Persona Outcomes Led Assessment Research in Total Knee Arthroplasty

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The objective of this study is to obtain clinical performance (outcomes) data andsurvivorship for commercially available Zimmer Persona knee implants implanted inprimary total knee arthroplasty.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON40356

Source
ToetsingOnline

Brief title
POLAR

Condition

- Joint disorders

Synonym
knee osteoarthritis, knee wear

Research involving
Human

Sponsors and support

Primary sponsor: Zimmer GmbH
Source(s) of monetary or material Support: Zimmer GmbH

Intervention

Keyword: Arthroplasty, Implant survival, Persona knee implant, Total knee

Outcome measures

Primary outcome

Implant survivorship based on removal of a study device.

Secondary outcome

Safety based on incidence and frequency of adverse events.

Clinical performance measured by overall pain and function, quality of life

data, radiographic

parameters and survivorship.

Study description

Background summary

Osteoarthritis (OA) is the most common type of arthritis causing considerable disability
across broad populations. The economic burden of arthritis, specifically osteoarthritis is
enormous with an estimated cost of $60 billion in the United States and expected to
increase to $100 billion by 2020.(1;2) The knee joint is the most common joint to develop
OA and total knee arthroplasty (TKA) is the most frequently performed joint arthroplasty
procedure for this condition.(3;4) With an increase in the prevalence of arthritis, obesity,
and old age, a further demand for TKA is projected to increase substantially over the next
few years. (5;6;7;8;9) In 2005, approximately 523,000 TKAs were performed nationally.(10) The American Academy of Orthopedic Surgeons (AAOS) and Kurtz et al,(11) have provided projections for future demand of TKA. In 2002, the AAOS had
suggested an annual replacement load of 474,000 by the year 2030. In 2007, Kurtz et

al,(11) described an annual demand of 3.5 million by 2030. While these projections vary widely, both suggest a strong increase in demand for TKA, prompting significant interest from surgeons, healthcare institutions and orthopedic device manufacturers interested to better understand the future technological and economic burden of TKA.

Although, TKA has demonstrated effectiveness with substantive and sustained improvement in quality of life for individuals with moderate to severe osteoarthritis,(12;13) functional performance in patients 1 year after TKA remains lower than for healthy adults, with reports of an 18% slower walking speed, 51% slower stair-climbing speed, and deficits of nearly 40% in quadriceps strength.(14) Additionally, certain limitations in knee design systems require surgeons to accept compromises which can result in surgical inefficiencies and challenges in seizing desired outcomes.(15;16;17;18;19) Patient expectations and an ever emerging population with active lifestyle also add a new requirement and need for innovative designs that bring advantages over traditional implants. Personalized implants with critical features of natural movement, contoured shape, and unique anatomic and physiologic composition can address these requirements. The current concepts in TKA warrant a personalized orthopedics initiative by offering a finer ability in identifying and precisely addressing the unique needs of patients. It is through this introduction of high fidelity implants, morphologic designs and intelligent instrumentation that each patient*s knee can be distinctively and accurately reconstructed, allowing for clinical outcomes to be better optimized. Furthermore, such personalized systems will empower the surgeon to advance performance by providing a leading design that efficiently accommodates surgeons* intraoperative needs with minimizing surgical trade-offs and maximizing efficiency.

To address these clinical challenges and methodologically address new implant characteristics, a prospective, multi-center, longitudinal data collection model is being proposed. The objective of this study is to determine clinical performance/ outcomes and implant survivorship for commercially available Zimmer Persona knee implants

used in
primary total knee arthroplasty.

Study objective

The objective of this study is to obtain clinical performance (outcomes) data and
survivorship for commercially available Zimmer Persona knee implants implanted in
primary total knee arthroplasty.

Study design

This is a prospective, multicenter, non-controlled clinical study designed to facilitate the
collection and evaluation of pain, function, quality of life, radiographic assessment, and
adverse event data. Up to 12 EMEA sites will contribute to this study with a maximum of
600 implanted knees. Each Investigator will be skilled in total knee arthroplasty and
experienced implanting the devices included in this study.
In order to avoid potential selection bias, each Investigator will offer study participation to
each consecutive patient presenting as a candidate for primary total knee arthroplasty
using the commercially available (CE marked and FDA cleared) Zimmer Persona knee
implants All study subjects will undergo preoperative clinical evaluations prior to their total knee
arthroplasty. The post-operative clinical and radiographic evaluations will be conducted at
5 days to 6 weeks, 3 to 6 months, 1 year, 2, 3, 4, and 5 years post-operative.

Intervention

The Persona knee prosthesis used in primary total knee arthroplasty.

Study burden and risks

When used in accordance with product labeling, the risks associated with the use of
Zimmer Persona knee implants are similar to those of standard, metal-on-polyethylene
knee systems used for the same clinical indication or purpose.
A list of anticipated adverse device effects (ADE) can be found in the Instruction For Use

of the system, a copy of which can be found in the Investigator Binder.

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

1. Patient is 18 to 75 years of age, inclusive
2. Patient qualifies for a primary total knee arthroplasty based on physical exam and medical history, including diagnosis of severe knee pain and disability due to at least one of the following:
a. Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis
b. Collagen disorders and/or avascular necrosis of the femoral condyle
c. Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy
d. Moderate valgus, varus, or flexion deformities

e. The salvage of previously failed surgical attempts that did not include partial or total knee arthroplasty of the ipsilateral knee
3. Patient is willing and able to provide written Informed Consent by signing and dating the EC approved Informed Consent form
4. Patient is willing and able to complete scheduled study procedures and follow-up evaluations
5. Independent of study participation, patient is a candidate for commercially available Zimmer Persona knee implants implanted in accordance with product labeling

Exclusion criteria

1. Patient is currently participating in any other surgical intervention studies or pain management studies
2. Previous history of infection in the affected joint and/or other local/systemic infection that may affect the prosthetic joint
3. Insufficient bone stock on femoral or tibial surfaces
4. Skeletal immaturity
5. Neuropathic arthropathy
6. Osteoporosis or any loss of musculature or neuromuscular disease that compromises the affected limb
7. Stable, painless arthrodesis in a satisfactory functional position
8. Severe instability secondary to the absence of collateral ligament integrity
9. Rheumatoid arthritis accompanied by an ulcer of the skin or a history of recurrent breakdown of the skin
10. Patient has a known or suspected sensitivity or allergy to one or more of the implant materials
11. Patient is pregnant or considered a member of a protected population (e.g., prisoner, mentally incompetent, etc.)
12. Patient has previously received partial or total knee arthroplasty for the ipsilateral knee.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-02-2014
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Persona knee implant
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	28-01-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	06-04-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	01-04-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL46683.098.13