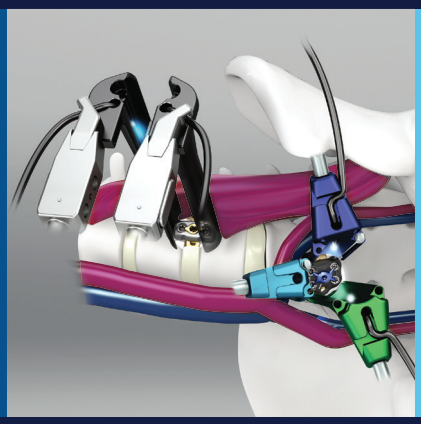
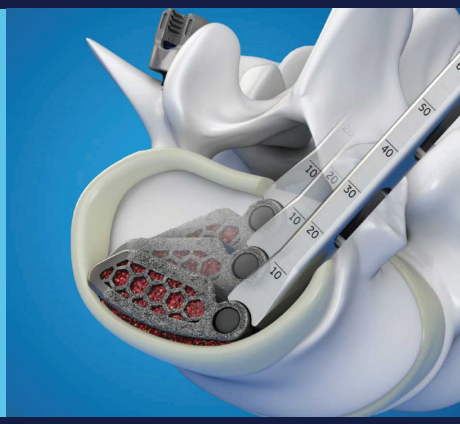
MINIMALLY INVASIVE SURGERY: WHAT DOES THE CLINICAL EVIDENCE TELL US?





Literature Review of Prospective, Randomized and Nonrandomized Clinical Studies

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Further, Together

"Published research suggests both an economic and clinical benefit to MIS surgery in comparison to open procedures, while maintaining equivalent or improved intermediate patient reported outcomes."

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WHAT IS MINIMALLY INVASIVE TLIF?

Transforaminal Lumbar Interbody Fusion (TLIF) is a form of spine surgery in which the lumbar spine is approached through an incision in the back. The name of the procedure is derived from: transforaminal (through the foramen), lumbar (lower back), interbody (implants or bone graft placed between two vertebral bodies) and fusion (spinal stabilization). Traditional, open spine surgery involves cutting or stripping the muscles from the spine. But today, a TLIF may be performed using minimally invasive spine surgery, a treatment that involves small incisions and muscle dilation, allowing the surgeon to gently separate the muscles surrounding the spine rather than cutting them. Minimally invasive instrumentation allows surgeons to perform TLIF in a minimally invasive fashion while accomplishing the same operative goals as open surgery. This instrumentation includes surgical tools and implants (e.g., dilators, tubes, retractors, and cannulated screws) that aim to preserve the posterior musculature of the spine.

There are a few deficiencies reported with minimally invasive spine surgery, such as longer fluoroscopy imaging and operating times, and a surgeon learning curve. Associated risks include transitioning to a conventional open procedure, neurological damage, damage to the surrounding soft tissue, and instrument malfunction such as bending, fragmentation, loosening, and / or breakage (whole or partial).

In order to compare the risks and benefits of MIS TLIF to Open TLIF procedures, a literature review* and summary of high (level 1 and level 2) quality evidence was conducted. The literature review was performed on August 30, 2017 through the PubMed database using the following keywords: *Minimally invasive surgery versus Open, minimally invasive spine surgery, Transforaminal Lumbar Interbody Fusion, Open TLIF, and MIS TLIF.* The search yielded 67 hits. Using the inclusion/ criteria below, abstracts and articles were evaluated and 9 were selected for analysis: five articles with Level 1 evidence and four with Level 2 evidence.[4-12] In the nine articles, 390 patients were treated with MIS TLIF and 351 patients were treated with Open TLIF. While systematic reviews were excluded, they were evaluated to identify any additional studies. The study characteristics are summarized in Table 1 and the data is summarized in the next section. Blank spaces in a chart indicate that these data points were not provided in the cited article.

QUALITATIVE INCLUSION/EXCLUSION CRITERIA

- Only experimental, comparative clinical studies (MIS TLIF versus OPEN TLIF) were included.
- Only Level 1 (prospective, randomized, controlled trials, PRCT) or Level 2 (prospective, non-randomized controlled trials, PNRCT) were included.
- Only studies published in English in the last decade were included.
- Retrospective reviews, case series and cohorts were excluded.
- Systematic reviews and Meta-analyses were excluded.

Author, year	Study Design	# of Levels	Follow-up (months)	Number of Patients	
				MIS	OPEN
Shunwu 2010[4]	PRCT	Single-level	24	32	30
Wang 2011[5]	PRCT	Single level	24	48	38
Rodriguez 2013[6]	PRCT	Single-level	36	21	20
Gu 2014[7]	PRCT	Two-levels	20	44	38
Yang 2017[8]	PRCT	Single-level	24	21	20
Lee 2012[9]	PNRCT	Single level	24	72	72
Parker 2012[10]	PNRCT	Single level	24	15	15
Wang 2014[11]	PNRCT	Not Reported	36	42	39
Li 2017[12]	PNRCT	Single level	48 (24-month data used in analysis)	95	79

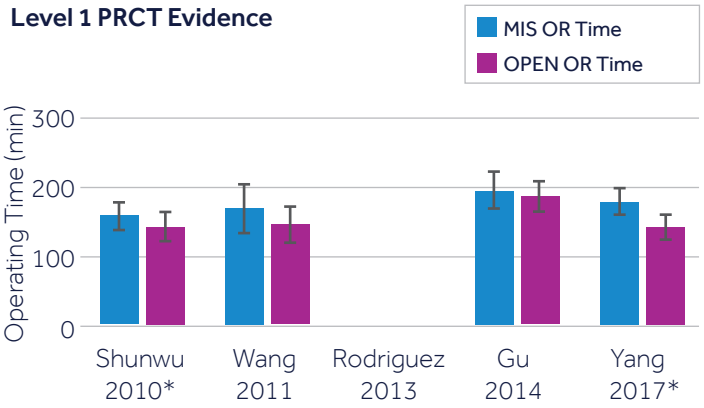
*Last updated on August 30, 2017.

PERIOPERATIVE OUTCOMES

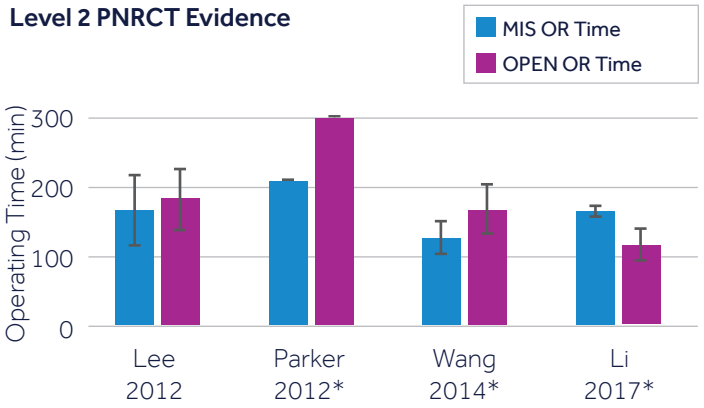
Operative times for MIS TLIF compared to OPEN TLIF

While the operating (OR) time tended to be longer in the MIS group, only three of the eight studies that reported OR time observed significantly longer times in MIS patients. In two studies, OR times were actually shorter in the MIS group.[9-11] Typically, a surgeon's learning curve cases were included in the MIS TLIF group, but not the OPEN TLIF group. Therefore, surgeon experience may have affected OR times.

Level 1 PRCT Evidence

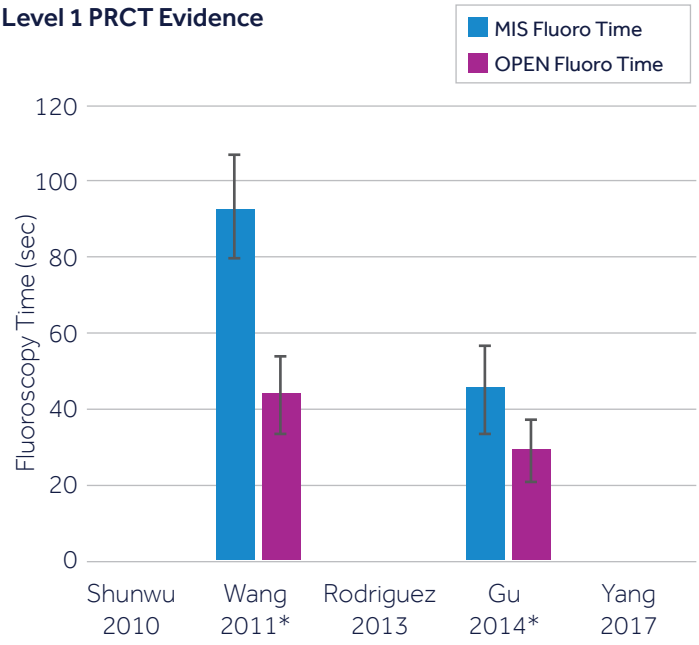


Level 2 PNRCT Evidence

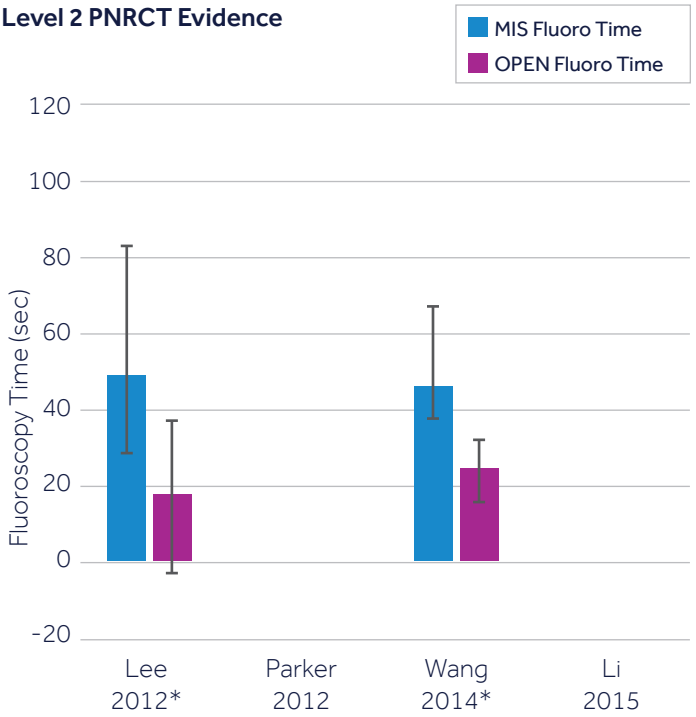


The amount of fluoroscopy time was reported to be significantly longer in MIS-TLIF cases compared to OPEN. In the four studies that reported intraoperative fluoroscopy time, the average amount of fluoroscopy time ranged from 45.3 sec to 92 secs in MIS procedures and from 17.6 sec to 43.9 sec in Open procedures. The need for intraoperative fluoroscopy to insert pedicle screws can result in longer x-ray exposure times in MIS procedures.

Level 1 PRCT Evidence



Level 2 PNRCT Evidence



Besides surgeon experience, another factor that may impact OR time and x-ray exposure time in MIS procedures is Navigation. In a prospective, nonrandomized, controlled study, Wu et al compared Navigated MIS-TLIF, to Fluoroscopy MIS-TLIF and Open TLIF procedures.[13] In that study, the OR time in the Fluoroscopy MIS TLIF group was significantly longer than in the Navigated MIS TLIF and OPEN TLIF groups (294.68 ± 36.61 min min vs. 247.55 ± 26.48 min vs. 261.29 ± 46.30 min, respectively, p=0.002).

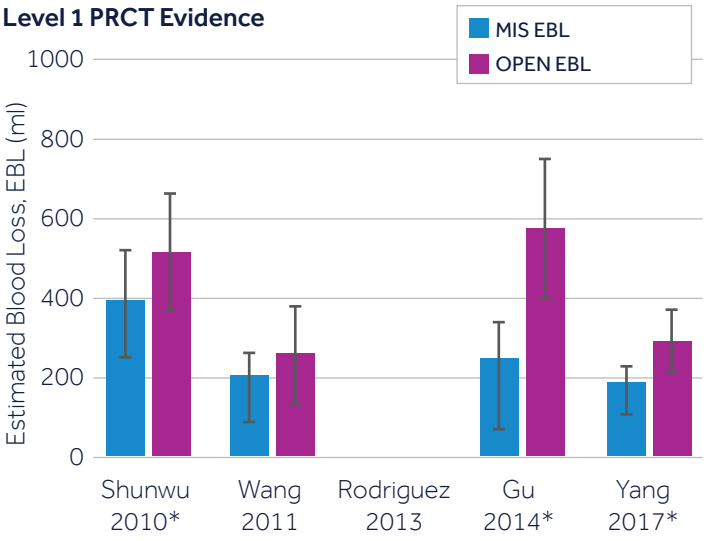
* = Significance p<0.05

PERIOPERATIVE OUTCOMES

Lower blood loss for MIS TLIF than OPEN TLIF

Of the seven studies that reported blood loss, intraoperative blood loss was lower for MIS TLIF compared to OPEN TLIF. The difference reached significance in all but one of the clinical studies. Only Wang et al did not report a significant difference.[5]

Level 1 PRCT Evidence



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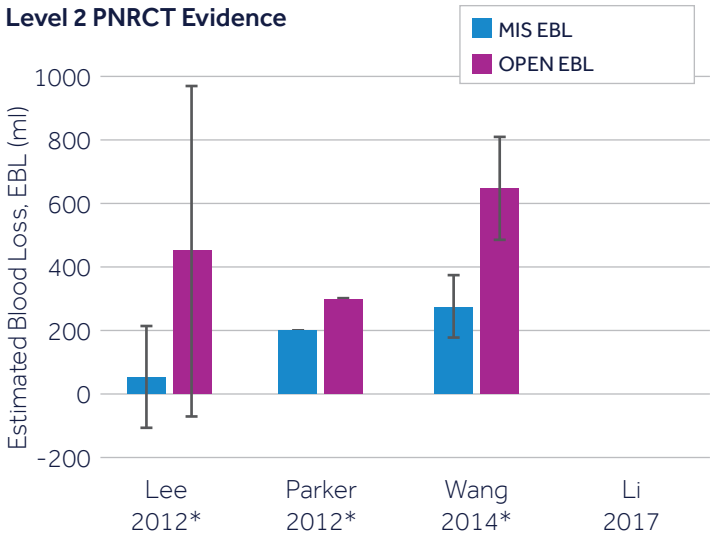
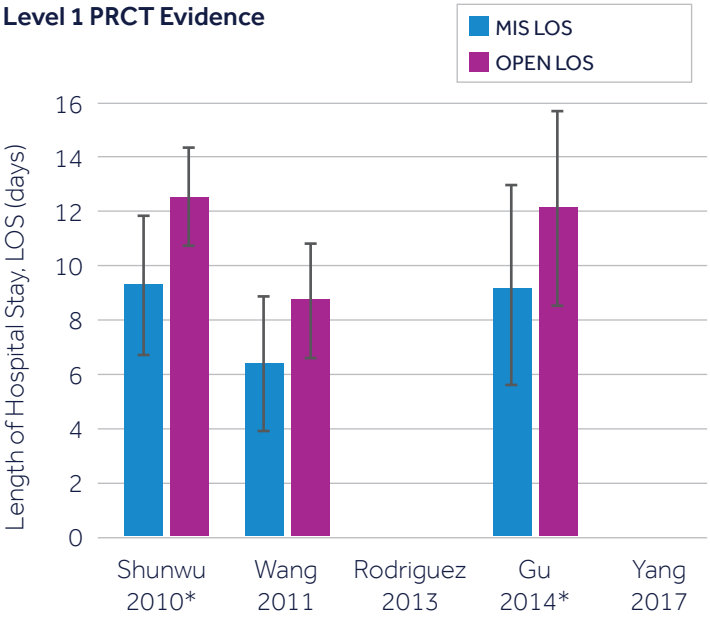


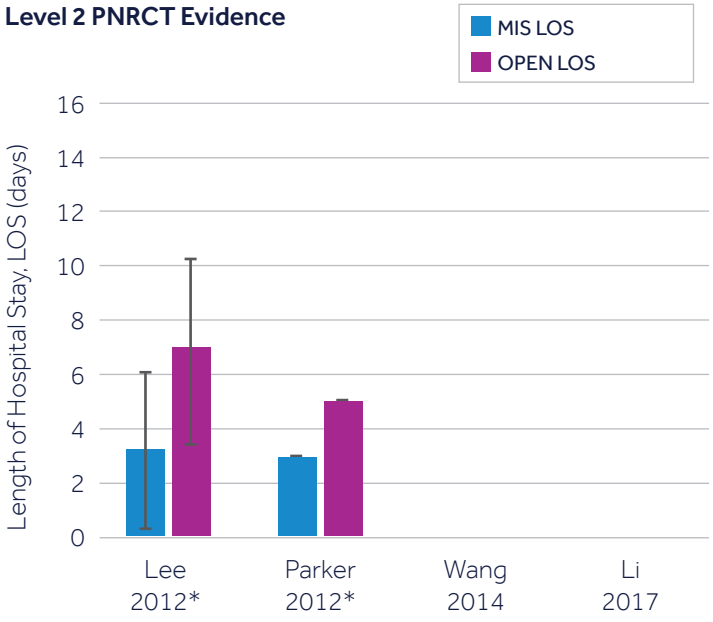
Shorter length of stay with MIS TLIF compared to Open TLIF

In the five studies that reported length of stay, the length of hospitalization was shorter for patients treated with MIS TLIF than for patients treated with Open TLIF. A majority (four out of five) of the studies observed a significant difference between MIS and Open groups.

Level 1 PRCT Evidence



Level 2 PNRCT Evidence



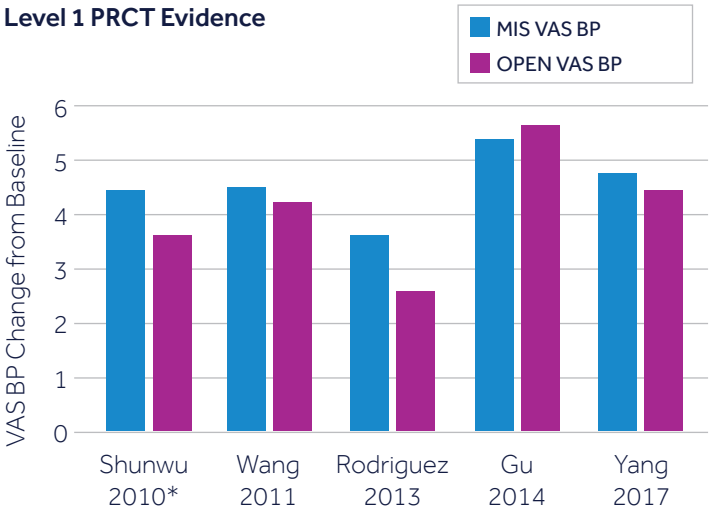
* = Significance p<0.05

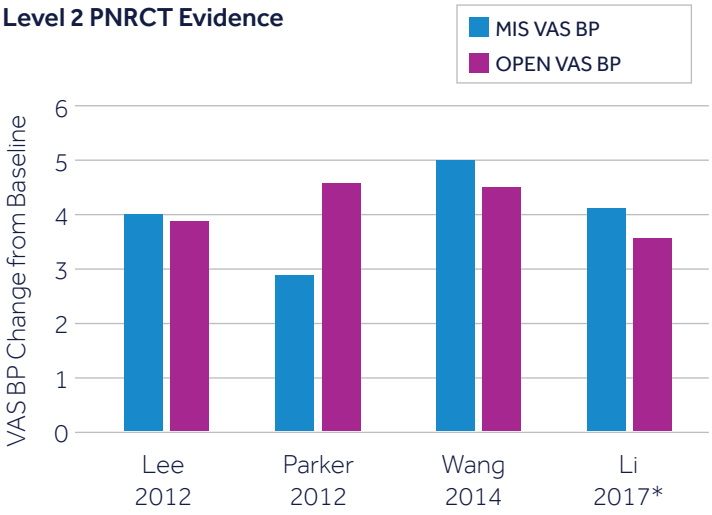
POSTOPERATIVE (> 12 MONTHS) OUTCOMES

Comparable Clinical Outcomes: VAS Low Back pain (BP)

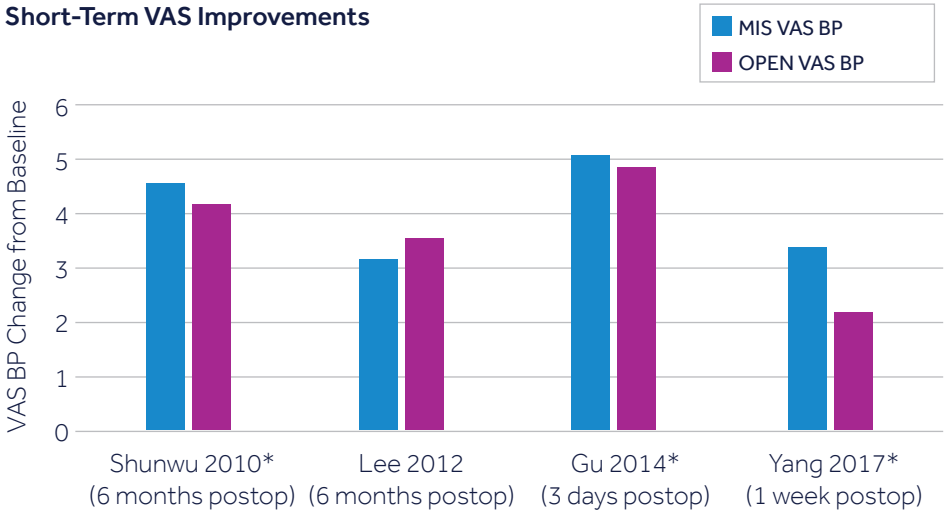
The Visual Analog Scale (VAS) was used to assess the intensity of both low back pain (BP) and leg pain (LP). Evaluation time points varied in the studies, but all studies had final follow-up > 12 months. Of the nine studies that reported VAS data, similar improvements in VAS BP at all time points were observed in both the MIS and OPEN patients. In seven of the nine studies, there was no significant difference between the MIS and OPEN groups at final follow-up. However, at earlier follow-up time points (≤6 months), a significant difference in pain relief was observed between the MIS and OPEN patients in three of the four studies that reported postoperative values at ≤6 months.

Outcome at final follow-up





Outcome at short-term (≤ 6 months) follow-up



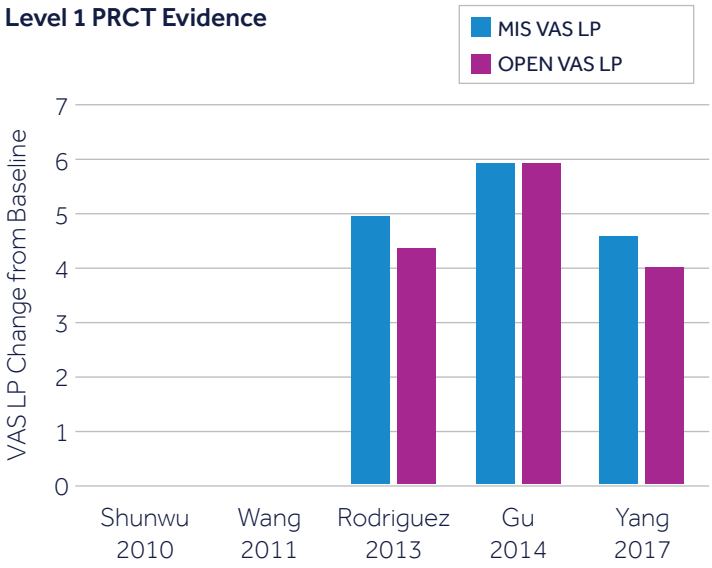
* = Significance p<0.05

POSTOPERATIVE (> 12 MONTHS) OUTCOMES

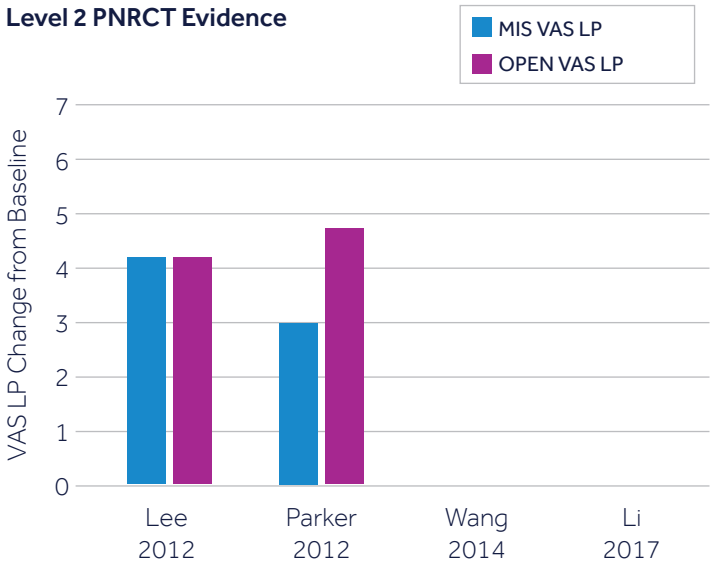
Comparable Clinical Outcomes: VAS Leg Pain (LP)

VAS was also used to assess improvements in the intensity of leg pain. All five of the studies that reported VAS leg pain showed similar improvements in VAS LP at all time points in both the MIS and OPEN patients, and no significant difference between the MIS and OPEN groups was reported at final follow-up.

Level 1 PRCT Evidence



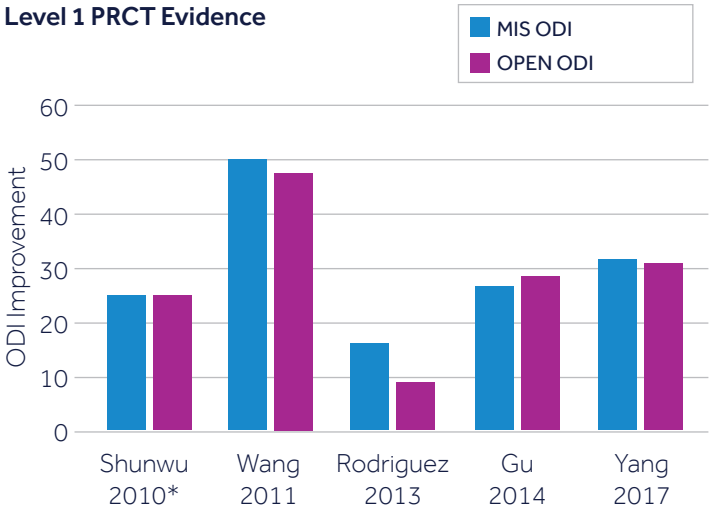
Level 2 PNRCT Evidence



Comparable Clinical Outcomes: Oswestry Disability Index (ODI)

All nine of the studies that reported ODI values observed similar improvements of ODI in both groups of patients. Compared with preoperative scores, there was significant improvements in both the MIS and OPEN group. In seven of the nine studies, there was no statistical difference between the MIS and Open groups at the final follow-up time point. Li et al, which evaluated ODI scores at 12, 24 and 48 months, observed a significant difference between the MIS and OPEN groups at each time point.[12]

Level 1 PRCT Evidence



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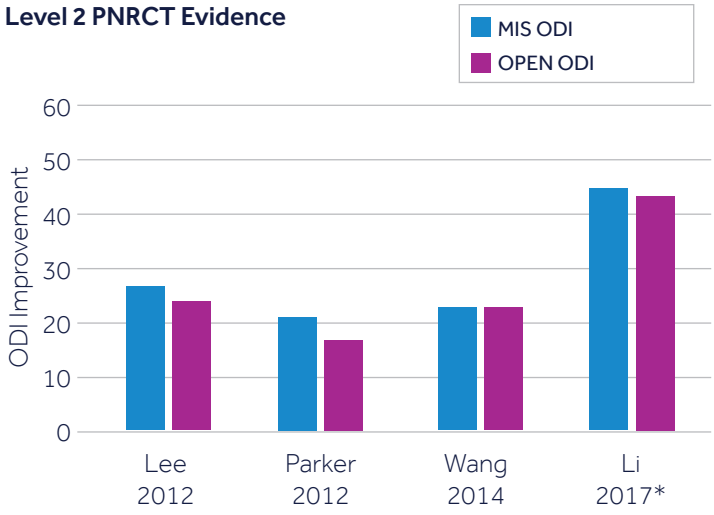


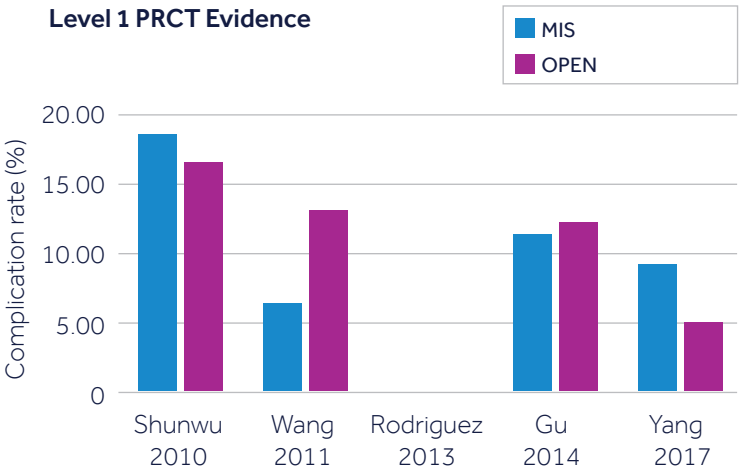
* = Significance p<0.05

POSTOPERATIVE (> 12 MONTHS OUTCOMES

Comparable complication rates between MIS and OPEN Groups

Types of complications found in both groups included dural tears, superficial wound infections, asymptomatic cage migration, and screw misplacement or loosening. Of the seven studies reporting complication rates, all but one of the studies found no significant difference in the complication rate between the MIS and Open groups.

Level 1 PRCT Evidence



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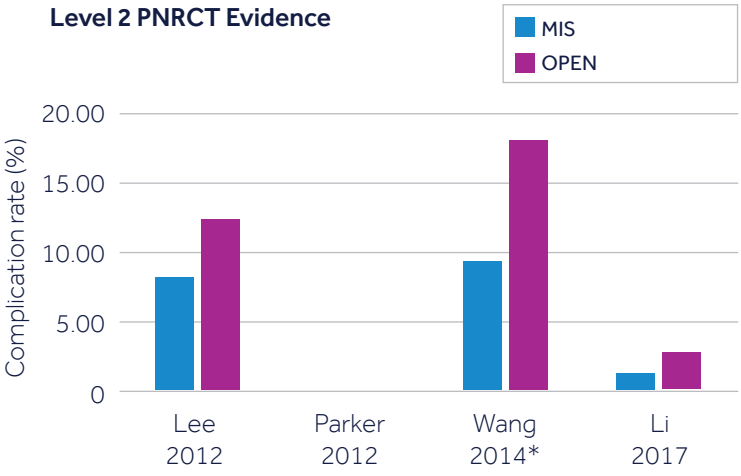


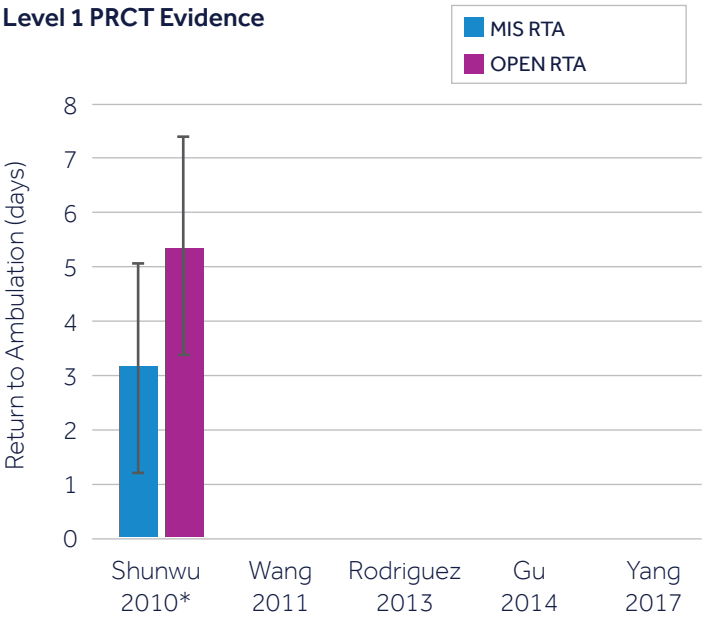
* = Significance p<0.05

COST-EFFECTIVENESS

Earlier Ambulation and Return to Work in MIS patients

A few studies assessed return to ambulation (RTA), return to work (RTW), narcotics use, and total costs. In the two studies that evaluated ambulation, the average time to ambulation was observed to be significantly shorter for MIS patients. In the two studies reporting return to work, the mean RTW was significantly shorter in the MIS group.

Level 1 PRCT Evidence



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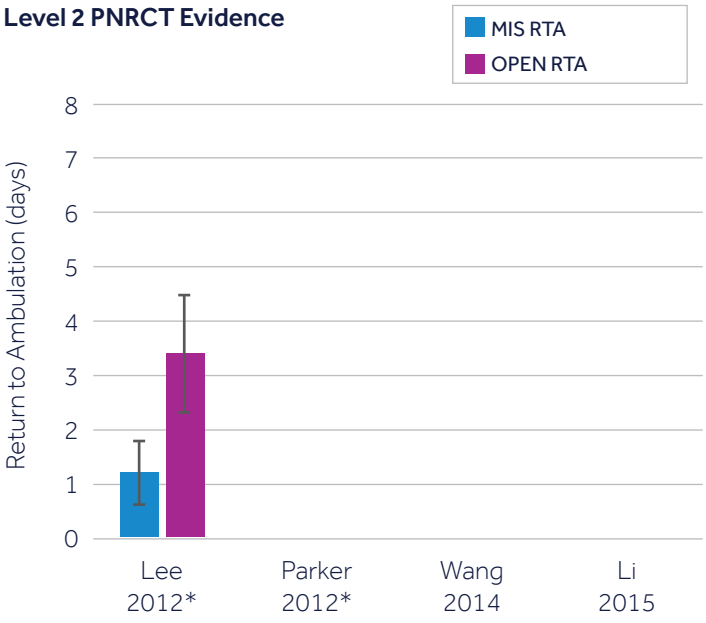

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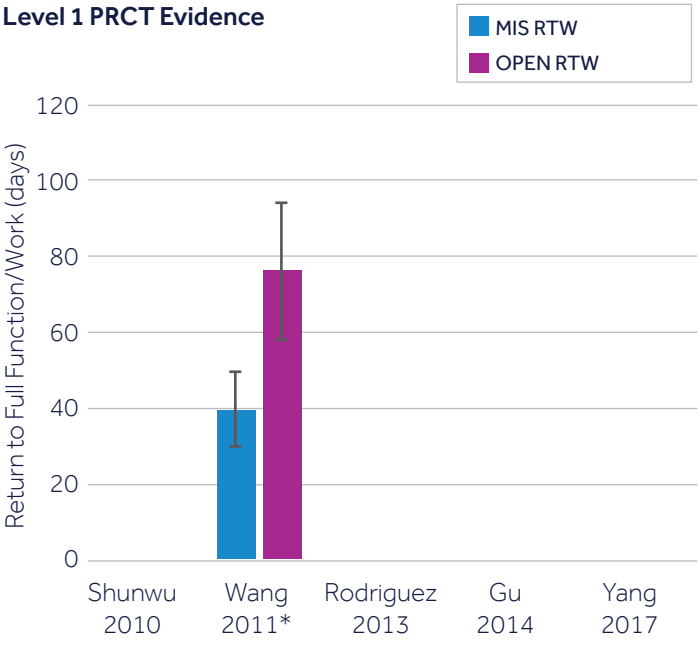

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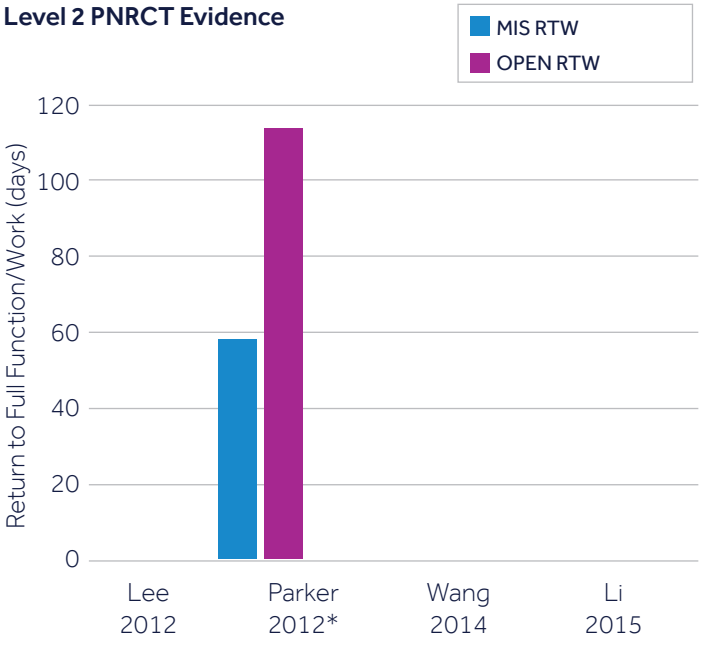


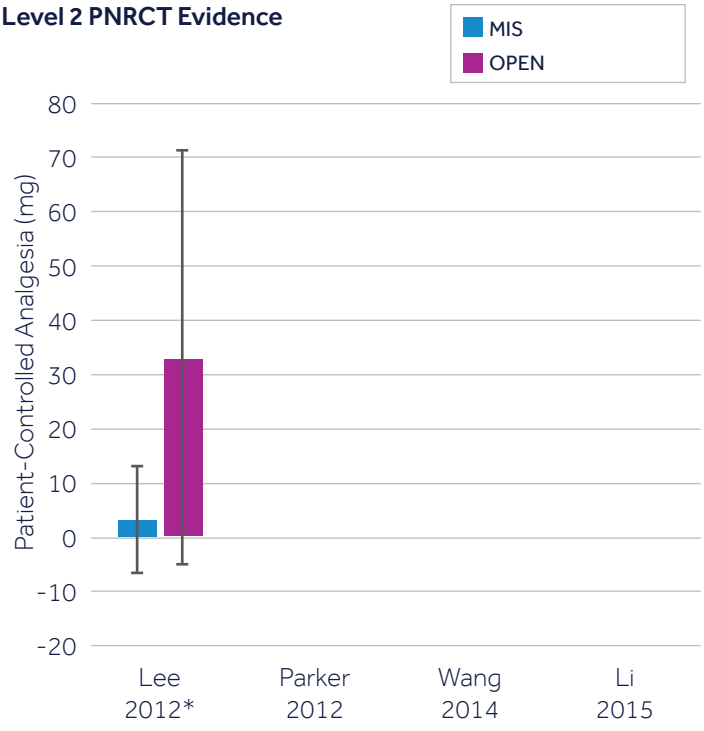
* = Significance p<0.05

COST-EFFECTIVENESS

Less Narcotic Use in MIS patients

Two studies evaluated narcotics use in patients treated with MIS and OPEN procedures. Lee et al observed that MIS patients needed less morphine than patients treated with open TLIF.[9] Parker et al reported that the mean duration of narcotics use was significantly shorter in the MIS group than the OPEN group.[10]

Level 2 PNRCT Evidence



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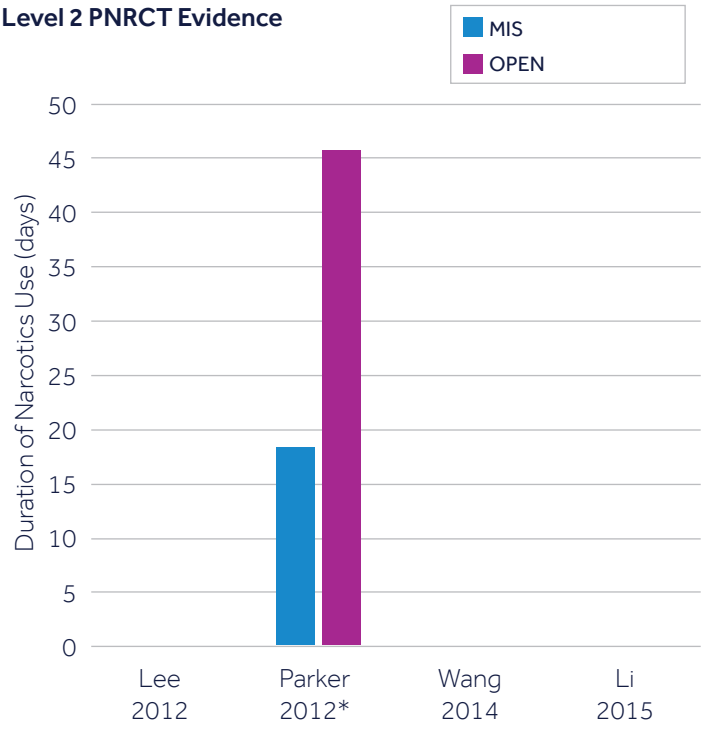

* = Significance p<0.05

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