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Comparing two surgical techniques for treating severe narrowing of the lower spine

Submission date
06/06/2024

Recruitment status
No longer recruiting

Registration date
05/11/2024

Overall study status
Completed

Last Edited
04/11/2024

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Over the past few decades, fusion surgery has become the preferred treatment for lumbar degenerative diseases, which involve the wearing down of the lower spine, causing pain and other issues. This type of surgery has generally yielded good results. Lumbar spinal stenosis (LSS), a condition where the spaces in the lower spine become narrow and put pressure on the nerves, is common in middle-aged and older adults and has been a focus of research for about 50 years. Surgery is often necessary for patients who do not respond to other treatments or who have serious nerve problems. Traditional surgical approaches, such as Anterior Lumbar Interbody Fusion (ALIF) and Posterior Lumbar Interbody Fusion (PLIF/TLIF), have shown good long-term outcomes but can have complications, including blood vessel injury and retrograde ejaculation in ALIF, and increased spinal instability and nerve damage in PLIF/TLIF. To mitigate these issues, some surgeons advocate for minimally invasive approaches like Extreme Lateral Interbody Fusion (XLIF) and Oblique Lumbar Interbody Fusion (OLIF), with OLIF being favored for avoiding major blood vessels and nerves. However, most data on OLIF come from mild to moderate LSS cases, with limited information on its effectiveness for severe LSS, a condition that is increasingly common in older adults. This study aims to compare OLIF with the traditional TLIF technique for treating severe LSS, assessing clinical and radiological outcomes to determine if OLIF is a feasible, effective, and safe option, thereby providing a minimally invasive surgical alternative for both surgeons and patients.

Who can participate?
Lumbar spinal stenosis patients aged 18 - 80 years requiring operation.

What does the study involve?
Participants will be randomly allocated to OLIF or TLIF group as part of their lumbar decompression and fusion surgery. Follow-up will be for 24 months.

What are the possible benefits and risks of participating?
The patients will gain added benefits such as the close monitoring by the treating physician before and for 2 years after the surgery, as well as the opportunity to discuss the problems they are facing and find solutions with their physician. The patients will have no added risks associated with the current study.

Where is the study run from?
The first affiliated Hospital of Soochow University (China)

When is the study starting and how long is it expected to run for?
September 2018 to September 2021

Who is funding the study?
This study has been supported by the Natural Science Foundation of Jiangsu Province (BK20130274), Research on collaborative innovation of medical and industrial integration in Suzhou (SZM2023010), Suzhou Medical Health Science and Technology Innovation Key Technology (SKY2021027) (China)

Who is the main contact?
Dr Xuefeng Li ,lixuefeng@suda.edu.cn

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Xuefeng Li

ORCID ID
https://orcid.org/0000-0002-9319-614X

Contact details
899 Pinghai Road
Suzhou
China
215006
+86 51267972285
lixuefeng@suda.edu.cn

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Yijie Liu

Contact details
899 Pinghai Road
suzhou
China
215006
+86 51267972285
liuyijie@suda.edu.cn

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Genglei Chu

Contact details
899 Pinghai Road
Suzhou
China
215006
+86 51267972285
chugenglei@suda.edu.cn

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
A multi-center, prospective, randomized, comparative study comparing Oblique lumbar interbody fusion (OLIF) supplemented with lateral vertebral screw fixation versus transforaminal lumbar interbody fusion (TLIF) for the treatment of severe lumbar spinal stenosis (Schizas C, D type)

Study objectives
OLIF supplemented with lateral vertebral screw fixation can ahieve sastisfactory outcomes comparable to TLIF for severe spinal stenosis patients, whereas with less invasiveness and more quicker recovery.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 20/09/2018, The Ethics Committee of The First Affiliated Hospital of Soochow University (899 pinghai Road, Suzhou, 215006, China; +86 51267972285; lixuefeng@suda.edu.cn), ref: ref:165

Study design
Multicenter interventional prospective randomized study

Primary study design
Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied
Surgical treatment of patients with severe lumbar canal stenosis

Interventions
The total duration of treatment and follow-up for all study arms: from November 2018 to September 2021,a total of 224 LSS patients rated as Schizas CD grade meeting above criteria were enrolled in this study following institutional review board approval and they were allocated randomly into two groups (OLIF or TLIF). The follow-up period was expected to be a minimum of 2 yrs.

A summary of the treatment given to each group:
OLIF group: the patient was placed into a right-sided lateral decubitus position under general anesthesia, a transverse skin incision of 3-5 centimeter centered over the anterior one-third of target space was made in the lateral abdominal region, the external oblique fascia was incised using monopolar cautery, and the abdominal muscle and transversalis fascia are divided bluntly. Once in the retroperitoneal space, blunt dissection was used to mobilize the peritoneum anteriorly and psoas posteriorly. Under direct visualization,serial dilators and tubular retractor were placed after the confirmation of the target level by C-arm followed by our special “egg-shell”discectomy and implantation of proper size Cage (Oracle Spinal System: DePuy-Synthes Spine, Raynham, Massachusetts, USA) filled with allograft bone. Then, additional fixation by lateral vertebral screw-rod system was done and after final radiographic confirmation, surgical site was rinsed by sterile saline and closed. TLIF group:the patient was placed in prone position, Under general anesthesia,after routine longitudinal skin incision and para-median stripping of spinal muscle, lamina and facet joint was exposed on the symptomatic side and a Wiltse approach was adopted on the contralateral side to expose facet joint only. After routine pedicle screw implantation, unilateral laminectomy and facetectomy was performed on the symptomatic side to expose disc space, followed by discectomy and end-plate preparation, implantation of an amount of autogenous morselized bone and a polyetheretherketone (PEEK) cage of appropriate size filled with autogenous morselized bone, two rods of proper length was then applied and fastened.after final radiographic confirmation,surgical site was rinsed and closed, with the placement of drain depending on local oozing. After surgery, all patients were given antibiotic and painkiller therapy in accordance with guideline recommendations and encouraged to take ambulation with help of brace on the first postoperative day.

Details of the randomisation process:
Randomization codes were obtained by a computerized random assignment generator program and the balanced randomization blocks were also randomized.After randomization codes were obtained, they were placed individually in envelopes and sequentially numbered. Sealed envelopes were sent to each participating site. Site staff opened the next available sequential randomization envelope to facilitate surgical planning, and participants were informed of the randomized procedure postoperatively.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Clinical outcome is evaluated by Oswestry disability index (ODI) and visual analogue scale (VAS) at baseline, 3, 6, 12, 24 m postoperatively
2. Radiological parameters include disc height(DH), fused segmental lordosis(FSL), lumbar

lordosis (LL),cross-sectional area of the thecal sac(CSA),all of which are measured at baseline, 3, 6, 12, 24 m postoperatively
3. Interbody fusion rate(IFR) is measured using CT/X-ray at 6, 12, 24 m postoperatively.

Key secondary outcome(s))
Measured after surgery using patient records:
1. Operation time(min)
2. Blood loss(ml)
3. First ambulation time(d)
4. Length of hospital stay(d)

Completion date
30/09/2021

Eligibility

Key inclusion criteria
1. LSS patients presenting with radicular symptom or neurogenic claudication, relieved by lying in bed rest, with or without low back pain
2. Disabling symptoms refractory to a minimum of 3 months of conservative treatment
3. Single-level (L2-L5) central canal, recess or neuroforamina stenosis estimated as Schizas C, D grade on radiologic imaging in consistent with clinical symptoms

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Total final enrolment
224

Key exclusion criteria
1. Failure of relief of symptom by lying in bed rest
2. Congenital stenosis, ossification of ligamentum flavum or PLL, bony lateral recess stenosis, arthrodesis of facet joint, disc sequestration, complete loss of disc height
3. High grade spondylolistheis(IIIo or more)
4. Abnormal anatomylimited corridor between major vessel and psoas ,anatomical variation of

greater vessel);
5. Previous operation of left abdomen;
6. Infection, tumor, and so on

Date of first enrolment
01/11/2018

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
China

Study participating centre
The first affiliated Hospital of Soochow University
899 Pinghai Road
Suzhou
China
215006

Study participating centre
The fourth affiliated Hospital of Soochow University
9 Chongwen Road
Suzhou
China
215125

Study participating centre
The ninth people’s Hospital of Wuxi affiliated to Soochow university
999 Liangxi Road
wuxi
China
214061

Study participating centre
Jiangbin Hospital affiliated to Jiangsu University
438 Jiefang Road
Zhenjiang
China
212001

Study participating centre
Taicang district of Ruijin Hospital of Shanghai Jiao Tong University
New District of Loujiang
Suzhou
China
215008

Sponsor information

Organisation
The first affiliated Hospital of Soochow University

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The first affiliated Hospital of Soochow University

Funder Name
Natural Science Foundation of Jiangsu Province (BK20130274)

Funder Name
Research on collaborative innovation of medical and industrial integration in Suzhou (SZM2023010)

Funder Name
Suzhou Medical Health Science and Technology Innovation Key Technology (SKY2021027)

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Xuefeng Li (lixuefeng@suda.edu.cn)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes