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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 0651.4-2025

**Joint replacements - Wear of total hip-joint prostheses - Part 4:
Testing hip prostheses under variations in component
positioning which results in direct edge loading**

关节置换植入器械 全髋关节假体的磨损 第4部分：部件位置变化导致边缘加载条件下髋关节假体测试

(English Translation)

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents".

Drafting.

This document is Part 4 of YY/T 0651 "Wearing of Total Hip Prostheses in Joint Replacement Implants". YY/T 0651 has been...

The following sections were published.

---Part 1: Load and displacement parameters of the wear testing machine and related test environment conditions;

---Part 2: Measurement Methods;

---Part 3: Load and displacement parameters and related test environment conditions of the track bearing wear testing machine;

---Part 4: Testing of hip prostheses under edge loading conditions due to component position changes.

This document is modified to adopt ISO 14242-4:2018 "Surgical implants - Wear and tear of total hip prostheses - Part 4: Changes in component position".

This leads to testing of hip prostheses under edge loading conditions.

The technical differences between this document and ISO 14242-4:2018, and the reasons therefor, are as follows.

---ISO 14242-1:2014 has been replaced with YY/T 0651.1-2016 (normatively referenced) to adapt to my country's technical conditions;

---ISO 14242-2 has been replaced with YY/T 0651.2 (normatively referenced) to adapt to my country's technical conditions;

---ISO 14242-3 has been replaced with YY/T 0651.3 (normative reference) to adapt to my country's technical conditions.

The following editorial changes have been made to this document.

---The standard name has been changed to "joint replacement implants" instead of "surgical implants" to clarify the specific areas of application of the standard.

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed by the National Medical Products Administration.

This document was prepared by the Orthopedic Implants Subcommittee of the National Technical Committee on Standardization of Surgical Implants and Orthopedic Devices (SAC/TC110/SC1) is under the jurisdiction of the relevant authorities.

Introduction

YY/T 0651 "Wearing of Total Hip Prostheses in Joint Replacement Implants" consists of four parts.

---Part 1: Load and displacement parameters of the wear testing machine and related test environment conditions;

---Part 2: Measurement Methods;

---Part 3: Load and displacement parameters and related test environment conditions of the track bearing wear testing machine;

---Part 4: Testing of hip prostheses under edge loading conditions due to component position changes.

Wear assessment of the load-bearing surfaces in hip replacement surgery plays an important role in the design and development of wear materials and in the ongoing evaluation of current products.

YY/T 0651.1-2016 and YY/T 0651.3 specify the test conditions, assuming the component is placed at the expected acetabular component tilt angle.

No dynamic separation occurred, and the patient's range of motion and load were within

normal stride (e.g., 30° between the polar axis of the acetabular component and the loading line).

Within the state limit.

However, the researchers' findings suggest that various factors, including different hip joint surface designs and materials, and unintended implant placement, may contribute to the problem.

Soft tissue relaxation, excessive patient movement, and increased load can lead to unexpected edge loading conditions in clinical practice, and the consequences can be severe.

In severe cases, it may lead to implant failure.

Many factors can lead to edge loading conditions. The test condition is defined as. edge loading caused by differences in rotation and translation positioning.

Under these conditions, preclinical evaluation of the device's performance can be performed, and comparison with control or comparative devices that have a clinical history is permitted.

Compare.

Edge loading

Edge loading is a complex phenomenon influenced by many factors. There are two main types of edge loading.

- a) Indirect edge loading, caused by impact or prying out of the femoral head;
- b) Direct edge loading, where the femoral head is directly positioned at the edge of the acetabular component (without collision), which is determined by component positioning and joint loosening.

This is caused by the patient's biomechanical mechanisms.

This document addresses the direct edge loading condition.

The expected normal (no edge) loading condition refers to the expected bearing surface where the contact surface is located between the femoral head and the acetabular component [see Figure 1a).

These conditions are tested according to YY/T 0651.1-2016 and YY/T 0651.3.Edge loading refers to the contact surface being located at the femoral head.

Between the non-spherical bearing surface (e.g., edge, chamfer, or other non-bearing surface) of the acetabular component and the contact surface [see Figure 1a)]. When the contact surface [see Figure 1a) is in part or edge loading occurs during all gait cycles when the acetabular component is removed from the intended load-bearing surface, as shown in

the figure. This is due to the acetabular component relative to the patient.

Due to the influence of the anatomical structure, the acetabular component tilts at a large angle [see Figure 1b)], or the center of the femoral head and the center of the acetabular component dynamically separate.

[See Figure 1c].

a) Not under edge loading conditions b) Under edge loading conditions c) Under edge loading conditions

Figure 1. Contact surface between the femoral head and the acetabular component.

Rotary positioning

The rotational positioning of the acetabular components can be divided into rotations about three anatomical axes.

- a) Forward-rearward axis;
- b) Up-down axis;
- c) Inner-outer direction axis (see Figure 2).

The angular rotations around the three anatomical axes are.

- a) Inward and outward rotation. about the front-back (AP) axis;
- b) Internal rotation and external rotation. about the up-down (SI) axis;
- c) Flexion and extension. rotation about the inner-outer (ML) axis.

Index number explanation.

- 1---Up;
- 2---Inside;
- 3---Outside;
- 4---Next.

Figure 2. Frontal view of the rotation axis of the left hip joint [around the medial-lateral axis, anterior-posterior axis (in this frontal view)]

(Not visible in the diagram) and the upper and lower axes. Achilles acetabular component movement - lateral. negative, medial. positive.

Translation Positioning the translational position of the femoral head and acetabular components is defined as the relative orientation of the rotation centers of the acetabular components and the femoral head along the axis shown in Figure 3.

Positioning. Translational displacement can occur along medial-lateral (see Figure 3),