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

Published: 21-05-2013 Last updated: 26-04-2024

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 reviewApproved WMOStatusRecruitingHealth condition typeJoint disordersStudy typeInterventional

### **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

1 - Zimmer Maxera acetabular system in total hip arthroplasty: a multi-center, prosp ... 14-05-2025

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
  - 4 Zimmer Maxera acetabular system in total hip arthroplasty: a multi-center, prosp ... 14-05-2025

- 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).
- $\bullet$  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.

Emilie Rohmer, 11.05.2012, Rev. 0 page 17 of 57

F WT.30.0108-1 Effective Date 21. Okt. 2010

Clinical Investigation Plan Revision 0

- 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

<sup>7 -</sup> Zimmer Maxera acetabular system in total hip arthroplasty: a multi-center, prosp ... 14-05-2025

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