Zimmer Maxera acetabular system in total hip arthroplasty: a multi-center, prospective, non-controlled post marktet clinical follow-up study

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The objectives of this study are to confirm the safety and performance of the Zimmer Maxera Cup mated with either a BIOLOX delta or BIOLOX OPTION femoral head when used in primary total hip arthroplasty.

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

Summary

ID

NL-OMON53064

Source
ToetsingOnline

Brief title
Maxera study

Condition

- Joint disorders

Synonym
hip osteoarthritis, hip wear

Research involving
Human

Sponsors and support

Primary sponsor: Zimmer Biomet GmbH

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

Intervention

Keyword: arthroplasty, implant survival, total hip, Zimmer Maxera cup

Outcome measures

Primary outcome

The primary endpoint is defined as the implant survival at 10 years.

Secondary outcome

Assessment of Outcome Measures:

• Safety (adverse events)

• Performance (implant survival, overall pain and functional performances,

subject quality-of-life and radiographic parameters)

Study description

Background summary

Total hip arthroplasty (THA) is a medical procedure where an arthritic, degenerative or fractured total hip joint is replaced with a prosthetic device. Since the inception of modern THA in 1961, THA has become a widely accepted orthopedic procedure.

Over the last several decades, technological advancements have been made to improve implant strength, fixation, and wear properties of implant surfaces in THA systems. Due to the friction and wear properties in other systems, researchers began looking at ceramic on ceramic (COC) systems first introduced in 1970. Early outcomes associated with COC systems were mixed and failures were attributed to poor implant design and material quality of alumina ceramic.

Since its original introduction, substantial improvements have been made to alumina ceramic. It has been a standardized material since 1984 (International Standard Organization, ISO 6474) and its mechanical properties are largely dependent on grain size, purity, porosity, and grain distribution. BIOLOX forte1, the third generation of alumina ceramics, is roughly three times as hard as metal and thus much more scratch resistant. The wettability of alumina,

or relative degree to which a fluid will spread or coat a solid surface in relation to its surface energy, is higher than polymers and metals which allows water to be adsorbed with high bond strength and proteins to cover ceramic surfaces with a
monolayer (i.e. synovial fluid).

While the tribologic properties of alumina are excellent, there have been many concerns over the past decades regarding orientation and wear of the ceramic couple, noise during articulation and eventual fracture of the ceramic acetabular liner.

Although implant design and correct implant positioning have been a concern in COC systems, they have some advantages over other alternate bearing systems. COC systems are accepted as the coupling that produces the lowest wear, and early to midterm reports demonstrate less osteolysis.

Additionally, dislocation has been reported as one of the most common reasons for early revision in primary THA. Large-diameter femoral heads theoretically can reduce dislocation risk.

Study objective

The objectives of this study are to confirm the safety and performance of the Zimmer Maxera Cup mated with either a BIOLOX delta or BIOLOX OPTION femoral head when used in primary total hip arthroplasty.

Study design

A multi-centre, prospective, non-controlled post-market clinical follow-up study.

Intervention

The Zimmer Maxera Cup mated with either a BIOLOX delta or BIOLOX OPTION femoral head used in primary total hip arthroplasty.

Study burden and risks

The risks associated with the use of the Zimmer Maxera Acetabular System are similar to those with the use of other standard ceramic on ceramic hip systems when used for the same clinical indication. These risks are categorized as those anticipated to be related to general surgical risks, total hip arthroplasty risks, or those potential risks associated with the investigational system. Unanticipated adverse events may occur as well. A list of anticipated adverse device effects (ADE) can be found in the IFU of the

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

Contacts

Public
Zimmer Biomet GmbH

Sulzerallee 8
Winterthur CH-8404
CH
Scientific
Zimmer Biomet GmbH

Sulzerallee 8
Winterthur CH-8404
CH

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Patient is 18 to 75 years of age, inclusive.
• Patient is skeletally mature.
• Patient qualifies for primary unilateral or simultaneous bilateral total hip arthroplasty
(THA) based on physical exam and medical history including at least one of the following:
o Osteoarthritis
o Avascular necrosis (AVN)
o Inflammatory arthritis

o Rheumatoid arthritis with adequate bone quality
o Post-traumatic arthritis
o Congenital hip dysplasia.
• Patient has no history of previous total hip replacement or arthrodesis of the affected hip
joint(s).
• Patient has a Harris Hip Score <70 in the affected hip and a Harris Hip pain rating of
moderate, marked, or disabled.
• Patient is willing and able to provide written informed consent.
• Patient is willing and able to cooperate in the required post-operative therapy.
• Patient is willing and able to complete scheduled follow-up evaluations as described in
the Informed Consent.

Exclusion criteria

• The patient is:
o A prisoner
o Mentally incompetent or unable to understand what participation in the study entails.
o A known alcohol or drug abuser
o Anticipated to be non-compliant
• The patient has a neuromuscular disorder, vascular disorder or other condition that
could contribute to prosthesis instability, prosthesis fixation failure, or complications in
postoperative care.
• The patient has local bone tumors and/or cysts in the portion of bone to be retained in
the operative hip that could inhibit implant fixation.
• The patient has insufficient bone stock or poor bone quality to fix the component. Insufficient
bone stock exists in the presence of metabolic bone disease (i.e. osteoporosis), cancer, and radiation. Note: Dual Energy X-ray Absorptiometry (DEXA) may be required
to assess the presence of adequate bone stock.
• The patient has rapid disease progression as obvious by joint destruction or bone absorption
seen on x-ray.
• The patient has osteoradionecrosis in the affected hip.
• The patient has a neuromuscular condition in the ipsilateral or contralateral limb which
affects lower limb function.

• The patient has loss of abductor musculature in the affected hip.
• The patient has a vascular (large and small vessel disease) insufficiency.
• The patient has had previous prosthetic hip replacement device (any type, including
surface replacement arthroplasty, endoprosthesis, etc.) in the joint to be operated.
• The patient has had previous girdlestone procedure (resection arthroplasty) or surgical
fusion of the hip to be operated.

• The patient has an acute femoral neck fracture in the operative hip.
• The patient has had a procedure on the operative hip in the last 6 months (i.e. arthroscopy,
ORIF femoral neck fracture, etc).
• The patient has undergone a total hip replacement, endoprosthesis, or surface arthroplasty
of the contralateral (opposite side) hip within the past 6 months regardless of whether the previous hip was enrolled in this clinical study.
• The patient has a moderate to severe limb length discrepancy greater than 3.2 cm.
• The patient has an active, old or remote infection in or about the affected hip joint or an
infection distant from the hip joint that may spread to the hip hematogenously.
• The patient has poor skin coverage around the affected hip joint.
• The patient has a diagnosed systemic disease that could affect his/her safety or the
study outcome.
• The patient is currently receiving, or within the past three months, has received any drug
known to potentially interfere with bone/soft tissue healing (e.g. long-term chronic systemic
steroid or inhaler steroid therapy).
• The patient has received an investigational drug or device within the previous 6 months.
• The patient is known to be pregnant.
• The patient is unwilling or unable to give informed consent, or to comply with the followup
program.
• The patient is known to have a highly communicable disease that may limit follow-up.
• The patient has a known sensitivity or allergic reaction to one or more of the implanted
materials which include metal and ceramic.
• The patient is Grade III obese with a Body Mass Index (BMI) > 35.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-11-2013
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	21-05-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	16-03-2015
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	20-05-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	06-11-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	21-11-2022
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	NL41295.098.12