

# Safety and effectiveness of TOPS™ System

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<b>Registration date</b> 02/08/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 27/02/2018	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Degenerative spondylolisthesis is a condition where abnormal and excessive movement of the bones in the spine (vertebrae) causes pain in the lower back and legs. Spinal stenosis is a condition where compression of the nerves in the spine causes pain, numbness and tingling in the legs. When non-surgical treatment of these conditions is not effective, pain relief is typically achieved with surgery to fuse the affected vertebrae. While fusion may decrease the pain generated at the treated vertebrae, it increases the load on the adjacent vertebrae, causing a condition which may require further surgery in the future. The TOPS™ System is a mechanical device that effectively replaces the structures that are removed from the vertebrae during surgery. It is an alternative to spinal fusion that is designed to stabilize but not fuse the affected vertebrae, protecting against the problems associated with fusion. The aim of this study is to establish the safety and effectiveness of the TOPS™ System and provide evidence that the TOPS system provides better clinical outcomes than fusion.

### Who can participate?

Patients aged 40-85 with lower back and leg pain resulting from spinal stenosis and/or degenerative spondylolisthesis.

### What does the study involve?

Participants undergo spinal surgery with the TOPS™ System and are followed up for 2 years. They complete questionnaires to evaluate pain-related issues, wellbeing and quality of life, and have a series of x-ray images taken to evaluate the function and performance of the TOPS™ System.

### What are the possible benefits and risks of participating?

Not provided at time of registration

### Where is the study run from?

University Southampton Hospital (UK)

### When is the study starting and how long is it expected to run for?

October 2013 to November 2015

Who is funding the study?  
Premia Spine Ltd (Israel)

Who is the main contact?  
John Fowler

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mr John Fowler

**Contact details**  
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## Additional identifiers

**Protocol serial number**  
1513-CL-VL-01 SOU UK

## Study information

**Scientific Title**  
A study to evaluate the safety and effectiveness of TOPS™ System: a non-randomized single centre study

**Study objectives**  
The purpose of this prospective clinical study is to establish the safety and effectiveness of the TOPS™ System used following decompression, in the treatment of lower back and sciatic pain with, or without spinal claudication, that results from degenerative spondylolisthesis or spinal stenosis at one vertebral level between L3 and L5, with or without concomitant adjacent segment disease that requires a lumbar fusion.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
University Hospital Southampton NHS Foundation Trust, 24/02/2014, ref: RHM T&O0155

**Study design**  
Non-randomized single-centre study

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Single Level Lumbar Spine Stenosis (with up to a grade 1 spondylolisthesis)

## **Interventions**

This study will involve patients having surgery for their back/leg pain as per the standard of care currently offered to them.

Patients will be followed up for a period of 2 years post-operation. They will be questioned using standard ODI, VAS and ZCQ to evaluate pain related issues and well being / quality of life etc.

They will also have a series of radiographic images taken, again to evaluate the resultant function of the TOPS and monitor its performance in line with current clinical evidence.

## **Intervention Type**

Procedure/Surgery

## **Phase**

Not Applicable

## **Primary outcome(s)**

1. Individual Patient Success
2. Pain/Function/Disability at 24-month evaluation: Subjects who exhibit a reduction of 15 percent in their Oswestry Low Back Pain Disability Questionnaire score compared to their preoperative Oswestry score will be considered a success. Beurkens et al. has reported a change of 4 to 6 points of the 100 points for the Oswestry to represent a clinically significant improvement
3. Subjects who exhibit a reduction of 20mm in their VAS Leg Score (combined leg score)
4. Radiographic: Any TOPS subject will be considered a failure if fusion occurs as defined in the radiographic protocol

## **Key secondary outcome(s)**

Although the main goal of this trial is to address the primary endpoint of overall effectiveness at 24 months, individual outcome endpoints will be evaluated and will include average improvement in back and leg visual analog scales (VAS), ZCQ scores, quality of life (SF-36), and maintenance or improvement in neurological symptoms. When possible, other factors such as vertebral range of motion, disc height, length of stay, OR time, blood loss, work status pre-surgery, return to work status, time to recovery and narcotic use will be evaluated. An economic analysis of patient and hospital costs for each study group may also be performed.

## **Completion date**

30/11/2015

## **Eligibility**

### **Key inclusion criteria**

The study population will be comprised of patients suffering from lower back and leg pain which results from degenerative spondylolisthesis and/or spinal stenosis who meet the eligibility criteria as follows

1. Patients with one or both of the following conditions at a single spinal level between L3 and L5 are eligible for the TOPS™ System implant:

1.1. Symptomatic monosegmental lumbar spinal stenosis

1.2. Degenerative Spondylolisthesis up to and including grade 1 (see radiographic protocol)

2. Patients with one or more of the following conditions at one or two levels adjacent to the TOPS System between L4 and S1 are eligible for the Versalink™ Fixation System implant:

2.1. Symptomatic monosegmental lumbar spinal stenosis

2.2. Degenerative Spondylolisthesis up to and including grade 1 (see radiographic protocol)

2.3. Discogenic pathology

3. At least three (3) months of failed, conservative treatment prior to surgery, including use of anti-inflammatory medications at maximum specified dosage; administration of epidural/facet injections, unless deemed inadvisable due to progressive motor weakness or other evidence of rapidly deteriorating condition; rest, heat, electrotherapy/physical therapy

4. Narrowing of the lumbar spinal canal classified as moderate to severe using CT scans/MRI

5. Age 40-85 years old (male or female)

6. Lower back pain and sciatica with or without spinal claudication

7. Psychosocially, mentally and physically able to fully comply with the clinical protocol and willing to adhere to follow-up schedule and requirements.

8. Leg pain of at least 40/100 at baseline as per visual analogue scale (VAS)

9. Oswestry Questionnaire score of at least 40/100 at baseline

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Key exclusion criteria**

Patients who have any of the following conditions or meet any of the following criteria are excluded from participating in this study:

1. Primary diagnosis of discogenic back pain at the TOPS System level

2. Back or non-radicular leg pain of unknown etiology at the TOPS System level

3. Lytic spondylolisthesis at the TOPS System level

4. More than one (1) motion segment involved in the degenerative pathology to the extent that justifies its inclusion in the surgical procedure, unless a decompression alone can be done at that level without compromising stability or the Versalink System is implanted.

5. Known allergy to titanium and/or polyurethane

6. Prior surgery at any lumbar vertebral level

7. Supplemental interbody support required (e.g., bone graft, spacers, VBRs, or fusion cages) at the TOPS System level

8. Clinically compromised vertebral bodies at the affected level(s) due to any traumatic,

neoplastic, metabolic or infectious pathology.

9. Deformity of the spine that would compromise the implant, e.g. scoliosis of greater than ten (10) degrees

10. Morbid obesity defined as a body mass index > 40 or a weight more than 100 lbs. over ideal body weight

11. DEXA bone density measured T score equal to or lower than -2.0

12. Paget's disease, osteomalacia, osteogenesis imperfecta, thyroid and/or parathyroid gland disorder and/or any other metabolic bone disease

13. Active infection - systemic or local

14. AIDS, HIV, or active hepatitis

15. Rheumatoid arthritis or other autoimmune disease

16. Tuberculosis active or in the past 3 years

17. Active malignancy: A patient with a history of any invasive malignancy (except non-melanoma skin cancer), unless he/she has been treated with curative intent and there have been no clinical signs or symptoms of the malignancy for at least 5 years

18. Medical conditions requiring treatment with any drugs known to potentially interfere with bone/soft tissue healing

19. Pregnant or interested in becoming pregnant in the next 3 years

20. Current chemical/alcohol dependency or significant psychosocial disturbance

21. Subject is currently involved in another investigational study

22. Cauda equina syndrome or neurogenic bowel/bladder dysfunction

23. Severe arterial insufficiency of the legs, peripheral vascular disease

24. Sustained pathologic fractures of the vertebra or multiple fractures of the vertebra or hip

25. Unremitting pain in any spinal position

26. Significant peripheral neuropathy

27. Immunologically suppressed, received steroids > 1 month out of the past year

28. Insulin-dependent diabetes mellitus

29. Currently taking anticoagulants other than aspirin (e.g., Plavix)

30. Life expectancy less than 3 years

31. Waddell signs > 3

32. Currently involved in active spinal litigation

33. Subject is incarcerated

**Date of first enrolment**

01/10/2013

**Date of final enrolment**

30/11/2015

**Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

University Southampton Hospital

Southampton

United Kingdom  
SO16 6YD

## Sponsor information

### Organisation

Premia Spine Ltd (Israel)

## Funder(s)

### Funder type

Industry

### Funder Name

Premia Spine Ltd (1513-CL-VL-01 SOU UK) (Israel)

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration