Comparison of Quality-of-Life after the Three Different Techniques of Transpedicular Screw Fixation (TPSF) in Lumbar Spondylolisthesis (LS): Results of a Therapeutic Cohort Study

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Background: *Transpedicular screw fixation in lumbar spondylolisthesis remains debatable for which aspects that provide better quality of life outcomes such as procedure of convention, navigation-assisted or mini-open technique.*
Objective: *To analyze the clinical outcomes and assess pre-operative versus postoperative quality-of-life outcomes of patients diagnosed with LS who underwent three different techniques of spinal fusion.*
Material and Method: *A prospective cohort study was conducted with 60 patients with LS who received conventional TPSF or navigation-assisted TPSF or mini-open TPSF at Prasat Neurological Institute between 2010 and 2012. The 12-month follow-up patients were recruited for a structured interview regarding social life, mental health, functional capacity or an independent living status. The quality-of-life measurement was determined using Oswestry Disability Index (ODI) and the Short Form-36 Health Survey (SF-36).*
Results: *Comparisons of quality of life outcomes declared significant differences through the 12-month follow-up evaluation. According to ODI, navigation-assisted group presented with significant level of faster recovery than conventional and mini-open groups at one week (p = 0.031) and one month (p = 0.008) after surgery. At one year follow-up, the navigation-assisted technique was noted to have a significant better improvement (p = 0.033 and mean ODI scores = 5.8) compared with conventional and mini-open techniques (mean ODI scores = 8.7 and 10.6, respectively). Moreover, SF36 assessment indicated considerably improvement at 12 months after surgery. In addition, the finding reveals no statistically significant differences among three techniques.*
Conclusion: *Overall, three different techniques provide the positive outcomes of quality of life. The 12-month follow-up of quality of life measures based on ODI suggest that the navigation-assisted technique was significantly associated with well-recovered at one week and one month after surgery. However, in terms of clinical outcomes, they do not make any considerable differences to patient care within the 12-month follow-up period.*

Keywords: *Quality of life, Oswestry Disability Index, Short Form-36 Health Survey, Clinical outcomes, Pedicle screw, Lumbar spondylolisthesis.*

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Lumbar Spondylolisthesis (LS) is an osseous discontinuity of the vertebral arch of isthmus-pars interarticularis leading to forward or anterior displacement of one vertebra in relation to the adjacent lower vertebra[1-3]. Anterior placement is classified using four-grading degrees in accordance with Meyerding[4]. LS can cause low back pain, radicular pain to leg and neurogenic claudication[1,2,4], which are treated with specific methods, including medication, physiotherapy and decompression with solid spinal fusion.

Transpedicular screw fixation (TPSF) in lumbar and sacral spine is widely acceptable method to achieve solid fusion for LS. Different surgical procedures of TPSF are introduced as a technique of choice, including conventional (open) TPSF, minimal invasive (per-cutaneous) TPSF, mini-open TPSF and navigation-assisted TPSF.

Each surgical method has been discussed along with it advantages and disadvantages of clinical

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outcomes[5-12]. Quality of life (QoL) evaluation is a derived standard measure of a comparison between pre-operative and postoperative surgery, which measures the impact on patient's recovery using the Oswestry Disability Index (ODI)[13] score and Short Form-36 Health Survey (SF-36)[13,14]. This present study aimed to compare the clinical outcomes and QoL of patients who different underwent surgical procedures of TPSF.

Material and Method

The present study was a prospective cohort analysis of quality of life outcomes in 60 patients with low grade LS (grade I and II), single or two-level listhesis. The patients received conventional TPSF (20 patients) or navigated-assisted TPSF (20 patients) or mini-open TPSF (20 patients) at Prasat Neurological Institute between 2010 and 2012. Patients who underwent fusion for all other conditions, including spinal infection, revision surgery and tumor were excluded. The study protocol was approved by the ethics committee of Prasat Neurological Institute. All outcome data were collected prospectively. Peri-operative clinical outcomes were collected, including operative time, blood loss and length of stay. Standardized Thai-Language ODI and SF-36 questionnaires were conducted at pre- and postoperative follow-ups at 1, 3, 6 and 12 month(s).

Statistical analysis

Mean and standard deviation were used to compare all patient groups. Clinical outcomes were evaluated using Kruskall Wallis H test and Mann Withney U test. Additionally, Scheffe method was used to examine the relationship between the changes of quality of life (ODI, SF-36) scores and time interval in each group. Significance was considered at a probability value lower than 0.05. All demographic and statistical analyses were performed using SPSS software (SPSS version 22, USA).

Operative techniques

All patients were operated on at Prasat Neurological Institute, a tertiary referral centre of Ministry of Public Health, Bangkok, Thailand.

Conventional TPSF

After anesthetic procedure, patients were placed in prone position. Fluoroscopy was used to confirm the level of the lumbar spine. Around 10 cm vertical midline incision was performed and paraspinal muscles were separated to expose the lumbar spine. The pedicle screw was fixed by anatomical landmark. Laminectomy and interbody fusion were performed depending upon disease severity. Screw positions were verified intra-operatively by fluoroscopy.

Mini-open TPSF

Patients were operated by a sophisticated neurosurgeon (TT), who deeply experiences in this technique. The location of skin incision was planned using fluoroscopy to identify the skin overlying coverage and appropriate facet complex. Bilateral vertical incisions were two finger breadths of the midline (Fig. 1D), 3.5 cm in length, which was adequate for a paraspinal muscle splitting approach. The appropriate length retractor, Spine Classic MLD-System (Aesculap, Tuttlingen, Germany) (Fig. 1E) were positioned covering lamina-facet junction overlying the disc space and both pedicle screw entry point. Then, one-side facet was completely resected. The ligamentum flavum was also removed to expose the exiting and transversing nerve roots. Afterwards, the targeted disc was removed and interbody fusion

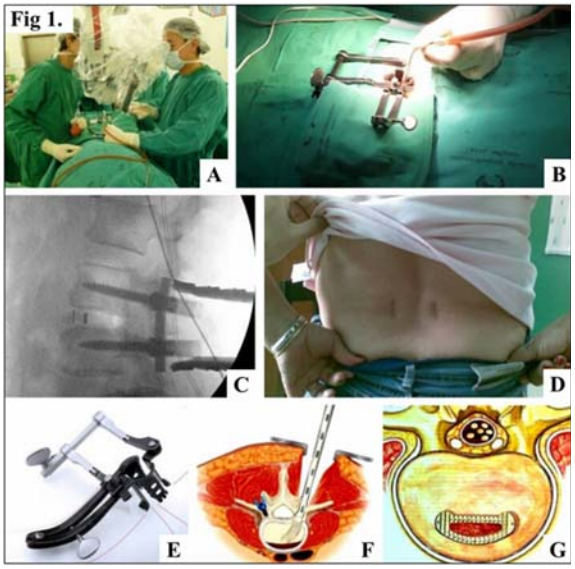

Fig. 1 Mini-open TPSF: intraoperative photograph (A,B) and fluoroscopic picture (C). Small skin incisions resulting from mini-open TLIF L4-5 level (D). The model of Spine Classic MLD-System, Aesculap AG & Co. KG, Germany (E). Intraoperative illustration shows the pedicle screws and interbody cage inserting through the minimally invasive access (F,G) (Reprinted with permission from Tangviriyapaiboon T.).

was performed. The pedicle screws were fixed subsequently. Lastly, screw positions were verified using intra-operative fluoroscopy (Fig. 1C).

Navigation-assisted TPSF

The patients were operated on by an experience neurosurgeon (IP) according to The Stealth Station Navigation System (Medtronic SNT, Louisville CO, USA), which is the optical tracking system. CT scan of the vertebra was obtained prior to surgery with the protocol consisting of contiguous, non-skipped axial slices with constant slice thickness of 2.0 mm. At least six to ten fiducial points at the tip of spinous processes and the tip of transverse process were selected by covering the whole instrumented surgical area on the workstation monitor displaying in axial, coronal, sagittal and 3D reconstruction images (Fig. 2). Skin and paraspinal muscles were separated by the conventional technique to expose the pathologic lumbar spine. Paired point matching was completed by introducing a registration probe equipped to touch the anatomical landmarks on the exposed spine to the chosen registration point. The registration error was less than 3 mm. Combined with anatomical technique, multiplanar image guidance was used to assist in finding a proper entry point and trajectory of the pedicle. The pedicle screws were fixed and laminectomy was then performed. Interbody fusion was done upon severity of disc pathology. Screw positions were verified postoperatively using fluoroscopy with only one or two shot exposure.

Results

Twenty patients were included in each study group of three different surgical techniques (Fig. 3). Demographic data were collected from three groups as listed in Table 1. None of selected patients suffered from other causes of leg or back pain. There were no significant differences in demographic data between three groups, including gender, average age, smoking and body weight. In all, 41 patients (70%) were females. The most of the patients were diagnosed as grade 1 LS (55 patients, 91%). Most cases underwent one level of fusion. L4-L5 fusion was performed in 70% of the patients (Table 2). Three patients had accidental intra-operative dural sac injury (two patients in conventional group and one in navigation-assisted group). No patients had any other peri-operative complications such as nerve root injury or surgical site infection and none needed re-operation during the one-year follow-up.

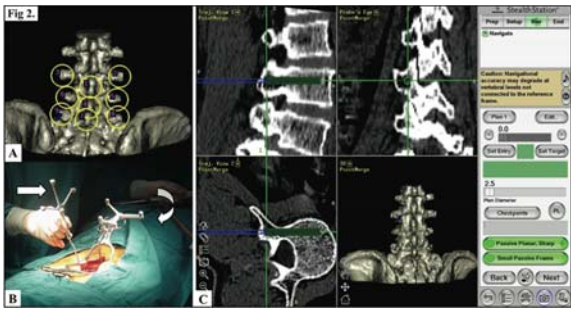

Fig. 2 Navigated-assist TPSF. Registration point was chosen by neurosurgeon (A). Paired point matching was completed by introducing a registration probe equipped to touch the anatomical landmarks on the exposed spine (B). Workstation screen demonstrated navigation for left L3 under multiplanar plane (C) (reprint with permission from Iampreechakul P.).

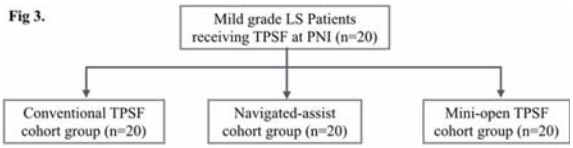

Fig. 3 Patient selection.

Clinical outcomes in three groups are shown in Table 3 and 4. The conventional group showed less operative time than mini-open group (281 versus 323 mins, $p = 0.035$). The navigation-assisted group had significantly less operative time (222 mins) than the conventional group (281 mins, $p = 0.015$) and the mini-open group (323 mins, $p<0.001$), likewise significantly less operative blood loss than the conventional method (236 ml versus 808 ml, $p<0.001$). The mini-open group had the shortest length of stay (7.3 days) compared with the conventional group (9.6 days, $p = 0.013$) and the navigated-assist group (11.3 days, $p = 0.001$).

Comparisons of QoL outcomes among the three groups declared some interesting different aspects through the 12-month follow-up evaluation. According to Oswestry Disability Index score (ODI) (Fig. 4), the navigation-assisted group presented significantly better recovery after surgery than the mini-open group at one week ($p = 0.031$) and one month ($p = 0.008$). At one year follow-up, the navigated-assist technique was showed significantly better improvement ($p = 0.033$ and mean ODI scores = 5.8) compared with the mini-open technique (mean ODI

Table 1. Demographic data based on three different surgical techniques

Characteristics	Conventional (n = 20)		Navigation-assisted (n = 20)		Mini-open (n = 20)		*p*-value
	n	%	n	%	n	%	
Gender							0.926
Males	6	30	6	30	7	30	
Females	14	70	14	70	13	70	
Age mean ± SD (min-max) (years)	57.25±8.83 (36-75)		54.70±11.79 (33-79)		54.80±14.40 (24-78)		0.746
Smoke	1	5	5	25	2	10	0.246
DM	1	5	5	25	2	10	0.246
Overweight/obesity (BMI ≥25kg/m^2)	13	65	11	55	9	45	0.046

BMI = body mass index; DM = diabetes mellitus; n = number of patients; SD = standard deviation

Table 2. Clinical characteristics based on three different surgical techniques

Characteristics	Conventional (n = 20)		Navigation-assisted (n = 20)		Mini-open (n = 20)		*p*-value
	n	%	n	%	n	%	
Severity of spondylolisthesis							0.603
Gr I	19	95	19	95	17	85	
Gr II	1	5	1	5	2	10	
Level of surgery							0.117
1 level	11	55	14	70	17	85	
2 level	9	45	6	30	3	15	
Level of surgery	n = 28		n = 25		n = 23		
L2-L3	1	3.6	0	0	0	0	
L3-L4	6	21.4	6	24.0	2	8.7	
L4-L5	18	64.3	18	72.0	16	69.6	
L5-S1	3	10.7	1	4.0	5	21.7	

Gr = grade; L = lumbar spine; n = number of patients; S = sacrum

Table 3. Peri-operative clinical outcomes

Group	Conventional		Navigation-assisted		Mini-open		*p*-value
	Mean ± SD	(Min-Max)	Mean ± SD	(Min-Max)	Mean ± SD	(Min-Max)	
Operative time (minutes)	281±68.10	(180-435)	222±67	(90-375)	323±49	(240-415)	0.001
Operative blood loss (ml)	808±474	(150-1,900)	236±109	(100-450)	330±248	(50-1,050)	<0.001
Length of stay (day)	9.6±3.8	(2-21)	11.3±4.1	(4-24)	7.3±2.7	(3-14)	<0.001

ml = milliliter; SD = standard deviation

Table 4. Comparisons among the three different surgical techniques

Group comparison	Operative time	Operative blood loss	Length of stay
Conventional vs. navigation-assisted	0.015*	<0.001*	0.072
Conventional vs. mini-open	0.035*	0.001*	0.013*
Navigation-assisted vs. mini-open	<0.001*	3.349*	0.001*

The *p*-value from Mann-Whitney U test for group comparisons
* statistical difference

Fig. 4 Oswestry Disability Index score (ODI) at pre-op until 12 months, respectively. Lower ODI score shows improvement. Navigation-assisted vs. Mini-open have significantly differences by Scheffe's method (p<0.05).

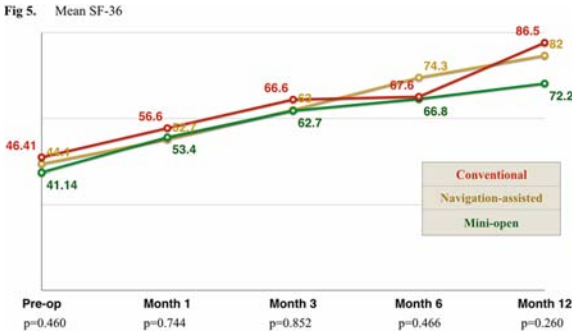

Fig. 5 Mean of Short Form-36 Health Survey (SF-36). Higher SF-36 score shows improvement. No statistical difference in the three cohort groups.

scores = 10.6). Moreover, the Short-Form 36 (SF-36) (Fig. 5) assessment showed an improvement at 12 months after surgery. In addition, the findings revealed no statistically significant differences among the three techniques.

Discussion

The conventional TPSF is imposed with anatomical landmarks and intra-operative fluoroscopy. However, this technique may contribute pedicle screw misplacement causing neurogenic complication[5,16-19]. Several previous studies have reported the incidences of significant muscle stripping and retraction causing adverse postoperative clinical outcomes[7,8,18].

The navigation-assisted TPSF employs anatomical landmarks, computer-assisted requirement but less intra-operative fluoroscopy exposure[9]. This surgical modality comprising the axial view of lumbar spine provides benefits to reduce possibility of transpedicular screw misplacement. According to a study by Iampreechakul et al[9], computer-guided pedicle screw approached accurately more than 95% of 363 screw placements. Technically, patients undergoing this technique also experienced postoperative pain due to back muscle injury.

The mini-open TPSF uses anatomical landmarks, intra-operative fluoroscopy, microscope and tubular self-retraction[10]. During past decades, novel minimal invasive techniques have been noted to decrease iatrogenic back muscle injury, which results in minimization of blood loss, shorter hospitalization time and faster recovery compared to the conventional TPSF[10-12,15]. However, screw misplacement may occur due to no computer-guided operation and a review on this issue has not been reported.

The present study is the first study that conducted in a prospective cohort fashion to compare the clinical outcomes of these three different TPSF techniques. According to peri-operative clinical outcomes (Table 3), the navigation-assisted technique provided the less operative time compared with either conventional or mini-open group. Potentially, the navigation-assisted technique employs interactive image guidance in multiplanar view of the unexposed spinal anatomy in order to find the entry point and trajectory of the pedicle[9]. Thus, this technique does not acquire fluoroscopy frequently to assure the position of pedicle screws[9], resulting in a shorter

operative period. On the other hand, the mini-open technique takes more time than the others because this technique is done in a narrow surgical trajectory through the paraspinal muscle under tube retractor. Subsequently, it spends longer surgical time due to more frequent use of fluoroscopy to select position of the pedicle screws.

Our present study found that the navigated-assist technique had significantly less operative blood loss than mini-open group. However, the difference was only hundred milliliters. Therefore, this may not considerably make any critical difference in terms of patient care. Conversely, the conventional TPSF group revealed the greatest amount of operative blood loss. This may be explained by several neurosurgeons performing this method using one's own individual surgical technique in handling with hemostasis or different techniques of spinal exposure, which resulted in the greater amount and wide range of operative blood loss (150-1,900 ml).

The mini-open TPSF group had the shortest hospital stay. The conventional and navigation-assisted TPSF groups did not have significant difference in the length of hospital stay. Both convention and navigation-assisted TPSF may need wider exposure in order to split paraspinal muscle and to expose the whole affected spines, which lead to the high chance of injury to paraspinal muscle, soft tissue and posterior spinal ligament complex[6-8,10]. On the other hand, the mini-open technique provides less stripping paraspinal muscle and small paramedian incision, less iatrogenic soft tissue and ligament injury for exposed spine[10-12,15]. Therefore, patients operated with the mini-open method may obtain faster recovery and shorter length of stay than the others.

Glassman et al[14] reported ODI improvement of 22.9% at a one-year follow-up from a group of 152 patients who underwent open lumbar procedures. Perez-Cruet et al[20] reported ODI improvement of 34.5% and slightly improvement of SF-36 from a group of 318 patients who underwent minimally-invasive transforaminal lumbar interbody fusion (MITLIF). Nevertheless, the previous studies were not prospectively compared between the other techniques.

According to the best of our knowledge, our present report is the first study that compared three various TPSF techniques in prospective fashion. The ODI scores (Fig. 4) of the navigation-assisted group showed significantly better recovery than the other groups at one week, one month and one year follow-up. According to Fairbank et al[13], ODI scores which less than 20 (minimal disability) would consider no significant effect on postoperative clinical outcomes. This explanation was in accordance with our results of SF-36 survey that revealed no different QoL among three groups of patients, which may have resulted from gradual fusion of the spine after operation and all patients suffered from a short segment of spinal stenosis.

In additions, Glassman et al[21] revealed ODI and SF-36 physical component score (SF-36 PCS) improvement from 357 patients at one year after lumbar spine fusion surgery. They postulated that substantial clinical benefit thresholds for SF-36 PCS should have at least one from three following criteria: firstly, 6.2-point net improvement; secondly, 19.4% improvement; and thirdly, final raw score of 35.1 or more points. Whereas, substantial clinical benefit thresholds for the ODI comprises of at least one of three conditions: 18.8-point net improvement; 36.8% improvement; and final raw score less than 31.3 points. The present study has demonstrated that the 12-month ODI and SF-36 PCS of our three groups of patients met at least one Glassmann's criterion (Table 5). This means that all of our patients achieved the substantial clinical benefit thresholds for both SF-36 PCS and ODI. Therefore, our three different TPSF techniques are effective in the treatment of LS patients.

Evidently, our three different TPSF groups had positive outcomes of quality-of-life. However, participants were included only mild grade LS (grade 1 and 2), so the severity of disease and clinical complaint may be less than the preceding study[14,15,20,21].

This present study was performed at a single centre hospital and focused on a small number of patients. The findings were subjective data collected for one-year follow-up, which may be not sufficient to determine the long-term outcomes such as adjacent level LS and re-operation rate. This present study was not a randomized control trial, so selection bias may be involved. Future research should be conducted and focused on long-term outcomes.

Overall, three different techniques provide the positive outcomes of quality-of-life. The 12-month follow-up of quality of life measures based on ODI show statistically significant differences in the surgical treatments, in which the navigation-assisted technique was significantly associated with well-recovery after surgery at one week and one month. However, in terms of clinical outcomes, these techniques did not make any difference to patient care within the 12-month follow-up period.

Table 5. Grassman's criteria for improvement threshold

Parameters	Conventional			Navigation-assisted			Mini-open		
	Baseline	1 year	Change (%)	Baseline	1 year	Change (%)	Baseline	1 year	Change (%)
ODI ± SD	23.5±6.8	8.7±5.8	14.8 (62)	21.4±7.3	5.8±4.2	15.6 (72)	23.0±7.3	10.6±6.8	13.3 (55)
SF-36 PCS ± SD	23.5±14.4	77.3±20.0	53.8 (70)	22.5±18.4	83.5±18.3	61.0 (73)	29.8±22.3	70.5±23.8	40.7 (57.7)

ODI = Oswestry Disability Index score; SD = standard deviation; SF-36 PCS = Short Form-36 Health Survey Physical Component Score

What is already known on this topic?

There are many options of surgical treatments for spondylolisthesis grade I-II. Typical surgical procedures employed into clinical practice are Mini-open TPSF, Navigation-assisted TPSF and Conventional TPSF techniques, which have been reviewed for their clinical and quality of life outcomes after surgery. Moreover, relative benefits of these techniques have been debated for which surgical technique should be the best possible one to accomplish the treatment.

What this study adds?

Prospective comparisons of clinical outcomes and quality of life after one-year surgery among three techniques has been presented for the first time. The patients' quality of life at one-year follow-up approached greater improvements. However, each surgical technique provides significantly different clinical outcomes, in terms of intra-operative bleeding, hospital stay and so on. Although differences appear in quality of life, there is no discrepancy in clinical outcomes among these three techniques. Therefore, surgeons should be able to consider his own preference in treating the spondylolisthesis grade I-II.

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Potential conflicts of interest

None.

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การเปรียบเทียบติดตามคุณภาพชีวิตของผู้ป่วยกระดูกสันหลังเคลื่อนหลังได้รับการผ่าตัดใส่ pedicle screw ด้วยสามวิธีที่แตกต่างกัน

เอื้ออังกูรย์ สิทธิมงคล, ธีระ ตั้งวิริยะไพบูลย์, ประเสริฐ เอี่ยมปรีชากุล, กุลพัฒน์ วีรสาร, สวิง ปันจัยสีห์, วุฒิพงษ์ ฐิรโฆไท

ภูมิหลัง: การเลือกวิธีการผ่าตัดใส่ pedicle screw ในผู้ป่วยกระดูกสันหลังเคลื่อนยังเป็นที่ถกเถียงว่าการผ่าตัดเชื่อมกระดูกสันหลังด้วยวิธีดั้งเดิม วิธีคอมพิวเตอร์ช่วยนำวิถีหรือวิธีผ่าตัดแบบเปิดแผลเล็กให้คุณภาพชีวิตที่ดีกว่า

วัตถุประสงค์: เพื่อวิเคราะห์ผลการรักษาทางคลินิกประเมินคุณภาพชีวิตก่อนผ่าตัดและติดตามหลังผ่าตัด จนกระทั่งครบ 1 ปี ในผู้ป่วยกระดูกสันหลังเคลื่อนที่ต้องรับการผ่าตัดเชื่อมกระดูกสันหลังทั้งสามวิธี

วัสดุและวิธีการ: ผู้นิพนธ์ได้เปรียบเทียบการผ่าตัดทุกวิธี ด้วยการติดตามคุณภาพชีวิตเป็นระยะเวลา 1 ปี ในผู้ป่วยทั้งสิ้น 60 ราย ที่ต้องเข้ารับการผ่าตัดใส่ pedicle screw ที่สถาบันประสาทวิทยา กรุงเทพมหานคร โดยแบ่งผู้ป่วยเป็น 3 กลุ่ม ติดตามประเมิน และสัมภาษณ์ถึงคุณภาพชีวิตในด้านต่างๆ เช่น สังคม สุขภาพจิต การใช้ชีวิตประจำวัน ผ่านแบบสอบถามชื่อ Oswestry Disability Index (ODI) และ Short Form-36 Health Survey (SF-36) ฉบับแปลภาษาไทย

ผลการศึกษา: ผลที่ได้พบว่าคุณภาพชีวิตของผู้ป่วยทั้ง 3 กลุ่มมีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ ผลสำรวจ ODI ในกลุ่มที่ได้รับการผ่าตัดด้วยวิธีคอมพิวเตอร์ช่วยนำวิธี มีคุณภาพชีวิตที่ดีขึ้นเร็วกว่าทั้งสองกลุ่มที่เวลา 1 สัปดาห์และ 1 เดือน ($p = 0.031$, $p = 0.008$ ตามลำดับ) นอกจากนั้นยังพบว่าที่เวลา 1 ปี กลุ่ม navigation-assisted มีคุณภาพชีวิตที่ดีกว่าทั้ง 2 กลุ่ม (mean ODI score = 5.8, $p = 0.033$) ในส่วนของ SF-36 ทั้ง 3 วิธีให้ผลว่าหลังการผ่าตัดมีคุณภาพชีวิตที่ดีขึ้นและไม่แตกต่างกันระหว่างทั้ง 3 กลุ่ม

สรุป: ทั้ง 3 วิธีการผ่าตัดเชื่อมกระดูกสันหลัง ให้ผลการรักษาในมุมของขุณภาพชีวิตที่ดีขึ้น แม้ว่าในทางสถิติแล้วกลุ่มที่ได้รับการผ่าตัดด้วยวิธีคอมพิวเตอร์ช่วยนำวิธี จะให้ผลว่ามีการฟื้นตัวที่เร็วกว่ากลุ่มอื่นๆ แต่ในทางคลินิกแล้ว ไม่ได้ให้ความแตกต่างกันในการดูแลผู้ป่วยในช่วงการติดตาม 1 ปี