activL® Artificial Disc Clinical Trial Results Media Summary

About the study:

Aesculap Implant Systems conducted a head-to-head study against conventional lumbar disc designs to determine if its activL Artificial Disc technology was as effective as conventional disc replacement procedures in the treatment of patients with symptomatic lumbar degenerative disc disease (DDD) who are unresponsive to nonsurgical therapy. These conventional disc designs had previously been compared to spinal fusion with favorable outcomes.

- 24 months
- 324 patients – 218 received activL Artificial Disc and 106 received control discs
- Prospective, multicenter, randomized, single-blind, controlled trial approved by the FDA

While the primary objective of the study was to determine if the activL Artificial Disc was as effective as conventional disc designs, the study found statistically significant improved outcomes in patients with the activL Artificial Disc over the control in a number of key areas, most notably range of motion.

Results:

Overall, subjects who received activL Artificial Disc were 14 percent more likely to succeed at 24 months. Success was defined based on a number of factors detailed below.

Implant/procedure

- Patients in the control group were 1.5 times more likely to have at least one procedure- or device-related serious adverse event than patients with activL Artificial Disc implanted.
- 93 percent of activL Artificial Disc patients had neurological success, defined as no decline in motor or sensory evaluations.

Range of motion

- Range of motion success was greater in the activL group (70 percent) compared to the control group (52 percent).

Pain improvement

- The trial used the Oswestry Disability Index (ODI) to evaluate the patient's quality of life after surgery. The index uses a patient questionnaire that includes 10 topics relating to quality of life and for each topic asks patients to select a statement that best describes their condition in this area. A lower score indicates less disability due to back pain. The ODI score was lower in the activL group than in the control group.
- At a six-week follow-up appointment, activL Artificial Disc patients saw more than a threefold decrease in back pain. This decrease persisted for the duration of the two-year study.
- activL Artificial Disc subjects returned to work 29 days sooner than those in the control group.
- In looking at just the individuals who were working up until their operation, activL Artificial Disc subjects returned to work a median of 85 days sooner than their control group counterparts.

AESCULAP®
Implant Systems

activL® Artificial Disc Intelligent Motion Technology™

Indications for Use

The activL® Artificial Disc is indicated for reconstruction of the disc at one level (L4-L5 or L5-S1) following single-level discectomy in skeletally mature patients with symptomatic degenerative disc disease (DDD) with no more than Grade I spondylolisthesis at the involved level. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history, physical examination, and radiographic studies. The activL® Artificial Disc is implanted using an anterior retroperitoneal approach. Patients receiving the activL® Artificial Disc should have failed at least six months of nonoperative treatment prior to implantation of the device.

Contraindications, Warnings and Precautions

The activL® Artificial Disc should not be implanted in patients with the following conditions:

- Active systemic infection or localized infection near the surgical site.
- Osteoporosis or osteopenia defined as dual-energy X-ray absorptiometry (DEXA) bone mineral density T-score less than or equal to -1.0
- Allergy or sensitivity to the implant materials (cobalt, chromium, polyethylene, titanium, tantalum, or calcium phosphate)
- Isolated radiculopathy, especially due to herniated disc
- Chronic radiculopathy (unremitting pain with predominance of leg pain symptoms greater than back pain symptoms extending over a period of at least a year)
- Extruded disc material with sequestrum (i.e., free disc fragment)
- Myelopathy
- Spinal stenosis
- Spinal deformity such as scoliosis
- Spondylolysis/isthmic spondylolisthesis, degenerative spondylolisthesis > Grade I, or segmental instability
- Clinically compromised vertebral bodies at the affected level due to current or past trauma (e.g., current or prior vertebral fracture) or disease (e.g., ankylosing spondylitis)
- Facet ankylosis or facet joint degeneration
- Preoperative remaining disc height < 3 mm
- Symptoms attributed to more than one vertebral level
- Abdominal pathology that would preclude an anterior retroperitoneal approach
- Involved vertebral endplates dimensionally smaller than 31 mm in the medial-lateral and/or 26 mm in the anterior-posterior directions

For a complete list of Warnings, Precautions and Risks please visit www.aesculapimplantsystems.com

Rx Federal (USA) law restricts this device to sale by or on the order of a physician.

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