Clinical Study of the Valeo OL Interbody Fusion Device for Posterior Lumbar Interbody fusion versus PEEK: the Silicon Nitride and PEEK (SNAP) trial.

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Primary ObjectiveThe primary objective is to show that fusion with the Valeo OL spacer produces similar improvement in MRDQ at all follow-up time points as compared to the same procedure with PEEK cages.Secondary ObjectivesTo show that the fusion…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON36245

Source
ToetsingOnline

Brief title
Silicon Nitride and PEEK (SNAP) trial

Condition

- Bone and joint therapeutic procedures

Synonym
Lumbar degenerative disc disease/ spinal stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Amedica Corporation

Source(s) of monetary or material Support: Fabrikant van de medical device/ Amedica

Intervention

Keyword: Cage, Fusion, Interbody, Spine

Outcome measures

Primary outcome

Primary Endpoint

Disability as measured with the MRDQ.

Secondary outcome

Secondary Endpoint

Fusion rate will be evaluated by comparing flexion and extension radiographs

correlated to clinical improvements on the MRQD/SF-36 and VAS. Fusion quality

will be verified with a CT scan at 12 months

Study description

Background summary

Fusion cages have become popular for use in interbody fusion procedures1. These devices are strong enough to provide mechanical support for the normal axial loads borne by the spine. They are also often used to restore the height of the disc space and are generally designed to contain the bone graft which encourages fusion of the adjacent vertebrae. Initially, fusion cages were implanted in pairs via the traditional posterior lumbar interbody fusion (PLIF) technique, but more recently, a single oblique cage has been used2;3. Cages were originally titanium alloy but in the last ten years have more often been made from polyetheretherketone (PEEK) plastic. PEEK is relatively inert, and does not provoke a strong foreign body reaction in the body, generally being surrounded by a thin fibrous tissue capsule4. In literature PEEK cages have reported to promote spinal interbody fusion with high fusion rates and have shown good to excellent clinical outcomes compared to other cages 26;27;28. These results confirm the safety and superiority of PEEK cages. They are often used as the standard cages in interbody fusion procedures. PEEK is invisible on x-ray and CT scan5; in order to be able to visualize the cages

during and after the procedure, radio-opaque metal markers are drilled or molded into the cages. PEEK cages have an advantage over the earlier metal cages: they do not cause artifacts on CT or MR scans. Follow-up imaging is often important to determine the cause of ongoing symptoms and/or to verify that fusion has occurred.

Silicon nitride, Si3Ni4, is a ceramic material with a compression strength exceeding the plastic and metal materials used as interbody fusion spacers. Unlike many ceramics, silicon nitride resists brittle fractures; its toughness exceeds that of alumina, a material with 30+ years of use in joint replacements7. Silicon nitride is highly compatible with standard spinal imaging techniques. The material produces no artifacts on x-ray, CT or MR images8. Several studies have demonstrated the biocompatibility of silicon nitride9-11. One case report showed good clinical and radiological results in 2 patients one year after a transforaminal lumbar interbody fusion procedure with use of the Si3Ni4 Valeo TL implant 29. An abstract presented at the 7th World Biomaterials Congress in May 2004 demonstrated the results of a 10 year follow-up of a clinical study in which 30 patients underwent anterior interbody fusion of the lower spine using silicon nitride intervertebral spacers. They showed a maintainence of interbody fusion in all cases after 10 years30. Amedica Corporation has been manufacturing orthopedic implants from silicon nitride for several years, and received the CE Mark and FDA marketing clearance for its use as interbody spacers in 2008.

Study objective

Primary Objective
The primary objective is to show that fusion with the Valeo OL spacer produces similar improvement in MRDQ at all follow-up time points as compared to the same procedure with PEEK cages.

Secondary Objectives
To show that the fusion rate of Valeo OL patients is similar to the fusion rate of PEEK cages at 3 months, 6 months, 12 months and 24 months and to show that Valeo OL shows more bone inside the cages at 12 month based on CT images.

Study design

This research project will be conducted on a prospective, randomized, multicentre basis with a 2-year longitudinal follow-up with repeated measurement analysis. Patient-recorded data will be entered by research nurses or physicians who are blinded to the implant used.

Intervention

All patients will be planned for spine surgery in which the Valeo or the PEEk

cage is used. Patient will be followed for 2-years (3 months, 6 months, 12 months and 24 months) for CT scans and to complete all te required questionnaires. (SF-36/ MRMDQ/ VAS backpain /VAS legcomplaints/ EQ-5D).

Study burden and risks

As with any surgery, there are serious risks. These include, but are not limited to pain, infection, blood clots, blood loss, allergic reaction and even death. Other risks and discomforts that could happen because of the procedures are: disassembly, breakage, degradation, or displacement (migration) of the implant; collapse of the implant or graft into the vertebrae; spinal instability; a change in the curvature of the spine; vessel damage/bleeding; nerve injuries; tears or hardening of the tissue surrounding the disc; dural tears; paralysis or a continuation of pain; numbness; tingling; sensory loss or spasms; cauda equina syndrome; scar formation; urinary control changes; postoperative changes in the curvature of the spine; bone loss; loss of spinal mobility or function; non-union or delayed union of the spinal bone; fracture or microfracture of the spinal bone or the bone graft material; sexual dysfunction; development of respiratory problems (e.g. pulmonary embolism, bronchitis, pneumonia, etc); change in mental status and death.
Risks associated with the use of allograft include but are not limited to: failure of graft material resulting in nonunion; and allergic reaction to the antibiotics or chemicals used during processing.
It is possible that the surgery will not reduce or relieve symptoms, and the treatment may not result in therapeutic or direct health benefits. This cannot be predicted for either the SiN or the PEEK implant. If the study implant does not relieve symptoms or if there is a problem with the device, it is usually possible to have it removed. This would require another surgery.
This research study involves additional exposure to radiation. The subject will receive 3-5 mSv from the CT scan of the lumbar spine done after 12 months, and 1.5 mSv form each RSA visit done at baseline, 3, 6, 12 and 24 months. The amount of background radiation that people receive during the course of their daily lives is 3 mSv per year. Those that participate in this study will receive approximately 3 times the average yearly dose over the course of 2 years.

In addition to the general risks of spine surgery, there are specific potential risks associated with the use of the Valeo OL spacer: implant migration or subsidence, implant fracture, and pseudarthrosis (fusion failure).
The potential benefits of PLIF procedures include the potential to dramatically improve the patient*s quality of life by reducing back pain. The fusion procedure also offers the possibility to stop the progression of spondylolisthesis, preventing an increase in disability. The level of potential improvement is also related to pre-existing medical conditions.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

_Subjects must be 18-75 years old.
_ at least 6 months of back pain/leg pain
_Grade 3 or higher disc degeneration on the MRI (by the Pfirrmann classification) with or without nerve root compression

Exclusion criteria

•Osteoporosis
•Patients with prior failed fusion at the same level
•Degenerative scoliosis
•Degenerative spondylolisthesis greater than Grade II

•Pregnancy
•Psychiatric or mental disease
•Alcoholism (drinking more than 5 units per day)
•Active infection or prior infection at the surgical site
•Active cancer
•Insufficient language skills to complete questionnaires
•Participation in another study
•More than two symptomatic levels that need fusion

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-02-2012
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Valeo® OL Silicon Nitride Interbody Fusion Device en de Pioneer® Bullet PEEK Interbody Fusion Devic
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	01-11-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-07-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL34808.100.10