Thesis

BioBall Universal Head Neck Adapters – Mix & Match in Total Hip Arthroplasty. A Retrospective Study

submitted by

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Graz, June 10, 2024.

Declaration of Academic Integrity

I hereby confirm that the present diploma thesis is the result of my own independent scholarly work. I also confirm that in all cases, where material from the work of others (in books, articles, essays, dissertations, and on the internet) is acknowledged, quotations and paraphrases are clearly indicated. No material other than that cited in the reference list has been used. I have read and understood the Medical University's regulations and procedures concerning plagiarism.

Graz, June 10, 2024 *Alexander Thaller m.p.*

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Zusammenfassung

Hintergrund. Die Sicherheit von universellen Kopf-Hals-Adaptern (UHNA) ist nach wie vor Gegenstand von Diskussionen im Rahmen des „Mix und Match"-Konzepts in der Totalendoprothetik der Hüfte (THA), insbesondere bei Revisionsoperationen. Die vorliegende Studie analysiert die Komplikations- und Revisionsraten, mögliche Einflussfaktoren und die Überlebensrate bei Verwendung dieser Implantate.

Material und Methoden. Im Rahmen einer retrospektiven Studie am Landekrankenhaus Graz wurden zwischen 2006 und 2022 insgesamt 306 mit UHNA (alle BioBall®, Merete®, Berlin, Deutschland) behandelte PatientInnen (n = 288 (94,1 %)) analysiert. Es wurden Diagnosen, demografische Parameter, Begleiterkrankungen, Implantat- und UHNA-Spezifikationen sowie Komplikationen erfasst. Zudem wurde eine multifaktorielle Analyse durchgeführt und Revisionsraten sowie das Implantatüberleben bestimmt. Der primäre Endpunkt der Studie wurde dabei als Implantatversagen, definiert als Revisionsoperation, festgelegt.

Ergebnisse. Die PatientInnen hatten zum Zeitpunkt der Operation ein durchschnittliches Alter von 74 Jahren (*IQR* 62–81 Jahre); der berechnete mediane Nachbeobachtungszeitraum war 57 Monate (*IQR* 23–85 Monate). Bei 19,9 % (n = 61) der PatientInnen trat mindestens eine Komplikation auf. Die häufigsten Komplikationen waren postoperative wiederholte Luxation (n = 27; 8,8 %), periprothetische Infektion (n = 13; 4,2 %), periprothetische Frakturen (n = 11; 3,6 %) und aseptische Lockerung (n = 10; 3,3 %). Bei 14,1 % (n = 43) der Fälle wurde mindestens eine Revisionsoperation durchgeführt. Darüber hinaus wurde ein Fall (0,3 %) einer Prothesenschaft-Hals-Fraktur als spezifische „Mix und Match"-Komplikation identifiziert. Als statistisch signifikante Risikofaktoren für postoperative Komplikationen konnten u.a. folgende Faktoren identifiziert werden: postoperative rezidivierende Luxationen und postoperative aseptische Lockerungen waren jeweils mit Luxation als Indikation für die UHNA-Implantation (p < .001) und übergroßen Halslängen (≥ 2 XL; p = .004) assoziiert. Das revisionsfreie Gesamtüberleben betrug 92 % (95 % CI 88,1–95,9 %) nach einem Jahr und 82 % (95 % CI 76,1–87,9 %) nach zehn Jahren. Es wurden bessere revisionsfreie Überlebensraten bei Patienten im Alter von ≥ 60 Jahren, mit weniger Komorbiditäten (< 2) und mit normalen Halslängen (S–XL) registriert.

Schlussfolgerung. UHNA sind insgesamt eine sichere Langzeitoption für die „Mix und Match"-Anwendung bei THA, insbesondere für PatientInnen mit besonderer Hüftanatomie oder Revisionsoperationen. Ein Komplikationsfall im Zusammenhang mit „Mix und Match"

konnte beobachtet werden (Schafthalsfraktur, 0,3 %). Dennoch müssen zahlreiche Risikofaktoren berücksichtigt werden, um ein gutes Ergebnis mit UHNA in „Mix und Match“-THA zu erzielen. Diese Faktoren betreffen die PatientInnen, die verwendeten Implantate, ChirurgInnen und perioperative Faktoren. In der Gesamtschau sind jedoch weitere Studien und Kompatibilitätstests mit allen Prothesenherstellern erforderlich, um endgültige Schlussfolgerungen ziehen zu können.

Schlüsselwörter: BioBall, universeller Kopf-Hals-Adapter, universeller modularer Halsadapter, Implantatüberleben, Revisionshüfttotalendoprothese.

Abstract

Background. The safety of "mix & match" total hip arthroplasty (THA) using universal head-neck adapters (UHNA) remains unclear and is an important topic of discussion. The aim of this study is to analyze the complication and revision rates, potential influencing factors, and implant survival of UHNA in "mix & match" settings.

Materials and Methods. A retrospective study was performed at the General Hospital Graz including 306 patients treated with THA (n = 288 (94.1%) of which were revisions) using UHNA (all BioBall®, Merete®, Berlin, Germany) between 2006 and 2022. Diagnoses, demographics, comorbidities, implant and UHNA specifications, and complications were recorded. Analyses of multifactorial outcome, revision rates, and implant survival were performed. Implant failure, defined as reoperation, was the primary outcome.

Results. The median age at UHNA implantation was 74 years (*IQR* 62–81 years), 58.5% of patients were female, and the median calculated follow-up was 57 months (*IQR* 23–85 months). 19.9% (n = 61) of the included cases had at least one postoperative complication. The most common complications were postoperative recurrent dislocation (n = 27; 8.8%), periprosthetic infection (n = 13; 4.2%), periprosthetic fracture (n = 13; 4.2%), and aseptic component loosening (n = 10; 3.3%). 14.1% *(*n = 43) of patients had at least one re-revision surgery. One case of stem-neck fracture was recorded (0.3%), which was categorized as the only specific "mix & match" complication. Statistically significant risk factors included: postoperative recurrent dislocation and postoperative aseptic loosening were associated with dislocation as an indication for UHNA implantation ($p < .001$) and oversized neck lengths (≥ 2 XL; p = .004), respectively. Overall revision-free survival was 92% (95% CI 88.1–95.9%) at 1 year and 82% (95% CI 76.1–87.9%) at 10 years. Better survival rates were seen in patients ≥ 60 years of age, with fewer comorbidities (< 2), and with normal neck lengths (S–XL).

Conclusion. The results of this study underline the overall safety of the use of UHNA in THA through "mix & match" solutions. One mix & match specific complication was identified (0.3%, stem neck fracture). The highlighted risk factors for failure must be considered in patient education and decision making. Numerous variables must be considered to achieve favorable outcomes with UHNA in "mix & match" THA, including patient, implant, surgeon, and perioperative factors. However, further research and compatibility testing by prosthesis manufacturers is needed.

Keywords: BioBall, universal head-neck adapter, universal modular neck adapter, implant survival, revision total hip arthroplasty.

Manuscripts Based on This Thesis

The results of this thesis have already been drawn up in a manuscript for publication entitled:

Mix and Match Use of BioBall Universal Head Neck Adapters in Total Hip Arthroplasty: A Multifactorial Outcome and Survival Analysis.

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The manuscript was submitted to The Journal of Arthroplasty on the May 1, 2024, and is currently under review.

All data shown is originally from this manuscript, even if not directly stated in the text.

Table of Content

Glossary and Abbreviations

AO ..... acetabular offset
ARDS ..... acute respiratory distress syndrome
ARMD ..... adverse reactions to metal debris
AVN ..... avascular necrosis of the femoral head
CCD angle ..... caput-collum-diaphyseal angle
CI ..... confidence interval
CoC ..... ceramic-on-ceramic
CoP ..... ceramic-on-polyethylene
COPD ..... chronic obstructive pulmonary disease
COR ..... center of rotation
DAIR ..... Debridement, Antibiotics, and Implant Retention Procedure
DDH ..... developmental dysplasia of the hip
DVT ..... deep vein thrombosis
EFORT . European Federation of National Associations of Orthopaedics and Traumatology
FCI ..... Functional Comorbidity Index
GO ..... global offset
GRA ..... Girdlestone resection arthroplasty
IQR ..... interquartile range
mo ..... months
MoP ..... metal-on-polyethylene
n or *N* ..... sample size
OR ..... odds ratio
ORIF ..... open reduction and internal fixation
p ..... p-value or significance level
PJI ..... periprosthetic joint infection
rTHA ..... revision total hip arthroplasty
s/p ..... *status post*
SPSS ..... Statistical Package for Social Sciences
THA ..... Total Hip Arthroplasty
TIA ..... transient ischemic attack
UHNA ..... BioBall® universal head neck adapter
UHXLPE ..... ultra-highly cross-linked polyethylene

we ..... weeks

ϕ ..... phi coefficient

χ^2 ..... chi-square test

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1 Introduction

This thesis is part of a project conducted at the Department of Orthopaedics and Trauma at the Medical University of Graz. It follows the IMRD scheme (Introduction, Methods, Results, Discussion).

This thesis aims to contribute to the research on use of "mix & match" in primary total hip arthroplasty (THA) and revision total hip arthroplasty (rTHA) in combination with the BioBall® system (Merete®, Berlin, Germany), which will be referred to as universal head neck adapter (UHNA) from here on. Up to now there are only a few studies offering long-term results for a modular head-neck adapter system and its "mix & match" use, especially in larger study populations. Therefore, long term results of the UHNA, indications, complications, re-revision rates and reasons for revisions UHNA implantation are of great interest. Hence, this thesis aims to address this gap by investigating the hypothesis that the use of the UHNA system in a "mix & match" approach, will yield favorable long-term results in both primary THA and rTHA scenarios, characterized by low complication and re-revision rates.

The introduction of the thesis will provide an overview on the topic, focusing on the clinical significance of the UHNA in primary THA and especially rTHA and the concept of "mix & match". The introduction will also present indications, complications, comorbidities, and risk factors associated with the UHNA, as these factors are of great importance in the methods and results sections.

General information: All data presented in the Introduction section are cited from other authors. The author of this diploma thesis underlines that the Introduction section is only a summary of knowledge, published from other authors.

1.1 Significance and Epidemiology of "Mix & Match" and UHNA

Arthroplasty is known as the replacement of a joint by creating an artificial joint [1]. These artificial joints, or endoprostheses, are designed as long-term implants to replace damaged or dysfunctional joint surfaces. While a hemiprosthesis or hemiarthroplasty replaces only one joint surface, a total endoprosthesis replaces both (or all) joint surfaces. In the field of hip arthroplasty, THA involves the replacement of both the femoral head and the acetabulum [2].

Revision in THA refers to the replacement of individual components of the hip endoprosthesis, by undergoing a reoperation: a subsequent hip operation on a patient who

has already undergone primary THA [3]. There are several surgical options for rTHA, ranging from single component replacement to more complex procedures to address extensive bone and soft tissue defects [4]. Often, however, only a partial revision is necessary, in which only part of the hip endoprosthesis needs to be replaced. The following partial replacements are possible: replacement of the tribological components (head and liner), the cup (with the stem remaining in place), and the stem (with the cup remaining in place). In the case of a stem replacement, the head and liner are usually also replaced [5]. When performing a partial replacement, the specific implants on the operative side must first be identified using surgical reports or implant registers and accurate preoperative planning is necessary. There are many factors to be considerd, including patient-related factors such as individual hip anatomy, landmarks, implant positioning, indications [5-8], as well as surgical and implant related factors such as endoprosthesis design, component sizing, tribological bearing, compatibility of planned implants, potential need for bone or defect filling material (allograft), or weight-bearing capacity [5, 7, 8]. Because a prosthesis consists of several different, interconnected and partially mobile parts, it is necessary for the components to be made of different materials to minimize material wear and to maximize the durability of the endoprosthesis over time [7, 9, 10]. After preoperative planning, the most likely procedure is outlined and usually the same approach as for primary THA is used to minimize additional muscle damage [7].

THA is widely regarded as one of the most successful procedures in orthopaedic surgery [6, 11]. It has helped numerous patients with end-stage hip osteoarthritis and other hip pathologies to improve their quality of life by improving hip joint function and reducing pain [12]. The first attempt at THA was performed by Philip Wiles in 1938, but it was John Charnley's low friction arthroplasty in 1962 that marked the breakthrough. Since then, various types of hip arthroplasty and prosthetic materials have been developed. In 1968, Bernhard Georg Weber introduced the first modular THA [6, 13]. Depending on the location of the hip stem coupling, modularity can be classified as distal, middle, or proximal [14]. Proximal modularity with modular necks originated in 1987 with Cremascoli Ortho in Italy [15]. Another type of so-called proximal modularity are head-neck or taper adapters. These adapters are used, for example, in cases of partial rTHA when a well-fixed stem is maintained, and only the head or head and cup need to be replaced, including the liner. Therefore, it can often be advantageous to retain a well-fixed stem and replace only the other loosened component. This reduces operative time, blood loss, bone loss and patient stress [5, 16, 17]. As a result, it is generally preferred to replace only loosened components [18,

19]. If a ceramic head is to be placed on the undamaged taper of a stem from another company, the use of a metal head-neck adapter, such as the UHNA is crucial to prevent ceramic breakage. This is an example of “mix & match” in THA [5, 18-21]. Several types of these adapters are currently available [22]. The BioBall® UHNA system was introduced by Merete® in the late 1990s [23]. It is a modular joint prosthesis system and acts as a link between the prosthesis head and the prosthesis stem, allowing for variable reconstruction of the biomechanics in the area of the prosthesis neck stem of the hip joint without the need to replace a well osteointegrated femoral stem [12, 20, 24].

In THA, “mix & match” is a term used to describe the combination of compatible prosthetic components from different manufacturers. On the other hand, “off-label use” generally refers to the use of a medical device outside the manufacturer’s instruction for use [21, 25]. “Mix & match” and “off-label use” are common practices in THA [21]. An example of “off-label use” in hip arthroplasty is obesity [5, 18-21]. Typical examples of “mix & match” include legacy implants when the original manufacturer's implants are not available, or situations where alternative components are a better solution for the patient, medical conditions that allow only partial revision, e.g. in multimorbid patients, cases of partial component loosening, cementing a new polyethylene liner into the existing implant, anatomically challenging situations characterized by significant bone and soft tissue defects, etc. [4, 5, 18-21]. The term multimorbidity is used when a patient has at least two or more comorbidities [26].

Endoprosthesis registers are used for epidemiological information and to collect clinically relevant information to improve patient care and reduce the need for revision. In Austria, endoprostheses have been centrally registered since 2009 [27]. According to the 2018 Austrian report on hip and knee arthroplasty, Austria is among the world leaders in the number of THAs per inhabitant, with an implantation rate of 210 per 100,000 people per year [28]. The main indications for primary THA are osteoarthritis, avascular necrosis, and fractures in the different parts of the hip joint [29]. While primary implants have a survival rate of over 90% at 10 years and over 80% at 20 years, at least 15% of patients are expected to require revision surgery [11]. Thus, in addition to an increase in primary THA, an increase in rTHA can also be expected [27, 30, 31], as well as an increase in “off-label use” and “mix & match” in orthopaedics. It is predicted that between 86% and 92% of THA procedures could fall into the “off-label use” category by 2040 [32]. One reason for the increase in rTHA is the decreasing time to the next revision with each revision procedure [33]. Other reasons include demographic changes (aging population, increasing multimorbidity, more

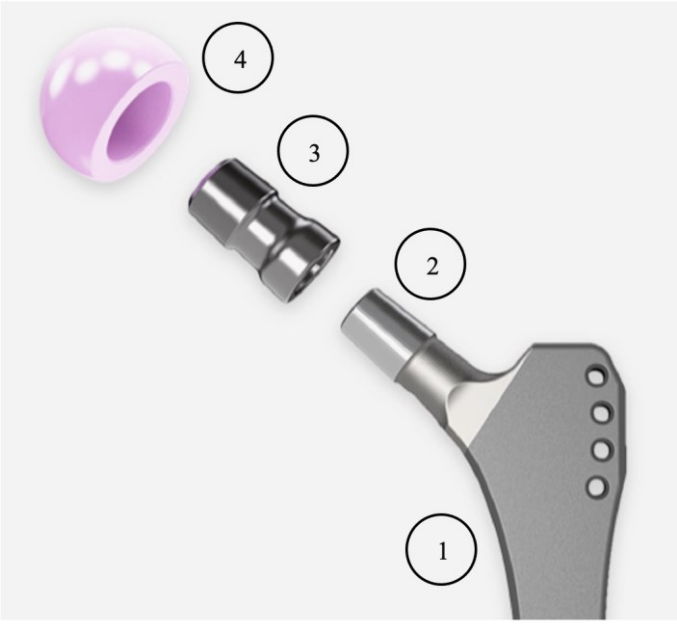
procedures in younger patients, higher life expectancy), an increase in risk factors (obesity, osteoarthritis), improved medical care, and unrestricted access to orthopaedic procedures, and the improved functionality and quality of life resulting from these interventions [27, 31]. However, overall revision rates after THA range from 6% at 5 years to 13% at 10 years [34]. Although adapter sleeves such as the UHNA may help to reduce the re-revision rate [35], there are conflicting results regarding revision and survival rates in different studies analyzing this device [16, 17, 22, 36-38]. The reported re-revision rate of UHNA also varies widely, ranging from 5.2% to 23% at 4–8 years [20, 36, 37, 39-41].

Finally, the European Federation of National Associations of Orthopaedics and Traumatology (EFORT) published evidence- and consensus-based recommendations for the safe use of "off-label use" and "mix & match" in primary and revision hip and knee arthroplasty in 2021 [21]. Some of these recommendations are summarized below.

- The benefits and risks for patients should be carefully weighed and documented when "mix & match" is used [21].
- Only compatible components should be combined in "mix & match" [21], including the use of compatible UHNA from the same manufacturer in the case of all-ceramic heads [25]. Furthermore, treatment errors such as "mismatch", the combination of incompatible components, should be avoided [21, 25].
- Manufacturers should ensure product availability for revisions after discontinuation of production and standardization of tapers to avoid incompatibility [21].
- Surgeons should be familiar with the components used, have adequate training, and monitor outcomes over time [21].
- Due to the common practice of "off-label use" and "mix & match" as well as potential medicolegal issues, further research and data collection is needed to demonstrate the safety of these interventions. From a medical device law perspective, the surgeon assumes the role of a manufacturer in these cases [21].

1.2 Universal Head Neck Adapters (UHNA)

Figure 1. UHNA with a Standard Configuration and Ceramic Head.



Note. Merete®. BioBall® Adapter Standard 2024. The original image has been trimmed, and numbering was added. The original image is available from: https://merete.de/wp-content/uploads/2021/01/merete-hueftchirurgie-bioball-adapter-standard-2.jpg. Reprinted with kind permission from the company Merete®.

Figure 2. Explanted UHNA with a Lateralized Configuration and Ceramic Head.

Note. The picture shows an explanted example of a UHNA with a lateralized configuration, ceramic head and a Corail-type uncemented prothesis stem by DePuy Synthes. The prosthesis on the picture shows signs of mechanical wear and bone residue.

As shown in Figure 1, the femoral stem (1) typically has a tapered part at its proximal end, also known as a trunnion or (neck) taper (2). This is the point of connection between the femoral stem and the modular head of the endoprosthesis (4). The head has a corresponding taper on its underside. These tapers are designed to (press-)fit together securely to provide effective load transfer and stability in the hip joint. However, different hip implant systems from different manufacturers may have slightly different taper designs, which can cause compatibility issues when using components from different systems. Taper adapters (3) help bridge this gap by providing a standardized interface that can connect different femoral stem tapers to different femoral head tapers. These devices, like the UHNA, are used as an intermediary between the femoral stem and the femoral head of the hip prosthesis. Another example of this design is shown in Figure 2.

In revision situations, defects may occur on the stem taper surface and therefore taper adapters are required to reduce the risk of ceramic fracture, when using ceramic heads. In revision situations, where one component (cup or stem) is well fixed, these adapters can also avoid total replacement of the endoprosthesis. Thus, they are of great importance in selected cases and can reduce morbidity and mortality, operating time, blood loss and preserve bone stock by preventing the extraction of well-fixed femoral components [5, 16, 17].

The UHNA is made from a titanium alloy and is available in standard taper sizes of 12/14 or 14/16 millimeters or other sizes upon request. They are available in various lengths from S (-3.0 mm) up to 5XL (+21.0 mm), with standard or non-skirted lengths ranging from S to XL. Above 2XL, the neck adapters are considered skirted or oversized. Depending on the inclination angle of the adapter, a standard adapter configuration (neutral or 0° angulated) or an offset adapter configuration (7.5° angulated) can be selected. This allows for good joint stability and biomechanical reconstruction of the hip joint in a combination with different taper and head sizes. Furthermore, modular heads are available in different materials (ceramic, metal) and sizes (28–48 mm). However, it should be verified intraoperatively that all these combinations do not exceed the maximum stem extension approved by the manufacturer [5, 20]. For a proper fixation, the UHNA has a high surface roughness. This is especially important since there is no standardization of the adapters so far [5, 42].

The UHNA can compensate for minor taper surface damage up to 0.3 mm [43], due to scratches, which can be caused primarily by head removal in rTHA [44], poor pre-coupling, component breakage, or poor extraction technique [22]. However, the taper must only be minimally damaged, and the taper angle of the shaft and adapter must be identical.

Compatibility of the taper with the adapter can be checked using taper charts or intraoperative adapter selectors [4, 45]. The problem with major taper damage is a reduced fracture resistance of the head [46]. If the extent of taper damage is uncertain, a metal head is a good alternative instead of a ceramic head, because it is less prone to chipping or cracking [44]. Furthermore, the original ceramic heads should not be reused in revision situations once they have been implanted, as they are considered damaged upon removal [7].

Another aspect of UHNA is their advantages in unconventional hip anatomy, such as developmental dysplasia of the hip (DDH), coxa vara, post-traumatic cases, or revision cases. Potential benefits include easier reconstruction of femoral retro-/antetorsion, lateralization/medialization, neck or leg length, femoral offset (FO) and soft tissue tension at the level of the femoral neck. The therefore optimized interaction of the components may lead to less tribological wear, better joint stability with lower loosening or dislocation rates, reduced load, better joint mobility, improved soft tissue tension and finally a more durable prosthesis [12, 20, 24]. However, major stem malalignment cannot be compensated by the UHNA and will most likely requires component replacement [47].

1.3 Anatomical Modifications and Biomechanical Aspects of the UHNA

Restoration of optimal proximal femoral anatomy is particularly important for achieving favorable clinical outcomes [48, 49]. Therefore, preoperative radiographs are typically used to determine the required values [11, 48, 50]. Several individual factors influence the hip anatomy and biomechanics, including age, weight, height, sex, environment, lifestyle, geographic factors, edge loading, soft tissue balance, component positioning, leg length discrepancy, acetabular and femoral offset, surgical approach, implant design, and proper reconstruction of the hip's center of rotation (COR) [48].

In particular, offset is a very important parameter for hip joint stability, providing a good lever arm for the gluteal muscles and influencing leg length. The global offset (GO) of the hip consists of the FO plus the acetabular offset (AO). Correct intraoperative reconstruction of the GO results in better functional outcomes [50, 51]. Overall, there are several factors that contribute to the GO, such as cup design, modular cup systems, angled neck adapters, different head lengths and diameters, and the COR. When reconstructing the GO, the healthy hip can be used as a reference point, with reference values within plus or minus five millimeters [11, 50, 52].

FO is the vertical distance between the center of rotation of the femoral head and the longitudinal axis of the femoral shaft [53]. It is influenced by several factors, including femoral stem design and positioning, modular neck design, caput-collum-diaphyseal angle (CCD angle), abductor lever arm, and head size [11, 48, 50]. Normal monobloc stems sometimes fail to adequately restore the FO, leading to the development of lateralized offset stems and modular neck stems [54]. However, modularity carries certain risks, such as a potentially higher rate of implant failure and fretting corrosion at the neck-shaft junction [55]. In most cases, the goal during surgery is to achieve a larger FO of up to five millimeters. This results in a longer lever arm, which reduces the abductor force required to maintain horizontal pelvic alignment. This results in improved ROM, better tension in the abductor muscles and surrounding soft tissues of the hip joint, reduced PE wear, fewer dislocations, and ultimately fewer revisions. A disadvantage is the increased medial bending stress on the prosthesis, which can lead to conditions such as trochanteric bursitis [11, 48, 50]. The UHNA plays a central role in optimizing FO in rTHA, thereby restoring hip biomechanics and minimizing post-operative complications [12, 20, 24].

However, not only the reconstruction of the FO, but also the AO is important in this context. It is the distance between the center of the femoral head and the true floor of the acetabulum (inner wall of the quadrilateral plate) [11, 50]. Both acetabular cup positioning and head size are important factors for the AO and related complications are leg length discrepancy, reduced ROM, increased dislocation rate, bearing wear, squeaking of CoC bearings, PE or ceramic fracture, iliopsoas tendinitis, osteolysis, aseptic loosening, component migration, and higher revision rates [48, 56]. However, medialization of the COR or AO requires an increase in FO to restore the GO [57].

1.4 Indications of UHNA

There are many indications for the UHNA in the context of primary THA or rTHA, particularly for correction of biomechanics [16, 20]. These indications include: Coxarthrosis, avascular necrosis (AVN), DDH, conversion from hemiarthroplasty to THA, failure after primary revision, septic and aseptic implant loosening, recurrent dislocation and instability, component malalignment, liner wear, metallosis, adverse reactions to metal debris (ARMD), pain without loosening, periprosthetic fracture, component fracture (head, liner, neck, cup), ossification, periprosthetic joint infection (PJI), superficial and deep infection, and squeaking of CoC bearings. Overall, the two most common reported diagnoses leading to

UHNA implantation are cup aseptic loosening and primary instability (recurrent dislocation) [16, 17, 21, 36-38, 40].

1.5 Complications of UHNA

Revision arthroplasty is considered to be a more technically challenging procedure than primary arthroplasty [7], which increases the risk of postoperative complications [7, 58], reoperation [59], and less predictable outcomes [60]. There are different revision procedures depending on the specific complication [61]. In addition to general complications in THA, there are also more specific complications related to the modular system of the UHNA.

General complications in THA include intraoperative vascular or nerve injury, implant instability, joint instability, acetabular or femoral fracture, coagulopathies, embolism, and cardiopulmonary complications. Postoperative complications may include bleeding, PJI, wound healing problems, instability and (recurrent) dislocation, periprosthetic fracture, heterotopic ossification, aseptic loosening, coagulopathies, thrombosis, embolism, cardiopulmonary complications, and residual pain without an obvious cause [62-64]. In the context of the UHNA general complications such as PJI [22, 38], instability and (recurrent) dislocation [16, 17, 20, 38, 65] have been described.

Recurrent dislocation is a significant factor contributing to early rTHA [22], as well as multiple revisions [22, 66], particularly isolated head/liner or acetabular cup replacement [67]. Patient-related risk factors include indications, age, and various comorbidities [58, 66], such as periprosthetic fracture, [66, 68], depression and psychiatric disorders [69-71], and heart disease [69, 70, 72]. Surgical and prosthesis-related factors are also important, including the number of hip surgeries and rTHA procedures [73], surgical technique, approach, component mispositioning, smaller prosthesis heads, incorrect offset reconstruction, leg length, abductor and soft tissue insufficiency, low head-neck ratio due to increased risk of impingement, prosthesis lifetime [7, 11, 33, 48, 66], and PE wear and decentered heads [33]. To reduce the risk of dislocation in revision situations, the largest possible head diameter is considered, given the increased jumping distance for dislocation [51, 74]. This typically results in increased offset and leg lengthening. In such cases, UHNA can be used to restore offset without significant leg lengthening by using different neck lengths [7, 11, 12, 20, 48]. Nevertheless, recurrent dislocation appears to be a challenge even

after UHNA implantation [20, 22], where offset reconstruction and component loosening may be involved [75].

Another common problem with THA is prosthetic joint infection (PJI) and septic loosening [7], but it is rarely mentioned in the context of UHNA [22, 38]. It seems to be a risk factor for the increasing revision rate especially in the younger population under or equal to 60 years [76, 77], with reported risk factors such as obesity (especially in combination with an active lifestyle) [78], substance abuse and liver disease [79], smoking habits, diabetes mellitus, rheumatoid arthritis, and many other factors [80]. On the one hand, younger patients generally have a longer prosthesis life and therefore an increased risk of revision [81, 82], with revision itself being a known risk factor for PJI [80, 83]. Previous studies have also shown that patients with a history of PJI have an increased risk of subsequent postoperative PJI (known as metachronous PJI) [84], with possible risk factors being female sex, diabetes and polymicrobial index PJI [84]. In the clinical setting, a simple distinction is often made between early and late PJI [85]. Early infections often require quick revision of mobile components such as the liner and head, usually in the form of a one-stage procedure known as Debridement, Antibiotics, and Implant Retention (DAIR). Late infections offer the option of either a one-stage or two-stage revision. The gold standard two-stage revision aims to eradicate the infection with high doses of local antibiotics, typically antibiotic-loaded bone cement or antibiotic-impregnated allografts, while maintaining soft tissue balance with the use of a spacer [7, 86]. The spacer, which is used for six to twelve weeks, maintains limb length, joint mobility, and partial weight bearing, although complications such as dislocation and fracture may occur. Alternatively, Girdlestone resection arthroplasty (GRA), which involves complete removal of the hip arthroplasty, may be performed as part of a two-stage revision or as a permanent solution for patients with poor bone or soft tissue status, uncontrolled infection, or multiple comorbidities. These procedures are typically considered salvage procedures after other methods have failed or are not feasible [87]. Other rescue options in revision are arthrodesis, or amputation. However, it is important that all inflammatory and ischemic tissue is removed intraoperatively in late infected hips and that treatment is followed by systemic antibiotic therapy for approximately six weeks [7, 80]. Finally, in cases where surgery is not feasible or considered too risky, antimicrobial suppression may be considered [83].

Periprosthetic fractures in the context of UHNA implantation are rare events [17, 37, 38]. Known risk factors in the context of THA are patient risk factors, including implant loosening, female sex, osteoporosis [7, 33], older age (≥ 60 and especially ≥ 90 years),

multiple comorbidities (≥ 3 comorbidities) [88, 89], and lower weight (≤ 50 kg), among others, as well as surgeon-specific factors such as low surgical volume or endoprosthetic design [88]. Osteoporosis in particular increases the risk of periprosthetic femoral fractures [90] and atraumatic fractures due to cup loosening and osteolysis are more common than traumatic fractures [91]. Periprosthetic fractures can be divided into periprosthetic femoral and acetabular fractures [33], although periacetabular fractures are rare in THA [92]. The more common periprosthetic fractures are associated with an increased mortality within one year and may require revision surgery [7, 33]. Revision surgery varies depending on factors such as component loosening, with loosened components requiring replacement and fixed components being treated conservatively or with osteosynthesis [91].

Aseptic loosening, particularly cup loosening, is one of the main reasons for revision after UHNA implantation [22, 37] and is generally a major cause of rTHA and is highly dependent on bone quality [7, 67, 77]. Aseptic cup loosening is defined as a radiographic loosening margin of two millimeters, a positional change of four millimeters, or an angle change of more than four degrees. On the other hand, stem loosening is described radiographically as a loosening margin of two millimeters, a subsidence of more than four millimeters, or a cement fracture [7]. However, there are many factors that contribute to aseptic loosening, such as cement loosening, osteolysis, surgeon-related factors, implant design and materials, tribological wear and stress shielding [33, 93], secondary osteoarthritis and increased physical activity, etc. [77]. Stress shielding appears to be a problem due to altered load distribution, potentially leading to bone loss and stem loosening [94]. In combination with high femoral offset combinations, the risk of stem loosening is even higher [75].

While wound healing defects are a common complication of THA with various influencing factors, they have not been described as a problem after UHNA implantation. Patient-related risk factors and comorbidities such as increasing age [95], diabetes mellitus [96], smoking [97], rheumatoid arthritis [95], steroid use [98], and obesity play a significant role [96, 98]. In addition, studies suggest that the metabolic syndrome may have a greater impact on wound healing than obesity alone [99]. Intra- and perioperative parameters also contribute to postoperative wound healing complications. These include preoperative [98] and intraoperative blood transfusions, use of different antiseptics [95], surgical site infections [98], and wound closure methods [100]. Finally, postoperative wound care practices may contribute to the risk of wound healing failure in selected cases [101].

Bearing surface wear and adverse reactions to particle debris are also common complications leading to rTHA [7, 30, 67], particularly PE wear in the cup area, defined as a radiographically decentered head greater than 0.2 millimeters [7]. The combination of liner and femoral head materials is known as tribological or sliding bearing. Modern tribological bearings offer options such as metal-on-PE (MoP), ceramic-on-ceramic (CoC), and ceramic-on-PE (CoP). Today, ultra-highly cross-linked polyethylene (UHXLPE) or vitamin E-infused PE are used to address the problem of increased PE wear [7, 9, 10]. Factors influencing increased PE liner wear include implant-related aspects such as reduced bearing surface contact area due to smaller heads, increased bearing clearance, or cup positioning. Patient-related factors, particularly increased BMI with higher bearing loads, especially in combination with increased activity levels, also contribute to wear [9]. An immunological and inflammatory response to PE wear and particles can lead to osteolysis, resulting in progressive periprosthetic bone loss or even fracture and subsequent component loosening [9, 102]. However, comparative analysis of wear patterns between different tribological bearings has demonstrated the superiority of CoC bearings over CoP and MoP bearings [9].

Larger studies have the advantage of being more likely to identify rare complications [103]. In the context of UHNA implantation, the specific complications are such rare events and include interfacial fretting corrosion of modular components [16, 17, 37], trunnionosis or metallosis [16, 17, 37, 104], ceramic head fractures [35, 37, 38, 104], femoral neck or taper fractures [22, 37, 105], adapter fractures [17, 20, 37, 38], mechanical dissociation at the neck-shaft junction [20, 38], and the occurrence of squeaking in CoC bearings [65].

Although CoC bearings offer better implant survival than other tribological bearings [106, 107], they cannot be recommended for all patients because problems such as squeaking, ceramic fracture, impingement, chipping during insertion, and iliopsoas irritation have been reported with modern fourth-generation Delta ceramics [9, 108]. Delta ceramics have been used by Merete® since 2003 [22] and in general the Delta or fourth generation ceramics show better results than the older third generation [57, 58]. Advantages include their extreme hardness, scratch resistance, wettability, lubrication, low wear rate, and high biocompatibility without serious local or systemic adverse reactions, which are favorable especially in younger patients [109, 110]. While ceramic fractures in general remain rare events, cases of ceramic liner fractures appear to be more common than head fractures [109, 110], but both remain rare events associated with UHNA implantation [37, 111]. Risk factors for ceramic fracture include: ceramic composition, smaller prosthesis heads (< 32 mm), short

head or neck lengths, male sex, higher BMI [112], and contamination of the taper connection [113]. The problem is that a fractured CoC bearing requires revision with radical debridement and complete removal of all ceramic parts and particles [35, 44, 109], followed by placement of a PE liner. Any remaining ceramic particles will press into the PE liner and increase bearing wear, but reduce the risk of another ceramic fracture [7].

Another problem with "mix & match" in UHNA implantation is corrosion due to different metal alloys [45, 105, 114], although any modular connection with metal alloys shows corrosion in contact with body fluids [16, 17, 105]. As the UHNA is not designed for specific tapers, this could lead to accelerated wear and early metallosis [22], especially in cases of taper mismatch [21]. Metallosis, or trunnionosis in the case of the stem, is fretting corrosion at the taper junction [16]. Potential influencing factors include taper design, contact surfaces, neck stiffness, higher offset, component orientation and assembly, micromotion, higher bearing loads (due to obesity) [16, 105, 115], mismatch or insufficient impaction force, closed reduction technique, traumatic causes [21, 116], and even inflammatory conditions [105, 117]. Therefore, it is particularly important to achieve dry and clean assembly conditions combined with sufficient assembly force [16, 105, 115] to avoid subsequent problems such as ARMD [33, 118], periprosthetic osteolysis [9, 16], mechanical dissociation of the modular components, especially between the tapered connections [105, 114, 119], fatigue fracture of the UHNA [120], component loosening, component damage, or recurrent impingement and dislocation [7, 33, 118]. All of these factors contribute to the risk of early revision, which may even require removal of a well-fixed femoral stem [119]. However, some authors discuss a lower risk of mechanical failure or fretting corrosion in the UHNA system than previously thought [121].

There are other potential risks associated with the UHNA, most notably implant fractures, specifically fractures of the adapter system or femoral neck. However, both of them appear to be rare events [17, 20, 37, 122] and are rarely described in the context of UHNA implantation [37, 122]. The typical fracture location is near the modular stem-neck interface due to the extended lever arm. Risk factors include elongated femoral necks, skirted or oversized neck lengths (increased corrosion or microscopic fracture lines due to the greater offset), high BMI, high activity level, component loosening or misalignment, and specific prosthesis design features. Other contributing factors include male sex, head size and material, corrosion, and surgeon-related variables such as stem condition (corrosion, scratches), assembly force on the taper, and taper mismatch [22, 40, 122, 123]. Additional factors documented in the literature include stem contamination and a CCD angle less than

or equal to 135° [120], among other mechanical properties, heat treatment reduction, and iatrogenic implant damage [124]. However, “mix & match” arthroplasty itself may be part of the problem [123, 124], as well as rTHA [123].

1.6 Comorbidities and Other Risk Factors in Orthopaedic Surgery

There are several factors that influence the potential outcome of hip arthroplasty. Therefore, patient selection is critical in elective THA [125]. These factors include the endoprosthesis itself, surgeon skill and experience, individual patient characteristics, and appropriate physical therapy [126]. Individual factors include insurance status, younger age, sex, race, smoking, antibiotic prophylaxis, medical conditions, infection, dislocation, implant failure, endoprosthesis design, primary diagnoses other than osteoarthritis (such as hip fracture or AVN) [125, 127], alcohol and substance abuse [128], immunodeficiency syndrome [129], and so on. Other issues are associated with worse functional outcome and more complications, at least in short-term follow-up up to one year [140, 141], such as revision surgery [59] and more comorbidities due to a higher risk of complications [71, 129]. In the context of UHNA implantation, age [20], multimorbidity [40], and BMI [37, 38] have been described as possible influencing factors in addition to other comorbidities.

An important term in this context is comorbidities. Comorbidities are conditions that are etiologically unrelated to the observed condition [130], such as the risk of rTHA in our case. However, the influence of comorbidities on joint function before and after THA has been assessed differently in different studies [131-133]. In general, the increasing number of comorbidities and multimorbidity is a worldwide problem, not only in orthopaedics [26].

One of the comorbidities discussed as an influential factor in the context of UHNA is a higher BMI [37]. The use of UHNA in overweight patients is considered “off-label use” [45], although many obese patients also benefit from THA [128, 134]. However, obesity (BMI $\geq$ 30 kg/m^2) is an independent risk factor for early THA failure and early revision [135, 136], with some studies reporting BMI $\geq$ 25 kg/m^2 as a risk factor [137]. In addition, obese patients have an increased risk of postoperative complications such as thromboembolism, PJI, early prosthesis loosening, dislocation, material failure (especially in modular systems with higher offset), etc. [4, 15, 128, 134].

There are many different comorbidity assessment tools and indices used in THA studies, but there is no consensus on the best one for patient risk adjustment because they have different primary endpoints [138, 139]. The most commonly used indices are the Charlson

Comorbidity Index (CCI) and the Elixhauser Comorbidity Index [140]. Attempts have been made to use a modified version of the CCI as a prognostic model for complications and mortality [141]. However, less common indices may also be useful for THA studies [138, 139] because the CCI does not include important factors such as hypertension, obesity, weight loss, psychiatric disorders, visual impairment, osteoporosis and arthritis [29, 33, 77, 142], neurological disorders in general [118], or degenerative disc disease [143]. Another aspect is that many comorbidities in CCI are less common in THA patients [131, 133]. Furthermore, functional outcome is more interesting in orthopaedic research than mortality, but it is not the primary endpoint in CCI. Previous studies used comorbidity indices that did not focus much on physical function. This may have led to studies concluding that comorbidities had little effect on physical function [144, 145].

An index focusing on physical function as the only outcome of interest is the Functional Comorbidity Index (FCI) [144, 145]. The FCI has a better predicting value concerning the functional outcome and quality of life after THA, but worse predicting value for mortality than the CCI [138, 144, 145]. With only 18 diagnoses to be considered, the FCI is easy to administer. For each diagnosis one point is scored and the points are summarized. This results in a minimum score of 0 points and a maximum of 18 points. A simple count of diagnoses seems to be sufficient since a weighted score did not perform better [144, 145].

But there are also lots of other comorbidities associated with a worse outcome not included in the FCI: preoperative anaemia [127, 128, 142, 146] and blood transfusion [147], liver disease [70, 148], renal disease [70, 72, 147], fluid/electrolyte disorders [29, 128, 149], coagulopathy [129], (metastatic) cancer, [70, 142], psychiatric diseases in general (depression, dementia, psychosis, schizophrenia) [71, 130], hypothyroidism [29], frailty [127], malnutrition [127] etc.

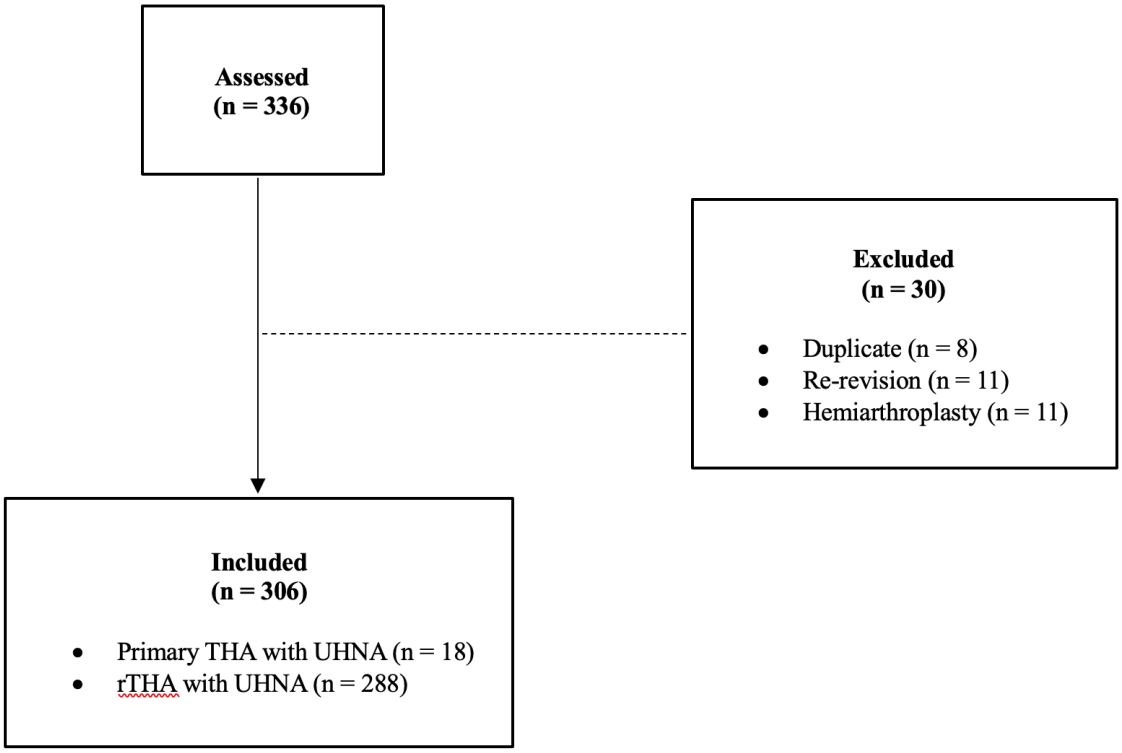
1.7 Aim

As the safety of “mix & match” THA with UHNA is still unclear and an important topic of discussion in the literature, the aim of this study was to analyze the complication and (re-) revision rates of BioBall® UHNA at our institution. Following the EFORT recommendations, we aimed to identify potential factors influencing the outcome and to analyze the implant survival of UHNA in “mix & match” settings.

2 Materials and Methods

Our database at the University Hospital of Graz was initially screened for 336 patients (sample size or $N = 336$) who underwent hip arthroplasty with the BioBall® UHNA between October 2006 and May 2022. Most patients met the inclusion criteria ($n = 306$; 91.1%), being primary THA ($n = 18$; 54%) or rTHA (n = 299; 94.1%) with UHNA "mix & match" use, as shown in Figure 3. Some patients were excluded ($n = 30$; 9.1%) because they were duplicates ($n = 8$; 26.7%), re-revision procedures due to complications after UHNA implantation ($n = 11$; 36.7%), or hemiarthroplasties ($n = 11$; 36.7%). The latter were excluded because they were not considered as "mix & match" procedures.

Figure 3. Inclusion and Exclusion Criteria.



Note. THA = total hip arthroplasty, UHNA = BioBall® universal head neck adapter, rTHA = revision total hip arthroplasty.

A retrospective data analysis was performed on the 306 enrolled study participants. These cases were followed up until July 24, 2023, or the dare of death.

The study was approved by the Ethics Committee of the Medical University of Graz (Institutional Review Board Number: 35-033 ex 22/23). No external funding was received.

The decision to retain or revise the stem in addition to UHNA implantation was based primarily on preoperative evaluation. Joint restoration was based on the contralateral hip and digital templating. Well-fixed stems were considered for retention, while unstable or loosened stems with evidence of osteolysis around the stem were revised. For cases with reduced offset compared to the contralateral side, reconstruction with an offset adapter was planned. Intraoperative trials guided the restoration of the version, the final adapter, and the femoral head. These were manually assembled and fixed to the trunnion of the stem. Intraoperative stability was assessed with UHNA in situ, including ROM, shuck test, leg length assessment, and evaluation of soft tissue tension to avoid laxity and instability.

For each patient, we recorded epidemiologic parameters, details of their hip endoprosthesis including UHNA specifications, diagnoses leading to UHNA implantation, complications after UHNA implantation, and re-revision procedures following UHNA implantation. Failure was defined as the need for re-revision (reoperation) of the UHNA system and the follow-up time was calculated. We also assessed comorbidities using the FCI and screened for other potentially relevant comorbidities for THA outcome. Regarding arthritis, only patients with rheumatic diseases (e.g. rheumatoid arthritis) were documented under the variable “comorbidity arthritis”. Osteoarthritis was not documented under this comorbidity category.

Medical data were retrieved from the hospital’s internal data systems using keyword identification, whereas mortality data were obtained from insurance records. Medical follow-up data were obtained from our hospital database and other regional public hospitals as well, to reduce the risk of undetected revision surgery. All data were gathered using Excel (Microsoft, version 16.73) and anonymized to protect patient confidentiality. Data analysis was performed using Statistical Package for Social Sciences (SPSS, IBM, version 29) and Excel. Tables and figures were generated using SPSS, Excel, and Word (Microsoft, version 16.82).

Relative and absolute frequencies were determined for the variables indicated. Unless otherwise specified, results were rounded to one decimal place. Therefore, minor discrepancies may occur when percentages are added up manually. Statistical tests were considered statistically significant at a p-value (p) < .05 Normal distribution was tested using the Shapiro-Wilk and Kolmogorov-Smirnov tests. Median and interquartile range (*IQR*) were calculated for non-normally distributed data.

The aim of the study was to evaluate the safety of the UHNA system. Therefore, factors influencing the complications and revision-free survival after UHNA implantation were

determined. The chi-squared test (χ^2) or Fisher's exact test was used to identify potential factors influencing postoperative complications after UHNA implantation. The variables tested include the following: sex category, age cohorts (< 60 or ≥ 60 years), bilateral THA, primary THA or rTHA with UHNA, revisions before UHNA, diagnoses leading to UHNA implantation, UHNA specifications, intraoperative complications, and comorbidities (both individually and as a cohort).

To test the strength of possible associated variables, we calculated the phi coefficient (ϕ) for the Pearson chi-squared test (χ^2) and the odds ratio (*OR*) for Fisher's exact test. Possible interpretations include $0 < \phi < 0.3$ (weak association), $0.3 \leq \phi < 0.5$ (moderate association), and $\phi \geq 0.5$ (strong association). While an *OR* of 1 indicates that there is no association between the two groups being compared, an *OR* greater than 1 (positive association) indicates a higher frequency of events in group A than in group B. Conversely, an *OR* less than 1 (negative association) indicates a lower frequency of events in group A than in group B.

Finally, survival analysis was performed using the log-rank test and Kaplan-Meier curves to examine revision-free survival time in years after UHNA implantation. The primary endpoint was defined as reoperation after UHNA implantation. Censoring criteria included instances of no re-revision after UHNA implantation and death unrelated to UHNA implantation. Further re-revision-free survival calculations were performed using mortality tables for the identified significant factors. The following formula was used to calculate the confidence interval (CI): CI = cumulative proportion of survivors at the end of the interval ± (Z-value x standard error of the cumulative proportion of survivors at the end of the interval). A Z-value of 1.96 was assumed for the 95% confidence interval.

3 Results

3.1 Patients Demographics and Specifications

Table 1. Baseline Characteristics.

	n (%)[a]
Total no. of patients	**306 (100)**
Sex	
Female	179 (58.5)
Male	127 (41.5)
Median age at UHNA implantation (yrs)[a]	**74 (62–81)**
Age groups	
< 60 years	58 (19)
≥ 60 years	248 (81)
BMI group (kg/m^2)[b]	
Underweight or normal weight (< 30)	156 (51)
Overweight or obese (≥ 30)	150 (49)
Burden of comorbidity	
Median no. of comorbidities[a]	3 (1–4)
< 2 comorbidities	137 (44.8)
≥ 3 comorbidities	169 (55.2)
Median follow-up (mo)[a]	**57 (23–85)**

[a] Reported as median (*IQR*).

[b] Further comorbidities are listed in Table 2.

Note. no. = number, UHNA = BioBall® universal head neck adapter, primary THA = primary total hip arthroplasty, rTHA = revision total hip arthroplasty, yrs = years, BMI = body mass index, mo = months, *IQR* = interquartile range.

As shown in Table 1, the majority of patients were female (*n* = 179; 58.8%). The median age of the patients at the time of surgery was 74 years (*IQR* 62–81 years), with a range of 47–97 years at the time of surgery (see Figure 4). Overall, most patients were older than or equal to 60 years (*n* = 248; 81%), with the largest subgroup between 71–80 years (n = 100; 32.7%), followed by 81–90 years (*n* = 78; 25.5%), and 61–70 years (*n* = 56; 18.3%). The

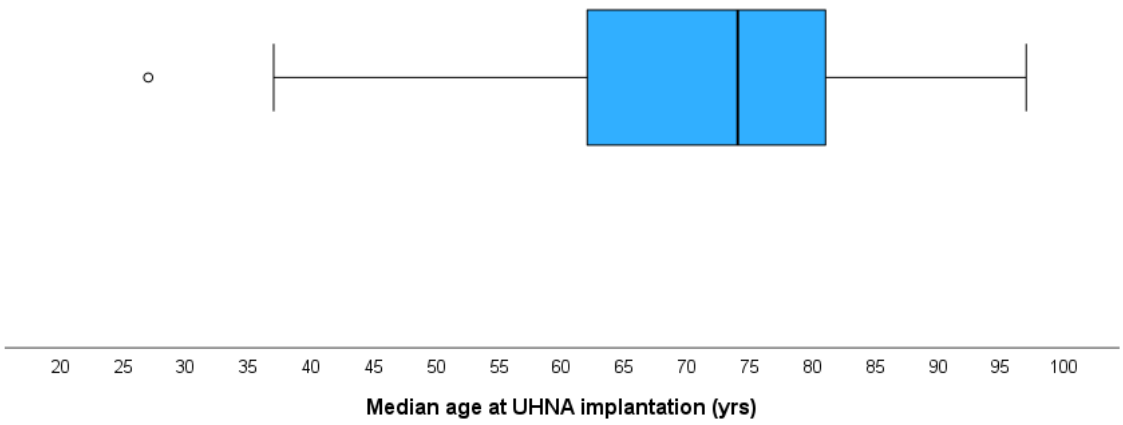
smallest groups were those older than 90 years (n = 6; 2%) and those younger than or equal to 40 years (n = 2; 0.7%).

Regarding BMI, the study population was almost equally divided into two categories: normal weight, overweight or underweight patients (BMI < 30 kg/m^2) and obese patients (BMI ≥ 30 kg/m^2). However, most of the patients (n = 154; 50.3%) were of normal weight (BMI 18.5–24.9 kg/m^2) or overweight (BMI 25–29.9 kg/m^2), followed by obese patients (n = 150; 49%), and the least common group of patients (n = 2; 0.7%) were underweight (BMI < 18.5 kg/m^2).

Overall, most patients had at least three comorbidities (n = 169; 55.2%). Figure 5 shows the median number of comorbidities (n = 3; *IQR* 1–4; range 0–8). Two patients (0.7%) had as many as nine or ten comorbidities.

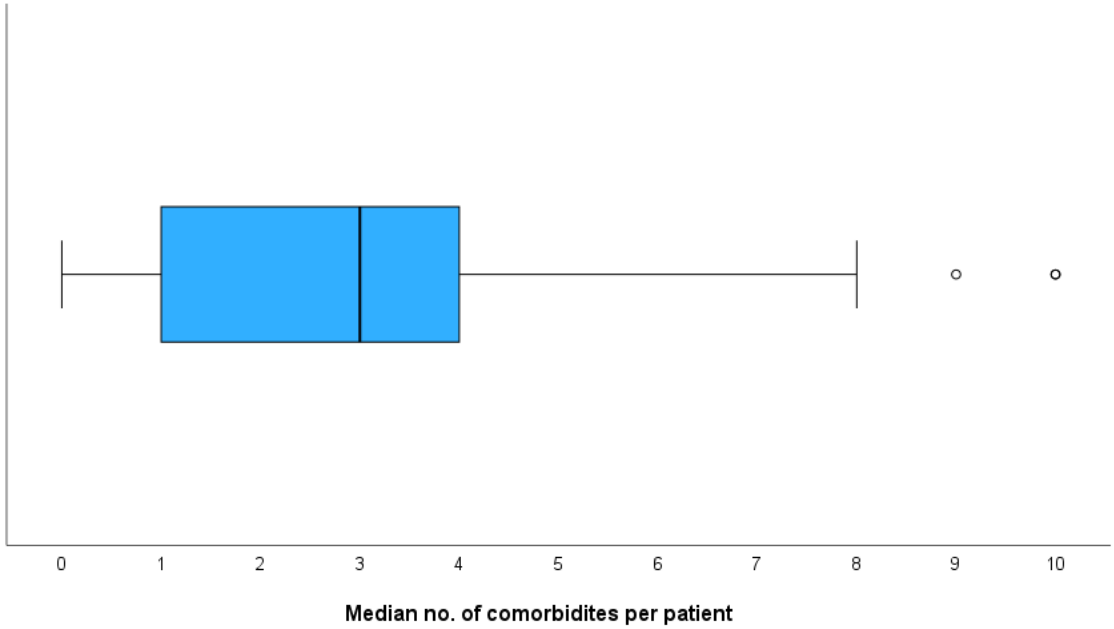
Follow-up after UHNA implantation was measured in months (years). The end points of the follow-up period were defined as death, reoperation after UHNA implantation or date of last follow-up at our department. As shown in Figure 6, the median follow-up period was 57 months (4.7 years), *IQR* 23–85 months (1.9–7.1 years), and range 0–167 months (0–13.9 years). The two longest follow-up periods were 188 months (15.7 years) and 200 months (16.7 years).

Figure 4. Median Age at UHNA Implantation and *IQR* in Years.



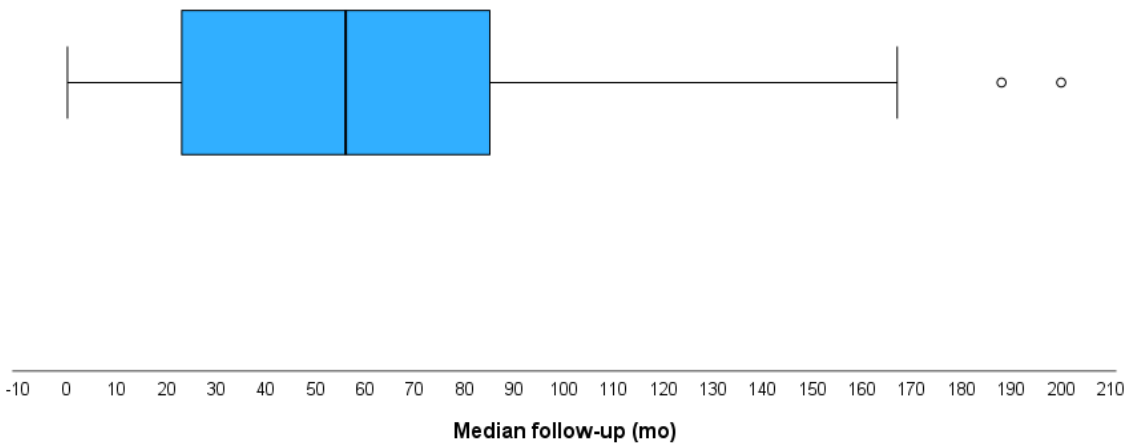
Note. yrs = years.

Figure 5. Median No. of Comorbidities per Patient.



Note. no. = number.

Figure 6. Median Follow-up Period and *IQR* in Months (mo).



Note. mo = months.

Table 2. Distribution of Comorbidities in the Study Population.

	n (%)[a]
Total no. of patients	**306 (100)**
Comorbidities according to the FCI	
1 Rheumatoid arthritis[b]	19 (6.2)
2 Osteoporosis	62 (20.3)
3 Asthma	5 (1.6)
4 COPD, ARDS, or emphysema	24 (7.8)
5 Angina	75 (24.5)
6 Congestive heart failure (or heart disease)	69 (22.5)
7 Heart attack (myocardial infarction)	28 (9.2)
8 Neurological disease	52 (17)
9 Stroke or TIA	32 (10.5)
10 Peripheral vascular disease	24 (7.8)
11 Diabetes types I and II	52 (17)
12 Upper gastrointestinal disease	39 (12.7)
13 Depression	32 (10.5)
14 Anxiety or panic disorders	4 (1.3)
15 Visual impairment	65 (21.2)
16 Hearing impairment	16 (5.2)
17 Degenerative disc disease (or severe chronic pain)	125 (40.8)
18 Overweight or obesity (BMI $\geq$ 30 kg/m^2)	150 (49)
Other registered comorbidities	
Bone tumor or metastases	5 (1.6)
AVN	25 (8.2)
Underweight	2 (0.7)
Multiple myeloma	2 (0.7)
DVT or lung embolism	31 (10.1)

[a] Multiple comorbidities for each patient were possible. The percentages of each comorbidity should be interpreted as a percentage of the total no. of patients (N = 306).

[b] The FCI listed under arthritis, cases of rheumatoid arthritis and osteoarthritis.

Note. no. = number, FCI = Functional Comorbidity Index, COPD = chronic obstructive pulmonary disease. ARDS = acute respiratory distress syndrome, MS = multiple sclerosis, TIA = transient ischemic attack, AVN = avascular necrosis of the femoral head, DVT = deep vein thrombosis, BMI = body mass index, *IQR* = interquartile range.

Table 2 shows the distribution and burden of comorbidities. Multiple comorbidities were possible for each patient. In addition to the 18 comorbidities included in the Functional Comorbidity Index (FCI), other conditions with a potential impact on the patient's postoperative outcome were recorded. These included bone tumor or metastases, avascular osteonecrosis of the hip (AVN), underweight, multiple myeloma, deep vein thrombosis (DVT) or lung embolism. The most common comorbidity was overweight or obesity (*n* = 150; 49%), followed by degenerative disc disease or severe chronic back pain (*n* = 125; 40.9%).

3.2 Indications for rTHA with UHNA

Table 3. Diagnoses Leading to Implantation of UHNA in rTHA.

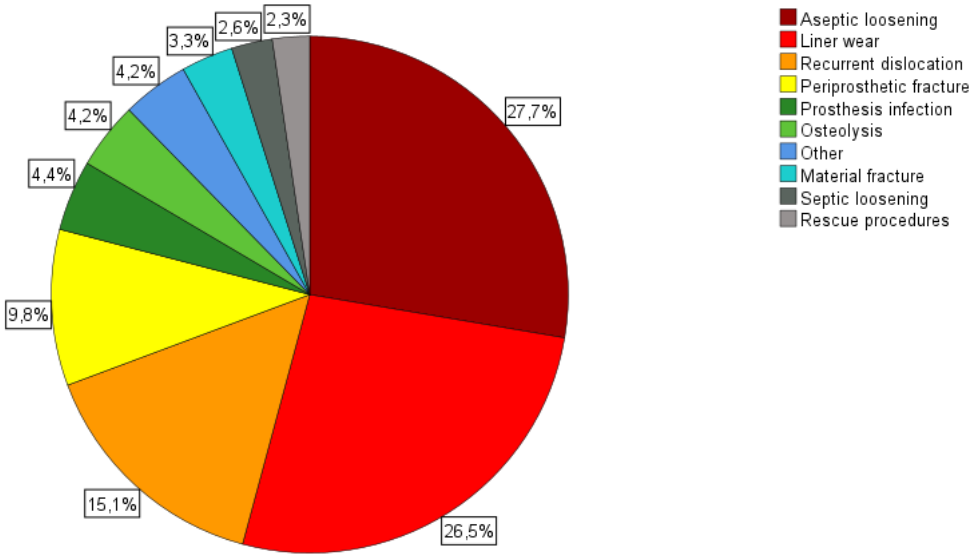
Indication	*n* (%)[a]
Aseptic loosening	**119 (27.7)**
Cup aseptic loosening	100 (23.2)
Stem aseptic loosening	16 (3.7)
Total aseptic loosening	3 (0.7)
Liner wear	**114 (26.5)**
PE liner wear	106 (24.7)
Metal liner wear	8 (1.9)
Recurrent dislocation	**65 (15.1)**
Periprosthetic fracture	**42 (9.8)**
Periprosthetic femoral fracture	30 (7)
Periprosthetic acetabular fracture	12 (2.8)
PJI	**19 (4.4)**
Early PJI (< 3 mo.)	4 (0.9)
Delayed PJI (3–24 mo.)	3 (0.7)

Late PJI (>24 mo.)	6 (1.4)
Chronical PJI	6 (1.4)
Osteolysis	**18 (4.2)**
Periacetabular osteolysis	9 (2.1)
Femoral osteolysis	6 (1.4)
Trochanteric osteolysis	3 (0.7)
Other	**18 (4.2)**
Psoatic impingement	9 (2.1)
Conversion to THA	5 (1.2)
Heterotopic ossification	3 (0.7)
Offset dysfunction	1 (0.2)
Material fracture	**14 (3.3)**
Liner fracture	8 (1.9)
Screw fracture	3 (0.7)
Cup fracture	2 (0.5)
Head fracture	1 (0.2)
Septic loosening	**11 (2.6)**
Cup septic loosening	8 (1.9)
Stem septic loosening	2 (0.5)
Total septic loosening	1 (0.2)
Rescue procedures	**10 (2.3)**
S/p spacer implantation	9 (2.1)
S/p GRA	1 (0.2)

[a] Multiple diagnoses for each patient were possible. The percentages of each indication should be interpreted as a percentage share of the total number of indications ($N = 430$; 100%).

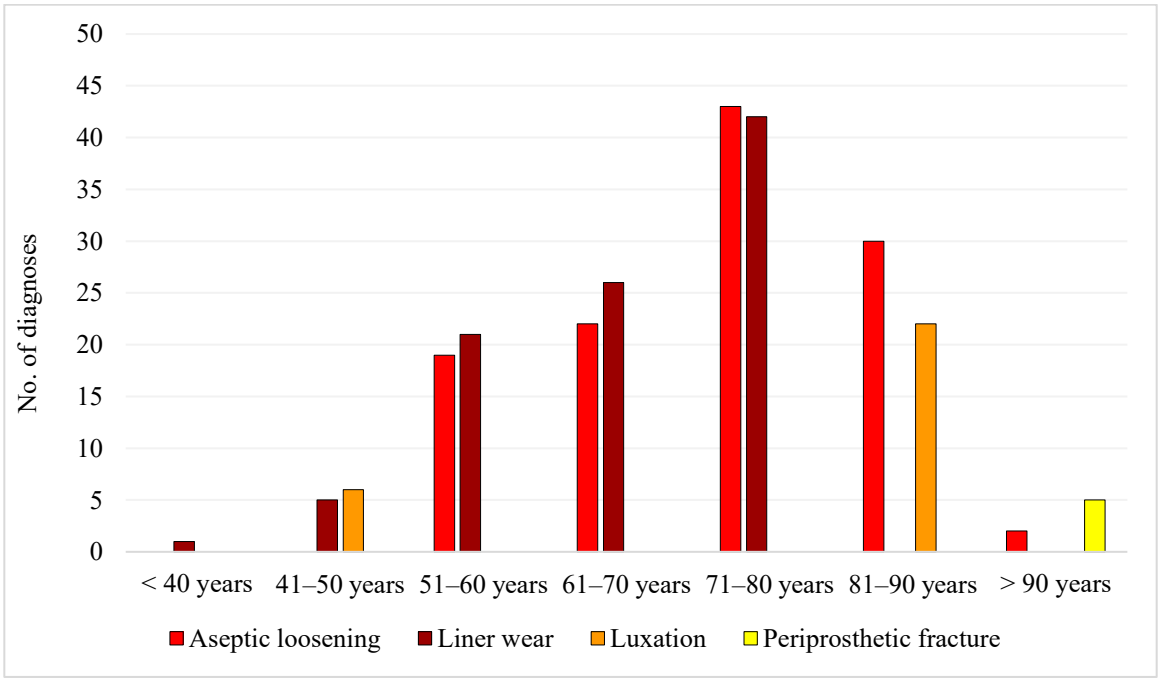
Note. UHNA = BioBall® universal head neck adapter, rTHA = revision total hip arthroplasty, PE = polyethylene, THA = Total Hip Arthroplasty, *S/p = status post*, GRA = Girdlestone resection arthroplasty.

Figure 7. Diagnosis Leading to Implantation of UHNA in rTHA.



Note. UHNA = BioBall® universal head neck adapter, rTHA = revision total hip arthroplasty.

Figure 8. Main Diagnoses Leading to UHNA Implantation in rTHA Concerning Age Cohorts.



Note. UHNA = BioBall® universal head neck adapter, rTHA = revision total hip arthroplasty.

Table 3 and Figure 7 illustrate the various diagnoses, that led to UHNA implantation in rTHA in the study population, including aseptic component loosening, liner wear, recurrent

dislocation, periprosthetic fracture, PJI, osteolysis, and other indications such as psoatic impingement, conversion from hemiprosthesis to THA, heterotopic ossification, offset dysfunction, material fracture, septic component loosening, and rescue procedures such as status post spacer implantation or GRA. Patients could have multiple diagnoses leading to the UHNA implantation.

The most common diagnosis was aseptic loosening (*n* = 119; 27.7%), of which cup aseptic loosening accounted for the largest proportion (*n* = 100; 23.3%). The second most common diagnosis was liner wear (*n* = 114; 26.5%), the majority of which was PE liner wear (*n* = 106; 24.7%). The third most common UHNA indication was prosthesis dislocation (*n* = 65; 15.1%).

Figure 8 illustrates the two most common diagnoses categorized by age cohort. Aseptic loosening and liner wear were the main reasons for UHNA implantation in the age groups of 51–60 years, 61–70 years, and 71–80 years. In patients younger than 50 years, recurrent dislocation was the most common indication, followed by liner wear, while aseptic loosening remained the most common indication in patients older than 80 years. Notably, in the 81–90 year age group, recurrent dislocation became the second most common indication. In those patients over 90 years of age, periprosthetic fracture was the main indication for UHNA implantation.

3.3 Implant Specifications

Table 4. Specifications of UHNA in the Study Population.

	n (%)
Total no. of implants	**306 (100)**
UHNA configuration	
Standard adapter (0°)	253 (82.7)
Offset adapter (7.5°)	35 (11.4)
Unknown configuration	18 (5.9)
UHNA cone size	
12/14 mm	166 (54.2)
14/16 mm	44 (14.4)
Unknown cone size	96 (31.4)
UHNA neck length group	

S–XL	130 (42.5)
2XL–5XL	143 (46.7)
Unknown neck length	33 (10.8)
UHNA neck length	
S (-3 mm)	13 (4.2)
M (+0 mm)	27 (8.8)
L (+3.5 mm)	29 (9.5)
XL (+7 mm)	61 (19.9)
2XL (+10.5 mm)	54 (17.6)
3XL (+14 mm)	36 (11.8)
4XL (+17.5 mm)	30 (9.8)
5XL (+21 mm)	23 (7.5)
Unknown neck length	33 (10.8)
BioBall® head size	
28 mm head	24 (7.8)
32 mm head	77 (25.2)
36 mm head	194 (63.4)
Unknown head size	11 (3.6)

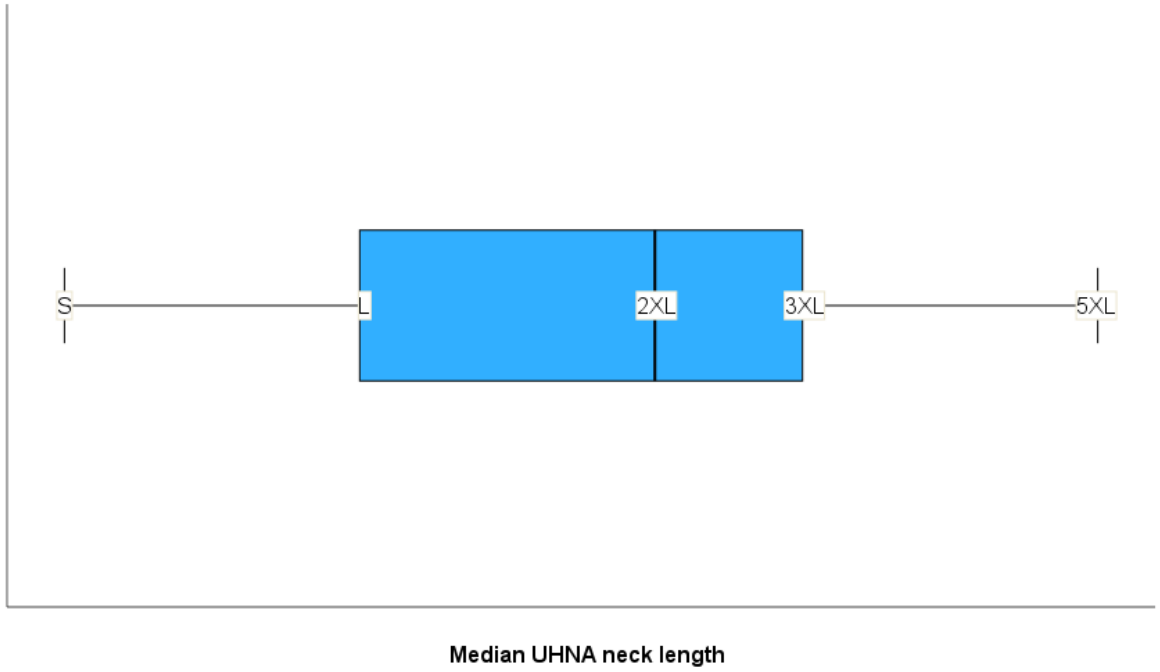
Note. UHNA = BioBall® universal head neck adapter, no. = number.

As shown in Table 4, standard adapters with an angle of 0° were predominant (*n* = 253; 82.7%). These were most commonly combined with a 12/14 mm cone size (*n* = 166; 54.2%).

A comparison of adapter neck lengths shows that oversized necks (2XL–5XL) were most common (*n* = 143; 46.7%), with the largest subgroup being XL (*n* = 61; 19.9%) and 2XL (*n* = 54; 17.6%). As shown in Figure 9, the median neck length was 2XL (*IQR* L–3XL). Only a few patients had an adapter neck length of 5XL (*n* = 23; 7.5%), or S (*n* = 13; 4.2%). The latter fell into the normal neck length group (S–XL; *n* = 130; 42.5%).

The most common head size combined with the UHNA was 36 mm (*n* = 194; 63.4%), followed by 32 mm (*n* = 77; 25.2%) and 28 mm (*n* = 24; 7.8%).

Figure 9. Median UHNA Neck Length.



Note. UHNA = BioBall® universal head neck adapter.

Table 5. Intraoperative Procedures Performed Besides UHNA Implantation.

	n (%)[a]
Total no. of procedures besides UHNA implantation	**319 (100)**
Revision of the cup	**190 (59.6)**
Uncemented cup	98 (51.6)
Cemented cup	92 (48.4)
Hip stem replacement	**45 (14.1)**
Uncemented hip stem	8 (17.8)
Cemented hip stem	37 (82.2)
Strut graft	**41 (12.9)**
Support cup implantation	**26 (8.2)**
Spacer implantation	**3 (0.9)**

[a] Multiple procedures within each patient were possible.

Note. UHNA = BioBall® universal head neck adapter, no. = number.

Possible procedures in addition to UHNA implantation (see Table 5) were support cup implantation, cup and/or stem replacement, spacer implantation, or strut grafts. A total of 319 other procedures were performed besides UHNA implantation, with multiple procedures

possible within each patient. The most common procedure besides UHNA implantation was cup revision (*n* = 190; 59.6%). The second most common procedure was stem revision (*n* = 45; 14.1%), which was mainly cemented (*n* = 37; 82.2%). Overall, the majority of primary hip stems did not require revision (*n* = 261; femoral retention rate = 85.3%).

Table 6. Materials Combined in the Tribological Bearings at UHNA Implantation.

	n (%)
Tribological bearings	**306 (100)**
CoP bearing	158 (51.6)
CoC bearing	105 (34.3)
Other / unknown	43 (14.1)
Liners	**306 (100)**
PE liner[a]	175 (57.2)
Ceramic liner	121 (39.5)
Other or unknown liner	10 (3.3)
BioBall® head	**306 (100)**
Delta ceramic head	273 (89.2)
Metal head	16 (5.2)
Unknown head	17 (5.6)

[a] PE liners including Müller cups.

Note. UHNA = BioBall® universal head neck adapter, CoC = Ceramic heads on Ceramic liners, CoP = Ceramic heads on polyethylene liners, PE = polyethylene.

Table 6 shows the main materials used for tribological bearings at the time of UHNA implantation. Most patients had CoP bearings (*n* = 158; 51.6%), followed by CoC bearings (*n* = 105; 34.3%) and patients with unknown or other bearings (*n* = 43; 14.1%). Thus, PE was the main material used for liners (*n* = 175; 57.2%), followed by ceramic liners (*n* = 121; 39.5%). For the prosthesis head, Delta ceramic was the most commonly used material (*n* = 273; 89.2%) and metal heads were rarely used (*n* = 16; 5.2%).

3.4 Complications and Reasons for Re-Revision

Table 7. Postoperative Complications and Diagnoses Leading to Re-Revision.

	No. of complications after UHNA implantation (%)[a]	No. of complications leading to re-revision after UHNA implantation (%)[b]	No. of re-revisions due to primary OP indication (%)[c]
Total no.	**71**	**52 (100)**	**19 (100)**
Recurrent dislocation	**27 (8.8)**	**19 (36.5)**	**14 (73.7)**
PJI	**13 (4.2)**	**10 (19.2)**	**–**
Early PJI (< 6 we)	4 (1.3)	3 (5.8)	–
Late PJI (> 6 we)	3 (1.0)	3 (5.8)	–
Chronic PJI	6 (2.0)	4 (7.7)	–
Periprosthetic fracture	**11 (3.6)**	**7 (13.5)**	**1 (5.3)**
Femoral fracture	9 (2.9)	6 (11.5)	–
Acetabular fracture	2 (0.6)	1 (1.9)	–
Aseptic loosening	**10 (3.3)**	**8 (15.4)**	**3 (15.8)**
Cup aseptic loosening	7 (2.3)	5 (9.6)	3 (15.8)
Stem aseptic loosening	3 (1.0)	3 (5.8)	–
Septic loosening	**5 (1.6)**	**5 (9.6)**	**–**
Cup septic loosening	3 (1.0)	3 (5.8)	–
Stem septic loosening	2 (0.6)	2 (3.8)	–
Minor complications	**3 (1.0)**	**1 (1.9)**	**–**
Wound healing defect	3 (1.0)	1 (1.9)	–
Liner wear	**1 (0.3)**	**1 (1.9)**	**1 (5.3)**
Stem-neck fracture	**1 (0.3)**	**1 (1.9)**	**–**
Patients with re-revisions after UHNA implantation, *n* (%)[a]			**43 (14.1)**
One re-revision			37 (12.1)
Multiple re-revisions			6 (2.0)
Complications depending on tribological bearing, *n* (%)[a]			
CoP bearing			38 (12.4)
CoC bearing			13 (4.3)

Re-Revisions depending on tribological bearing, *n* (%)[a]	
CoP bearing	25 (8.2)
CoC bearing	12 (3.9)

[a] Percentages of the total number of included patients (*N* = 306). Multiple complications for each patient were possible: 61 patients developed 71 complications.

[b] Percentages of the total no. of indications for re-revisions (*n* = 52). Multiple diagnosis leading to re-revision after UHNA implantation for each patient were possible: 43 patients required re-revisions due to 52 diagnoses.

[c] Percentage of the total no. of re-revisions due to the primary diagnosis of UHNA implantation (*n* = 19).

Note. no. = note, UHNA = BioBall® universal head neck adapter, we = weeks.

Table 7 shows the postoperative complications and diagnoses, that led to reoperation after UHNA implantation. These were: recurrent dislocation, liner wear, component loosening (aseptic or septic), PJI, periprosthetic fracture, material failure, and minor complications such as wound healing defects.

A total of 71 complications were registered, occurring in 61 patients (19.9%). The corresponding percentages are percentages of the total number of patients included (*N* = 306; 100%). Postoperative recurrent dislocation was the most common complication after UHNA implantation (*n* = 27; 8.8%), followed by postoperative PJI (*n* = 13; 4.2%), postoperative periprosthetic fracture (*n* = 11; 3.6%) and postoperative aseptic loosening (*n* = 10; 3.3%). Rare complications such as recurrent liner wear (*n* = 1; 0.3%) and stem-neck fracture (*n* = 1; 0.3%) were also observed.

Regarding the complications leading to re-revision after UHNA implantation, postoperative recurrent dislocation was also the leading factor (*n* = 19; 36.5%), followed by postoperative PJI (*n* = 10; 19.2%), postoperative aseptic loosening (*n* = 8; 15.4%) and postoperative periprosthetic fracture (*n* = 7; 13.5%).

When analyzing the cases with reoperation for the primary indications (the indication for reoperation and the primary indication for UHNA implantation were the same), recurrent dislocation was again the leading factor (*n* = 14; 73.7%), followed by aseptic loosening (*n* = 3; 15.8%). There was only one patient with multiple complications of liner wear requiring several revisions. In addition, there was one patient with a primary diagnosis of periprosthetic acetabular fracture leading to UHNA implantation, who later developed a periprosthetic femoral fracture requiring revision.

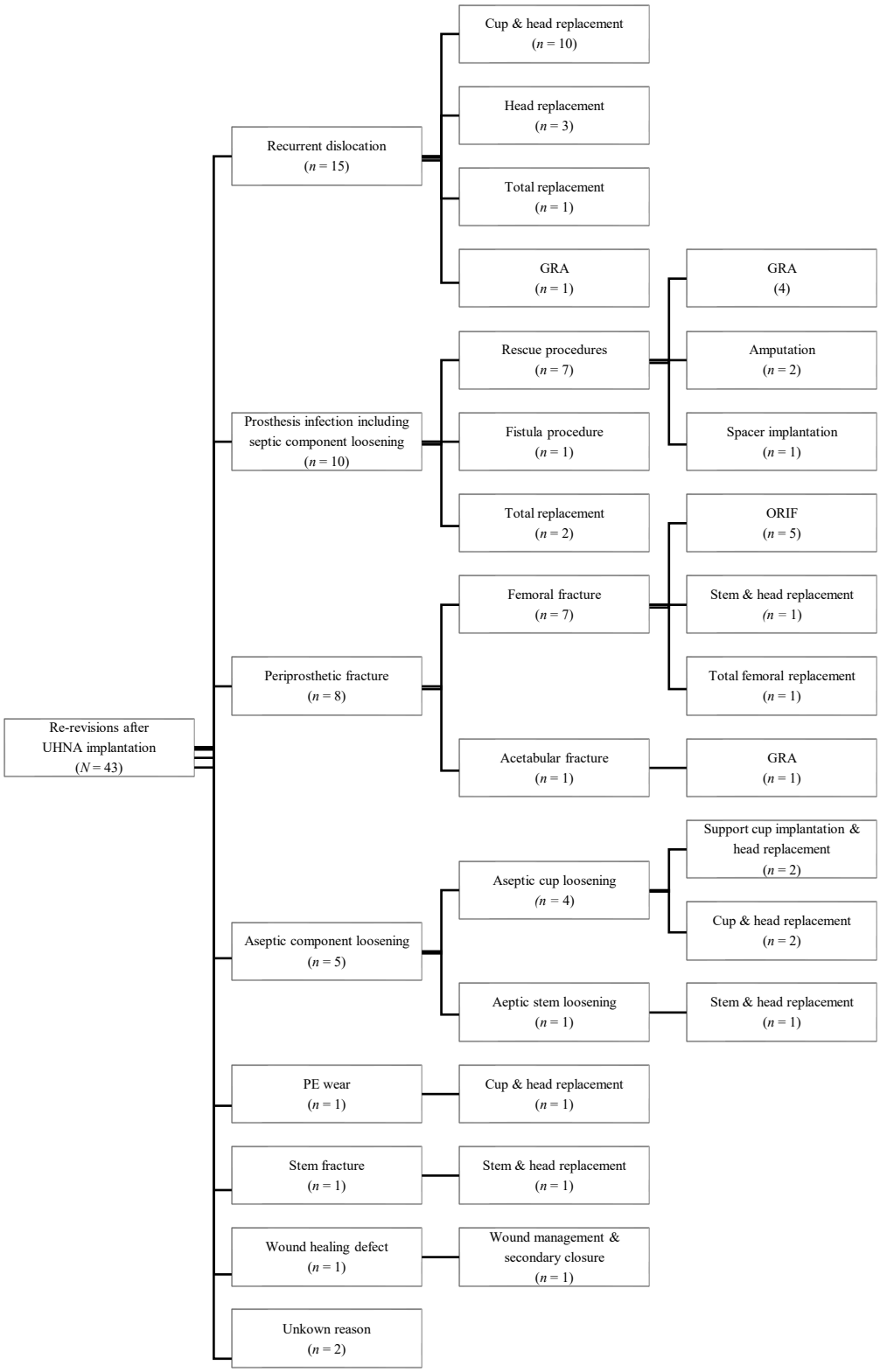
Only one case of UHNA-related material failure requiring revision for femoral prosthesis stem-neck fracture was recorded (0.3%).

In the total study population, 43 patients underwent reoperation after UHNA implantation (*n* = 43; 14.1%). Therefore, the re-revision rate after UHNA implantation in our study population was 14.1%. Some of these patients even had multiple revisions after UHNA implantation (*n* = 6; 2%), while most had only one further reoperation (*n* = 37; 12.1%).

Most of the patients with complications after UHNA implantation had CoP bearings (*n* = 38; 12.4%) and these required reoperations more often (*n* = 25; 8.2%) compared to CoC bearings. When comparing re-revision rates, CoP bearings had worse results (*n* = 25/158; 15.8%) than CoC bearings (*n* = 12/105; 11.4%).

Some patients in the study population had undergone rTHA prior to UHNA implantation (*n* = 100; 32.7%). Of these 100 patients, 23 underwent reoperation after UHNA implantation, representing more than 50% of the patients requiring reoperation (*n* = 23; 7.5%).

Figure 10. Procedures Performed in Re-Revision due to Complications Following UHNA Implantation.



Some patients had several complications, but data was weighted in the shown figure and only the main indication for each patient leading to re-revision after UHNA implantation was added. Most revisions were due to postoperative complications. One patient had an intraoperative complication, another one intraoperative and postoperative complications.

Note. ORIF = open reduction and internal fixation, PE = polyethylene. GRA = Girdlestone resection arthroplasty.

Because multiple complications leading to re-revision were possible in each patient, Figure 10 provides an overview of the procedures performed during reoperation after UHNA implantation, considering a single count of the main diagnosis for each of the 43 patients (14.1%) wo required reoperation after UHNA implantation (14.1%).

Fifteen patients required reoperation for recurrent dislocation. Of these, ten patients underwent cup replacement, and three patients underwent head replacement only. One patient underwent a total replacement, and another a GRA.

Another ten patients underwent reoperation due to septic complications. Thereof seven patients underwent rescue procedures including four GRA, two amputations and one spacer implantation. One patient with chronic PJI underwent a fistula procedure and two patients underwent total replacement.

Eight patients underwent reoperation for periprosthetic fracture. Seven of these were periprosthetic femoral fractures. Treatment options included open reduction and internal fixation (ORIF) in five patients, stem and head replacement in one patient, and total femoral replacement in one patient. Only one patient had an acetabular fracture after UHNA implantation and underwent a GRA in reoperation.

Of the five cases of aseptic component loosening, four patients had aseptic cup loosening. Two of these patients underwent support cup implantation and head replacement, while the remaining two patients underwent both cup and head revision. The other patient with aseptic stem loosening underwent a head and stem replacement.

One person required re-revision due to PE wear and received a cup and head exchange. This patient is discussed in more detail in the case report below.

In addition, one patient experienced a stem-neck fracture, that resulted in both a stem and head replacement. This was the only reported material fracture and “mix & match” related complication and reason for reoperation (0.3%, n = 1).

Another patient underwent revision for wound healing failure and was treated with wound management and secondary sutures.

In our retrospective evaluation, the reason for revision remained unclear in two patients.

3.5 Categorical Data Analysis: χ^2 and Fisher's Exact Test

Table 8. Association Between Postoperative Complications After UHNA Implantation and Statistically Significant Surveyed Variables: χ^2 Test and Fisher's Exact Test Analysis.

Independent variable	***p***	**Test Method**	**Effect size**	
			ϕ	***OR* (95% CI)**
Postoperative complication				
Comorbidity: rheumatoid arthritis	.017	Fisher	–	3.287 (1.260–8.575)
Postoperative aseptic loosening				
Oversized UHNA neck length (2XL–5XL)	.004	Fisher	–	1.067 (1.023–1.113)
Postoperative recurrent dislocation				
Indication: recurrent dislocation	< .001	χ^2	0.350	–
Indication: periprosthetic fracture	.041	Fisher	–	2.732 (1.118–6.629)
UHNA head size (36 versus 32 mm)	.007	Fisher	–	0.268 (0.112–0.640)
Lateralized UHNA configuration (offset)	< .001	Fisher	–	4.926 (2.064–11.755)
Comorbidity: heart attack	.036	Fisher	–	3.024 (1.114–8.207)
Comorbidity: depression	.021	Fisher	–	3.207 (1.247–8.249)
Postoperative periprosthetic fracture				
Comorbidity: osteoporosis	.049	Fisher	–	3.480 (1.026–11.804)
Postoperative PJI				
Age cohort (≥ 60 versus < 60 years)	.021	Fisher	–	0.252 (0.081–0.780)
Revisions before UHNA implantation	.033	Fisher	–	3.496 (1.113–10.977)
Septic loosening				
Age cohort (≥ 60 versus < 60 years)	.049	Fisher	–	0.149 (0.024–0.913)

Note. χ^2 = chi-square test, UHNA = BioBall® universal head neck adapter, p = p-value, ϕ = phi coefficient, *OR* = odds ratio, CI = confidence interval.

As shown in Table 8, there were statistically significant associations between postoperative complications and various factors, including age, revisions prior to UHNA implantation, indications for recurrent dislocation, and periprosthetic fracture, as well as oversized UHNA neck length (2XL–5XL) and lateralized UHNA configuration (offset), and comorbidities such as rheumatoid arthritis, osteoporosis, heart attack and depression.

Our results showed higher odds of postoperative complications in patients with rheumatoid arthritis compared to those without the disease (p = .017, OR 3.287; 95% CI 1.260–8.575).

Regarding postoperative aseptic loosening, there was a positive association with adapter neck length. The odds of postoperative aseptic loosening were higher for oversized UHNA neck lengths (2XL–5XL) compared to normal neck lengths (S–XL, p = .004, *OR* 1.067; 95% CI 1.023–1.113).

Several statistically significant factors were identified regarding postoperative recurrent dislocation. A moderate effect size ($\phi = 0.350$) was observed in patients with multiple events of recurrent dislocation (p = < .001). Patients with the following variables also had higher odds of postoperative recurrent dislocation: those with periprosthetic fracture as an indication for UHNA implantation (p = .041, *OR* 2.732; 95% CI 1.118–6.629), those with a lateralized (offset) adapter versus standard adapters (p < .001, *OR* 4.926; 95% CI 2.064–11.755), and also those with the comorbidities heart attack (p = .036, *OR* 3.024; 95% CI 1.114–8.207) and depression (p = .021, *OR* 3.207; 95% CI 1.247–8.249).

Patients with osteoporosis were also more likely to have a periprosthetic fracture than those without osteoporosis (p = .049, *OR* 3.480; 95% CI 1.026–11.804).

In addition, older study participants (≥ 60 years) had lower odds of postoperative PJI than younger patients (< 60 years; p = .021, *OR* 0.252; 95% CI 0.081–0.780) and of septic loosening (p = .049, *OR* 0.149; 95% CI 0.024–0.913). The odds of postoperative PJI were also higher in those patients with prior revisions before UHNA implantation (p = .033, *OR* 3.496; 95% CI 1.113–10.977).

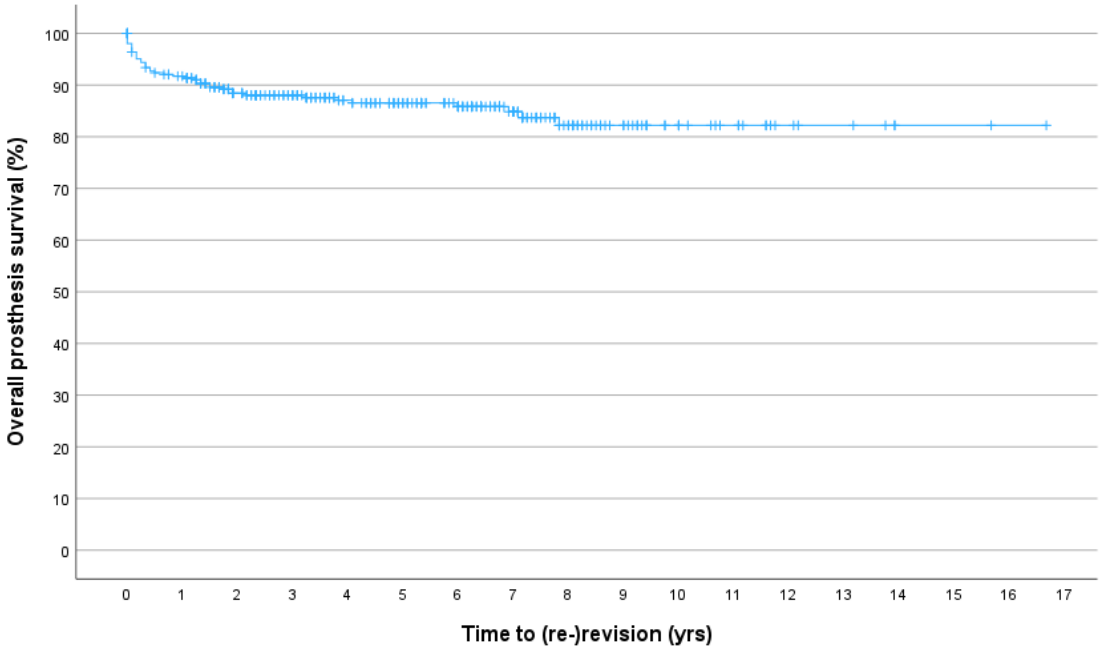
3.6 Survival Analysis

Cumulative survival after UHNA implantation (Figure 11 and Table 9) showed the following results: At one year, 282 of the 306 UHNA implants remained without further revision (92.2%; 95% CI 88.1–95.9). At three years, 269 (87.9%; 95% CI 84.1–91.9), at five years, 263 (86%; 95% CI 82.1–89.9), at seven years, 260 (85%; 95% CI 81.1–88.9), and at ten years, 251 implants (82%; 95% CI 76.1–87.9) remained. However, two patients died within the postoperative period of 4 weeks, one of them during intraoperative resuscitation.

Statistically significant differences in revision-free survival after UHNA implantation were observed with respect to age cohorts ($\chi^2 = 5.58$; p = .018), burden of comorbidity ($\chi^2 = 4.24$; p = .039), and adapter neck length ($\chi^2 = 4.80$; p = .028). Younger patients (< 60 years)

had revisions sooner (at earlier time in follow-up) after UHNA implantation than older patients (≥ 60 years): see Figure 12 and Table 10. It was also shown that patients with more comorbidities (≥ 3 comorbidities) had revisions earlier after UHNA implantation compared to those with fewer comorbidities (< 2 comorbidities): see Figure 13 and Table 11. Moreover, survival analysis showed that the length of the adapter neck also had an influence on the time of revision after UHNA implantation: see Figure 14 and Table 12. Patients with an oversized or skirted neck (2XL–5XL) had revisions earlier than those with a normal or non-skirted neck length (S–XL). However, factors such as BMI, tribological bearing, and primary THA or rTHA with UHNA did not show significant results. However, the indications for UHNA presented ambiguous results and need further investigation.

Figure 11. Overall Revision-Free Survival.



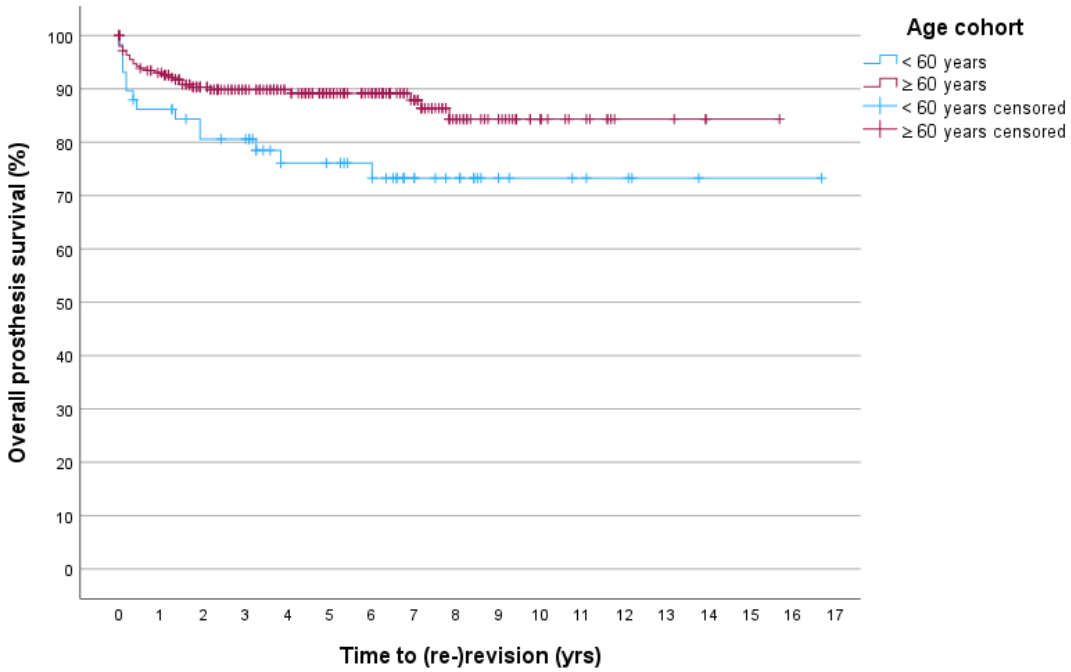
Note. yrs = years.

Table 9. Cumulative Revision-Free Survival (95% CI).

	1 year	3 years	5 years	7 years	10 years
UHNA	92.2 (88.1–95.9)	87.9 (84.1–91.9)	86 (82.1–89.9)	85 (81.1–88.9)	82 (76.1–87.9)
Remaining implants	282	269	263	260	251

Note. CI = confidence interval, UHNA = BioBall® universal head neck adapter.

Figure 12. Revision-Free Survival Depending on Age Cohorts.



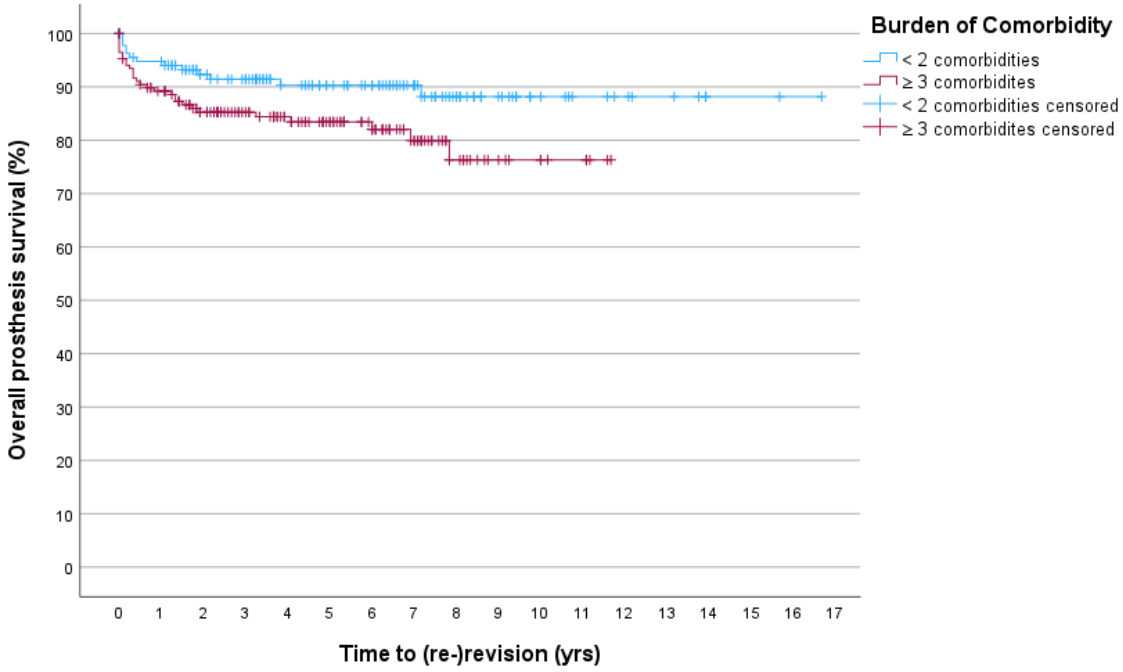
Note. yrs = years.

Table 10. Revision-Free Survival Depending on Age Cohorts (95% CI).

	1 year	3 years	5 years	7 years	10 years
< 60 years	86 (76.2–95.8)	81 (71.2–90.8)	76 (64.2–87.8)	73 (61.2–84.8)	73 (61.2–84.8)
Remaining implants	50	47	44	42	42
≥ 60 years	93 (89.9–96.1)	89.7 (85.8–93.6)	89 (84.9–93.1)	87.9 (83.4–92.4)	84.6 (78.3–90.9)
Remaining implants	231	222	221	218	210

Note. CI = confidence interval.

Figure 13. Revision-Free Survival Depending on Burden of Comorbidity.



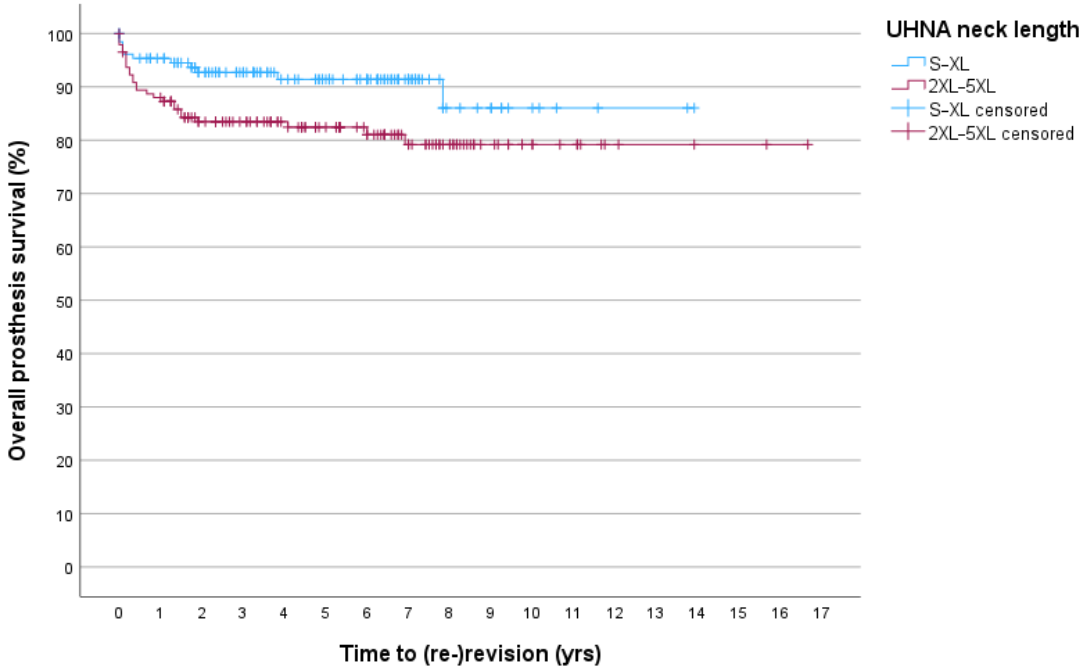
Note. yrs = years.

Table 11. Revision-Free Survival Depending on Burden of Comorbidity (95% CI).

	1 year	**3 years**	**5 years**	**7 years**	**10 years**
< 2 comorbidities	95 (91.1–98.9)	91 (87.1–94.9)	90 (84.1–95.9)	90 (84.1–95.9)	88 (82.1–93.9)
Remaining implants	130	125	123	123	121
≥ 3 comorbidities	89 (85.9–92.1)	85 (79.1–90.9)	83 (77.1–88.9)	80 (72.2–87.8)	77 (67.2–86.8)
Remaining implants	150	144	140	135	130

Note. CI = confidence interval.

Figure 14. Revision-Free Survival Depending on UHNA Neck Length.



Note. UHNA = BioBall® universal head neck adapter, yrs = years.

Table 12. Revision-Free Survival Depending on UHNA Neck Length (95% CI).

	1 year	**3 years**	**5 years**	**7 years**	**10 years**
S–XL	95 (91.1–98.9)	93 (89.1–96.9)	91 (85.1–96.9)	91 (85.1–96.9)	87 (77.2–96.8)
Remaining implants	124	121	118	118	113
2XL–5XL	88 (82.1–93.9)	83 (77.1–88.9)	82 (76.1–87.9)	79 (71.2–86.8)	79 (71.2–86.8)
Remaining implants	126	119	117	113	113

Note. UHNA = BioBall® universal head neck adapter, CI = confidence interval.

4 Discussion

As an increase in rTHA is expected in the coming years [27, 31, 32], and "mix & match" procedures are likely to play an increasing role [21], a study focusing on the safety, possible risks and complications of the use of BioBall® UHNA in "mix & match" situations in THA is very important. Especially since UHNA have become a standard in (r)THA in "mix & match" settings and the current EFORT recommendations emphasize the need for further studies on this topic [21]. The safety of these products requires consideration of many parameters, such as biomechanical, patient-related factors (e.g. age, comorbidities), as well as surgical and surgeon-related parameters. Other aspects include implant- and UHNA-specific parameters such as neck lengths, indications, complications, revision rates, and implant survival. Many of these factors have only been partially addressed in literature, or data is lacking. Therefore, our work contributes to the ongoing discussion on the safety of UHNA in "mix & match" THA by performing a multifactorial analysis on a study population of 306 patients.

Overall, the median age of our study cohort was 74 years (*IQR* 62–81), which is older than the mean age reported in other studies and even older than the mean age of 69.8 years (range 29–89) reported by Pardo et al. [37]. While Woelfle et al. concluded that their poor clinical outcomes were due to the comorbidities of their patients and the advanced age of their patients with a mean of 71 years (range 38.7–90.5) [20], our study did not find an overall worse outcome for older patients (≥ 60 years). In fact, younger patients (< 60 years) had a shorter reoperation-free survival than older patients (≥ 60 years). This point will be discussed in more detail later.

Older patients may benefit from the good femoral stem retention rate of UHNA as reported by Garabadi et al. [38]. Regarding the retention rate of the femoral prosthesis stem, previous studies' results reported retention rates between 43.7% to 97.5% (reported by Dabis et al. and Woelfle et al., respectively) [16, 20]. However, our results support the thesis of an overall good femoral prosthesis stem retention rate in combination with UHNA at 83.3% (*n* = 255).

Another finding of our study was, that the influence of comorbidities and multimorbidity is underrepresented in previous studies. More than half of the patients in our study (*n* = 169; 55.2%) had at least three or more comorbidities and are therefore classified as multimorbid [26]. Only Kock et al. addressed the aspect of UHNA implantation in multimorbid patients

[40], and Woelfle et al. attributed their poor clinical results to comorbidities without going into further detail [20]. Pardo et al. demonstrated in a statistical analysis that several patient-related factors such as age, sex, weight, and BMI had no influence on implant survival [37]. However, there has been no systematic evaluation of comorbidities in UHNA. Therefore, we recorded the 18 comorbidities for each patient according to the FCI, as several studies have shown that these are associated with more complications, a higher revision rate, or a worse functional outcome after THA (see references below).

1. Arthritis (rheumatoid and osteoarthritis) [29, 147]
2. Osteoporosis [29, 33, 77]
3. Asthma [70, 72]
4. Chronic obstructive pulmonary disease (COPD), acute respiratory distress syndrome (ARDS), or emphysema [29, 70, 72, 127]
5. Angina [127]
6. Congestive heart failure (or heart disease) [70, 72, 127, 129, 147]
7. Heart attack (myocardial infarction) [70, 72, 147]
8. Neurological disease (e.g., multiple sclerosis or Parkinson's disease) [72, 118, 129, 147]
9. Stroke or transient ischemic attack (TIA) [70]
10. Peripheral vascular disease [72, 127, 128, 142]
11. Diabetes types I and II [29, 70, 72, 127]
12. Upper gastrointestinal disease (e.g., ulcer, hernia, reflux)
13. Depression [29, 70, 71, 130]
14. Anxiety or panic disorders
15. Visual impairment (e.g., cataracts, glaucoma, macular degeneration) [118]
16. Hearing impairment (i.e., very hard of hearing, even with hearing aids)
17. Degenerative disc disease (e.g., back disease, spinal stenosis, or severe chronic pain) [133, 142, 143]
18. Obesity and/ or body mass index (BMI) >30 kg/m^2) [29, 30, 127, 128, 142].

We also recorded additional conditions that may affect the patient's postoperative outcome. These included bone tumor or metastases, avascular osteonecrosis of the hip (AVN), low body weight, multiple myeloma, deep vein thrombosis (DVT), or pulmonary embolism.

However, other comorbidities could have been included in this study, as several previous studies have shown that they may influence postoperative outcomes after THA. These include preoperative anemia and blood transfusion [127, 128, 142], liver disease, kidney disease [70, 72, 147], fluid/electrolyte disorders [29, 128], coagulopathy [129], (metastatic) cancer, [70, 142], psychiatric disorders in general [71, 130], hypothyroidism [29], frailty and malnutrition [127]. Nevertheless, the most common comorbidities (which can be associated with THA failure) have been included in this analysis, as listed above.

As a result, our data showed that patients with at least three comorbidities had revisions earlier after UHNA implantation than those with less than two comorbidities. This is supported by previous studies, reporting increased odds of revision with greater burden of comorbidity [72, 142].

Speaking in favor of a specific index focusing on comorbidities in orthopaedic surgery, we also found that patients with rheumatoid arthritis had higher odds for postoperative complications than those without any disease (p = .017; *OR* 3.287), as previously reported by Dy et al. [29]. In order to develop this specific index, a systematic review of the individual factors influencing postoperative outcome, risk of complications and re-revision would be necessary.

Overall, the most common comorbidity was obesity defined as BMI ≥ 30 kg/m^2 (n = 150; 49%), followed by degenerative spinal disc disease or severe chronic back pain (n = 125; 40.9%). As obesity is a comorbidity with a rapidly increasing prevalence in the general population [134], it is not surprising that this patient group represented almost half of the study population. In particular, higher BMI and obesity have been found to be independently associated with early THA failure and early revision in previous studies [135]. While some studies have already shown that a BMI above 25 kg/m^2 (overweight) is associated with an increased complication rate [137], other studies have shown a rapid increase in complications, especially with a BMI above 30 kg/m^2 (obesity) [4, 15, 134]. Therefore, we decided to use a BMI cut-off of ≥ 30 kg/m^2 for our study and divided our study population into two cohorts. However, our study could not identify an increased risk of postoperative complications or earlier revision in obese patients (BMI ≥ 30 kg/m^2), while the use of modular head-neck adapters in overweight patients is still considered “off-label use” [45].

Other factors influencing postoperative complications include the indications for UHNA implantation, as shown in our analysis discussed later. These again depend on many factors (see section 1.4 Indications of UHNA). Overall, the main reported indications for the UHNA

system in rTHA were similar in the current literature, with the leading diagnoses being aseptic loosening, particularly cup loosening, and recurrent dislocation (primary instability) [22], although reported in different order of frequency [37]. In contrast, our study showed a different distribution of the most common indications: PE liner wear was the leading indication with 24.7%, followed by aseptic cup loosening with 23.2% and recurrent dislocation with 15.1%. Notably, our study reported a higher prevalence of periprosthetic fractures at 9.8%, in contrast to the 1.4% reported by Pardo et al. [37]. Finally, our study included cases with PJI and septic loosening as indications for UHNA implantation (7%). To our knowledge, only Dabis et al. have previously reported septic causes as an indication for UHNA implantation [16]. Another indication closely related to liner wear was osteolysis (4.2%). These cases were probably related to wear debris in the tribological bearings caused by inflammatory processes [9].

All types of common hip arthroplasty complications can also occur with UHNA implantation, as evidenced by our cumulative re-revision rate of 19.9%. This includes both intraoperative and postoperative complications. Many common complications have been reported with the UHNA system, such as (recurrent) dislocation and instability, aseptic and septic loosening of components (especially aseptic cup loosening), superficial infection, periprosthetic fracture, neck fracture, cup fracture [22, 37], deep infection, recurrent infection [22], sensation of instability [16], Trendelenburg gait, proximal femoral osteolysis, persistent pelvic pseudotumor, postoperative anemia, and lower extremity phlebitis [41].

Looking at the results of our study, most of the general complications occurred postoperatively after UHNA implantation in a comparable rate as previously described. Our reported general complications were recurrent dislocation (n = 27; 8.8%), followed by PJI (n = 13; 4.2%), periprosthetic fracture (n = 11; 3.6%), aseptic loosening (n= 10; 3.3%), septic loosening (n= 5; 1.6%), wound healing defect (n = 3; 1%), and liner wear (n = 1; 0.3%).

Recurrent dislocation is a major cause of early rTHA [22], and it is the first cause of multiple revisions [22, 66], especially isolated head/liner or acetabular component revisions [67]. While most dislocations (up to two-thirds) can be tightly repositioned and do not require rTHA [33, 66], revision is sometimes necessary to ensure stability [11, 20, 48]. Some authors reported that recurrent dislocation remains a challenge after UHNA implantation [20, 22], while others, such as Hoberg et al. reported acceptable postoperative dislocation rates [36]. However, the results of our investigations were as follows: recurrent dislocation remains a

problem in many patients after UHNA implantation, especially in those with a history of previous dislocation ($p < .001$; $\phi = 0.350$), as already noted by Novoa et al. [22], and by Woelfle et al., who reported a recurrent dislocation rate of up to 50% [20]. This is supported by our similarly high rate of 51.9% (n = 14/27) of postoperative events of recurrent dislocation in those, who underwent revision with UHNA for the same indication. The risk of recurrent dislocation may be even up to seven times higher in those with prior dislocation events compared to those without prior recurrent dislocations, as reported by Berlinberg et al. [73]. Thus, it can be assumed that the risk of recurrent dislocation increases with each revision procedure. Potential influencing factors may be the damage and increased scar tissue formation around the hip prosthesis with each operation. With each revision, the surrounding soft tissues and muscles are further weakened, accelerating instability in the hip joint and increasing the risk of (recurrent) dislocation. This has already been reported by authors such as Prodinger et al. [74]. However, there are many other known factors influencing instability and recurrent dislocation, such as patient-related factors, surgical factors, and prosthesis-related factors [74]. And there may be other factors not considered in this thesis.

Another potentially influential factor for postoperative recurrent dislocation identified in our study was the diagnosis of periprosthetic fracture ($p = .041$; *OR* 2.732), as previously reported by Falez et al. [66] and Ezquerra-Herrando et al. [68]. First, the biomechanics of the hip itself are potentially altered by the fracture, which could lead to increased hip instability and thus increased risk of dislocation. Second, surrounding muscles and soft tissues may be injured by the fracture and THA itself, further increasing instability. Finally, poorer bone structure after fracture may result in altered stability of the hip endoprosthesis. Together with patient-related factors such as obesity (BMI $\geq$ 30 kg/m^2), the increased weight bearing and reduced muscle support may increase the risk of hip arthroplasty dislocation.

Moreover, our study results support previous research indicating that larger head size and greater jump distance reduce the risk of dislocation [11, 48]. We found that patients with larger 36 mm heads had lower odds of postoperative dislocation compared to patients with smaller 32 mm heads ($p = .007$; *OR* 0.268). This is consistent with previously published results such as those of Prodinger et al. [74].

The majority of the literature supports avoiding a reduced FO, whereas increasing the FO by up to 5 millimeters may result in improved patient outcomes, improved hip biomechanics and reduced PE wear [50]. Interestingly, however, lack of accurate reconstruction or reduction of the FO has been shown to result in poorer gait and an increased

risk of hip dislocation [50, 52]. This association was particularly highlighted by Robinson et al. [52]. As our study results showed a higher likelihood of recurrent dislocation in patients with a lateralized or offset UHNA configuration compared to standard adapters ($p < .001$; OR 4.926), the question remains whether an offset UHNA is a risk factor for recurrent dislocation. However, as only the UHNA configuration was considered and neither the femoral stem prosthesis configuration nor the acetabular component configuration was included in the analysis, this result should be treated with caution as the GO remains unclear. One problem may have been, that the offset could often not be accurately reconstructed. However, as shown by the better results of the larger femoral heads, it is always important to consider the individual GO for each patient. In addition to a modular femoral head adapter and its offset correction, the positioning and configuration of the prosthetic stem, acetabular cup and liner are also important factors that contribute to GO [11, 50, 52]. Another consideration, in our opinion, is the possible influence of contractures due to multiple hip surgeries. Not surprisingly, in our study, dislocation was also the most common cause of revision after UHNA implantation (n = 19; 36.5%), followed by PJI (n = 10; 19.2%), aseptic loosening (n = 8; 15.4%) and periprosthetic fracture (n = 7; 13.5%).

Furthermore, we found higher odds of postoperative recurrent dislocation in patients with depression ($p = .021$; *OR* 3.207), a finding previously reported by Gausden et al. [69]. Possible reasons could be reduced activity levels and consequently reduced compliance with rehabilitation, increased risk of falls associated with antidepressant medication, and a variety of comorbidities associated with depression that may in turn increase the risk of recurrent dislocation, such as obesity or diabetes.

Finally, higher odds of postoperative recurrent dislocation were identified in our cohort for patients with a history of myocardial infarction ($p = .036$; *OR* 3.024). Previously, Gausden et al. reported an association between congestive heart failure and recurrent dislocation [69]. Cardiovascular disease may lead to decreased physical fitness and activity, with consequent decreased muscle strength, which may predispose to hip instability. In addition, antiplatelet agents may promote hematoma formation and delayed wound healing, contributing to the risk of recurrent dislocation. However, patients with a history of heart attack [70, 72] or depression, despite other psychiatric disorders [70, 71], have previously been shown to have an overall increased risk of postoperative complications, which was not highlighted in our study. The individual associations of recurrent dislocation highlighted in the study may require further investigation.

Another common problem with THA is PJI and septic loosening, [7], but it is rarely mentioned in the context of UHNA [22, 38]. However, in our study they accounted for 13 (4.2%) and 5 (1.6%) cases of complications after UHNA implantation, respectively. All patients with septic loosened components were revised in our study. In particular, septic complications (as well as recurrent dislocation) seem to be reasons for increased revision rates in the younger population ≤ 60 years, as previously reported [76, 77]. Our studies confirm an increased risk of early revision after UHNA implantation in younger patients (< 60 years) compared to older patients (≥ 60 years). We also demonstrated that patients ≥ 60 years of age were less likely to experience postoperative PJI (p = .021; *OR* 0.252). Patients with previous revisions also had a higher risk of developing postoperative PJI (p = .033, *OR* 3.496). A higher revision rate in patients < 55 years compared to patients ≥ 65 years was also reported by Prentice et al (hazard ratio 1.3) [78]. Their reported risk factors for early septic complications include increased BMI, substance abuse, and liver disease [79]. Kummerant et al. also highlighted the fact that younger patients have an increased risk of revision for septic complications [77]. One aspect may be that patients who undergo THA at a young age have a longer prosthesis life than older patients and are therefore at increased risk for revision. The accumulation of scar tissue and soft tissue damage with each revision could increase the likelihood of developing PJI. In addition, each revision surgery itself carries a risk of infection. Therefore, it is not surprising that younger patients are generally at increased risk for PJI compared to older patients. Additionally, there are a significant number of known patient-related risk factors for PJI, such as obesity, especially when combined with an active lifestyle [78], smoking habits, diabetes mellitus and rheumatoid arthritis [80]. In our study, patients with PJI and other septic complications were more likely to have obesity, heart disease such as coronary artery disease, depression, and degenerative disc disease. As discussed before, there may be an association between reduced postoperative mobility due to depression and degenerative disc disease and weakened immune defenses. In addition, conditions such as obesity, coronary artery disease, and depression are associated with increased inflammatory activity in the body and therefore with immunologic changes and poorer wound healing [80]. These are all factors that may increase the risk of PJI and other septic complications.

Previous studies have also shown that patients with a history of PJI have an increased risk of subsequent postoperative PJI (known as metachronous PJI) [84]. In general, there are several classifications of PJI that focus on different parameters, but in the clinical setting, a simple division into early and late PJI is often made [80]. In addition to this clinical

subdivision, we added a category of chronic infection, meaning that patients had PJI both before and after UHNA implantation. While there were a few patients with postoperative PJI (n = 13; 4.2%), only six of these patients (2%) had chronic PJI. Four of these patients were obese (1.3%). It could be assumed that PJI may be an ongoing problem after UHNA implantation in patients with previously diagnosed PJI (metachronous PJI). However, since we did not document the indications for revisions prior to UHNA implantation, it is difficult to make definitive statements here. Nonetheless, it should be noted that many patients (n = 100; 32.7%) had undergone a revision prior to UHNA implantation, which may have increased the risk of PJI in some patients: higher odds of postoperative PJI were identified for patients that received revision surgeries prior to UHNA implantation (p = .033; *OR* 3.496).

Periprosthetic fractures in the context of UHNA implantation are rare events [17, 37, 38], but our study also included eleven cases (3.6%) with postoperative periprosthetic fracture. Seven of these required revision and one patient had multiple revisions due to periprosthetic fractures. This patient's indication for UHNA implantation was a periprosthetic acetabular fracture, and the reason for revision in this case was a periprosthetic femoral fracture.

Risk factors for periprosthetic fractures include implant loosening, poor bone quality due to osteoporosis or osteolysis, older age and female sex [7, 33]. This is supported by our results, as we found an increased risk of periprosthetic fracture in patients with osteoporosis (p = 0.049; *OR* 3.480). Osteoporosis is a known risk factor for periprosthetic fractures, particularly periprosthetic femoral fractures [90]. This may be due to reduced bone structure and quality, which increases the likelihood of fractures around the endoprosthesis, especially if additional bone material has to be removed intraoperatively for implant removal, replacement or fixation. Secondly, altered hip biomechanics caused by the implant, or the biomechanical reconstruction itself, may predispose to periprosthetic fractures.

In addition, periprosthetic fractures require different treatment depending on many factors, including component loosening. While loosened components have to be replaced, fixed components are treated conservatively or with osteosynthesis [91]. Treatment is individualized, as shown in our study. While five of the seven femoral fractures were treated primarily with ORIF, in one particularly severe case, the only possible treatment for an acetabular fracture was a GRA.

Periprosthetic fracture has been described as an independent risk factor for mortality within one year [7, 33] and for further revision surgery. In our study, seven out of eleven patients required revision after UHNA implantation due to periprosthetic fracture.

Periprosthetic fractures can be divided into the more common periprosthetic femoral fractures and periprosthetic acetabular fractures [33]. However, periacetabular fractures are rare events in THA [92]. This is supported by our study, with fewer cases of acetabular fractures than femoral fractures, both in terms of complications and revisions. On the other hand, we experienced more cases of periprosthetic femoral fractures. The higher number of periprosthetic femoral fractures could be due to several factors. Patient-related factors include older age (≥ 60 years and especially ≥ 90 years) and increased number of comorbidities (≥ 3 comorbidities) [88, 89], lower weight (≤ 50 kg) and sex (women), among others [88]. In our study, seven out of nine patients (77.8%) with periprosthetic femoral fractures were female, eight out of nine (88.9%) were ≥ 60 years old, but none were ≥ 90 years old, and seven out of nine (77.8%%) had at least three comorbidities. These may have been potential factors contributing to an increased risk of periprosthetic fracture.

Aseptic loosening, especially cup loosening, has been described as one of the main reasons for revision surgery after UHNA implantation [22, 37]. In general, aseptic cup loosening has been reported more frequently than stem loosening and total system loosening [77]. This is supported by our results with more events of aseptic cup loosening than stem loosening in the categories of complications and reasons for revision after UHNA implantation. Aseptic loosening is highly dependent on bone quality [7, 67, 77]. Overall, five of the seven patients with postoperative aseptic cup loosening required at least one additional revision. Two of these five patients required multiple revisions. Poor bone quality may be indicated by the fact that at least three of these patients had osteoporosis as a comorbidity, and two also required revision for periprosthetic acetabular fractures. In addition, the initial UHNA implantation required the use of allograft in the acetabular region in two patients. Two of the three patients with postoperative aseptic stem loosening also had periprosthetic fractures, all of which required revision. One patient had underlying avascular necrosis (AVN), which will also have a significant impact on bone structure. These are all indicators of significant bone defects that contribute to an increased risk of aseptic component loosening. It would also be interesting to investigate whether aseptic loosening could be a persistent problem, as four patients with postoperative aseptic cup loosening had already received UHNA implantation for the same reason.

Other known factors for aseptic loosening are cement loosening, osteolysis, surgeon related factors, implant design and materials, tribological wear and stress shielding [33, 93]. In contrast, none of the patients with aseptic loosening in our study showed osteolysis or tribological wear. However, stress shielding may be a problem. It is the result of a different load distribution, especially in the proximal metaphyseal region due to the prosthesis stem, with subsequent bone loss and possible stem loosening [94]. Obesity and increased physical activity, especially in combination with an oversized neck, may be a contributing factor. This results in a longer lever arm acting on the hip joint and thus on the individual components of the prosthesis, as well as higher applied forces, increasing the risk of component loosening by micromotion over time. Our results showed an association between oversized or skirted neck lengths (2XL–5XL) and postoperative aseptic loosening (p = .004; *OR* 1.067) compared to those with normal neck lengths (S–XL). This is supported by the previous findings of Jud et al. who reported a 3.7-fold increased risk of aseptic stem loosening in patients with high femoral offset combinations [75]. It's important to note that the problem with oversized adapter neck length does not appear to be material fracture. Our findings suggest that overlength is associated with aseptic prosthetic loosening.

Another common complication associated with THA is wound healing failure, with several factors contributing to postoperative wound healing complications. Some of these include patient-related risk factors and comorbidities such as increasing age [95], diabetes mellitus and obesity [96], while other studies suggest a greater impact of metabolic syndrome compared to an elevated BMI (≥ 30 kg/m^2) alone [99]. In our study, the issue of postoperative wound healing defects was underrepresented with only 3 patients (1%). However, two out of three patients were obese (BMI $\geq$30 kg/m^2) and had diabetes mellitus and other comorbidities such as visual impairment. In addition, all were over 60 years of age, with one patient over 70 and one over 90. Therefore, age [95], obesity (BMI $\geq$30 kg/m^2) [96] and diabetes mellitus, especially in combination with metabolic syndrome [99], may be factors that contribute to an increased risk of postoperative wound healing defects.

Interestingly, two of these patients had received their primary THA with UHNA, while another patient had previously undergone revision surgery. However, only one patient required re-revision and a split thickness skin graft. This patient may have been at increased risk for wound healing defects due to his previous revision procedures and the resulting increased soft tissue damage. Although the effect of UHNA on postoperative wound healing

complications has not been described, our study suggests that these are rare events following UHNA implantation.

Bearing surface wear and adverse reactions to particular debris are common complications leading to rTHA in general [7, 30, 67], and PE wear in the cup area in particular [7, 150]. To date, an increased rate of liner wear associated with UHNA has not been described in the literature. Therefore, our single report of recurrent PE liner wear in a 61-year-old male patient is of particular interest. At the time of UHNA implantation, he had a BMI ≥ 30 kg/m^2 and five comorbidities. He had undergone THA on both sides with revision surgeries prior to UHNA implantation due to recurrent PE liner wear. In addition to recurrent PE liner wear, his indications for UHNA implantation included a periprosthetic acetabular fracture that was treated with antibiotic augmented allograft at the acetabular base. After UHNA implantation (M standard adapter, 32 mm ceramic head, CoP bearing), the patient underwent an additional revision at 94 months (7.8 years) due to another event of recurrent PE liner wear, including replacement of both the acetabular cup and the prosthetic head.

Although PE liner wear is not a complication specific to the UHNA system, it is a common complication in THA, often leading to rTHA [7, 150]. It is also a known risk factor for osteolysis to inflammatory processes and bone loss and can lead to component loosening or bone fracture [9, 102], as it was most likely the case in this patient. Known risk factors for tribological PE wear are implant-specific factors such as a smaller head, increased bearing clearance or poor cup positioning [150]. However, none of these were present in this patient. Another potential risk factor for the patient was his increased BMI and therefore increased bearing load. This is a known risk factor for increased wear in the long term, especially in combination with an increased activity level [150]. Overall, this case cannot be considered as a specific complication in a “mix & match” setting, but as an example of recurrent PE liner wear, probably favored by obesity and periprosthetic fracture due to poor bone quality due to adverse reaction to PE debris. Although several other materials with better wear patterns have been developed to address the problem of PE wear, such as UHXLPE or vitamin E-infused PE [9, 10], this case shows that recurrent PE wear can still occur. Therefore, CoC bearings have been specifically designed to avoid complications such as wear and osteolysis [106, 107]. It is known that CoC bearings are superior to CoP or MoP bearings in terms of wear pattern [9]. However, as many different factors may have led to increased PE wear in this case, it is difficult to argue for the superiority of CoC bearings on the basis of this case.

Although CoC bearings demonstrate superior results in comparison to other tribological bearings, they are not suitable for all patients, as there are still issues with the current fourth generation of Delta ceramics. These include squeaking, stripe wear, ceramic fracture, impingement, chipping during insertion, and iliopsoas irritation [9, 108]. Delta ceramic heads have been used by Merete® since 2003 [22]. As our patient cohort extends back to 2006, all patients in our study population were treated with fourth generation ceramics. While Pardo et al. reported a higher prevalence of CoC bearings than CoP bearings [37], our study yielded the opposite result. The most commonly used bearings were CoP bearings with 51.6% (n = 158), exceeding CoC bearings with 34.3% (n = 105). Since CoC bearings generally have a lower revision rate than other types of bearings, it is not surprising that our patients with CoP bearings also had a higher reoperation rate (n = 25; 15.8%) than those with CoC bearings (n = 12; 11.4%). Thus, our study tends to support the superiority of CoC bearings over CoP bearings in terms of re-revision rate, but without statistical significance. In addition, our previously reported case study of recurrent PE liner wear further underscores the superiority of CoC bearings in some cases.

Furthermore, there were no ceramic-related complications in our studies, supporting the durability of fourth-generation ceramics. As reported by Pardo et al. who documented a ceramic cup fracture [37], and Valentini et al. who reported a ceramic head fracture [111], our study's results suggest that ceramic fractures are rare events (no cases in our cohort).

In comparison to previous studies [16, 17, 20, 36-38, 40] and a systematic review [22], the study conducted at the University Hospital Graz with 306 patients represents the second largest single-center study on UHNA to date, surpassed only by the study by Pardo et al. with 331 patients and 354 implants [37]. The larger study cohort allows for more robust conclusions to be drawn, despite the absence of a control group. This is especially true for the incidence of rare events [103] associated with the UHNA system: fretting corrosion of modular components [16, 17, 37], trunnionosis or metallosis [16, 17, 37, 104], ceramic head fracture [35, 37, 38, 44, 104] femoral neck or taper fracture [22, 37, 105], adapter fracture [17, 20, 37, 38], mechanical dissociation at the neck-shaft junction [20, 38], and the occurrence of squeaking in CoC bearings [65].

Mechanical dissociation may be a complication of modular adapters [20] and may occur due to manufacturing errors such as taper mismatch or insufficient impaction force. Other possible causes include the closed reduction technique or traumatic causes [21, 116]. As the

UHNA system is not designed for specific tapers, this could lead to accelerated wear and early metallosis [22], particularly in cases of taper mismatch [21]. Nevertheless, some authors discuss a lower risk of mechanical failure or fretting corrosion in the UHNA system than previously thought [121].

Although cases of mechanical dissociation following UHNA implantation are theoretically possible, no cases of dissociation at the neck-shaft junction were reported in the study. This indicates that there were no manufacturing defects, such as taper mismatch or insufficient impaction force. However, since the explanted prostheses were not subjected to examination for early metallosis, fretting corrosion, or trunnionosis, no conclusion can be drawn regarding accelerated wear due to the modularity of UHNA in our study.

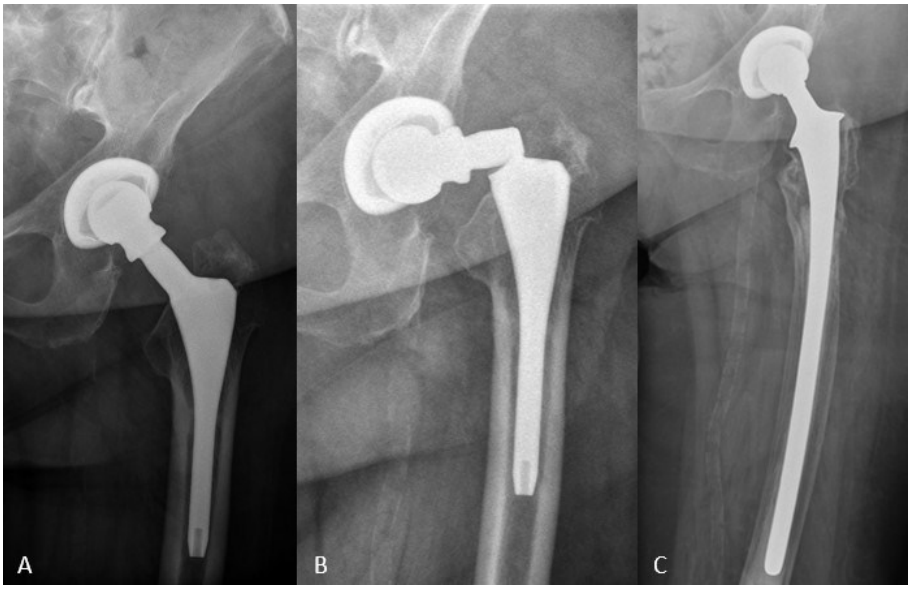
Another potential risk associated with the UHNA system is implant fracture, including fracture of the adapter system and the prosthesis stem-neck. Nevertheless, neck and taper adapter fractures remain rare events [17, 20, 37, 122]. The typical location of these fractures is near the modular stem-neck interface rather than the modular head-neck interface, due to the longer lever arm. Potential risk factors include a long femoral neck, skirted or oversized femoral neck lengths due to corrosion or microscopic fracture lines (higher offset), a high BMI, a high activity level, component loosening or malalignment, and prosthesis design factors. Other risk factors include male sex, head size and material, corrosion, and surgeon-related factors such as the use of a clean, dry, corrosion-free, scratch-free stem, inappropriate assembly forces on the taper, and taper mismatch [22, 40, 122, 123].

In our cohort, there were no material fractures associated with the UHNA bearing pair (adapter and head). Only one UHNA system and “mix & match” related complication was recorded: a femoral prosthesis stem neck fracture, requiring revision In accordance with our findings, Pardo et al. reported no fractures of the adapter system or ceramic head, while one femoral neck failed (0.3%) [37]. Similarly, Novoa et al. identified a total of two ceramic head fractures and one stem-neck fracture in their systematic review [22]. Conversely, Garabadi et al. reported no instances of mechanical dissociation, adapter fracture, or ceramic head fracture [38].

The particularly interesting case of stem neck fracture (only specific complication identified) is hereby discussed. A female patient with a BMI $\geq$ 30 kg/m^2 and a total of eight comorbidities underwent rTHA with UHNA implantation (standard adapter with 2XL adapter neck length, 28mm ceramic head, CoP bearing) at the age of 71 years due to PE liner wear. At the 16-month follow-up after UHNA implantation, a fracture of the prosthesis neck

(Future stem by DePuy Synthes, Johnson & Johnson, New Brunswick, New Jersey, US) occurred after a fall (inadequate trauma). This led to a revision with head and stem exchange (see Figure 15). A further revision was necessary 64 months after the index surgery, due to a periprosthetic femoral fracture that was treated with ORIF and allograft. Although the patient's physical activity status was not assessed, her obesity and oversized UHNA resulted in increased load bearing with a longer lever arm. Both factors may have favored prosthesis stem neck fracture by increasing the risk of stem neck overload, microscopic fractures, and corrosion. In addition, the force applied to the stem neck during rTHA could have potentially caused damage to the prosthesis neck. Other known risk factors in the literature include contamination of the stem with tissue or bone particles, male sex, and a CCD angle of less than or equal to 135° [120], previous revisions, and “mix & match” arthroplasty [123]. In addition, Cook et al. have identified further factors that may influence the outcome, including heat-treatment, reduction of mechanical properties and iatrogenic implant damage [124]. Unfortunately, a retrospective visual inspection of the removed implant was not possible. Similarly to our findings, one case of femoral stem neck fracture after UHNA implantation was reported by Pardo et al. in a patient with a long valgus neck and offset correction [37] and by Lizano-Díez et al. in a patient with a 4XL neck length and a BMI of 32.14 kg/m^2 [122].

Figure 15. Prosthesis Stem-Neck Fracture: Radiographs of a Challenging Case.



X-rays after rTHA with UHNA (Future stem and Duraloc cup, by DePuy Synthes) in 2014 [A], stem-neck fracture at 16 months follow-up [B], and situation after the re-revision surgery [C].

Unfortunately, revision rates for the UHNA system have been inconsistently reported in the literature. For this reason, and because of differences in demographics (e.g., age, comorbidities), indications, procedures other than UHNA implantation, complications, implant specifications, and THA settings (primary THA/rTHA), it has been challenging to compare these studies. Pardo et al. reported 40 re-revisions after UHNA implantation involving 354 implants and 331 patients [37]. When the re-revision rate was calculated as a percentage of implants, the revision rate was 11.3%. However, when the number of patients was considered, the revision rate was 12.1%. In comparison to previous re-revision rates of 5.2% to 23% after 4–8 years [20, 36, 37, 39, 40] and the 12.1% reported by Pardo et al., our study demonstrates an overall favorable re-revision rate of 14.1% (n = 43/306).

Although our median follow-up period of 4.7 years (*IQR* 1.9–7.1) is slightly shorter than the median follow-up period of 5 years reported by Pardo et al. [37], there were cases with a long-term follow-up of up to a maximum of 16.7 years. 143 patients (46.7%) had a follow-up of ≥ 5 years, 84 patients (27.5%) of ≥ 7 years and 22 patients (7.2%) of ≥ 10 years. Therefore, our research makes an important contribution to the long-term results of UHNA and we were able to follow the overall prosthesis survival over a long period of time.

While several papers have reported the revision-free survival rate after UHNA implantation of the modular device [36-38, 40], the results have shown significant differences. Hoberg et al. reported an 8-year revision-free survival rate of 92.8% [36], while Kock et al. reported a 12-year survival rate of 86% [40], and Garabadi et al. reported a survival rate of 98% without specifying the time frame [38]. Compared to the 5-year survival rate of 87.9% reported by Pardo et al. and Caternicchia et al. [37, 41], our study demonstrates similarly good outcomes (see Table 14). We reported our long-term results at five years (n = 263; 86%), seven years (n = 260; 85%), and ten years (n = 251; 82%). However, the results of Pardo et al. demonstrated that there were no differences in implant survival on multivariate analysis, which was adjusted for adapter neck length, standard or offset devices, age, sex, weight, BMI, and implant-related variables [37]. In contrast, our results of the log-rank test suggested differences in revision-free survival with respect to age cohorts (p = .018), comorbidity burden (p = .039), and UHNA neck length (p = .028). Subgroup analysis revealed that prosthesis survival was superior in older patients (≥ 60 years) compared to younger patients (< 60 years), those with fewer (< 2) compared to those with more (≥ 3) comorbidities, and those with normal adapter neck lengths (S–XL) compared to those with oversized adapter neck lengths (2XL–5XL). In terms of implant-specific parameters, neck lengths have been the most consistently reported in the current literature. In their study,

Pardo et al. reported XL as the leading neck length [37], which contributes to our findings. Morevoer, the majority of patients in our study had oversized or skirted neck lengths between 2XL and 5XL (*n* = 143; 46.7%), with a median of 2XL. Of particular interest is the finding that patients with oversized or skirted neck lengths underwent revision after UHNA implantation at an earlier stage than patients with normal or non-skirted neck lengths (S–XL). Again, our findings were in contrast to those of Pardo et al. who found no differences in survival between normal and oversized adapter neck lengths [37].

Table 13. Cumulative Revision-Free Survival of UHNA Compared to Pardo et al. (95% CI).

	1 year	3 years	5 years	7 years	10 years
Our study	92.2 (88.1–95.9)	87.9 (84.1–91.9)	86 (82.1–89.9)	85 (81.1–88.9)	82 (76.1–87.9)
Pardo *et al.*	93.5 (90.3–95.7)	91.1 (87.4–93.7)	87.9 (83.6–91.2)	86.9 (82.3–90.4)	85.7 (80.6–89.7)

Note. UHNA = BioBall® universal head neck adapter, CI = confidence interval. The comparative data derived from the study conducted by Pardo et al. [37].

The present study has several limitations as well as many strengths. Firstly, due to the retrospective study design, the study lacks a control group, and therefore causal conclusions should be drawn with caution. On the other hand, UHNA implantation obviously was the only treatment option in many cases, with no opportunity for a "control treatment". Secondly, there is a possibility of information bias. This is because some of the prosthesis specifications are missing from the operative reports, and comorbidities are recorded based on existing patient records. Prospective studies with standardized questionnaires would be beneficial. On the other hand, because the data were collected retrospectively, this study could be conducted quickly and cost-effectively. Thirdly, another challenge is the heterogeneity of the study population. In particular, factors such as comorbidities, UHNA parameters, and age have an impact on complications and revision-free survival. Other issues include the wide range of implants from different manufacturers used in combination with the UHNA, possible prior surgeries and/or revisions, and the many different indications for UHNA implantation. To address the potential risk of confounding factors, stratification will be performed to account for factors such as age, sex, indications, neck length, comorbidities, and other potential influencing factors. Furthermore, we do not provide specific clinical scores or patient-reported outcome measures to assess functional or subjective improvement due to their heterogeneous endpoints, as reported by Novoa et al. [22].

Nevertheless, this is the first study to systematically analyze potential risk factors for UHNA failure in “mix & match” THA, including demographics, comorbidity burden, indications, and UHNA specifications. The objectives of the present study are met by the chosen design.

At the same time, our study demonstrates the need for further research on modular head-neck adapters in the “mix & match” setting. Further studies are needed to make precise statements about the use of the UHNA system and to identify additional factors that influence complications and revision-free prosthesis survival. Follow-up studies focusing on “mix & match” in hip arthroplasty and UHNA are needed, taking into account various factors, including implant-related factors (e.g., fretting corrosion), patient-related factors (e.g., alcohol and smoking habits, other comorbidities, perioperative mobility, postoperative care and rehabilitation, patient satisfaction, indications), and surgeon-related factors. This would require prospective studies, controlled trials, and further multifactorial analyses.

Finally, our results support the use of a comorbidity index to assess the risk of postoperative complications, revision, and implant survival in retrospective studies of primary THA and rTHA with UHNA. However, there is still a need for an index specific to orthopaedics and THA. In general, more attention should be paid to possible comorbidities in orthopaedic research, especially when dealing with multimorbid and elderly patients, as these are important factors influencing complications and earlier revision.

5 Conclusion

In conclusion, the results of this study underscore the safety and efficacy of UHNA in “mix & match” (r)THA. While one prosthesis stem-neck fracture was identified, no other UHNA or “mix & match” specific failures were found. However, caution should be exercised regarding oversized stem-neck lengths and recurrent dislocations, which were associated with postoperative complications. While potential factors influencing postoperative complications were identified, overall, the BioBall® UHNA system appears to be a safe long-term option with rare complications. Despite the positive results, further studies and inter-prosthesis compatibility testing are needed.

6 References

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