)
9 cauda equina/ (2257)
10 (facet adj4 fusion).mp. (58)
11 spondylolysis.mp. (977)
12 spondylosis.mp. (1464)
13 exp spondylolisthesis/ (2717)
14 (lateral adj4 mass).mp. (698)
15 (anterior adj4 fusion).mp. (2122)
16 (posterior adj4 fusion).mp. (2034)
17 exp intervertebral disk displacement/ (10720)
18 exp bone transplantation/ (17435)
19 (bone adj4 graft).mp. (7171)
20 (fixation adj4 (spine$ or spinal)).mp. (858)
21 (stabilis$ adj4 (spine$ or spinal)).mp. (130)
22 (pedicle adj4 fusion).mp. (141)
23 exp back pain/ (17790)
24 exp low back pain/ (7274)
25 exp lumbar vertebrae/ (25034)
26 degenerat$.mp. (109202)
27 (spine$ or spinal or disc or discs or disk or disks).mp. [mp=title, original title, abstract, name of substance word, subject heading word] (284878)
28 exp spinal osteophytosis/ (3041)
29 19 and 27 (1213)
30 20 and 27 (858)
31 26 and 27 (13404)
32 (spinal adj4 stenosis).mp. (3282)
33 foraminotomy.mp. (154)
34 ((foramen$ or foramina$) adj4 stenosis).mp. (208)
35 (lumbar adj4 body).mp. (814)
36 (vertebra$ adj4 body).mp. (4197)
37 ((spine$ or spinal or disc or discs or disk or disks) adj4 body).mp. (1541)
38 (lumbar adj4 vertebra$ adj4 body).mp. (295)

39 plif.mp. (154)
40 graf.mp. (251)
41 ligamentotaxis.mp. (64)
42 (cage adj4 fusion).mp. (174)
43 (screw adj4 fusion).mp. (182)
44 (pedicle adj4 screw).mp. (892)
45 exp surgery/ (22474)
46 or/1-18,21-25,28-44 (95148)
47 or/1-18,21-25,28-45 (117596)
48 (2004$ or 2005$ or 2006$).ed. (1671558)
49 46 and 48 (13706)
50 randomized controlled trial.pt. (231998)
51 controlled clinical trial.pt. (74618)
52 Randomized Controlled Trials/ (47473)
53 Random Allocation/ (58452)
54 Double-Blind Method/ (90193)
55 Single-Blind Method/ (10492)
56 or/50-55 (393703)
57 Animal/ not Human/ (3080358)
58 56 not 57 (371207)
59 clinical trial.pt. (455245)
60 exp Clinical Trials/ (193020)
61 (clinic$ adj25 trial$).tw. (127830)
62 ((singl$ or doubl$ or trebl$ or tripl$) adj (mask$ or blind$)).tw. (86315)
63 Placebos/ (25562)
64 placebo$.tw. (99866)
65 random$.tw. (364437)
66 Research Design/ (45621)
67 (latin adj square).tw. (2311)
68 or/59-67 (842979)
69 68 not 57 (783464)
70 69 not 58 (426942)
71 Comparative Study/ (1337598)
72 exp Evaluation Studies/ (591986)
73 Follow-Up Studies/ (336557)
74 Prospective Studies/ (216934)
75 (control$ or prospectiv$ or volunteer$).tw. (1738970)
76 Cross-Over Studies/ (18802)
77 or/71-76 (3448879)
78 77 not 57 (2662227)
79 78 not (58 or 70) (2108687)
80 58 or 70 or 79 (2906836)
81 49 and 80 (5557)
82 49 and 58 (1003)
83 or/1,15-16,20-22,42-44 (11651)
84 83 and 48 (2189)

85 80 and 84 (1060)
86 limit 85 to humans (1051)
87 limit 86 to english language (946)
88 limit 87 to abstracts (903)
89 su.fs. (1085251)
*90 88 and 89 (806)
*91 limit 84 to (english language and "review articles") (273)

APPENDIX B (Evidence Table)

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
Agazzi 1999[1]	**Age:** NR **Gender:** 42 men; 29 women **Total N =** 71 **Diagnostic subgroups:** Chronic mechanical low back pain	**Posterior Approach:** Posterolateral gutter fusion surgery **Length of Follow Up:** Median 28 mos	**Short term outcomes:** Other 9 complications: 7 neurological (6 radicular pain, 1 radial palsy due to positioning during surgery), 2 minor (dural tears) **Long term results:** Other Prolo scale: 39% of patients excellent or good results 46% resumed work Clinical outcomes and return to work related to socioeconomic status (p=0.001), and length of preoperative sick leave (p=0.01). Radiographic fusion was not related to clinical outcome **Radiographic evidence of fusion:** Fusion rate 90%.	Patients continue to experience incapacitating pain despite successful fusion and neurological recovery.
Aiki 2005[2]	**Age:** 51 yrs (16-75) **Gender:** 59 men; 58 women **Total N =** 117 **Diagnostic subgroups:** DDDsp = 44 DDDsc = 2 DDDu = 11 DDDn = 1 SIS = 54 Src = 15	**Posterior Approach:** Posterolateral fusion surgery 116 pts Instrumentation used in 86 pts (pedicle screws 61; wire/rod 25) **Comparison or controls (if any):** None **Length of Follow Up:** NR	**Short term outcomes:** NR **Long term results:** Reoperation 9 (7.7%) **Radiographic evidence of fusion:** 100%	INCLUDED in ASD summary table

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Bertagnoli 2005[3]	**Age:** 47.5 yrs (36-60) **Gender:** 47 men; 57 women **Total N =** 118 **Diagnostic subgroups:** DDDs = 118 (62 had prior partial nucleotomy surgery)	**Comparison or controls (if any):** Other (non-fusion) surgical PRODISC total disc arthroplasty **Length of Follow Up:** 31 mo (range, 24-45)	**Short term outcomes:** Other morbidity No device-related AE or additional procedures were necessary. 2 retroperitoneal hematoma required surgical decompression; 1 subcutaneous hematoma 1 retrograde ejaculation 1 persistent leg pain that required exploration and decompression at L5-S1 **Long term results:** Acceleration of adjacent area disease Pain-back Preop 3mo 6 mo 12mo 24mo Reg 84.6%->11.6%->14.8%->11.9%->9% Occ 15.3%->67.0%->62.4%->59.4%->59.2% Pain-radicular Reg 42.6%->10.3%->11.0%->13.2%->8.8% Occ 45.5%->36.1%->28.6%->41.6%->29.5% Narcotic use Regular 15.8% preop-> 8.9% 24 mo Occasional 0% preop->0.1% 24 mo Other ODI 53% preop-> 29% 24 mo Significant decrease in ODI at 3 mo; no significant change from 3 mo to 24 mo. **Radiographic evidence of fusion:** NR	PRODISC TDA was associated with reduced pain and disability among patients with single level DDD
Bezer 2004[4]	**Age:** NR	**Posterior Approach:** Posterolateral gutter fusion surgery	**Short term outcomes:** Pain	Intrafascial posterior bone-graft harvesting resulted in less

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	Gender: NR **Total N =** 117 **Diagnostic subgroups:** DDD = all	With iliac bone graft and instrumentation Randomized comparison of traditional posterior bone-graft harvesting versus intrafascial posterior bone-graft harvesting **Comparison or controls (if any):** No surgery Conservative treatment Other (non-fusion) surgical **Length of Follow Up:** NR	Post op VAS pain score at donor site 2 (0-6) versus 0.25 (0-4) (p<0.0001) **Long term results:** NR **Radiographic evidence of fusion:** NR	postoperative pain than traditional posterior gone-graft harvesting. No outcomes related to the lumbar fusion were reported.
Block 2001[5]	**Age:** 41.8 yrs (21 – 72) **Gender:** 100 men, 104 women **Total N =** 86 (fusion) 118 laminectomy/disc **Diagnostic subgroups:** Src = 96 (47%) Degenerative spine conditions (including disc-related pain and spondylolisthesis), disc herniation, postlaminectomy syndrome, and pseudoarthrosis.	**Spinal fusion approach:** NR (presumably posterior) **Length of Follow Up:** 8.6 mo	**Short term outcomes:** NR **Long term results:** Acceleration of adjacent area disease Pain VAS 6.8 pre->5.2 post (p<0.001) Narcotic use 135 pts pre-> 110 pt post(<0.001) Other ODI 67.9 pre-> 53.5 post (p<0.001) **Radiographic evidence of fusion:** NR	Presurgical psychological screening were related to outcomes with poorest results obtained by patients having high psychological and/or medical risk. Comments Pt population were pt referred by orthopedic surgeons for psychosocial screening No f/u data could be obtained on 55 subjects (21% of total operated subjects) Results lump spinal fusion with laminectomy/discectomy pts; however a subgroup analysis found no difference by type of surgery.
Blumenthal 2003[6]	**Age:** (18 - 60) yrs **Gender:** NR **Total N =**	**Anterior Approach:** Link SB Charite disc replacement device **Comparison or controls (if any):** None	**Short term outcomes:** Pain VAS pain pre-op 70; 6-wk 33; 3-mo 35 Oswestry score: preop 53; 6-wk 32; 3-mo 27	

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	57 **Diagnostic subgroups:** DDDs = 57	**Length of Follow Up:** 12 mo	**Long term results:** Pain VAS pain: 6-mo 28; 12-mo 31 Oswestry score: 6-mo 23; 12-mo 22 **Radiographic evidence of fusion:** NR	
Blumenthal 2005[7]	**Age:** 39.6 yrs (19 - 60) **Gender:** **157 men,** 147 women **Total N =** 304 **Diagnostic subgroups:** DDDs = 100% (34% had prior nonfusion back surgery)	**Anterior Approach:** ALIF with BAK threaded fusion cages Versus Total disc replacement with Charite artificial disc **Length of Follow Up:** 24 mos	**Short term outcomes:** Pain VAS pre 6 wk 3 mo TDR 72->36.4->35.7 ALIF 72->43.9->40.4 P 0.022 0.017 Donor site pain 18.2% ALIF pts Other Device failures 5.4% TDR; 9.1% ALIF ODI pre TDR 50.6->37.7->29.9 ALIF 52.1->43.7->37.4 P 0.0198 0.0014 **Long term results:** Pain VAS pre 6 mo 12 mo 24 mo TDR 72->33.1->32.9->31.2 ALIF 72->43.9->40.4->37.5 P 0.004 0.042 0.107 Other ODI pre TDR 50.6->27.5->26.0->26.3 ALIF 52.1->35.8->31.8->30.5 P 0.002 0.039 0.267 **Radiographic evidence of fusion:** NR	TDR (Charite artificial disc) outcomes are equivalent to ALIF Further details on complications in Geisler et al (neurological) Holt et al McAfee et al Two center data previously reported in Guyer et al 2004
Brantigan 2000[8]	**Age:** 44.3 ± 11.7 yrs (24 - 77) **Gender:** 126 men; 95 women	**Posterior Approach:** PLIF using Brantigan I/F cage and pedicle screw fixation using Variable Screw Placement System (VSP)	**Short term outcomes:** Mortality – 2 intraoperative deaths; 2 suicide; 2 after discharge of unrelated medical causes Infections	Study was large, done to satisfy FDA, reasonably well designed, but uncontrolled.. Outcome measures are not common.

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
	Total N = 221 **Diagnostic subgroups:** DDDsp = 51 DDDs = 110 (recurrent disc disease) Src = 60 failed fusion	**Comparison or controls (if any):** None **Length of Follow Up:** NR	8 deep, requiring reoperation Other morbidity No major device-related complications 30 (13.5%) minor device-related complications 23 major non-device-related, including 6 deaths, 2 DVT, 3 RSD, 3 motor deficits, 1 MI 29 minor non-device-related complications 58 insignificant events including 41 intraop dural penetrations, repaired at surgery **Long term results:** Pain (5 point Likert scale – higher is better) Pre 1mo 3mo 6mo 12mo 24mo 48mo 2.0->3.3->3.7->3.7->3.7->3.8->4.1 **Radiographic evidence of fusion:** 176 (98.9%) In pts with prior failed discectomy 91 (100%)	
Brau 2004[9]	**Age:** (18 – 84) yrs **Gender:** 643 men; 667 women **Total N =** 1,310 **Diagnostic subgroups:** NR	**Anterior Approach:** ALIF Or Total disk replacement **Comparison or controls (if any):** NR **Length of Follow Up:** NR	**Short term outcomes:** Other morbidity Iliac a. thrombosis 6 (0.45%) Major v. laceration 19 (1.4%) **Long term results:** NR **Radiographic evidence of fusion:** NR	The incidence of vascular injury is relatively low 1.9% (25/1310) in anterior lumbar surgery.
Brox 2003[10]	**Age:** 43.3 yrs. (25-60)	**Posterior Approach:** Fusion with posterior transpedicular screw and physiotherapy	**Short term outcomes:** NR	There was equal improvement in patients with chronic low back pain and disk degeneration randomized to

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
	Gender: 37% men, 63% women **Total N =** 64 **Diagnostic subgroups:** DDDs = 64 (chronic low back pain and disc degeneration)	**Comparison or controls (if any):** Conservative treatment: Cognitive intervention and exercises **Length of Follow Up:** 1 yr.	**Long term results:** For all results: Fusion / cognitive intervention ODI: change from 41 to 26/ 42 to 30 (p=0.33) **Radiographic evidence of fusion:** NR	cognitive intervention and exercises, or lumbar fusion.
Brox 2006[11]	**Age:** 43 yrs (35-50) **Gender:** 31 men, 29 women **Total N =** 60 **Diagnostic subgroups:** DDDs = 100% (all had previous discectomy for HNP)	**Posterior Approach:** Posterolateral fusion surgery With pedicle fixation **Comparison or controls (if any):** Conservative treatment – cognitive intervention and exercises (25 hr/wk x 3 wk **Length of Follow Up:** 1 yr	**Short term outcomes:** NR **Long term results:** Pain Fusion 64.6 ± 15.4->50.7± 27.3 Cog/ex 64.7± 11.1->49.5± 20.0 P=0.42 Other ODI both groups improved 47± 9.4->38.1± 20.1 (p=0.023) fusion; 45.1± 9.1->32.3± 19.1 cog/exer (NSD between groups) **Radiographic evidence of fusion:** NR	No difference in ODI or back pain between lumbar fusion and cognitive and exercise intervention after 1 year.
Burkus 2002[12]	**Age:** 42.8 yrs **Gender:** 146 men; 133 women **Total N =** 279 **Diagnostic subgroups:** DDDs = 279	**Anterior Approach:** ALIF with LT-CAGE Lumbar tapered fusion device. rHBMP-2 versus ALIF with autogenous iliac crest bone graft (control) **Length of Follow Up:** 24 mos	**Short term outcomes:** Other morbidity Mean operative time: 1.6 hrs vs 2 hrs days in control gp. Av. Blood loss; 109.3 mL.vs .8 mL days in control gp. Av hospital stay 3.1 vs 3.3 days in control gp. Complications 6 vs 5 in control gp – 6/11 were iliac vein laceration, 2 control gp developed DVT. 6 male patients (6/146) developed retrograde ejaculation In control gp: 8 events related to donor site.	Lumbar fusion using rhBMP-2 and a tapered titanium fusion cage can yield a solid fusion and eliminate the need for harvesting iliac crest bone graft.

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			Long term results: Other ODI preop 12mo 24 mos Inv 53.7 25.5 23.9 Con 55.1 25.6 23.8 Overall neurologic success rate was 81.8% and 82.8% at 12 mos. ad 24 mos. respectively. For control gp. The scores were 84.7% and 83.3%. Mean back pain scores improved in both gps, but were significantly greater for investigational gp. Back pain success (at least 3 point improvement): At 12 mos and 24 mos. 79.1% and 74.6% respectively, 72.8% and 78.7% for control gp. Mean leg pain scores improved in both gps, but were significantly greater for investigational gp. Leg pain success rates: At 12 mos and 24 mos. 72.1% and 72.8% respectively, 80.3% and 74.1% for control gp. At 24 mos. 81.2% of investigation and 80.4% of controls were satisfied with their procedures. **Radiographic evidence of fusion:** Plain radiographs and CTs: AT 6 mos.: 97% had evidence of fusion vs 95.8% of controls. AT 12 mos. this was 96.9% vs 92.5%. At 24 mos. 94.5% vs 88.7% showed fusion. 7% in invest. Gp and 10.3% in control gp. Had second surgeries.	
Burkus 2002[13]	**Age:** 43 yrs (19 – 68) **Gender:**	**Anterior Approach:** ALIF with threaded cortical allograft dowels with InFUSE Bone Graft (rhBMP-2)	**Short term outcomes:** Pain-back Pre 6wk 3mo rhBMP 16.3-> 8.9-> 7.9	rhBMMP-2 group had greater improvements in Oswestry scores ($p<0.05$ at 3,6,24mo)

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	18 men; 28 women **Total N =** 46 **Diagnostic subgroups:** NR	versus autogenous iliac crest bone graft **Length of Follow Up:** NR	control 16.3->10.4->10.9 Pain-leg rhBMP 12.8-> 7.0-> 6.2 control 14.6-> 8.8-> 8.3 Other ODI rhBMP 52.4->39.9->29.0 control 55.3->47.2->42.0 **Long term results:** Pain-back Pre 6mo 1yr 2yr rhBMP 16.3->6.8->7.4->7.4 control 16.3->99->9.2->10.9 Pain – leg rhBMP 12.8-> 5.0-> 5.5-> 6.3 control 14.6-> 6.1-> 8.1->11.5 Other ODI rhBMP 52.4->21.4->20.8->18.9 control 55.3->34.4->30.0->32.8 **Radiographic evidence of fusion:** 6 mos: 90.5% versus 65% (p=0.067) 12 mos: 100% versus 89.5% (p=NR)	Fusion rates in the rhBMP group were higher than in the control group (p=0.067)
Carreon 2003[14]	**Age:** 72 yrs (65 - 84) **Gender:** 33 men; 65 women **Total N =** 98 **Diagnostic subgroups:** DDDsp = 38 (39%) DDDsc = 13 (13%) SSSa = 93 (95%) [note many of these also had DDDsp or DDDsc]	Posterolateral gutter fusion surgery Decompression and arthrodesis with instrumentation. **Length of Follow Up:** NR	**Short term outcomes: (limited to major complications)** Mortality 2 (2%) Infections Wound 10 (10%) Pneumonia 5 (5%) Other morbidity Renal failure 5(%) Myocardial infarction 3 (3%) Respiratory distress 2 (2%) Neurologic deficit 2 (2%) Congestive heart failure 2 (2%) Cerebrovascular accident 1 (1%) Other Blood loss 679 mL (300-800) Additional data presented on minor complications	Elderly patients are at high risk for major and minor complications.

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			Long term results: NR **Radiographic evidence of fusion:** NR	
Castro 2004[15]	**Age:** 49 ± 2 yrs (SD) **Gender:** 27 men; 57 women **Total N =** 84 **Diagnostic subgroups:** DDDs = 35 + 11 SIS = 1+ 3 SSSa = 15 + 5 Src = 11 +3 (pseudoarthrosis)	**Posterior Approach:** TLIF **Comparison or controls (if any):** Activated growth factor (AGF) gel or not **Length of Follow Up:** NR	**Short term outcomes:** Mortality 1/22; 0/62 Other LOS 5.3 vs 5.1 d **Long term results:** Acceleration of adjacent area disease 0/22; 6/62 Pain Intractable pain 2/22; 7/62 Other Any complication 14/22; 41/62 **Radiographic evidence of fusion:** NR	No benefit to AGF gel was demonstrated. Fusion rate appears to be decreased with AGF gel.
Christensen 2002[16]	**Age:** 45 yrs (20-67) **Gender:** 60 men, 69 women **Total N =** 129 **Diagnostic subgroups:** DDDsp = 41 SIS = 35 Src = 53	**Posterior Approach:** 64 patients- Cotrel- Dubousset supplemented fusion (instrument broke) Compare to 66 patients- non instrumented postero lateral intertransverse fusion (non instrumental) **Length of Follow Up:** 5 yrs	**Short term outcomes:** Other Mean surgical time instrumented 212 minutes Non instrumented 127 minutes (p less than 0.0001) Perioperative blood loss 1639 mL instrumented group 1155 mL non instrumented (p <.01) **Long term results:** Other 21% patients had a second operation- 28% in instrumented group and 14% in non instrumented (p<.03) Improvement seen in both groups in functional outcome between 2 and 5 yr follow up Significant Improvement in functional	The long term outcome: functional outcome of postero lateral spinal fusion improved significantly for both those with and without pedicle screw instrumentation.

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			outcome in the non instrumental group in categories of work and leisure activities and social concerns No significant differences in lower back pain or leg pain between the two groups 70% in instrumented and 67% in non instrumented group were satisfied with the procedure at 5 yrs. **Radiographic evidence of fusion:** 67% in instrumented 86% non instrumented group should fusion at 1 yr At 2 yrs 79% at instrumented 86% in non instrumented had fusion Median number lordosis in instrumented and non instrumented 40% A significant decrease in lumbar lordosis in instrumental group from preoperative to 1 yr but not significant at 2 yrs No significant change of the lordosis angle in the non instrumented group	
Christensen 2002[17]	**Age:** NR **Gender:** 58 men, 88 women **Total N =** 148 **Diagnostic subgroups:** DDDs = 51 SIS = 53 Src = 52	**Posterior Approach:** Posterolateral lumbar fusion with titanium CD-horizon 73 patients Compare to Circumferential fusion with ALIF Brantigan cage plus instrumentation 75 patients **Comparison or controls (if any):** No surgery Conservative treatment Other (non-fusion) surgical **Length of Follow Up:** 2 yrs	**Short term outcomes:** Other Mean surgical time posterolateral group: 220 minutes Circumferential group: 334 minutes (p<.0001) Perioperative blood loss: 906 mL posterolateral group Post operative day of discharge 15 for posterolateral and 18 for circumferential group. 985 mL Circumferential group 8 perioperative complications in posterolateral group (1 known route injury due to screw misplacement, 1 dura lesion, 2 hematomas, 1 superficial infection, 3 urinary tract	Circumferential conclusion: There was more resources but can restore lordosis and provide a significantly higher union rate with significantly fewer repeat operations, a tendency toward better functional outcome and less pain then posterolateral fusion.

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			infections 13 complications in circumferential group (4 vascular injuries, 3 nerve route injuries because of screw misplacement, 1 hematoma, 1 deep infection, 4 urinary tract infections) 5 patients in circumferential group and 16 in posterolateral group needed a second operation, 3 in posterolateral group needed a second re-operation **Long term results:** Dallas pain questionnaire (DPQ) at two years showed highly significant improvement in all categories (no significant difference between two groups) No significant differences in back pain between two groups at 1 and 2 yr follow up. At one year follow up patients with circumferential fusion had significantly less leg pain, at two yrs no significant difference between the two groups. At 2 yrs, 77% of posterolateral and 79% of circumferential group were satisfied with the procedure. **Radiographic evidence of fusion:** 80% of posterolateral and 92% of circumferential patients had confirmed union ($p<.04$) no difference between the three diagnostic groups regarding fusion rates. A significant increase in lumbar lordosis between preoperative examination and 1 yr follow up in circumferential group ($p<.01$) no change in lordosis angle in posterolateral group. At 2 yr follow up there was a significant correlation between union of fusion mass and functional outcome.	

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Chung 2003[18]	**Age:** 50 yrs (27 - 67) **Gender:** 11 men; 34 women **Total N =** 47 **Diagnostic subgroups:** DDDs = 47	**Anterior Approach:** ALIF Open mini-ALIF versus laparoscopic ALIF of L5-S1 **Comparison or controls (if any):** NR **Length of Follow Up:** Open – 30 mo (24-40) Laparoscopic – 43 mo (36-49)	**Short term outcomes:** Pain laparoscopic open VAS preop 9.1 (5-10) 9.4 (7-10) Postop 4.0 (1-10) 3.7 (1-10) Other Owestry preop 41 (14-68) 43(22-62) Postop 25 (2-62) 23 (0-60) **Long term results:** NR **Radiographic evidence of fusion:** Lap 20/22 (91%) Open 20/22 (91%)	Laparoscopic ALIF at L5-S1 showed similar clinical and radiological outcome compared with open mini-ALIF. However, no important clinical advantages to laparoscopic procedure were observed.
DeBerard 2002[19]	**Age:** 40 yrs (21.7 - 65.4) **Gender:** 73.3% men, 26.7% women **Total N =** 370 **Diagnostic subgroups: Low back pain** DDDs = all	**Posterior Approach:** Posterolateral gutter fusion surgery PLIF (PL) versus ALIF with BAK titanium cage interbody fusion (BAK) **Length of Follow Up:** 5 yr (data collected 2 yr after surgery)	**Short term outcomes:** NR **Long term results:** Other Patient satisfaction: Was better in all categories for BAK sample. Disability status: 24.6% in PL and 18.2% in BAK sample were totally disabled. Roland and Morris questionnaire: 11.4 for PL and 8.79 for BAK gp. Stauffer-Coventry data: No difference in 2 gps. SF-20 data: BAK procedure pts. Perceived better health on 3 subscales. **Radiographic evidence of fusion:** Fusion was achieved in 73% of PI, and 93.5% of BAK sample. Re-operation rates were 23.8% for PL, 14.3% for BAK sample. (p=0.047)	Medical and clinical outcomes for the BAK interbody lumbar fusion are better than posterolateral approaches among injured workers.

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Dehoux 2004[20]	**Age:** 39.5 yrs (14 - 63) **Gender:** 28 men; 22 women **Total N =** 52 **Diagnostic subgroups:** SIS = 52	**Posterior Approach:** Posterolateral gutter fusion surgery using a rigid Cotrel Dubousset construct and autologous bone chips Versus PLIF with rigid Steffee plates system and intersomatic Brantigan carbon cages filled with autologous graft **Length of Follow Up:** 75 – 100 mos	**Short term outcomes:** Other morbidity Epidural hematoma at 15 d (PLF) Impotence 1 pt (PLIF) resolved at 3 mo Pain 2 pts – continued pain required reoperation for hardware removal (PLF) **Long term results:** Acceleration of adjacent area disease 2 pts HNP above fusion level (PLF) **Radiographic evidence of fusion:** PLIF 93% PLF 68%	77% pts had good or very good result with PLIF and 68% with PLF; Fusion rates had not significant influence on functional outcome. The authors suggest that PLIF is useful for high grade spondylolisthesis; otherwise PLF is sufficient.
Deyo 1993[21]	**Age:** 70.2 yrs (59-97) **Gender:** 31% men, 69% women **Total N =** 1524 Medicare pt undergoing fusion from among a total of 27,111 Medicare pts undergoing lumbar spine surgery in 1985 **Diagnostic subgroups:** (primary dx/all dx) DDDsp = -/36.4% DH = 15.8%/22.5% DDDu = -/9.1% DDDs = 13.2%/24.7% SSSa = 38.7%/53% Src = -/10.9%	**Various procedures** **Comparison or controls (if any):** No surgery Conservative treatment Other (non-fusion) surgical **Length of Follow Up:** NR	**Short term outcomes:** Mortality any disc lam fus Fusion 1.2%* 1.1% 1.1 1.6 No fus 0.7% 0.6% 0.9 Mortality – spinal stenosis Fusion 1.0%* No fus 0.8% Mortality – spondylolisthesis Fusion 1.3%* No fus 0.4% Infections Other morbidity In hosp complications Fusion 14%* 12.1* 16* 16 No fus 7.7 5.8 9.8 In hosp comps – spinal stenosis Fusion 14.9%* No fusion 9.7% In hosp comps – spondylolisthesis Fusion 13.0% No fusion 7.1% **Long term results:**	Study used diagnostic codes (ICD-9) and procedure codes from administrative databases to identify cases (and exclude cervical or thoracic fusions, infection, trauma, malignancy, etc)

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			Other Reoperations at 1 yr Fusion No fus Reoperations at 2 yr Fusion No fus **Radiographic evidence of fusion:** NR	
Ekman 2005[22]	**Age:** 18-55 yrs **Gender:** 57 men, 54 women **Total N =** 111 **Diagnostic subgroups:** SIS = 100% (L5 of L4)	**Posterior Approach:** Posterolateral gutter fusion surgery With pedicle screws OR PLF with no instrumentation **Comparison or controls (if any):** Conservative treatment – exercise program (1 yr duration) **Length of Follow Up:** 9 yrs	**Long term results:** Pain- Between 2 yr and long-terms f/u pain index worsened in surgery group ($p<0.0001$) but improved in exercise group ($p=0.013$). NSD between groups at long-term f/u Fusion 37->40 Exercise 56->49 Between 2 yrs and long-term f/u ODI showed no significant change, and there was no difference between groups Fusion 26->28 Exercise 28->31 **Radiographic evidence of fusion:** NR	No differences were observed between fusion (instrumented or non-instrumented) and exercise at 2-years in ODI or pain index. Despite this, global outcome was better for fusion group Long term f/u of Moller and Hedlund (2000)
Fairbank 2005[23] **MRC trial**	**Age:** 15% of study pop ≥ 50 years **Gender:** 177 men, 172 women **Total N =** 349 (RCT) **Diagnostic subgroups:** DDDs = 81% SIS = 11% Src = 8% post laminectomy	**Lumbar spinal fusion surgery (n=176) approach at the discretion of surgeon** **Comparison or controls (if any):** Intensive CBT-based rehab program (n=173) **Length of Follow Up:** 24 mo	**Short term outcomes:** Other morbidity Intraoperative complications 19 (dural tear 5; bleeding 4; implant problems 5; bone fx 1; vascular injury 2; loss of fixation 3; broken drain 1; other 3) **Long term results:** Pain (SF-36 subscale) preop 24mo Fusion 28.6±17 48.1±26 Rehab 30.0±16 44.9±25 ($p=0.16$)	ODI improved more with fusion than rehab at 2 years, but the confidence interval excludes a difference of more than 10 points. QOL changes were not significant The authors conclude "No clear evidence that primary spinal fusion surgery is more beneficial than CBT-based intensive rehabilitation" Comments 48 pts randomized to rehab had

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
			QOL – SF-36 Fusion 19.4±9 28.8±15 Rehab 20.0±10 27.6±15 (p=0.21) ODI Fusion 46.5±15 34.0±21 Rehab 44.8±15 36.1±21 (p=0.045) Reoperation 11	surgery by 2yr; 7 pts randomized to surgery had rehab instead
Folman 2003[24]	**Age:** 45.2 ± 13.7 yrs **Gender:** 46 men; 42 women **Total N =** 87 **Diagnostic subgroups:** DDDsp = 87	**Posterior Approach:** Posterolateral gutter fusion surgery PLIF with B-Twin spacer **Length of Follow Up:** Av. 15 mos.	**Short term outcomes:** Other Mean operative time: 148 ±64 min. Mean blood loss: 410 ±U 330 mL. Complications: 2 malpositioned implants (reoperation), 1 migration of implant that had to be removed. **Long term results:** Other Mean disability score decreased from 8.5 to 3.3 (p<0.01). 86% patients at last follow-up visit thought that the procedure was worthwhile. VAS decreased by 60%, ODI decreased by 58% (from 31 to 12.7) **Radiographic evidence of fusion:** Fusion achieved in all but one case. Disc space height averaged 7.53 mm before surgery, 9.47 mm. at final follow-up.	PLIF using the spacer achieves the same outcomes as other methods but does not share the same handicaps and hazards and is more user-friendly to the surgeon.
Food and Drug Administration 2006[25]	**Age:** ~40 yrs **Gender:** 120 men; 122 women randomized 20 men; 30 women non-randomized **Total N =** 212	**Anterior Approach:** Anterior/posterior combined lumbar fusion with femoral ring allograft and posterolateral fusion with autogenous iliac crest bone graft combined with pedicle screw instrumentation (n=80) **Comparison or controls (if any):** Other (non-fusion) surgical PRODISC-L Total Disc Replacement	**Short term outcomes:** Mortality – no deaths Other morbidity Fusion Pro-R Pro-NR All AE 87.5% 84% 82% Device-related 20% 14% 17.9% Device failure 2.5% 2.8% (p=NS)	The PRODISC-L Total Disc Replacement is reasonably safe and effective by demonstrating non-inferiority when comparing Overall Success and adverse event rates to anterior fusion for single-level lumbar DDD. *The overall incidence of AEs in PRODISC-L group was no worse than in the control group.

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
	Diagnostic subgroups: DDDs = 100% (1-level)	(n=162 randomized; 50 non-randomized) **Length of Follow Up:** 24 mo	**Long term results:** Pain VAS – all 3 groups improved compared to baseline; no sig diff betw Prodisc and fusion except at 3 mo time point fusion 73.2±14.5 Prodisc 75.1±16.4 ProdiscNR 72±18 Narcotic use QOL SF-36 success (score improved) fusion 70% Prodisc 79.2% ProdiscNR 89.6% Other ODI success ≥15% improvement ≥15 point Fusion 64.8% 54.9% Prodisc 77.2% 67.8% ProdiscNR 85.4% 75% ODI mean 6wk 3mo 6mo 12mo 18mo 24mo Fusion 41.5->36.4->36.0->35.6->34.7->34.5 Prodisc 49.8->46.6->41.5->40.7->39.8->39.8 p=NR at 24mo **Radiographic evidence of fusion:** NR	*The number of AEs considered to be device-related in the PRODISC-L group was no worse than in the control group. *The Overall Success rate of the PRODISC-L group was no worse than the Overall Success rate of the control group, with a non-inferiority margin of 10% using FDA's criteria for Overall Success, which required all of the following: *improvement of ODI≥ 15% at 24 mo *no re-operation to remove or modify implant or fusion site *improvement in SF-36 score at 24 mo *neurological status improved or maintained *radiographic success Post-approval study to obtain 5-yr f/u data which will also evaluate adjacent segment degeneration and correlation between ROM and ODI and VAS.
Freeman 2000[26]	**Age:** 44 yrs (19 – 69) **Gender:** 36 men; 24 women **Total N =** 60 **Diagnostic subgroups:** DDDs = 28	**Posterior Approach:** PLIF combined with instrumented postero-lateral fusion Interbody fusion included any of autograft, allograft or interbody cages **Comparison or controls (if any):** None **Length of Follow Up:**	**Short term outcomes:** Other morbidity Neurological complication 4 (3 resolved) **Long term results:** Pain - reduction >90% 40 (83%) 50-90% 8 (17%) <50% 0 (0%) Narcotic use	Discussion cites several other series describing PLIF

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
	SIS = 6 SSSa = 10 Src = 8 (post discectomy)	5.3 yrs (range, 1-10)	Regular 2 (4%) Occasional 16 (33%) None 30 (63%) **Radiographic evidence of fusion:** 100%	
Fritzell 2001[27]	**Age:** 43.5 yrs (25 – 65) **Gender:** 49% men, 51% women **Total N =** 294 **Diagnostic subgroups:** DDDsp = 294	**Posterior Approach:** PLF=group 1A=73 PLF+internal fixation device=1B=74 PLF+internal fixation device+interbody bone graft (ALIF or PLIF)=Circumferential= group 1C=75 **Anterior Approach:** Anterior/posterior combined lumbar fusion Anterior lumbar interbody fusion Other **Comparison or controls (if any):** No surgery 72 Conservative treatment Other (non-fusion) surgical **Length of Follow Up:** 2 yrs	**Short term outcomes:** Other 17% in surgical group had an early complication- 9 patients had route pain, 3 deep and 2 superficial infections 2 patients suffered late implant Related infection at 6 and 12 months-implant removed Re-operation in 2 patients **Long term results:** Other At 2 yr follow up- Back and leg pain significantly reduced in surgically treated patients(p=.0002, .005 respectively) ODI- significant decrease in disability in surgical group-Oswestry (p=.015), Million (p=.004) and GFS (p=.005) Depression score significantly reduced in surgical group p<.0001 and non surgical group p=.041, no significant difference between groups Patient rating- result significantly better in surgical group, 63% reported to be improved, in non surgical group 29% improved Independent observer overall assessment- 45% in surgical group were “excellent” or “good”, 58% in non surgical group fell in this group (p=.003) 75% of surgical group and 53% of non surgical group would go through the treatment again	Improvement of pain and disability after surgical fusion was significantly superior to that of the non surgical treatment used.

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
			Radiographic evidence of fusion: 83% of surgical group had a fusion no significant correlation between radiographic fusion and patients rating or improvement in pain and disability.	
Fritzell 2002[28]	**Age:** (25 – 65) yrs **Gender:** NR **Total N =** 201 **Diagnostic subgroups:** DDDs = 100% (L4-S1)	**Posterior Approach:** PLF (non-instrumented) versus PLF+VSP versus PLF+VSP+ALIF/PLIF In gp 3, ALIF (n=56) vs PLIF (n=72)was performed according to the preference of the surgeon **Length of Follow Up:** 2 yrs	**Short term outcomes:** Other Any 5.6% ; 16.2% / 30.6% (p< 0.001 betw 1 & 3) **Long term results:** Pain – reduced significantly in all 3 groups, but increased in all groups between 12 and 24 mo Other ODI – highly significant decrease in all 3 groups, NSD between groups **Radiographic evidence of fusion:** Overall 83%, 72% / 87% and 91% respectively groups 1-3; instrumented vs non-instrumented (p=0.004)	All fusion techniques reduced pain/improved function; the combined interbody and instrumented posterior fusion had a higher compilation rate than non-instrumented fusion.
Fritzell 2003[29]	**Age:** (25 – 65) yrs **Gender:** NR **Total N =** 211 **Diagnostic subgroups:** NR	**Posterior Approach:** 3 surgical techniques- Group 1 Non instrumental posterolateral fusion (PLF, n=71) Group 2 Instrumented posterolateral fusion (VSP, n=68) Group 3 PLF + VSP + Bone graft (“360” n=72) **Comparison or controls (if any):** No surgery Conservative treatment Other (non-fusion) surgical **Length of Follow Up:** NR	**Short term outcomes:** NR **Long term results:** Other At 2 yrs complication rate- PLF=12% VSP=22% “360”= 40% p=.0003 Odds ratio of complication was 5.3 when “360” was used compared to PLF and 2.4 “360” compared with VSP No association between clinical outcome and complications Reintervention rate-6% PLF, 22% VSP, 17% “360” Odds ratio of having a reintervention	Complications increased significantly with increasing technicality of the surgical procedure. No fusion technique reduced superior clinical outcome.

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
			was 4.0 when instrumentation was used compared with non instrumented fusion **Radiographic evidence of fusion:** NR	
Gepstein 2005[30]	**Age:** 50.6 yrs (26 - 72) **Gender:** 36 men, 26 women **Total N =** 62 **Diagnostic subgroups:** DDDs = all	**Posterior Approach:** PLIF with B-Twin expandable spinal spacer (B-Twin ESS) performed percutaneously **Comparison or controls (if any):** Open PLIF with B-Twin expandable spinal spacer (B-Twin ESS) – historical controls **Length of Follow Up:** 29 mo (range, 24-40)	**Short term outcomes:** NR **Long term results:** Pain VAS preop 8.5 ± 1.3 (5.8-9.2) Followup 2.9 ± 1.8 (1.2-6.2) 66% decrease (p< 0.05) Other ODI preop 42.8 ± 6.0 (30-48) Followup 16.6 ± 5.0 (9-20) 61% decrease (p<0.05) **Radiographic evidence of fusion:** NR	Percutaneous PLIF shows comparable clinical outcomes (pain, disability) to open PLIF
Gertzbein 1996[31]	**Age:** 44 yrs (11 - 80) **Gender:** 54% men/ 46% women **Total N =** 82 **Diagnostic subgroups:** DDDs = 44.8% Src = 62%; 21.2% had pseudoarthosis from previous fusions; 25% previously failed fusions.	**Anterior Approach:** Anterior/posterior combined lumbar fusion + FRA + PSF **Comparison or controls (if any):** None **Length of Follow Up:** 2 yrs	**Short term outcomes:** Mortality 1/82 (1%) (pulm emb) Infections Deep 1.2% Other morbidity Hardware failure 4.9% Neurologic deficit 1.2% DVT 4.9% Vascular injury 2.4% **Long term results:** Pain (VAS) Back 7.2->2.1 (p<0.006) Leg 5.8->1.5 (p<0.0001) **Radiographic evidence of fusion:** 65/67 (97%) at 2 yrs	Fusion rate is satisfactory, good pain reduction and return to activity, few clinically important complications. Comments 17% attrition from 1 to 2 yrs No control 25% had previous fusion
Glaser	**Age:**	**Posterior Approach:**	**Short term outcomes:**	Lumbar fusion with pedicle screw

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
2003[32]	45.2 ± 12.5 yrs.(19 - 73) **Gender:** 48 men, 46 women **Total N =** 94 **Diagnostic subgroups:** NR	Pedicle screw fixation **Length of Follow Up:** 12.6 ± 1.6 yrs.	Infections: 8 patients Hardware complications: breakage in 11, loosening in 14 cases Pain Narcotic use: 26% used less, 56% used same, 18% greater (p<0.0002) Other Pain thermometer (n=71): mean 2.91 (sd 1.39) Pain interference (n=74): mean 53.44 (sd 22.15) Modified Roland and Morris (n=74): mean 52.77 (sd 25.67) ADL (n=73) mean 62.05 (sd=26.12) **Long term results:** (10 yrs) Other Pain thermometer (n=71): mean 2.87 (sd 1.09) Pain interference (n=74): mean 58.33 (sd 24.96) Modified Roland and Morris (n=74): mean 64.68 (sd 24.28) ADL (n=73) mean 73.10 (sd=24.45) SF-36: reports of bodily pain and physical functioning below age and gender-adjusted means but disability and function scores showed distinct improvement. Patient satisfaction was 80% **Radiographic evidence of fusion:** 86 of 244 levels were fused, 156 were without motion but equivocal regarding trabeculae and lucency, 2 showed significant motion. Repeat surgery performed for 19% patients Changes in spurring: no significant differences at fusion site.	fixation showed relatively good functional capacity compared to baseline, a low radiographic failure, satisfaction of patients, a low rate of repeat surgeries, and minimal complications.
Glassman 2003[33]	**Age:** ~60 yrs	**Posterior Approach:** Posterolateral fusion surgery with instrumentation	**Short term outcomes:** Other – Complications NIDDM IDDM Control	Patients with diabetes (NIDDM or IDDM) have a significantly increased risk of perioperative complications

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
	Gender: 52 men; 83 women **Total N =** 94 diabetics; 43 controls **Diagnostic subgroups:** NR	**Length of Follow Up:** NR	Tot 53% 56% 21% Major 24% 33% 7% Minor 29% 23% 14% **Long term results:** Other – Revision rate NIDDM IDDM Control Tot 20% 34% 19% **Radiographic evidence of fusion:** NR	from instrumented lumbar fusion compared with controls.
Glassman 2006[34]	**Age:** 47 yrs (17 – 86) **Gender:** 227 men, 270 women **Total N =** 497 **Diagnostic subgroups:** DDDs = all	**Posterior Approach:** Posterolateral fusion surgery (n=119) PLIF/TLIF (n=152) **Anterior Approach:** Anterior/posterior combined lumbar fusion (n=95) Anterior lumbar interbody fusion (n=125) **Comparison or controls (if any):** None **Length of Follow Up:** NR	**Long term results:** QOL – ALIF pts had better general health status (p=0.002) postoperatively; ALIF and PLF showed greater improvement than PLIF/TLIF and combined. Other ODI – preop 1yr Δ PLF 55.9 32.8 23.1 TLIF 46.1 30.1 16 A/P 51.4 33.5 17.9 ALIF 47.8 26.2 21.6 **Radiographic evidence of fusion:** NR	Comments – comparisons between surgical approaches may be confounded by other differences between patients
Greenough 1994[35]	**Age:** 41 median yrs (17 – 62) **Gender:** 77 men; 74 women **Total N =** 151 **Diagnostic subgroups:** DDDs = all	**Anterior Approach:** ALIF Other **Length of Follow Up:** 23 mos (men) 24mos (women)	**Short term outcomes:** NR **Long term results:** Other Low-back outcome score (disability) (correlates 0.9; p<0.001 with ODI) Score 65-75 Excellent 21 (17%) 50-64 Good 29 (23%) 30-49 Fair 44 (35%) 0-29 Poor 31 (25%) **Radiographic evidence of fusion:** 76%	40% of patients achieved a good or excellent result on disability score, in contrast to 68% self rating of significantly improved. Subgroup analyses showed worse outcome associated with compensation status, psychological disturbance, and reoperation.

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
Greiner-Perth 2004[36]	**Age:** 53 yrs **Gender:** 952 men, 728 women **Total n =** 1,680 **Diagnostic subgroups:** DDDsp = 266 DH = 171 DDDsc = 29 DDDu = 130 SIS = 385 SSSa =416 Post nuclectomy and postlaminectomy syndromes 188 Segmental instability 130 Erosive osteochondrosis 94	**Posterior Approach:** PLIF 1,680 **Length of Follow Up:** 5 yrs.(mean)	**Short term outcomes:** Other Intra-operative complications: 3.8% 0.3% root injury, 0.06% cauda equine injury, dural violation with CSF leak 3.3% Post-operative bleeding 4 patients **Long term results:** NR **Radiographic evidence of fusion:** Reoperation rate 13.2%, (14.4% in multisegmental PLIFs, 12.9% for mono or bi-segment) Psuedoarthrosis 4.5% Adjacent segment problems 7.4% (5.1% for multisegment, 2.3% for mono or bi-segemental PLIFs) Persistent radiculopathy 1.6% Delayed wound healing 1.5% Screw or rod breakage 1.2% Screw misplacement 1% Iatrogenic spondylitis 2 patients	Fusion rate does not show a significant difference in re-operations. Length of fusion should be carefully evaluated and attempt should be made to preserve as many segments as possible since a significantly higher rate of adjacent segments was noted after multisegmental PLIFs.
Hackenberg 2005[37]	**Age:** 48.6 yrs (19 - 69) **Gender:** 29 men, 23 women **Total N =** 52 (2 lost to follow-up) **Diagnostic subgroups:** DDDsp = 21 (degenerative disorders of spine) SIS = 22 (grade I or II) Src = 9	**Posterior Approach:** TLIF 52 **Length of Follow Up:** 46 mo.(36-64 mo)	**Short term outcomes:** Infections: one Pain: Pain relief on VAS was significant Narcotic use QOL: Reduction of ODI was significant Other Operation time 173 min for unilevel, 238 min for multi-level. Blood loss 485 ml. for unilvel, 560 ml for multi-. Complications: one infection, one persistent radiculopathy, one symptomatic disc herniation, one psudoarthrosis with loosening of implants.	Clinical outcomes of TLIF are comparable to PLIF and ALIF. The potential advantages of TLIF technique include avoidance of anterior approach and reduction of the approach related posterior trauma to the spinal canal.

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
			Long term results: QOL: No significant differences in ODI between etiology of disease or between uni (39 cases) or multilevel fusions (11 bi-level, 2 multi level). **Radiographic evidence of fusion:** Fusion rate 89%	
Hagg 2006[38]	**Age:** 43 yrs (25 - 64) **Gender:** NR (approximately an equal number of men and women) **Total N =** 264 N's are incorrect throughout manuscript **Diagnostic subgroups:** Chronic low back pain (CLBP) 264	**Posterior Approach:** (148) Posterolateral gutter fusion surgery PLIF 68 instrumented PLF 62 instrumented PLF + PLIF 18 **Anterior Approach:** PLF + ALIF 53 Other **Comparison or controls (if any):** No surgery 63 **Length of Follow Up:** 2 yrs.	**Short term outcomes:** NR **Long term results:** Other Surgically treated patients had a significantly better sex life (p=0.0004), women reported improved sexual function more frequently than men (62% vs 44%, p=0.04), no difference between anterior or posterior fusion. Improved sex life was associated with decreased back pain: 30 units among those improved vs 4 units among those not improved. For each unit change of back pain (VAS) the OR was 1.05 for men and women. Neurological sexual function disturbances were reported: they were similar in women in anterior and posterior procedures, but were more common among men with anterior procedures. **Radiographic evidence of fusion:** NR	Sexual function improved in majority of patients who were surgically treated for CLBP due to reduced pain reduction. The improvement was independent of the approach (anterior or posterior). This improvement is counteracted by surgically induced neurological disturbance. The anterior approach is associated with increased risk of sexual dysfunction in men.
Haid 2004[39]	**Age:** NR **Gender:** NR	**Posterior Approach:** PLIF using human bone morphogenetic protein type 2 with cylindrical interbody cages	**Short term outcomes:** NR **Long term results:** Pain	Similar results between rhBMP-2 versus autologous bone graft in ODI and leg pain. Better back pain outcomes in rhBMP-2 group at 24 mo.

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
	Total N = 67 **Diagnostic subgroups:** DDDs = 100%	RCT comparing rhBMP-2 of autologous bone graft **Length of Follow Up:** NR	Back pain - improved in both groups; greater improvement in rhBMP-2 than control at 24 mo p=0.009). Leg pain - improved in both groups; no difference between groups. QOL SF-36 improved in both groups; no difference between groups. Other ODI improved in both groups; no difference between groups. Imp in ODI 29.6 vs 24.9 **Radiographic evidence of fusion:** 92.3% (rhBMP-2) vs 77.8% (ABG) (NS)	Enrollment stopped in this trial due to concern over bone growth into spinal canal associated with threaded cages or rhBMP-2.
Hinkley 1997[40]	**Age:** 37.9 yrs (22 - 57) **Gender:** 52 men; 29 women (7 men; 9 women) **Total N =** 81 pts underwent surgery (16 pt control group – no surgery) **Diagnostic subgroups:** DDDs = 81 (100%)	**Anterior Approach:** Anterior/posterior combined lumbar fusion + allograft + PSF **Comparison or controls (if any):** No surgery **Length of Follow Up:** 2 yrs	**Short term outcomes:** Mortality - 0 Infections – 1 (1.2%) Other morbidity Ant compartment synd. – 1 Graft hematoma – 1 Dural leak – 1 Broken screw - 1 **Long term results:** Pain (VA) preop 6 mo 1yr 2yr 73.3 58.2 55.8 60.4 15.7 20.6 21.7 25.6 sd Other Reoperation 7 (8.6%) Pain Disability Index; Activity Level; Interference to life; Self-efficacy; Depression symptoms **Radiographic evidence of fusion:** 76 (94%)	A/P combined lumbar fusion can reduce pain and disability in patients receiving worker's compensation. Comments Small control group denied surgery by insurance company independent medical examiner who believer surgery unnecessary; this suggests that surgery and control patients were not clinically comparable.
Hsu 2005[41]	**Age:** 63.9 yrs	**Posterior Approach:** Lumbar instrumentation-augmented PLF	**Short term outcomes:** NR	Pure AIBG in left intertranseverse process space was associated with the best fusion rate. Laminectomy

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
	Gender: 24 men, 34 women **Total N =** 58 (Group 1: laminectomy bone and AIBG (20), Group 2: CHA and AIBG (19), Group 3: laminectomy bone and CHA (19) **Diagnostic subgroups:** SSSa = 68 (degenerative spinal stenosis induced segmental instability)	**Length of Follow Up:** 12 mos.	**Long term results:** NR **Radiographic evidence of fusion:** At 18 weeks: Left sided PLF had a higher fusion rate than right-sided in all groups (significant) Pure AIBG had better fusion potential than that mixed with laminectomy bone or CHA. In right-sided PLF: fusion rate in group 1 was significantly higher than that in groups 2 and 3. At 6 months: Fusion rate in right sided PLF was 85.0, 73.6, and 47.4% for groups 1, 2 and 3. CHA fared as well as laminectomy bone when combined with AIBG. Fusion rates between groups 1 and 3 were significantly different. Fusion mass did not progress satisfactorily without the addition of AIBG. At 12 months: Fusion rate difference between groups 1 and 2remained insignificant. For group 3 the fusion rate (7.9%) was markedly lower than that in groups 1and 2 (90% and 78.9%). Difference between groups 1 and 3 was statistically significant but not between groups 2 and 3. CHA granules were identical to their original form at 18 weeks but became smaller, but retained a granular form.	bone or CHA are equally good volume extenders. CHA combined with laminectomy bone was not an ideal graft material in the absence of AIBG for lumbar PLF.
Jang 2005[42]	**Age:** 58.9 yrs (46 - 70) **Gender:** 23 men, 61 women **Total N =** 84 (44 in Group 1: ALIF and percutaneous facet screw fixation PFSF, 40 in Group 2: ALIF and	**Anterior Approach:** Percutaneous facet screw fixation (PFSF) after ALIF compared to Post-ALIF screw fixation **Length of Follow Up:** 27.4 mo.(24-38 mo)	**Short term outcomes:** Infections: None Other 10.7% complication rate- liac vein injury: 4 cases Incisional hernia: 1 cases Dural injury: 2 cases DVT: 2 cases Operative time: 18 min Group1, 47 min Group 2	PFSF following ALIF produced clinically equivalent results as PSF and represents a safe and minimally invasive procedure with which to achieve solid fusion in the lumbar spine.

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
	pedicle screw fixation PSF) **Diagnostic subgroups:** DDDs =84		No blood transfusions reqd. **Long term results:** QOL: at 24 mos. Group1: ODI scores were better in 43 of 44; 68.4 preop to 28.6 postop ($p<0.05$) Group 2: 64.8 preop to 32.2 postop ($p<0.05$) No inter-group difference. Satisfactory outcome by Macnab criteria in 90.9% in Group 1 and 92.5% in Group 2 (not significant0 **Radiographic evidence of fusion:** No reoperations. Group1: Fusion rate 95.8% Subsidence of cage was noted at four fusion sites, one showed a collapsed non-union. 46 of 48 showed osseous union. Group 2: Fusion rate 97.5% ($p>0.05$) Subsidence of cage was noted at two fusion sites, all showed a collapsed non-union. 46 of 48 showed osseous union.	
Kilincer 2005[43]	**Age:** 58.6 yrs (25 - 91) Group I: 85 patients younger than 65 yrs. Group II: 44 patients 65 yrs or older **Gender:** 50 men, 79 women **Total N =** 129 **Diagnostic subgroups:** DDDsp = 62 DDDsc = 2 SIS = 15 Src = 50	**Posterior Approach:** PLIF +PSF 57 in younger, 22 in older PSF 26 in younger, 16 in older Other: NIF 2 in younger, 6 in older **Length of Follow Up:** NR	**Short term outcomes:** Mortality: none Infections: 3 cases with deep wound infections Other: 11% complication rate 8.75% intraop (2 (5%) in younger and 5 (12.5%) in older gp; $p>0.05$) CSF leak 6 cases Excessive EBL: one case Removal of instrumentation: one case Medical complications: 4 cases ICU admissions: 2 (for cardiac and pulmonary monitoring) Mean operative time similar: 408$\pm$ 114 min. for younger and 410$\pm$ 103 min. for older gp. Mean EBL was	Older patients, with a more conservative strategy, did not demonstrate an increased incidence of complications, lengthened operative time, or increased EBL. Hospital LOS was slightly longer in older patients.

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
			similar: 1182 ± 815 for younger and 1123 ± 1145 for older gps. LOS statistically significantly different, 5.5 ± 1.9 for younger and 7± 3.5 days in older gp. **Long term results:** NR **Radiographic evidence of fusion:** NR	
Kim 2006[44]	**Age:** 55 yrs (38 - 79) **Gender:** NR **Total N =** 167 RCT **Diagnostic subgroups:** DDDsp = 42 SIS = 48 SSSa = 77	**Posterior Approach:** Posterolateral fusion surgery 62 (Group1) PLIF 57 (Group 2) PLF +PLIF 48 (Group 3) **Length of Follow Up:** 57 in younger, 22 in older	**Short term outcomes:** Infections: Group 1, 2, 3: deep infection 1 In each Group 1: Transient nerve palsy – one case Pain in donor site 2 cases Nonunion 5 cases (revision in 2 cases) Group 2: Transient nerve palsy – one case Permanent nerve palsy – one case Nonunion 3 cases Group 3: Transient nerve palsy – 2 cases Pain in donor site 4 cases Nonunion 2 cases Mean operating time Gp 1 196 min., Gp 2 153 min, Group 3 235 min. Gp 2 was significantly shorter Blood loss intraop and on 1st postop day: Group 1 1082 mL, Group 2 738 mL, Group 3 1490mL. Group 2 was significantly less **Long term results:** Pain: Reduced pain significantly ($P<0.001$), Group 2 showed better results than groups 1 and 3 for back pain, (not significant) Groups 2 and 3 had better results than group 1 at 6 months and 1 yr. (not significant)	No significant differences in 3 groups were observed. PLIF had a better sagittal balance than PLF. PLIF without PLF had the advantages of elimination of donor site pain, shorter operating time and less blood loss.

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
			Narcotic use QOL: ODI scores showed improvement (no significant difference among groups) Other: Kirkaldy-Willis scores (no significant difference among groups)- Group 1 had good or excellent results in 82.3% after 1 yr, 77.5% at 2 yrs., 80.7% at 3 yrs. Group 2 had good or excellent results in 91.2% after 1 yr, 85.6% at 2 yrs., 87.8% at 3 yrs. Group 3 had good or excellent results in 89.6% after 1 yr, 87.5% at 2 yrs., 85.5% at 3 yrs **Radiographic evidence of fusion:** Postop. increases in disc heights stat.signific. No diff amongst gps. GPs 2 and 3 –stat.sign improvements in lumbar lordosis and segemental angle. % Fusion rates (6 mo/1yr/last followup): Gp 1: 72/86/92, Gp 2: 78/91/95, Gp 3: 86/93/96. % Non-union rate at last f.up in gps 1,2,3: 8, 5, and 4 stat.significant higher in groups 2 and 3 (not significant)	
Kornblum 2004[45]	**Age:** 73 solid fusion, 72 pseudo-arthrosis **Gender:** 11 men, 36 women **Total N =** 47 **Diagnostic subgroups:** Degenerative spondylolisthesis with spinal canal stenosis	**Posterior Approach:** Posterolateral gutter fusion surgery PLIF with autogenous bone graft **Comparison or controls:** Pseudoarthrosis **Length of Follow Up:** 7yrs 8 mo (5-14 yrs)	**Short term outcomes:** (solid fusion/ pseudoarthrosis) Infections: none Other: no neurologic deficits **Long term results:** Pain (0-5 scale) At 3 years: relief of pain and increase in activity in 86% (solid fusion), 56% (pseudoarthrosis) p=0.01 (All results: solid fusion/pseudoarthrosis) Pre-op back pain 3.7/3.5 Pre-op leg pain 4.5/4.2	Solid fusion in single level decompression and PL arthrodesis for spinal stenosis and spondylolisthesis improves long-tern clinical results.

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
			Post-op. back pain 1.4/2.6 p=0.02 Post-op leg pain 0.5/2.1 p=0.0001 QOL- Self administered spinal stenosis questionnaire: Solid fusion scored statistically significantly better in symptom severity and physical function categories. No statistical difference between the solid fusion and pseudoarthrosis group on the patient satisfaction scale. 2 patients in arthrodesis group and 5 in solid fusion group reqd. second surgery **Radiographic evidence of fusion: (clinical and radiog.)** Preop Spondylolisthesis 6.4/6.9mm Post-op spondylo. 6.4/7.3mm Pre-op sagittal motion 3.2/3.3mm Post-op sagittal motion ½.6mm Pre-op angular motion 6.6/10.1mm Post-op angular motion 0.5/8.4mm	
Korovessis 2004[46]	**Age:** 65 + 9 / 59 + 16 / 62 + 10 yrs **Gender:** NR **Total N = :** 135 (45 in each of 3 groups: rigid (A), semi-rigid (B) and dynamic (C)) (RCT) **Diagnostic subgroups:** Symptomatic degenerative lumbar spinal canal stenosis	**Posterior Approach:** Posterolateral gutter fusion surgery **Length of Follow Up:** 47 + 14 mo.	**Short term outcomes:** NR **Long term results:** Other Total lordosis decreased after surgery in group C. Segmental lordosis increased after surgery ($p<0.05$) in gp C Disc index L2-L3 decreased in gp A and C Disc index L3-L4 increased in gp C Disc index L4-L5 decreased in gp A,B and C Disc index L5-S1deecreased in gp B SF-36 preop: 13, 14, 11. A, B, C 1-yr post-op: 61,61,65 2 -yrs post-op and onwards: 74, 75, 77	All three instrumentations maintained preoperative global and segmental sagittal profile of the spine. Improvements of self- assessment and pain scores were equal.

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
			VAS for leg pain preop: 6.9, 7.1, 7.6 Post-op: 2.7, 2.5, 2.5 **Radiographic evidence of fusion**: All fusions healed without pseudoarthrosis or malunion 2 patients in gp C showed delayed hardware failure 1 year and 180d post-op. without radiological pseudoarthrosis. Asymptomatic radiolucent areas around pedicle screws in 4, 3 and 2 cases in gps A, B and C	
Korovessis 2005[47]	**Age:** 61 yrs **Gender:** NR **Total N =** 57 **Diagnostic subgroups:** NR	**Posterior Approach:** Posterolateral fusion surgery Using CH (Gp A) 45 IBG (Gp B) both (Gp C) **Length of Follow Up:** 48 mos	**Short term outcomes:** Infections: 1 superficial in Gp B, 1 hematoma in Gp A Other Mean duration of surgery (Gps A/B/C): 135,146, 118 min. Mean intra and postop. blood loss (Gps A/B/C): 554, 504, 371 mL **Long term results:** Acceleration of adjacent area disease Pain: VAS preop: 8/8/7, postop at 2yrs.:4.7/3.5/3.7 QOL: Improvement in ODI post-op upto 2 yrs.: Gps A/B/C: 41± 27/ 47± 39/ 43± 28. Other: 1 screw breakage in Gp A at 18 mos, 2 breakages in Gp C at 3 yrs. No change in sagittal alignment of lumbar spine, olisthesis or increased intersegemental angulation in any case during entire follow-up **Radiographic evidence of fusion:** Gp A: Increasing bony bridging at 3 mos, completed at 1 yr. Post spinal and facet fusion in 6 mos. Solid fusion in 1 yr. Gp B: Resorption of granules at 6mo.,	Autologous bone grafts remain gold standard for achieving solid posterior instrumented lumbar fusion. Hydroxyapatite was proven to be inappropriate in this series. However, its use over decorticated laminae was followed by fusion in the expected time.

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
			solid fusion at 1 yr. Solid facet fusion at 1 yr. Gp C: Resorption of granules , bridging and facet fusion at 6 mos, Solid facet fusion at 1 yr.	
Kuslich 1998[48]	**Age:** 41.5 yrs (19 - 73) **Gender:** 54% men; 46% women **Total N =** 947 **Diagnostic subgroups:** DDDsp = 12% concomitant) DH = (43% concomitant) DDDs = 88%) Src = 36% laminectomy; 5% fusion	**Posterior Approach:** y PLIF + cage (BAK) (n=356) Or **Anterior Approach:** ALIF + cage (BAK) (n=591) **Length of Follow Up:** NR	**Short term outcomes:** Mortality - 0 Infections - 0 Other morbidity Major complications 2% Intra-op (maj & min) 8.2% Post-op (maj & min) 9.5% Neurologic 2.0/3.9 ant/post Cage migration+reop 0.8/1.7 Cage migration-reop 1.5/1.4 Retrograde ejaculation 1.9/0.0 Vessel damage/bleeding 1.7/0.3 Atelectasis/pneumonia 1.9/0 Phlebitis, pulmonary embolus 0.7/0.3 **Long term results:** Pain pre 1yr 2yr P=0.001 5.0 3.2 2.9 Other Dysfunction (7-32 pt) 20.9 15.2 14.4 **Radiographic evidence of fusion:** Anterior PLIF Levels 1 2 1 2 1 yr 92% 78 87 75 2yr 98 80 94 71 3yr 98 100 100 90	"Selected middle-aged patients with chronic low back pain secondary to degenerative disc disease can be treated effectively and safely by skilled surgeons using the"…BAK cage for 1- or 2-level fusion Comments – large multicenter study – provides best comparative data between A/P combined versus PLIF in absence of RCT
Lai 2004[49]	**Age:** 59.6 yrs (36 - 77) **Gender:** 11 men, 49 women **Total N =** 70 (32 hypolordotic, 28 hyperlordotic)	**Posterior Approach:** Posterolateral gutter fusion surgery 70 **Length of Follow Up:** 6 yrs.	**Short term outcomes:** NR **Long term results:** Other Satisfactory rate (excellent or good) was 70%; 78% in hypo- and 61% in hyper-	Restoring lordosis of lumbar curve during one motion segment fusion does not prevent development of adjacent instability.

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
	Diagnostic subgroups: DDDsp = 18 DDDs = 42		Adjacent instability in 13 patients: upper level in 10, lower level in 3 cases Av. interval between fusion and instability was 2.2 yrs. (0.5-5 yrs.) 5 cases with complications: 3 implant failures, 1 pseudoarthrosis, 1 screw malposition **Radiographic evidence of fusion:** Successful fusion in 98.3%	
Lai 2004[50]	**Age: mean** 61 yrs (36 - 78) **Gender:** 28 men, 83 women **Total N =** 101 **Diagnostic subgroups:** DDDsp = 101	**Posterior Approach:** Posterolateral fusion surgery with pedicle fixation 101 **Length of Follow Up:** 6 yrs.	**Short term outcomes:** Other: I case: postop. epidural hematoma, 2 cases had broken implants, 1 case had osteoporotic compression fracture **Long term results:** Adjacent segment instability: 23 cases 19 cases: instability at cranial adjacent motion segment, 3 cases: caudal adjacent motion segment, 1 case: “skipping instability’ 2/19 and 3/3 cases: Integrity gp (post.complex integrity killed due to extended laminectomy). Higher incidence of cranial and caudal instability in Non-integrity gp.(17/19 and 3/3) QOL Results including cases with adjacent segment instability/of those without adjacent segment instability (n=78) 28 / 27: excellent results 41 / 36: good results 24/ 11: fair results 8 /4: poor results Overall satisfactory results rate 68.3%/80.8% **Radiographic evidence of fusion:**	Surgeons should either extend fused level or restrict laminectomy for better outcomes.

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
			NR	
Le Heuc 2005[51]	**Age:** 44 yrs (SD 7) **Gender:** 25 men; 39 women **Total N =** 64 **Diagnostic subgroups:** DDDsp = 64	**Anterior Approach:** Maverick lumbar total disc replacement **Length of Follow Up:** 2 yr	**Short term outcomes:** Other 4 complications: 2 with previous operations, 1 superficial infection, 3 patients had spinal pain in non-lumbar region. **Long term results:** Other Consumption of analgesics was reduced. 63% returned to work. ODI improved from 43.8 preop. To 23.1 at 2 yrs. Leg pain improved from 3.9 preop. To 2.1 at 2 yrs. Back pain improved from 7.6 preop. to 3.7 at 2 yrs. **Radiographic evidence of fusion:** Positio of prosthesis was satisfactory in 57 patients. Subsidence In 5 patients Correlations of ODI and radiological criteria: position of an implant, facet osteoarthritis, presence of high intensity zones, or an osteophyte, intradiscal gas, presence of Modic-type 1 or 2 signal in the indication did not change outcomes. Muscle degeneration gardes 1 and 2 led to a better outcome than grades 3 or 4, absence of osteophytes on spine other than at the operated region were associated with success.	The Maverick disc device is a promising technique.
Lee 1995[52]	**Age:** 37.9 yrs **Gender:** 39 men; 23 women	**Posterior Approach:** PLIF+ autogenous IC bone graft **Comparison or controls (if any):** No surgery	**Short term outcomes:** Mortality - 0 Infections – 2 superficial Other morbidity Neurologic -2 (palsies, resolved)	

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
	Total N = 62 **Diagnostic subgroups:** DDDs = 100%	Conservative treatment Other (non-fusion) surgical **Length of Follow Up:** 34 mo (range, 18-84) in 54/62 (87.1%) of patients	Any complication - 8 **Long term results:** Pain None 14 (25.9%); mild 33 (61.1%); mod-severe 7 (13%) Narcotic use None 32 (59.2%); non-narcotic 16 (29.6%); narcotic 6 (11.1%) Other Reoperation for non-fusion - 2 Physical restriction; Return to work; Patient satisfaction **Radiographic evidence of fusion:** 94%	
Lettice 2005[53]	**Age:** 44.3 yrs **Gender:** NR **Total N =** 298 **Diagnostic subgroups:** Chr. discogenic pain DDDs	**Anterior Approach:** Anterior/posterior combined lumbar fusion **2 groups:** Short segment group: Fusion at 1-2 levels Long segment group: Fusion at 3-5 levels **Length of Follow Up:** 2 yr	**Short term outcomes:** QOL: Mean physical functioning score increment was significantly less for long segment gp. Other SF-36 variances did not show significant differences Other Mean operative time was similar. Short segment gp. 4.2% complication rate 1 dural laceration, 2 post-op. would infections. Long segment gp.: 10.9% complication rate: 5 dural lacerations, 1 temporary neural deficit, 1 post-op wound infection. Pseudo arthrosis in 4 patients in short-segment and 19 in long segment gp. Reoperation in 2 patients in short segment and 12 in long-segment gp. **Long term results:** Other In the short segment gp. 1-yr. Physical Component Summary and	Number of discs fused may not significantly impact clinical outcomes measured by SF-36.

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
			Mental Component Summary score improved significantly. 2-yr. scores showed significant improvement for physical function, vitality function **Radiographic evidence of fusion:** NR	
Madan 2003[54]	**Age:** 42 yrs (24 - 67) **Gender:** 39 men, 35 women **Total N =** 74 (35 PLIF, 39 ALIF) **Diagnostic subgroups:** DDDs = Internal disc rupture	**Posterior Approach:** PLIF 35 **Anterior Approach:** ALIF 39 **Length of Follow Up:** 2 years	**Short term outcomes:** Infections: I superficial infection (ALIF) 2ti (PLIF) Other: 1 post-op pneum. (ALIF) 1 patient (ALIF) had severe sciatica due t impingement of a screw, reqd. reoperation 1 patient (PLIF) had donor site pain for 4 mo. **Long term results:** QOL satisfactory outcome (score ≤ 30) in 71.8% ALIF, 80% PLIF (p>0.05) ODI: Satisfactory outcome in 79.5% ALIF and 80% PLIF patient Other: ALIF/PLIF Walking distance 1305/12287 yrds Subjective score (23.7/23) Distress (MSPQ + ZDS) 28.5/25.1 Visual analogue scale 4.2/4 Pain drawing 5.2/5.1 No significant difference between compensation rate of disability benefit rate between two groups. **Radiographic evidence of fusion:** 2 non-unions in PLIF group (94.3% fusion rate) Fusion rate of ALIF cannot be conclusively proven (indirect evidence of no nonunions)	It is possible to treat discogenic back pain by ALIF or PLIF
Madan	**Age:**	**Anterior Approach:**	**Short term outcomes:**	Hartshill horseshoe cage does not

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
2003[55]	42 yrs (25-67) **Gender:** 19 men, 32 women **Total N =** 51 **Diagnostic subgroups:** DDDs = all	ALIF –HH: 27 cases ALIF bone graft: 24 **Length of Follow Up:** 4.7 yrs. For ALIF 3 yrs. For ALIF-HH	Infections: 1 post-op. pneumonia and 1 superficial infection in ALIF In PLIF gp. I had superficial infection, 2 had urinary infections. Other morbidity Pain: One patient in ALIF had had sever sciatica due to a screw impingement One PLIF patient had donor site pain **Long term results:** All results: ALIF/PLIF Walking distance: 1305/1229 yrds. ODI: 32.9/30.5 Subjective score: 23.7/23 Distress: 28.5/25.1 VAS: 4.2/4 Pain drawing: 5.2/5.1 **Radiographic evidence of fusion:** One segment each in 2 patients in PLIF gp. Had doubtful interbody fusion, but solid posterior fusion. No non-union in ALIF gp.	improve fusion rate, but does not affect clinical outcomes.
Matsudaira 2005[56]	**Age:** 67 yrs **Gender:** 17 men, 36 women **Total N =** 53 **Diagnostic subgroups:** DDDsp = grade I degen. spondylolisthesis	**Posterior Approach:** Group 1: Decompression laminectomy +PL fusion and pedicle screw (19) Group 2: Decompression of spinal canal with laminectomy (18) **Comparison or controls (if any):** Conservative treatment (16) **Length of Follow Up:** 2 yrs.	**Short term outcomes:** Infections: Deep infection, migration of screw and stenosis at adjacent level in one case **Long term results:** Other JOA score of subjective symptoms: Sign. improvement in gps 1 and 2 (no diff. between 1 and 2). Sign improvement: gp 1 and 2 (no diff. between 1 and 2). Each symptom showed sign. improvement in gp 2– low back pain, leg painand/or numbness, walking ability. In gp 1 only back pain was sign. alleviated. Satisfaction with surgery after 2 yrs. Higher in gp 2 (not sign.)	Decompressing the spinal canal while preserving posterior elements can be useful for treating patients with symptomatic spinal stenosis due to grade I degenerative spondylolisthesis.

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
			Radiographic evidence of fusion: Persistent slip increased significantly in gp 2 and 3, listhesis stabilized in gp 1. L4/5 range of motion almost eliminated in gp 1 and showed a significant decrease in gp 2, no change in gp 3. L4/5 angle on flexion and posterior enlargement: no change in gp 3, decreased significantly in gp 1, tended to decrease in gp 2. Corrected disc height of L4/5 significant decrease in all gps. At 2 yrs. Degenerative disease at adjacent levels significantly higher in gp 1 than gp 2. Degenerative changes noted in 7 subjects in gp 1, in 1 subject in gp 2.	
McGuire 1993[57]	**Age:** 35 yrs (24 - 42) **Gender:** 23 men; 4 women **Total N =** 28 **Diagnostic subgroups:** DDDsp = 28 (grade I-II, symptomatic)	**Posterior Approach:** Posterolateral fusion surgery with autogenous iliac crest graft (n=14) Versus Posterolateral fusion surgery with VSP and screws (n=13) **Length of Follow Up:** 2 yrs	**Short term outcomes:** Other morbidity All complications – 7 (25%) (hematomas, screw breakage, damaged nerve root, pedicle fx) **Long term results:** Acceleration of adjacent area disease 2 pts **Radiographic evidence of fusion:** Non-instrumented 10/14 (72%) Instrumented 10/13 (78%) (p=NR)	Fusion rates were similar with instrumented and non-instrumented fusions. Comment – no pain or disability outcomes Overall clinical outcome and work outcomes sketchily reported
McKenna 2005[58]	**Age:** 40 yrs (24 - 65) **Gender:** 35 men, 33 women **Total N =** 83 **Diagnostic subgroups:**	**Anterior Approach:** Anterior/posterior combined lumbar fusion With femoral ring allograft (n=37) versus Titanium cage (n=41) circumferential interbody fusion	**Long term results:** Pain VAS-back Pre 6mo 1y 2y FRA 7.2->5.0->4.8->5.2 (Δ1.9) TC 7.1->5.8->6.4->6.0 (Δ1.1) VAS-leg Pre 6mo 1y 2y FRA 3.8->2.3->2.8->2.5 (Δ1.3) TC 4.3->3.0->4.6->4.7 (Δ0.4)	Femoral ring allograft was associated with improved ODI scores and trends toward less pain. Compilations were similar. Previous retrospective series (n=5) prospective series (n=1) and another trial (n=1) of FRA are described in discussion

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
	DDDs = 100%	**Length of Follow Up:** 2 yrs	QOL SF-36 TC group had consistently lower score improvements than FRA (p=NS) Other ODI FRA 57->44->39->42 (Δ 15) TC 54->46->49->48 (Δ 6) Greater change in FRA than TC p=0.027 **Radiographic evidence of fusion:** NR	
Moller 2000[59]	**Age:** 39 yrs (18 - 55) **Gender:** 38 men, 39 women **Total N =** 77 pts RCT **Diagnostic subgroups:** SIS = 111 (100%)	**Posterior Approach:** Posterolateral fusion surgery With transpedicular fixation(Cotrel-Dubousset instrumentation-CDI)(n=39) Versus Without transpedicular fixation + autogenous IC bone graft (n=41) **Comparison or controls (if any):** Physiotherapy **Length of Follow Up:** 2 yrs	**Short term outcomes:** Other morbidity Neurologic (nerve root injury) 2 **Long term results:** Pain (VAS) pre 1yr 2yr Noninst 63 35 34 CDI 63 36 40 Other–Disability Rating Index (0-100) Noninst 52 28 29 CDI 44 30 29 Reoperation – 2 **Radiographic evidence of fusion:** NR	Similar improvements in pain and disability between instrumented and noninstrumented fusions – Instrumented group had Comments 3 patients were excluded – 2 got better and declined surgery; 1 got surgery elsewhere 2 pts lost to fu Inadequate concealment of allocation Results for physiotherapy group not given in this report Size of this study means that clinically important pain, disability, fusion rate differences might have been missed.
Moller 2000[60]	**Age:** 39 yrs (18 - 55) **Gender:** 57 men, 54 women **Total N =** 111	**Posterior Approach:** Posterolateral fusion surgery Posterolateral fusion is 77 (No instrumentation in 40, rigid pedicle screw fixation in 37) **Comparison or controls (if any):** No surgery Conservative treatment	**Short term outcomes:** Other 3 major operative complications in surgical group-2 of 37 who had transpedicular fixation had route injury with permanent sequelae, 1 non instrumented patient became permanently blind	Surgical management of adult is isthmic spondylo listhesis improves function and relieves pain more efficiently then an exercise program.

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
	Diagnostic subgroups: SIS = 111	Exercise=34 **Length of Follow Up:** 2 yrs	**Long term results:** Other (For all results before/1 yr/2 yrs/p) Surgery group Disability rating index-48/29/29/<.0001 Pain index 63/35/37/< .0001 Exercise group Disability rating index 44/45/44/.53 Pain index 65/54/56/.024 Overall outcome rated significantly better for surgical group by patient and observer 78% in surgical group and 67% in exercise group said they would go through the treatment again **Radiographic evidence of fusion:** NR	
Pappou 2006[61]	**Age:** 7% patients >70 yrs **Gender:** NR **Total N =** PLIF 267, ALIF 59 **Diagnostic subgroups:** Spinal stenosis and DDD 4 Degenerative spondylolysthesis 3 DDD 1 Adult scoliosis 3 Flatback syndrome 2 Adjacent level degeneration 1	**Posterior Approach:** PLIF (267) **Anterior Approach:** ALIF (59) **Length of Follow Up:** 18 mos (11-28 mos)	**Short term outcomes:** Infections: 4.3%, 13 deep infections, 1 superficial 8 PLIF (10%), 6 ALIF (3%) **Long term results:** NR **Radiographic evidence of fusion:** NR	Post-operative spinal wound infections are common, and prompt treatment is advisable.
Pavlov 2004[62]	**Age:** 37 yrs (22 - 57) **Gender:**	**Anterior Approach:** Anterior/posterior combined lumbar fusion with SynCage intervertebral cage	**Short term outcomes:** Infections 1-level 1(3%); 2-level 2 (11%) Other morbidity	360 degree fusion with intervertebral cage placement results in improvement in pain and disability.

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
	36 men; 16 women **Total N =** 52 **Diagnostic subgroups:** DDDs = 100%	**Comparison or controls (if any):** None **Length of Follow Up:** 4 yrs	Neurologic 1-level 1 (3%); 2-level 1 (5%) **Long term results:** Pain – VAS Decreased over time (p+0.000). higher at 4 than 2 yrs, but at 4 yr, still better than preop (p=0.000)(data not reported, except in fig) Other ODI 45.8 preop to 24 at 4 yrs (p=0.000) **Radiographic evidence of fusion:** 70/71 levels (98.6%) 100% single level patients (n=33) 97.4% double-level patients (n=19)	All pts underwent provocation disco manometry
Penta 1997[63]	**Age:** 48 yrs (28 - 73) **Gender:** 43 men; 60 women **Total N =** 108 **Diagnostic subgroups:** DDDsp = 8 DDDs = 98 Src = 13 fusion Discitis 2; postdiscectomy disc resorption 3; crush fx 1	**Anterior Approach:** ALIF + autologous bone blocks (n=60) or Crock dowels (n=65) **Length of Follow Up:** 10 - 12.6 years	**Short term outcomes:** Infections 2 (superficial) Other morbidity Pulmonary embolus 4 UTI 2 Prolonged donor site pain 2 Chest infection 1 Superf wound dehiscence 1 Urinary retention 1 **Long term results:** Pain Median 4 (range, 0-10) Other LBOS Fused 44 (11-75) Nonunion 39 (4-60) MSPQ, ZDS, Subjective score, Subjective opinion. Pseudoarthrosis 24 pts/29 levels with reoperation in 10pts/14 levels	Long-term clinical outcome strongly associated with psychological disturbance Clinical outcome was not associated with the presence of a bony union Already reported in Penta 1995 p743 (?radiographic outcomes)

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
			Radiographic evidence of fusion: 82.5% with Crock dowel verus 72.7% using bone blocks	
Potter 2005[64]	**Age:** 38 yrs (18 - 72) **Gender:** 69 men; 31 women **Total N =** 100 **Diagnostic subgroups:** DDDsp = 19 (Gr 1 or 2) DDDs = 55 SIS = 22 Src = 13 prior fusion 4 degenerative adult scoliosis	**Posterior Approach:** TLIF **Comparison or controls (if any):** None **Length of Follow Up:** 34 mo (range, 24-61)	**Short term outcomes:** Infections - 3 Other morbidity 20 minor complications; no major Complications Transient radiculopanty 7% **Long term results:** Pain >50% relief 66 (81%) Pain-free (29%) Narcotic use ≥ occasional use 52 (63%) preop-> 24 (29%) postop (p<0.0001) **Radiographic evidence of fusion:** PLF 78% of levels; interbody 88% per level 93% fusion success per pt	TLIF resulted in pain relief and radiographic fusion in a high proportion of pts; this report detailed complications. Subgroup analysis suggested better outcomes from degenerative spondylolisthesis than isthmic spondylolisthesis.
Pradhan 2002[65]	**Age:** 46 yrs **Gender:** 51 men; 71 women **Total N =** 122 **Diagnostic subgroups:** DDDel 51 DDDs 50 DDDsp 17 Pseudoarthrosis 4	**Posterior Approach:** PLF 64 **Anterior Approach:** ALIF with cage 58 **Length of Follow Up:** 24 mos	**Short term outcomes:** Other Operative time: 165 min ALIF, 257 min. PLIF Mean blood loss: 227 ALIF, 632 ml PLIF Hospital stay: 4.7 days ALIF, 6.3 days PLIF **Long term results:** Other Significant improvement= ratings good or excellent 74% in ALIF and 73% in PLIF were significantly improved. Revision cases did uniformly worse than primary cases, regardless of the approach. Of all cases 84% of primary cases	ALIF with cages for single level lumbar pathology is associated with significantly less operative and perioperative morbidity compared with PPLIF with pedicle screws. Revision fusions had poor results regardless of approach.

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
			showed primary fusion, significantly improved, while 56% of those who had revision surgery improved significantly. **Radiographic evidence of fusion:** Fusion evident in 95% ALIF, 92% PLIF (no diff. in primary or revision gp)	
Raffo 2006[66]	**Age:** ≥ 80 yrs **Gender:** NR **Total N =** 20 **Diagnostic subgroups:** DDDsp = 60% DDDu = 10% SSSa = 80% Scoliosis 30%	**Posterior Approach:** Posterolateral fusion surgery with instrumentation (75%) pedicle screw fixation and iliac creast autograft **Anterior Approach:** Anterior/posterior combined lumbar fusion Anterior lumbar interbody fusion Other **Comparison or controls (if any):** No surgery Conservative treatment Other (non-fusion) surgical **Length of Follow Up:** 2.6 yrs (range, 0.42-8.8)	**Short term outcomes:** Other morbidity Major complication total 7 (35%) As inpatient 4 (20%) As outpatient 4 (20%) Minor complication total As inpatient 6 (30%) As outpatient 4 (23%) **Long term results:** NR **Radiographic evidence of fusion:** NR	Comorbidity was predictive of risk for complications from spinal fusion among a population of very old (over 80 years of age). Complications were higher than among younger populations. Major complications defined as conditions that were life threatening, or could substantially impact treatment protocol or outcome (included death, paralysis or neurologic injury, epidural hematoma, wound infection, pneumonia or pulmonary edema, a new-onset cardiac arrhythmia, myocardial infarction, stroke thromboembolic disease, or gastrointestinal hemorrhage) Minor complications were not life threatening and did not compromise outcome or dramatically change treatment (included transient confusion, ileus, UTI).
Sasso 2003[67]	**Age:** NR **Gender:** 100% men **Total N =**	**Anterior Approach:** ALIF with tapered threaded titanium fusion device **Comparison or controls (if any):** No surgery Conservative treatment	**Short term outcomes:** Other morbidity Retrograde ejaculation 6/146 (4.1%) Retroperitoneal 2/116 (1.7%) Transperitoneal 4/30 (13.3%) (p=0.017) 2 resolved at 12 mo (1 from each	Transperitoneal approach has a greater chance of causing retrograde ejaculation than retroperitoneal approach.

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
	146 **Diagnostic subgroups:** NR	Other (non-fusion) surgical **Length of Follow Up:** NR	approach group) **Long term results:** NR **Radiographic evidence of fusion:** NR	
Sasso 2005[68]	**Age:** NR **Gender:** NR **Total N =** 471 **Diagnostic subgroups:** NR	**Anterior Approach:** ALIF with threaded (n=228) and nonthreaded(n=243) intravertebral devices **Length of Follow Up:** ≤ 30 days	**Short term outcomes:** Other morbidity Any intraoperative complication Threaded 4.8% Non-threaded 0.4% (p=0.0024) Any postoperative complication Threaded 3.51% Non-threaded 1.65% (p=0.25) **Long term results:** NR **Radiographic evidence of fusion:** NR	Cylindrical devices (cages or bone dowels) had more acute complications than trapezoidal interbody devices (cages) during intraoperative and perioperative time period. Vascular injuries were the most common intraoperative complication and the most common complication overall. There were more intraoperative complications with L4-L5 fusions compared to L5-S1 fusions.
Scaduto 2003[69]	**Age:** 45 yrs (20 - 70) **Gender:** 104 men, 95 women **Total N =** 119 **Diagnostic subgroups:** DDDsp = 18 DH = 65 DDDu = 38 Src = 88	**Posterior Approach:** PLIF **Anterior Approach:** ALIF **Length of Follow Up:** NR	**Short term outcomes:** Mean operating time: PLIF gp. 347min/ALIF 188 min. Mean blood loss: PLIF gp. 531 mL, ALIF gp. 238 mL. Av hospital stay: PLIF gp. 4.2 $\pm$ 2.8 days, ALIF gp. 4.8 $\pm$ 1.3 days 22% had periop complications. Relative risk 4.75 times higher in PLIF gp. (p=0.001) All intraop complications in PLIF gp.(durotomy) Relative risk of a major post-complication was 6.8 times higher in PLIF gp. 8 major post-op complications in PLIF gp., 3 in ALIF gp. (CSF leak, radiculopathy, meningitis, epidural	Patients who have had previous lumbar surgery are at a higher risk for certain complications with a posterior approach. An anterior approach may reduce the risk of a major perioperative complications.

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
			hematoma, DVT) ALIF gp. had higher rate of minor post-op complications (11% vs 3%) (ns) (ileus, new weakness, readmission for pain, urinary retention, atelectasis, transient brachial plexus palsy) ALIF gp. had visceral complications, PLIF gp. had neurologic and dura-related complications and were most common in patients who had previous posterior lumbar surgery. **Radiographic evidence of fusion:** NR	
Schofferman 2001[70]	**Age:** 42 yrs **Gender:** 21 women; 27 men **Total N =** 48 **Diagnostic subgroups:** NR	**Anterior Approach:** Anterior/posterior combined lumbar fusion 360 with FRA and PLF with autogenous posterior iliac crest bone Versus ALIF (270 degree fusion) with FRA plus transpedicular instrumentation without PLF **Length of Follow Up:** 25 mo (range, 24-45)	**Short term outcomes:** Infections - none Other morbidity – no serious complications 360 - 1 DVT; 3 incidental durotomies 270 – 2 incidental durotomies **Long term results:** Pain 360 7.8->4.3 270 7.2->4.7 (p=NR) Other – ODI 360 57.5->38.2 270 61.2->40.1 (p=NR) **Radiographic evidence of fusion:** 360 17/22 (77%) 270 16/18 (89%)(p=0.6)	Both 360 and 270 fusions are associated with similar pain reduction and functional improvement. Comment: Inadequate concealment of allocation; assigned to group based on clinic patient ID number
Sengupta 2006[71]	**Age:** 60 yrs (27 - 83) **Gender:** 26 men; 50 women **Total N =** 76	**Posterior Approach:** Posterolateral fusion surgery with PSF and autogenous local (n=40) or iliac crest (n=36) bone graft **Length of Follow Up:** 28 mo (range, 24-72)	**Short term outcomes:** NR **Long term results:** Other ODI improvement ICBG 32%; local 36%	Local autogenous bone graft achieved similar fusion rates to iliac crest for 1-level fusion, but lower rates for multilevel fusion.

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
	Diagnostic subgroups: DDDsp = 12 SIS = 12 SSSa = 47 Scoliosis = 5		**Radiographic evidence of fusion:** ICBG 27 (75%); local 26 (65%)(p=0.391)For 1-level fusion, rates were similar ~80%; for multilevel fusion ICBG>local (66% vs. 20%; p=0.029)	
Suk 1997[72]	**Age:** NR **Gender:** 11 men; 29 women **Total N =** 76 **Diagnostic subgroups:** SIS = 76 (100%) with symptomatic spinal stenosis	**Posterior Approach:** Posterolateral fusion surgery (n=40) PLIF (n=36) **Comparison or controls (if any):** None **Length of Follow Up:** 2 yrs	**Short term outcomes:** Infections PLF 1 (2.5%); PLIF 1 (2.7%) Other morbidity Neurologic PLF 0; PLIF 1 (2.7%) Instrument breakage PLF 2 (5%); PLIF 0 Nonunion PLF 3 (7.5%); PLIF 0 **Radiographic evidence of fusion:** NR	No efficacy outcomes except Kirkaldy-Willis categorical overall outcome (no pain, disability)
Suk 2001[73]	**Age:** ~50 yrs **Gender:** 10 men; 46 women **Total N =** 56 **Diagnostic subgroups:** DDDsp = all	**Posterior Approach:** Posterolateral fusion surgery With pedicle screw fixation **Anterior Approach:** Anterior/posterior combined lumbar fusion with pedicle screw fixation **Length of Follow Up:** ~36mo	**Short term outcomes:** NR **Long term results:** Pain –back PLF 7.3 (1-10) 360 8 (2-10) (p=0.374) Leg PLF 7.8 (1-9.5) 360 8.5 (0-9.5) (p=0.278) **Radiographic evidence of fusion:** PLF 94.3%; combined A-P 100% (p=0.523)	Pain outcomes, fusion rate and complications were similar. ALIF with PSF had longer operation time, time to fusion.
Thomsen 1997[74]	**Age:** ~45 yrs (20 – 67) **Gender:** NR	**Posterior Approach:** Posterolateral fusion surgery with no instrumentation (n=66) or with pedicle crew fixation (Cotrel-Dubousset)(n=64)	**Short term outcomes:** Infections PSF 2 (1.6%); nonins 0 Other morbidity Dural tear PSF 1 Pain	Similar results in functional outcome and fusion rate between PSF and non-instrumented PLF surgery.

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
	Total N = 130 **Diagnostic subgroups:** DDDsp = 100% (Gr 1-2)	**Length of Follow Up:** NR	Misplaced pedicle screw 3 (4.8%) **Long term results:** Pain – Dallas Pain Questionnaire No significant difference between groups (4 domains x 10 outcome categories x 2 groups = unwieldy table) **Radiographic evidence of fusion:** PSF 68%; noninst 85% (p=0.12)	
Tiusanen 1996[75] **And** **Tiusanen 1995**[76]	**Age:** 30.1 yrs (9 - 60) **Gender:** 39 men, 95 women **Total N =** 134 **Diagnostic subgroups:** DDDsp = 67 (50%) DDDu = 28 (20.9%) post laminectomy 22 (16.4) degenerative instab Src = 17 (12.7%) unsuccessful PLF	**Anterior Approach:** ALIF **Comparison or controls (if any):** None **Length of Follow Up:** 5.2 yrs (range, 2-10)	**Short term outcomes:** Other morbidity Retrograde ejaculation 7 (17.5%) **Long term results:** Other ODI preop 47.8 (1-82) f/u 20 (0-68) (p<0.001) **Radiographic evidence of fusion:** 107 (80%)	ALIF resulted in improvements in ODI scores; nonunion has little effect on functional results. Comments: a high proportion of this groups were revision surgeries.
Trief 2006[77]	**Age**: 44.2 ± 8.6 yrs (26 - 67) **Gender:** 83 men; 77 women **Total N =** 160 **Diagnostic subgroups:** DDDs = all	**Anterior Approach:** ALIF **Length of Follow Up:** 2 yrs	**Short term outcomes:** NR **Long term results:** Pain – back Baseline 1 yr 2 yrs 74.8±21.545.3±31.544.5±32.0 (p<0.001) Pain – leg 61.3±27.837.1±32.338.4±32.0 (p<0.001) Other ODI 60.6±16.238.2±26.039.8±26.2 (p<0.001)	Improved pain ad ODI scores. Comment: Study reports on patients from FDA RCT comparing BAK vs InFix lumbar cage

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
			SF-36 PCS 28.5±6.1 36.8±11.4 36.3±12.1 (p<0.001) **Radiographic evidence of fusion:** NR	
Vaccaro 2004[78]	**Age:** 64 yrs (43 - 80) **Gender:** 16 men, 20 women **Total N =** 36 **Diagnostic subgroups:** DDDsp = 100% (with spinal stenosis)	**Posterior Approach:** Posterolateral fusion surgery Autogenous iliac crest bone graft (n=12) versus OP-1 (BMP-7) putty (n=24) **Length of Follow Up:** 12 mos	**Short term outcomes:** Other morbidity AEs 29/36 pts No ectopic bone formation or recurrent spinal stenosis. No removals, revisions or supplemental fixations in 1 year. **Long term results:** Other ODI baseline 12 mo Putty 46±11.2 86% had >20%imp Autograft 47±10.6 73% had >20%imp p=NR **Radiographic evidence of fusion:** 74% BMP-7; 60% ICBG	Similar radiographic fusion and disability outcomes between BMP-7 putty or iliac crest bone graft.
Villavicencio 2006[79]	**Age:** ~48 yrs (19 - 83) **Gender:** 71 men; 96 women **Total N =** 167 **Diagnostic subgroups:** DDDu = all	**Posterior Approach:** TLIF (n=124) Minimally invasive n=73 Open n=51 **Anterior Approach:** Anterior/posterior combined lumbar fusion (n=43) **Length of Follow Up:** 3.2 mo (range 2.5-5.6)	**Short term outcomes:** Other morbidity Total Minor Major 360 76.7% 13.9% 62.8% TLIF-min 30.1% 21.9% 8.2% TLIFopen 35.3% 35.3% 0 **Long term results:** NR **Radiographic evidence of fusion:** NR	AP lumbar interbody fusion has twice the complication rate of TLIF Major complications included pedicle screw or allograft malposition that required reoperation, new or increased neurologic deficit that lasted more than 3 mo, blood vessel damage, deep venous thrombosis, pulmonary embolus, infection, or other complications that required readmission. Minor complications included allograft or pedicle screw malposition that did not require repositioning, transient (≤

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
				3mo) neurologic deficit, cerebrospinal fluid (CSF) leak, hematoma, and anemia.
Wang 2003[80]	**Age:** >75 yrs **Gender:** 55% men, 45% women **Total N =** 88 (52 underwent fusion) **Diagnostic subgroups:** SSSa = 88 (100%)	**Posterior Approach:** Posterolateral gutter fusion surgery PLIF TLIF Other **Anterior Approach:** Anterior/posterior combined lumbar fusion ALIF Other **Comparison or controls (if any):** No surgery Conservative treatment Other (non-fusion) surgical **Length of Follow Up:** 21 mo	**Short term outcomes:** Mortality- No perioperative deaths Other morbidity 12 wound complications 12 dural tears 16 systemic complications **Long term results:** NR **Radiographic evidence of fusion:** NR	Comment: only 52/88 underwent lumbar fusion. Outcomes not reported separately for fusion cases.
Wenger 2005[81]	**Age:** 40.6 yrs (15 - 70) **Gender:** 66 men, 66 women **Total N =** 132 **Diagnostic subgroups:** SIS = 132 (Gr 1 or 2)	**Posterior Approach:** Posterolateral fusion surgery with instrumentation **Length of Follow Up:** 9.9 yrs (range, 0.5-19.4)	**Short term outcomes:** Infections 2 deep; 1 superficial **Long term results:** Acceleration of adjacent area disease 13 (9.9%) Pain – back 2.13 Pain – leg 1.59 Narcotic use None 45.5%; sporadic 43.9% Other Pseudarthrosis 7 (5.3%) **Radiographic evidence of fusion:** NR	PLF with posterior instrumentation "yields favorable results"

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
Zigler 2003[82]	**Age:** (18 – 60) yrs **Gender:** NR **Total N =** 39 **Diagnostic subgroups:** DDDsp = 39	**Posterior Approach:** Posterolateral gutter fusion surgery PLIF TLIF Other **Anterior Approach:** Anterior/posterior combined lumbar fusion ALIF Other 25 patients with artificial disc replacement (prodisc) and 11 with a circumferential spine fusion Prodisc II **Comparison or controls (if any):** No surgery Conservative treatment Other (non-fusion) surgical **Length of Follow Up:** 6 mo follow up	**Short term outcomes:** Other No intraoperative complications in fusion group 1 patient in disk replacement group needed reintervention on 2nd postoperative day for an improperly inserted spacer, 1patient had an iliac vein laceration Postoperative 1 patient in the fusion group- bilateral leg pain In disk replacement group-1 patient with superficial wound infection, 1 patient with sacroiliac joint pain, 2 patients right leg pain At 6 wks, 4 patients in fusion group had graft side pain, 2 still had pain at 6 months Disk replacement group showed a significant improvement in range of motion and better motion then fusion group In disk replacement group 61%-no ambulatory limitations at 3 and 6 mos, slower recovery rate (45% no limitations for ambulation) for fusion group ODI- decrease in scores in disc group over 6 mos Smaller decrease in scores in fusion group No significant difference between groups when comparing the VAS scores Sharp decline in satisfaction for fusion group at 6 mos Operative time 218 minutes fusion group, 75.4 minutes disk group ($p<.01$) Estimated blood loss 68.9, 175 disc group Hospital stay 3.5 fusion group, 2.1 disc group **Long term results:**	Prodisc patients had shorter operative times and shorter hospital stays as well as less intraoperative blood loss at 6 mos prodisc group had greater satisfaction rates and lower ODI scores, with no significant difference in VAS.

Study ID	Patients (No. of patients Diagnostic subgroups)	Study Design (Test Arm and Description of Rx)	Outcome Measures & Results (Include adverse outcomes)	Conclusions
			NR **Radiographic evidence of fusion:** NR	
Zigler 2004[83]	**Age:** ~40 yrs **Gender:** 20 men; 19 women **Total N =** 78 **Diagnostic subgroups:** DDDs = 100%	**Anterior Approach:** Total disc arthroplasty using ProDisc II Versus ALIF - circumferential **Length of Follow Up:** Up to 1 year	**Short term outcomes:** NR **Long term results:** Pain VAS NSD between groups, but trend toward increasing improvement over time in ProDisc group Other ODI progressive decrease in ODI in ProDisc group during 6-mo; smaller decreased in fusion group; statistically significant only at 3-mo point (p=0.02) **Radiographic evidence of fusion:** NR	This study reports data from only 1 center of 19 center RCT; it s advantage is 1-year f/u data which was not reported in larger trial

Δ – change; A/P – anterior-posterior; ABG – autogenous bone graft; ADL – Activities of Daily Living; AE – adverse events; AGF – activated growth factor; AIBG – autologous iliac crest bone graft; ALIF – anterior lumbar interbody fusion; ASD – adjacent segment disease; BAK – Bagby and Kuslich cage a.k.a. "Bagby basket"; *BMP-7 – bone morphogenic protein; CDI – Cotrel-Dubousset Instrumentation; CH – coralline hydroxyapatite; CHA – coralline hydroxyapatite; CLBP – chronic low back pain; Cog/ex – cognitive behavioral training and exercise; Con – control; CSF – cerebrospinal fluid; CT – computed tomography; DDD – degenerative disc disease; DDDn – degenerative disc disease not specified as either DDDs or DDDu, excluding DDDsp, DH, or DDDsc; DDDs – stable degenerative disease (no evidence of instability); DDDsc – degenerative scoliosis; DDDsp – degenerative spondylolisthesis; DDDu – unstable degenerative disease with dynamic instability; DH – herniated disc; DPQ – Dallas Pain Questionnaire; DVT – deep vein thrombosis; dx – diagnosis; EBL – estimated blood loss; ESS – expandable spinal spacer; FDA – Food & Drug Administration; FRA – femoral ring allograft; f/u – followup; GFS – General Function Score; HH – Hartsill horseshoe cage; HNP – herniated nucleus pulposus; IBG – iliac bone graft; IC – iliac crest; ICBG – iliac crest bone graft; ICU – intensive care unit; ID – identification; IDDM – insulin dependent diabetes mellitus; Inv – investigational; JOA – Japanese Orthopedic Associaiton; L4 – lumbar 4; L5 – lumbar 5; LBOS – low back outcome score; LOS – length of stay; LT-CAGE® – lumbar tapered fusion device; MI – myocardial infarction; MSPQ – Modified Somatic Perception Questionnaire; NIDDM – non-insulin dependent diabetes mellitus; NR – not reported; NS – not significant; NSD – no significant difference; Occ – occaisonal; ODI – Oswestry Disability Index; PFSF – percutaneous facet screw fixation; PL – posterolateral; PLF – posterolateral fusion; PLIF – posterior lumbar interbody fusion; post op – post-operative; preop – pre-operative; PSF – posterior spinal fusion; pts – patients; QOL – Quality of Life; RCT – randomized controlled trial; Reg – regular; rhBMP-2 – recombinant human bone morphogenic protein; ROM – range of motion; RSD – reflex sympathetic dystrophy; Rx – treatment; S1 – sacral 1; sd – standard deviation; SF-36 – short form 36; SIS – spinal isthmic spondylolisthesis; Src – revision surgery; SSSa – spinal stenosis alone; TDA – total disc arthroplasty; TDR – total disc replacement; TLIF – transforaminal lumbar interbody fusion; UTI – urinary tract infection; VAS – visual analog scale; VSP – variable screw placement system; ZDS – Zung Depression Scale

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APPENDIX C: Glossary

360 degree fusion: A surgical procedure that achieves both intervertebral body fusion as well as posterolateral fusion. This may be achieved through both anterior and posterior combined approach, or sometimes using a posterior only approach (PLIF or TLIF®).

Allograft: Tissue transplant between non-identical individuals, in the case of spine surgery, usually bone. Allografts are from cadaver donors.

Anterior Lumbar Interbody Fusion (ALIF): A surgical procedure which involves the replacement of some or all of the disc with a bony graft through an anterior approach. This technique is also used in the lumbar spine to treat degenerative disc disease and HNP (herniated nucleus pulposus) or to accomplish a fusion in many situations.

Anterior-posterior combined fusion (A/P fusion): A surgical procedure which involves both a posterolateral fusion and an anterior interbody fusion.

Autograft: A bone graft taken from the patient and used for fusion in that patient.† Tissue taken from the site of the same patient to repair or replace another site (e.g., bone graft used for fusion).Typically, in spine surgery, the bone is taken from the patient's iliac crest (part of the pelvis).

Bone Growth Stimulator: A device worn or implanted to promote bone growth using an electromagnetic field in the case of fracture or surgery. It may be used to enhance the fusion in patients at higher risk for difficulty healing fusion, such as smokers.

Circumferential fusion: A surgical procedure that achieves both intervertebral body fusion as well as posterolateral fusion. This may be achieved through both anterior and posterior combined approach, or sometimes using a posterior only approach (PLIF or TLIF®).

Combined anterior/posterior fusion: A surgical procedure which involves both a posterolateral fusion and an anterior interbody fusion.

Degenerative Disc Disease (DDD): A catch-all term to describe degenerative changes in the disc(s) due to aging or wear and tear.

Degenerative Joint Disease (DJD): same as above

Disc: The intervertebral disc is a combination of strong connective tissues which hold one vertebra to the next, and acts as a cushion between the vertebrae. It is made of a tough outer layer called the "annulus fibrosus" and a gel-like center called the "nucleus pulposus."

Discectomy: Surgical procedure in which part of a herniated disc is removed. The goal of the surgery is to make the herniated disc stop pressing on and irritating the nerves which cause pain and weakness. These procedures may be done as an open procedure, with a microscope or minimally invasive method.

Discogram: see discography

Discography: Discography involves the injection of dye into the nucleus of an intervertebral disc. During the injection, the physician performing the procedure asks the patient if the injection generates pain similar to his/her “usual pain.” Discographic images are generated from plain radiographs and computed tomography (CT) scanning.

Facet Joints: The bones of the spine are connected in the front of the spine by intervertebral discs and in the back by paired joints. These paired joints are commonly called “facet joints,” “zygapophyseal joints,” or, “z-joints.” See Z-Joints.

Facet Injection: Injections of steroids and local anesthetic into the facet joints to determine if it is a source of pain or to reduce pain and inflammation.

Fusion: A surgical procedure performed to eliminate movement over painful or unstable spinal segments. Spinal fusion is often used to treat degenerative disc disease but is also used to treat scoliosis, kyphosis, fractures and tumors. Bone is grafted across a section of the spine where it grows together fusing the area.

Herniated Disc (HD): With age, the center of vertebral discs may start to lose water content, making the disc less effective as a cushion, causing displacement of the disc’s center (herniated or ruptured disc) through a crack in the outer layer. Most disc herniations occur in the bottom two discs of the lumbar spine, at and just below the waist. A herniated disc can press on a nerve root in the spine and may cause back pain or pain, numbness, tingling or weakness of the leg called “sciatica.” Also known as a slipped or ruptured disc, or herniated nucleus pulposus (HNP). Can also occur in the neck and rarely in the thoracic portion of the spine.

IDET: Intradiscal electrothermal therapy. A percutaneous procedure done on damaged discs to relieve pain by inserting a heated catheter into the damaged area.

Instability: When vertebrae move beyond their normal range of motion.

Interbody Fusion: Grafting bone in the space between discs for the purpose of fusing two vertebral segments.

Intervertebral Cage: A type of instrumentation used to promote fusion during surgery.

Isthmic spondylolisthesis: see “spondylolisthesis, isthmic”

Laminectomy: Surgical procedure removing the shingle-like portions of a vertebra to relieve pressure on the spinal cord and nerve roots (see anatomy section) .

Laminotomy: Surgical procedure removing a small bony portion of shigle-like elements (lamina) that protect the neural canal to relieve pressure on the nerve roots.

LBP: Low back pain.

Lordosis: Curve in the spine toward the front of the body.

Lumbar: Lower back.

Pars defect: A fracture of the pedicle, the projection of bone from the back of the vertebra that helps form the ring around the spinal canal.

Pedicle: Projection of bone from the back of the vertebra that helps form the ring around the spinal canal.

Posterolateral lumbar fusion (PLF): A surgical procedure, performed from the back side, which involves fusion of the transverse processes of two or more adjacent vertebrae using bone graft or instrumentation

Posterior Lumbar Interbody Fusion (PLIF): Spinal fusion technique in which the disc is removed through the back of the spinal canal and a bone graft is inserted in the invertebral space also through the back.

Radiculopathy: Impairment of a nerve root, usually causing radiating pain, numbness, tingling or muscle weakness that corresponds to a specific nerve root.

Sciatica: Pain, numbness, tingling in the distribution of the sciatic nerve, which travels from deep in the buttock down to the foot.

Scoliosis: Abnormal curve of the spine.

Spinal Stenosis (SS): Local, segmental, or generalized narrowing of the central spinal canal by bone or soft tissue elements.

Spondylolisthesis, Degenerative: When a vertebra slips forward over the vertebra below it as a result of arthritis of the small joints of the spine and degeneration of the discs.

Spondylolisthesis, Isthmic: When a vertebra with a crack in the “pars interarticularis” where the vertebral body and the posterior elements, protecting the nerves are joined, slips forward over the vertebra below it. Spondylolisthesis can be graded as I, II, III or IV based on how far forward the vertebra has slipped.

Spondylolysis: A fracture (crack) in the “pars interarticularis” where the vertebral body and the posterior elements, protecting the nerves are joined, In about 5 percent of the adult population, there is a developmental crack in one of the vertebrae, usually at the point at which the lower (lumbar) part of the spine (L5) joins the tailbone (sacrum). See section on spondylolysis and spondylolisthesis.

Transforaminal Lumbar Interbody Fusion (TLIF®): Spinal fusion technique in which the disc is removed through the spinal foramina and a bone graft is inserted in the invertebral space, using proprietary surgical equipment.