Status: The Wallis Stabilization Trial has now been completed.

Desert Institute for Spine Care has been selected to participate in the Wallis Stabilization System Clinical Trial.

Introduction to the Wallis Stabilization System
The Wallis Normalization System is a non-fusion, spinal stabilization device that is currently limited by US law to investigational use within the US. The Wallis clinical study is a multi-center, prospective, randomized study comparing the safety and effectiveness of the Wallis device to the latest non-surgical treatment regimen including medication, physical therapy and spinal injections. The Wallis System is designed to help with the pain caused by degenerative disc disease (DDD) by stabilizing the lumbar spine without a fusion procedure.

Study objectives
The primary objective of the Wallis Clinical Study is to demonstrate that the Wallis System is superior to non-surgical care at treating mild to moderate degenerative disc disease at one or two levels between L1 and L5 of the lumbar spine.

Study overview
Approximately 20 medical centers will be enrolling patients into this clinical study to assess the safety and effectiveness of the Wallis System for mild to moderate degenerative disc disease of the lumbar spine.
The Study will be randomized so that 67% of the study participants will receive a Wallis Device and 33% will receive non-surgical, conservative care treatment which will consist of a balance between medication, physical therapy and spinal therapy injections. Patients will be randomly assigned to receive either a Wallis Device or conservative care.

Study sponsor
Austin, TX based Abbott Spine is a wholly-owned subsidiary of Abbott Laboratories. The company researches, develops and sells spinal instrumentation in the treatment of degenerative spinal disorders.

For more information, please visit us at our website (www.abbottspine.com).

Inclusion criteria for Wallis Stabilization System Clinical Trial

- Age 18-60
- Diagnosis of mild to moderate degenerative disc disease, which requires the following:
  - Candidate for either surgery with Wallis or aggressive conservative management.
  - Patient requires surgical treatment at one or two lumbar levels between L1 and L5.
  - Experienced symptoms for at least three months without significant resolution.
  - Minimum baseline Oswestry Score of 30% (15/50);
  - Physically and mentally able to comply with the protocol, including ability to read and complete required forms, and willing and able to adhere to the follow-up requirements of the protocol; and
  - Voluntarily signs the Patient Informed Consent.

Exclusion criteria for Wallis Stabilization System Clinical Trial

- Radiographic evidence of degenerative disc disease at L5-S1;
- Leg pain without back pain;
- Greater than 50% disc collapse as compared to adjacent discs;
- Modic 2 or Modic 3 bone changes at the symptomatic level;
- Radiographic confirmation of severe facet joint disease or degeneration;
- Clinically compromised vertebral bodies at the affected level due to current or past trauma, e.g., sustained pathological fracture or multiple fractures of vertebrae.
- Unwilling to comply with 8 weeks of physical therapy.
- Refusal to consider epidural or facet injections for leg or back pain.
- Active systemic infection or infection at the operative site;
- Osteoporosis.
- Paget’s disease, osteomalacia, or any other metabolic bone disease other than osteoporosis, which is addressed above;
- Rheumatoid arthritis, lupus, or other autoimmune disease;
- AIDS, HIV, or Hepatitis;
- Known allergy to titanium, polyetheretherketone, or polyester;
- Pathological lesions, such as tumor;
- Congenital lumbar spinal stenosis;
- Cauda Equina syndrome;
- Pregnant at time of enrollment or with plans to become pregnant within the next three years;
- Concomitant conditions requiring steroid treatment or prior steroid usage for more than one of preceding three months;
- Diabetes mellitus requiring daily insulin management;
- Back or leg pain of unknown etiology;
- Extreme obesity, as defined by NIH Clinical Guidelines Body Mass Index (BMI >35);
- Fusion previously performed at the same or an adjacent level, or other instrumented spinal surgery at the operative level;
- Prior participation in study of any experimental spinal implant or treatment;
- Pending litigation relating to spinal injury;
- Life expectancy of less than three years;
- History of any invasive malignancy (except non-melanoma skin cancer), unless treated with curative intent and with no clinical signs or symptoms of the malignancy for at least 5 years;
- Current or recent history of substance abuse (alcoholism and/or narcotic addiction) requiring intervention;
- Anticipated or potential relocation >50 miles that may interfere with completion of follow-up examinations;
- Spondylolysis;
- Translation greater than 2 mm at the symptomatic level;
- Significant scoliosis (Cobb angle >25 degrees) or scoliosis otherwise requiring surgical correction;
- Kyphosis requiring surgical correction.