
# Hip joint replacement based on linear cylindrical articulations for reduced wear: A radical change in design

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**Article Title**

Hip joint replacement based on linear cylindrical articulations for reduced wear: A radical change in design

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**Abstract**

Hip replacement surgery is a common procedure for patients suffering from hip joint degeneration. However, wear of the implant components, particularly Ultra-High-Molecular-Weight Polyethylene (UHMWPE), remains a significant concern, often leading to complications such as osteolysis and implant loosening. This invention disclosure introduces a novel tri-axial hip replacement design aimed at addressing these issues. The design incorporates three orthogonal cylindrical articulations, each providing one rotational degree of freedom to replicate the natural movements of the hip joint. The prosthesis comprises two components made from UHMWPE (cup and rotator) and two components made from high-N stainless steel (flexor and abductor). Each articulation consists of metal-on-polyethylene bearing couples. Unlike traditional ball-and-socket implants, the novel design limits motion within each articulation to a single direction, taking advantage of friction-induced UHMWPE strain hardening. Moreover, cylindrical joints offer a larger contact surface area than their spherical counterparts, thereby reducing contact stresses. Mid-sized high-fidelity prototypes underwent wear resistance testing, demonstrating significantly superior performance compared

to a commercial ball-and-socket implant of similar size tested in the same conditions. Moreover, a cadaveric implantation performed by experienced orthopaedic surgeons showed the implant has good stability even for postures requiring a wide range of motion. This innovative design represents a promising advancement in hip replacement technology, offering improved wear resistance and longevity, thus potentially reducing the need for revision surgeries and enhancing patient outcomes.

**Keywords**

hip joint replacement, implant design, wear, orthopaedics, biomaterials, orientation hardening

**Specifications Table**

| | |
|---|---|
| **Subject code** | **Code:** 2732<br>**ASJC category:** Orthopaedics and Sports Medicine<br>**Subject area:** Health Sciences |
| **Specific subject area** | Hip joint replacements: devices designed to replace damaged hip joints with artificial implants to relieve pain and restore function. |
| **Industry code** | A: Human necessities |
| **Details of inventors** | **Prof. Pierre Schembri Wismayer**<br>Department of Anatomy, Faculty of Medicine and Surgery, University of Malta, Msida, MSD 2080, Malta.<br>Email: pierre.schembri-wismayer@um.edu.mt<br>**Dr. Inġ Donald Dalli**<br>Department of Metallurgy and Materials Engineering, Faculty of Engineering, University of Malta, Msida, MSD 2080, Malta.<br>Email: donalddalli@gmail.com<br>**Prof. Inġ Joseph Buhagiar**<br>Department of Metallurgy and Materials Engineering, Faculty of Engineering, University of Malta, Msida, MSD 2080, Malta.<br>Email: joseph.p.buhagiar@um.edu.mt<br>**Prof. Inġ Pierluigi Mollicone**<br>Department of Mechanical Engineering, Faculty of Engineering, University of Malta, Msida, MSD 2080, Malta.<br>Email: pierluigi.mollicone@um.edu.mt |
| **Dates of invention** | Conception 1 July 2014 |

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|---|---|
| | Disclosure: 26 June 2019 |
| **Patent details** | Date patent granted: 30 August 2023<br>Patent owner: L-Università ta' Malta<br>Patent attorney or agent: Potter Clarkson<br>Contact for service: patents@um.edu.mt<br>Link to patent: https://worldwide.espacenet.com/patent/search/family/067511739/publication/EP3989885B1?q=EP3989885B1 |
| **Intended use** | The invention patent is licenced to a start-up medical device company and is intended for use as a total hip replacement in orthopaedic surgeries. |
| **Related research articles** | • D. Dalli, J. Buhagiar, P. Mollicone, P. Schembri Wismayer, A novel hip joint prosthesis with uni-directional articulations for reduced wear, J Mech Behav Biomed Mater 127 (2022) 105072. https://doi.org/10.1016/j.jmbbm.2021.105072.<br>• D. Dalli, L. Fanton, B. Mallia, P.S. Wismayer, J. Buhagiar, P. Mollicone, Polyethylene wear simulation models applied to a prosthetic hip joint based on unidirectional articulations, J Mech Behav Biomed Mater 142 (2023) 105882. https://doi.org/10.1016/j.jmbbm.2023.105882. |
| **Related other sources: (datasets, software, diagrams, plans, etc.)** | N/A |



## 1. Value of the invention

- Hip joint replacements often fail due to wear-related complications, leading to revision procedures that are technically more difficult and require longer recovery times than the initial surgery. The invention described in this article is a novel total hip replacement designed to be more wear-resistant and last longer than current alternatives while offering a similar or better range of motion when compared to traditional ball-on-socket hip implants.
- More than one million people worldwide must undergo total hip replacement surgery yearly and could benefit from this invention. Its extended range of motion and longer lifespan can be particularly valuable to young and active individuals. Additionally, it helps minimize the risk of dislocation during movements such as kneeling and squatting, which are prevalent in Asian countries.

- This invention brings a significant change in the design of hip joint replacements with the capacity to change the market and encourage further developments.

## 2. Invention Description

A tri-axial hip joint replacement has been developed, characterised by its innovative design incorporating three orthogonal cylindrical articulations. Each of these articulations provides one rotational degree of freedom (DOF), reproducing the total three DOFs of the natural hip joint, i.e. flexion/extension, internal/external rotation, and abduction/adduction. The prosthesis comprises four components: the cup, flexor, rotator, and abductor (Figure 1). The cup is fixed to the pelvis, replacing the acetabulum. The flexor articulates with the cup's inner surface, enabling flexion and extension hip movements. The rotator then interfaces with the inner surface of the flexor, allowing for internal and external rotations. Finally, the abductor articulates with the inner surface of the rotator, allowing abduction and adduction. The abductor acts as the femoral head and, similarly to a conventional hip replacement, is connected via a Morse taper junction to a stem that is inserted into the femur. The cup and rotator components are produced from Ultra-High-Molecular-Weight Polyethylene (UHMWPE), while the flexor and abductor components are made of high-N stainless steel. Each articulation consists of metal-on-polyethylene (hard-on-soft) bearing pairs. Figure 1 shows (a) exploded and (b) assembled views of the hip replacement design.

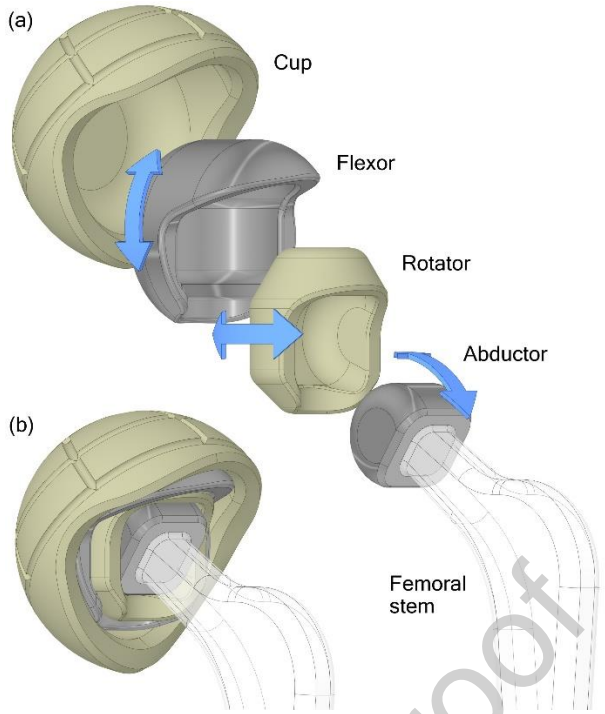


Figure 1: Computer-aided design model of the novel hip replacement based on cylindrical articulations, showing (a) exploded and (b) assembled views. The blue arrows indicate the rotational DOF of each moving component.

An interlocking mechanism exists between the cup-flexor and flexor-rotator pairs, created to minimise the incidence of dislocation. For this reason, a unique assembly sequence is required to assemble these components, as visually described in Figure 2. To initiate the assembly process, let us consider that the implant components are disconnected and in their normal orientation (Figure 2a), which is the orientation they assume when the implanted patient stands upright on two legs. The process of assembling the rotator into the flexor starts by turning it 180° from the normal position around its longitudinal axis (Figure 2b). This is the only orientation allowing the insertion of the rotator inside the flexor (Figure 2c). After the engagement, the rotator can be rotated back to its normal orientation (Figure 2d). In this position, the rotator is interlocked by superior and inferior overhangs of the flexor designed to create a converging angle between their faces (Figure 2e). The flexor is inserted into the cup in a similar procedure. First, it is rotated 180° from its normal orientation around its longitudinal axis (Figure 2f), assuming a specific position allowing its insertion into the cup (Figure 2g). Once placed inside the cup, the flexor can be rotated to its normal orientation (Figure 2h) and is interlocked by the cup overhang features with converging faces (Figure 2i). The interlocking mechanism operates on the principle that component assembly or disassembly is only feasible at joint angles unattainable during regular use of the hip implant.

No interlocking mechanism is present between the abductor and rotator for two main reasons. Firstly, the prosthesis needs at least one articulation that can be easily assembled/disassembled to aid in the hip reduction process during surgery (hip reduction is the insertion of the femoral head into the acetabular cup during the hip replacement surgery). Secondly, having at least one articulation capable of disengaging allows for hip subluxation (partial dislocation) during the patient's high-impact activities.

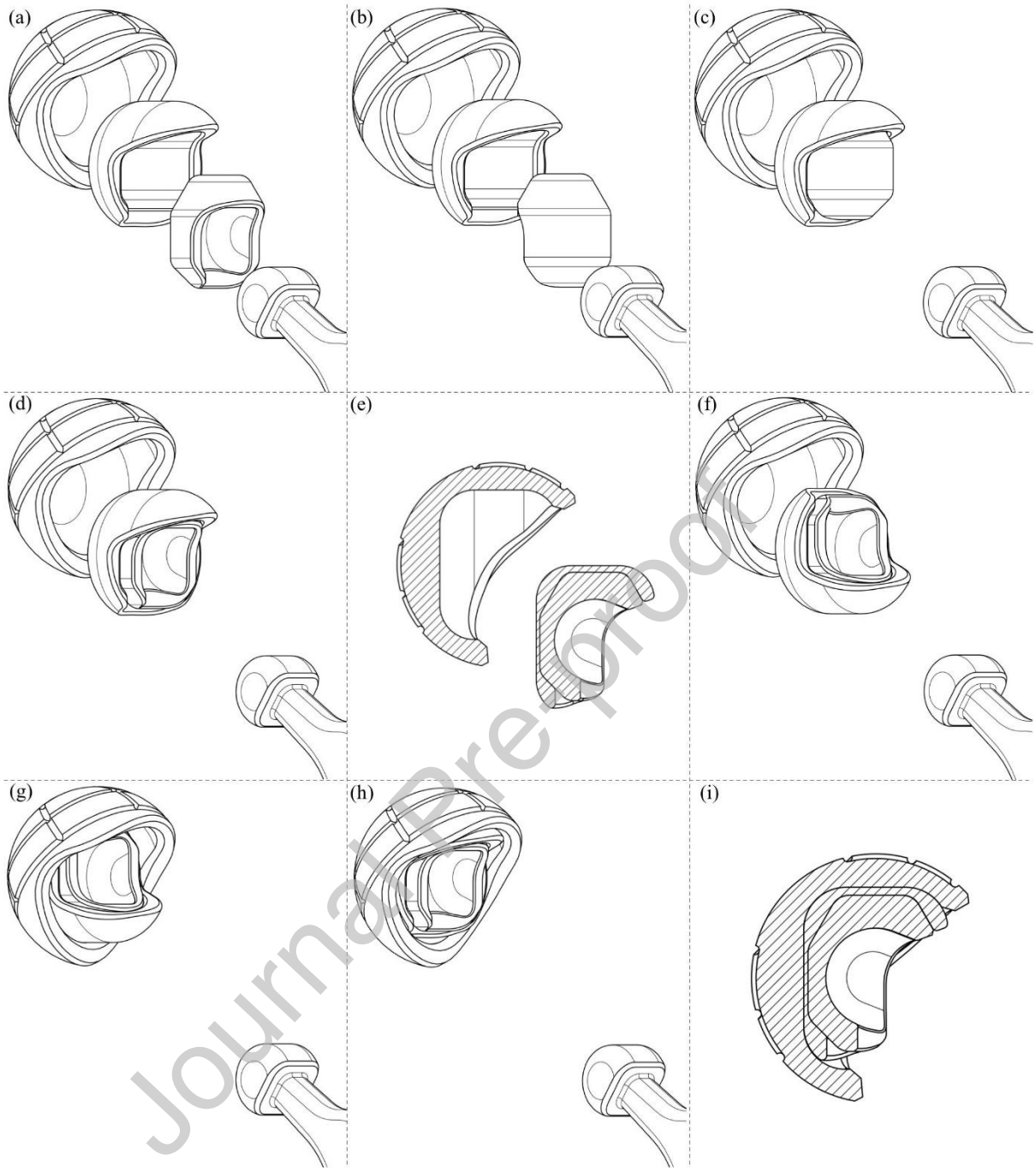




Figure 2: Steps to assemble the novel hip replacement and activate the interlocking mechanism between the cup, flexor, and rotator. (a) Implant components in their normal orientation. (b) The rotator is turned 180°, (c) inserted inside the flexor, and (d) rotated back to its normal orientation. (e) The rotator is interlocked by superior and inferior overhangs of the flexor. (f) The flexor is rotated 180° from its normal orientation, (g) inserted into the cup, and (h) rotated to its normal orientation. (i) The flexor is interlocked by the cup overhang features.

High-fidelity prototypes of the invention were manufactured at Empav Engineering Ltd. (Malta). They were dimensioned to be in the midsize range for hip replacements, with an external acetabular cup diameter of 53 mm. Two versions were produced, differing in the grades of UHMWPE used for the soft-bearing components (cup and rotator). One version was produced with cross-linked GUR-1020 treated with vitamin E and the other with virgin (non-cross-linked) GUR-1050, both common grades used in the medical industry. The hard-bearing components (flexor and abductor) were made of high-nitrogen austenitic stainless steel (ASTM F1586-21) in both versions. To take advantage of the polyethylene orientation hardening mechanism [1–3], the cup component was machined so that the polyethylene molecular chains were aligned in the flexor sliding direction. Figure 3 depicts a photo of one of the prototypes produced using cross-linked UHMWPE.

Figure 3: High-fidelity prototype of the novel hip replacement design. The cup, flexor, and rotator components (left hand) are assembled and interlocked. The abductor (right hand) is connected to the femoral stem.

The hip implant's motion ranges were tested as specified in ISO 21535:2007 (*Non-active surgical implants – Joint replacement implants – Specific requirements for hip joint replacement implants*) using computer-aided design software and physical evaluation of the prototypes. The range of motion results produced by the invention are presented in Table 1 [4].

Table 1: The minimum range of motion (ROM) required by ISO 21535:2007 and the invention's range of motion. Reproduced with permission from Dalli *et al.* [4].

| **Anatomical movement** | **Minimum required range of motion** | **Invention range of motion** |
|---|---|---|
| Flexion/Extension | 100° | 235° (130° flexion + 105° extension) |
| Internal/External Rotation | 90° | 145° (75° internal + 70° external) |
| Abduction/Adduction | 60° | 90° (50° abduction + 40° adduction) |

Invention prototypes were tested for wear resistance in a hip joint simulator machine according to the ISO 14242-1:2014 (*Implants for surgery — Wear of total hip-joint prostheses Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test*) at Endolab® (Germany). The machine simulated 5.0 million gait cycles, representing an average of five years of implant use. The experimental procedure and results are discussed in detail in the study of Dalli *et al.* [4]. The invention showed a significantly superior wear resistance compared to conventional commercial ball-and-socket implants tested under the same conditions. For implants employing virgin UHMWPE, the wear rate of the invention was about four times lower than the commercial one. In the cross-linked UHMWPE version, the release of wear particles was so small that the gravimetric wear loss could not be detected.

One of the prototypes was implanted in a Thiel embalmed cadaver by experienced orthopaedic surgeons to evaluate stability, range of motion, and ease of implantation. The orthopaedic surgeons noted that the implant could achieve squatting and other postures requiring a wide range of motion with high stability and no dislocation risk. They expressed that the implantation process was similar to the procedure commonly used for existing commercial implants. More information about the mock surgery procedure and surgeons' comments can be found in the study of Dalli *et al.* [4].

## 3. Background

The ball-and-socket is the current standard hip replacement design, having UHMWPE as the preferred material for soft-bearing acetabular components. The wear of UHMWPE is an important factor limiting the lifespan of hip implants. The wear particles generated at the implant articulation often induce an inflammatory response, causing progressive destruction of periprosthetic bony tissue (osteolysis) and subsequent aseptic loosening [5]. The hip replacement design described in this invention disclosure presents two main features that can reduce wear over time and enhance durability. Firstly, the cylindrical articulations provide a greater contact surface area than a spherical (ball-and-socket) articulation of similar size [6], reducing contact pressures. Secondly, the novel design limits motion within each articulation to occur in a single direction instead of the multidirectional sliding of the ball-and-socket joint. This is advantageous because, under linear-tracking motion, the UHMWPE molecular structure tends to align in the sliding direction by a friction-induced mechanism, leading to anisotropic strain-hardening and increased wear resistance [1–3].

## 4. Application potential

More than one million total hip arthroplasty surgeries are carried out yearly [7], and this number has been steadily growing due to an ageing population and advancements in surgical techniques. A recent study projects an increase in total hip arthroplasty surgeries in the United States of 176 % by 2040 and 659 % by 2060 [8], representing a large market to be exploited. A hip joint replacement with a radical change in design, offering higher wear resistance and a wide range of motion, can deliver several benefits. Lower wear rate decreases the need for revision surgeries due to osteolysis and aseptic loosening, enhancing patients' quality of life. It can also make hip replacement surgery a more viable option for younger patients who may hesitate due to concerns about the need for future revisions. In addition, a wide range of motion reduces the risk of dislocation during complex postures like kneeling and squatting, particularly common in Asian countries. This invention can potentially lead to substantial economic benefits by reducing healthcare costs associated with implant failures, revision surgeries, and post-operative complications.

## Credit author statement

**Leonardo Fanton:** Writing – Original Draft, Writing – Review & Editing, Visualization, Validation. **Pierre Schembri Wismayer:** Writing – Review & Editing, Supervision, Resources, Project administration, Funding acquisition, Conceptualization. **Donald Dalli:** Writing – Review & Editing, Visualization, Validation, Methodology, Investigation, Data Curation, Conceptualization. **Pierluigi Mollicone:** Writing – Review & Editing, Supervision, Resources, Methodology, Conceptualization. **Bertram Mallia:** Writing – Review & Editing, Supervision. **Maria Kristina Bartolo:** Validation, Methodology, Investigation, Data Curation. **Joseph Buhagiar:** Writing – Review & Editing, Supervision, Resources, Project administration, Funding acquisition, Conceptualization.

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## Declaration of interests

The authors declare the following financial interests/personal relationships that may be considered potential competing interests: Pierre Schembri Wismayer, Donald Dalli, Joseph Buhagiar, and Pierluigi Mollicone are inventors in the patent "A PROSTHETIC IMPLANT" (EP3989885B1), licensed to Garland Surgical Ltd, in which the latter also has a financial interest. The remaining authors declare no conflict of interest.

## References

[1] L.A. Korduba, A. Wang, The effect of cross-shear on the wear of virgin and highly-crosslinked polyethylene, Wear 271 (2011) 1220–1223. https://doi.org/10.1016/j.wear.2011.01.039.

[2] L. Kang, A.L. Galvin, T.D. Brown, Z. Jin, J. Fisher, Quantification of the effect of cross-shear on the wear of conventional and highly cross-linked UHMWPE, J Biomech 41 (2008) 340–346. https://doi.org/10.1016/j.jbiomech.2007.09.005.

[3] V. Saikko, A multidirectional motion pin-on-disk wear test method for prosthetic joint materials, J Biomed Mater Res 41 (1998) 58–64. https://doi.org/10.1002/(SICI)1097-4636(199807)41:1<58::AID-JBM7>3.0.CO;2-P.

[4] D. Dalli, J. Buhagiar, P. Mollicone, P. Schembri Wismayer, A novel hip joint prosthesis with uni-directional articulations for reduced wear, J Mech Behav Biomed Mater 127 (2022) 105072. https://doi.org/10.1016/j.jmbbm.2021.105072.

[5] A. Bistolfi, F. Giustra, F. Bosco, L. Sabatini, A. Aprato, P. Bracco, A. Bellare, Ultra-high molecular weight polyethylene (UHMWPE) for hip and knee arthroplasty: The present and the future, J Orthop 25 (2021) 98–106. https://doi.org/10.1016/j.jor.2021.04.004.

[6] R. Budynas, K. Nisbett, Shigley's Mechanical Engineering Design, 9th ed., McGraw Hill, 2011.

[7] R. Pivec, A.J. Johnson, S.C. Mears, M.A. Mont, Hip arthroplasty, The Lancet 380 (2012) 1768–1777. https://doi.org/10.1016/S0140-6736(12)60607-2.

[8] I. Shichman, M. Roof, N. Askew, L. Nherera, J.C. Rozell, T.M. Seyler, R. Schwarzkopf, Projections and Epidemiology of Primary Hip and Knee Arthroplasty in Medicare Patients to 2040-2060, JBJS Open Access 8 (2023). https://doi.org/10.2106/JBJS.OA.22.00112.

**Declaration of interests**

☐ The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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