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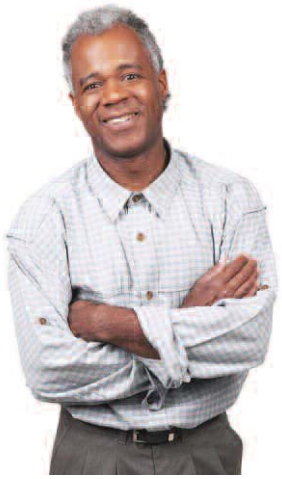
Clinical Study
Patient Information Brochure

Wallis® Device



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Clinical Study Information

What is the purpose of a clinical study?
When a new medical device, such as an implant for the back, is developed for use in the United States, it must first be thoroughly tested to make sure it is safe and effective. To do this, a clinical study is designed to test the device's safety and to make sure that the device is working as intended after surgery. Such a clinical study must be approved by the FDA and contain a limited number of patients who agree to take part in the study.

You are being asked to take part in the Wallis Clinical Study.

The Wallis Clinical Study will include roughly 340 patients and the follow-up time will be at least two years (along with annual visits until the study is closed, five years after your surgery date). Your surgeon's office is one of about 20-25 sites around the United States taking part in the Wallis study. Clinical studies typically require a control group for comparison to the investigational group, and this study is no exception. In the Wallis study, patients receiving the Wallis device will be compared to patients receiving an artificial disc replacement, an FDA-approved implant designed to replace an entire diseased or damaged spinal disc through a surgery called "total disc replacement" (TDR). When each patient enrolls in the Wallis study, they are equally likely to receive either a Wallis device or a total disc replacement. All patients enrolled in the Wallis study will receive surgery.

The purpose of the Wallis study is to see how well the Wallis device treats low back pain caused by the breakdown of the spinal disc(s) in your back, a condition known as degenerative disc disease. This study is for people who have suffered low back pain at a specific level, but have never had surgery to treat the pain.

Wallis Clinical Study Quick Facts

Number of patients in the study	~340
Number of hospitals taking part in the study	0-25
Patient follow-up time	5 years
Wallis control group comparison	Total disc replacement
Wallis device-to-Total Disc Replacement	1-to-1
Treatment focus	Lower (lumbar) spine

Wallis Device Option

What is the Wallis device?
The Wallis device is a spinal implant that is surgically inserted between the bones in your back (called vertebrae). The device is designed to relieve low back pain caused by degeneration or damage to a disc in your spine. Disc degeneration can change the normal movements and the overall strength of the spine. Additionally, a degenerated disc may lose its ability to act as a shock absorber, which is important for day-to-day, pain-free living. These problems could progress to persistent low back pain. The Wallis device attempts to restabilize or support the spine during the early stages of degeneration. It also aims to slow the breakdown of the disc while still allowing the spine to move normally. Unlike fusion surgeries, the Wallis device is designed to stabilize your spine without joining or "fusing" vertebrae. Unlike many spinal devices for the low back, the Wallis device is implanted using a posterior approach, which means the device is inserted through a small incision in your back. Alternatively, an artificial disc is implanted in your lower back using an anterior approach, meaning, through an incision near your stomach.

What does the Wallis device look like?
The actual implant is a small plastic spacer that fits between two spinous processes (the bumps that you feel in the middle of your back). There are also two stabilizing bands; one wraps around each of the spinous processes to provide additional stability (Fig. 1).

What is the process if I enroll in the study and receive a Wallis device?
After talking with your doctor, if you consent to take part in the Wallis study and are assigned to receive the Wallis device, there are a number of steps that must be taken both before and after the surgery. Before the surgery, there will be forms that you must read carefully and sign. After the surgery, you will have a series of follow-up visits in your surgeon's office. These visits will be six weeks, three months, six months, 12 months, and 24 months after your surgery. The follow-up visits will then continue annually until the end of the study, which is five years after your surgery. Each visit will include an exam with your doctor and x-rays, as well as questionnaires for you to complete. In addition to general x-rays, patients who receive the Wallis device will need to a have a form of x-ray called an MRI, taken at the 24-month and five-year visits.

What are some possible benefits and drawbacks to the Wallis device?
The purpose of the Wallis study is to investigate the safety and effectiveness of the device versus total disc replacement (TDR). The Wallis device has been in use throughout different parts of the world, but is now being studied in the United States for the first time. As with all new technologies, there are potential benefits and risks associated with the Wallis device. Some of the potential advantages and disadvantages of the Wallis device are outlined in the table (right).

Fig. 1 Wallis Implant

Wallis Potential Benefits	Wallis Potential Risks
May relieve pain without necessitating spinal fusion	May not fully rid patient of back pain
Surgery is relatively conservative when compared to other surgical choices like fusion or disc replacement	Patient may have instability after surgery
The procedure does not prevent another procedure, eg. Fusion or disc replacement, if symptoms persist	As with all surgeries, surgery-related complications may occur

Total Disc Replacement Option

What does it mean to have a total disc replacement (TDR)?
TDR is a surgical procedure in which a diseased or damaged disc is replaced with a mechanical device (artificial disc) that behaves similarly to the body's natural disc. Artificial discs have been approved for sale in the United States by the FDA. Like many spinal implants, TDR are implanted using an anterior approach, which means the surgeon inserts the device through an incision made near your belly button. The primary advantage of receiving the TDR implant is that, unlike current fusion implants used to treat degenerative discs, the design of the TDR device allows the treated area of the spine to maintain its ability to move.

What does an artificial disc look like?
The artificial disc consists of two metal "plates" (called endplates) with a plastic core located in between. After the patient's natural disc is removed, the artificial disc is placed between the vertebrae (bones of the spine).

What is the process if I enroll in the study and receive a TDR?
The process for patients receiving a TDR is very similar to patients receiving the Wallis device. The primary difference is that patients who receive a TDR will not need to have an MRI (similar to x-rays) taken at their 24-month and five-year follow-up visits. All other required paperwork and follow-up visits remain the same whether you receive a Wallis device or TDR.

What are some potential benefits and drawbacks to TDR?
Just like the Wallis device, TDR has some positives and negatives. Some of these are listed in the table (right).

TDR Potential Benefits	TDR Potential Risks
May relieve pain without necessitating spinal fusion	May not fully rid patient of back pain
Possibly preserves motion at the affected level unlike other surgical choices	The surgery is conducted through the abdomen (which is more invasive, or stressful to the body) rather than through the back
The procedure may prevent adjacent level disc disease, a pathology commonly associated with fusion surgeries	May reduce chance of having another procedure, such as a fusion, in the event that symptoms persist
	As with all surgeries, surgery-related complications may occur

Patients for the Wallis Study

Who is a good candidate for the Wallis study?
The Wallis study is intended for people with mild to moderate degenerative disc disease in the lumbar spine. Your doctor can help determine if your back pain is a result of mild to moderate degenerative disc disease. Patients must also meet the following criteria in order to take part in the Wallis study:

- Age 18 – 60
- Have experienced at least six months of failed non-surgical or "conservative care" treatments (physical therapy, oral medications, back injections, etc.)
- Voluntarily read and sign the informed consent document

Who is not a good candidate for the Wallis study?
If one or more the following things apply to you, then you will not be able to take part in the Wallis study:

- Disc problems at more than one level in the lower back
- Leg pain without back pain
- Unwilling to undergo surgery
- Bacterial infection
- Poor bone quality
- HIV or Hepatitis
- Lumbar Stenosis
- Pregnant
- Diabetes requiring daily insulin management
- Extreme obesity
- Prior participation in the clinical study of any investigational spinal implant or investigational spinal treatment
- Previous fusion surgery at the same level or levels next to the level being studied

Frequently Asked Questions

What will I need to do if I take part in the Wallis study?
If you take part in the study, you will be asked to:

- Read and sign an informed consent
- Schedule and show up for follow-up visits
- Take x-rays and answer additional questions at your follow-up visits
- Have an MRI at two years and five years post-enrollment if you have received the Wallis device
- Take other medical exams as determined by your doctor
- Quickly report any problems to your doctor

Is the Wallis device being used anywhere else in the world?
The Wallis device was originally developed in Bordeaux, France and has been in use in various parts of the world since 1986. More than 12,000 patients have been treated with a Wallis device. Up to this point, the FDA has not approved Wallis for use in the United States. The aim of the Wallis study is to gain approval to use the Wallis device in the United States.

How long will the study last?
Patient follow-up for the Wallis study will be five years from your surgery.

What if the surgery I receive—whether the Wallis device or TDR—does not get rid of the pain?
There is a chance that the surgery you receive in the Wallis study will not get rid of all of your back pain. If this occurs, you will then consult with your doctor to review all non-surgical and surgical options to address the pain.

Where will I go for the follow-up visits?
The surgeon that asked you to take part in the study is in charge of collecting all the information on your follow-up visits. Therefore, you will schedule these visits in his/her offices.

Why should I go to the doctor's office if my back feels fine?
It is very important that the doctor's office is aware of how well you are doing. This information is important for the Wallis study and it is the only way your doctor can follow your progress. Further, by attending your follow-up visits, you allow Abbott Spine to report the most accurate information to the FDA, so that an appropriate decision about approval for the device can be made. The treatments cannot be compared if participants don't return to their physicians for follow-ups visits.

What if I miss my doctor's appointment?
If you cannot make a follow-up visit, please notify your doctor's office and reschedule the visit as soon as possible. It is important that these follow-up visits happen. The study requires that visits occur within specific windows of time (i.e., six weeks, three months, six months, etc.).

What should I do if I am planning to move?
If you plan to move out of the area before enrolling, you may not be a good candidate for the Wallis study and should consider not participating in the study. If you enroll in the study and an unanticipated move becomes necessary before all of your follow-up visits are complete, please contact your doctor's office or the Clinical Affairs department at Abbott Spine. Another doctor might be suggested so you can continue with your follow-up visits. Please make sure that your doctor's office has your most current address and phone number at all times throughout the study.

What should I do if I enroll in the study, but change my mind later?
Participation in the Wallis study is completely voluntary. Even after you have enrolled, you can decide to withdraw your participation at any time without consequence to you or the care you receive from you doctor. However, if you are unsure that you would like to participate in the study prior to enrolling, you may not be the best candidate for the Wallis study. It is important that you carefully consider all of your treatment options prior to enrolling.

Where can I go to find more information on degenerative disc disease, spine health, and the Wallis study?

Additional Information
For additional information on degenerative disc, total disc replacement, and the Wallis Study, please ask your doctor's office for additional resources. Remember to take advantage of the internet. Some sites that may be of use include:

www.abbottspine.com
www.clinicaltrials.gov
www.spine.org
www.charitedisc.com
www.spine-health.com
www.spineuniversity.com
www.spineuniverse.com
www.understandspinesurgery.com