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REDUCING DISLOCATIONS OF TOTAL HIP ARTHROPLASTY

Mikko Karvonen



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The originality of this publication has been checked in accordance with the University of Turku quality assurance system using the Turnitin OriginalityCheck service.

Cover Image: Mikko Karvonen, own X-ray files

ISBN 978-951-29-8769-6 (PRINT)

ISBN 978-951-29-8770-2 (PDF)

ISSN 0355-9483 (Print)

ISSN 2343-3213 (Online)

Painosalama, Turku, Finland 2022

To my family

UNIVERSITY OF TURKU
Faculty of Medicine
Department of Clinical Medicine
Orthopaedics and Traumatology
Mikko Karvonen: Reducing Dislocations of Total Hip Arthroplasty
Doctoral Dissertation, 115 pp.
Doctoral Programme in Clinical Research
March 2022

ABSTRACT

Dislocation is one of the most common complications following total hip arthroplasty (THA). There are several concepts that can be used to reduce the number of dislocations, including elevated liners, larger femoral heads, dual mobility devices and constrained acetabular devices. However, the data on their success has been somewhat contradictory.

In studies I and IV, we aimed to assess the implant survival of a constrained acetabular device, the Biomet Freedom constrained liner (Biomet, Warsaw, IN, USA), in primary THA based on data from the Finnish Arthroplasty Register (FAR) and Turku University Hospital. We also aimed to assess the failure rate of this device, either in revision surgery for recurrent dislocation, or as a preventive method in high dislocation-risk revision THA patients, based on medical records from Turku University Hospital.

Metal-on-metal (MoM) THA and hip resurfacing arthroplasty (HRA) allow the use of large diameter femoral heads, that prevent THA dislocation. It is now well known that adverse reaction to metal debris (ARMD) are associated with HRAs, not only with large-diameter MoM THAs. The aim of the study II was to assess the medium- to long-term survivorship of HRA based on the FAR. Special attention was paid to dislocation revisions.

The use of Trabecular Metal (TM) cups for primary THA is increasing due to their better osteointegration and theoretical lower risk of aseptic loosening. Some recent data suggest that the use of TM in primary THA might be associated with an increased risk of revision. In study III, we compared the implant survival of Continuum acetabular cups (Zimmer Biomet, Warsaw, IN, USA), with other commonly used uncemented cups. Special attention was paid to revision for dislocation and the effect of elevated liners on dislocation revision risk.

In studies I and IV, we found that the mechanical failure rate of a Freedom constrained device was low. This device had good survival in primary THA, and our results support its continued use even in high-risk patients and in revision surgery.

In study II, we found that the 10-year implant survival of MoM HRAs is 86% in Finland. According to new recommendations from NICE (National Institute for Health and Care Excellence), an HRA/THA should have a revision rate of 5% or less at 10 years. None of the HRAs studied achieved this goal. However, the dislocation revision rate using HRA was very low.

In study III, we found that THA with Continuum cups are associated with an increased risk of revision compared with other uncemented cups, due to revisions because of dislocation. Our results support the use of an elevated liner when Continuum cups are used for primary THA.

KEYWORDS: Constrained cup, Dislocation of THA, HRA, Elevated liner

TURUN YLIOPISTO

Lääketieteellinen tiedekunta

Kliininen laitos

Ortopedia ja traumatologia

MIKKO KARVONEN: Lonkan kokotekoniveleen liittyvien sijoiltaanmenojen ehkäisy

Väitöskirja 115 s.

Turun kliininen tohtoriohjelma

Maaliskuu 2022

TIIVISTELMÄ

Lonkan kokotekoniveleen sijoiltaanmeno on yksi merkittävimmistä komplikaatioista liittyen lonkan tekonivelleikkaukseen. On useita tekonivelkomponenttikohtaisia tekijöitä, joilla voidaan estää dislokaatioita. Korotelinert, isonuppiset proteesit, dual mobility linerit ja -kupit, lukkolinerit ja -kupit on kehitetty estämään tekoniveleen sijoiltaanmenoja. Näiden komponenttien tulokset pysyvyyden, kestävyuden ja toimivuuden suhteen ovat olleet kuitenkin osin ristiriitaisia.

Osatöissä I ja IV selvitimme, nykyään suositun lukkokupin (Biomet Freedom, Warsaw, IN, USA), tuloksia pysyvyyden ja kestävyuden suhteen, perustuen Suomen tekoniverekisterin (FAR) ja Turun yliopistollisen keskussairaalan dataan. Tulokset kartoitettiin liittyen lonkan ensi tekonivelleikkauksiin korkean riskin potilailla, sijoiltaanmenon hoidoksi tehtyihin uusintaleikkauksiin sekä sijoiltaanmenon suhteen korkean riskin potilaille, muusta syystä tehtyihin uusintaleikkauksiin.

Metalli metalli -liukupintainen (MoM) kokotekonivel ja pinnoitetekonivel (HRA) sallivat tekoniveleen ison nuppikoon käytön ja näin ollen pienentävät sijoiltaanmenon riskiä. On kuitenkin jo aiemmin todistettu, että MoM liukupintoihin liittyvä metallihierrekomplikaatio (ARMD), liittyy myös pinnoitetekoniveliin. Tutkimuksen II tarkoitus oli selvittää keskipitkän- ja pitkän aikavälin tulokset erimallisilla lonkan pinnoitetekonivelillä, perustuen FAR-dataan. Erityishuomio kiinnitettiin dislokaatiorevisioihin.

Trabekulaari metalli (TM) -pintaisten acetabulum kuppien käyttö on lisääntynyt lonkan tekonivelkirurgiassa perustuen parempaan osteointegraatioon ja näin ollen teoreettisesti pienempään aseptisen irtoamisen riskiin. Jotkin viimeaikaiset tutkimukset ovat osoittaneet, että TM-pintaisten kuppien käyttö saattaisi olla yhteydessä lisääntyneeseen uusintaleikkauriskiin. Osatyössä III vertasimme yleisesti käytetyn Continuum -kupin (Zimmer Biomet, Warsaw, IN, USA) tuloksia muihin yleisesti käytettyihin sementittömiin acetabulum -kuppeihin, perustuen FAR-dataan. Erityishuomiota kiinnitettiin dislokaatiorevisioihin ja korotelinertin vaikutusta dislokaatiorevisio riskiin.

Osatöiden I ja IV tuloksena totesimme, että Freedom tekonivelkomponentilla on hyvät lyhyen aikavälin tulokset kestävyuden ja pysyvyyden suhteen, liittyen lonkan kokotekoniveleen sijoiltaanmenojen ehkäisyyn, niin korkean riskin ensi tekonivelpotilailla kuin haastavammissakin tapauksissa, erittäin korkean riskin uusintaleikkauksissa.

Osatyön II tuloksena totesimme, että pinnoitetekonivelten 10 -vuotistulokset pysyvyyden suhteen, ovat keskimäärin 86 %. Uusimman NICE -suosituksen mukaisesti, tekoniveleen pysyvyys 10 vuoden ajalla täytyy olla vähintään 95 %. Yksikään tutkimuksen pinnoitetekonivel ei pääse tähän. Tässä ryhmässä kuitenkin sijoiltaanmenojen vuoksi tehtyjen uusintaleikkausten määrä oli hyvin alhainen.

Osatyön III tuloksena totesimme, että Continuum kupeilla, käytettäessä neutraalia lineria, on lisääntynyt revisioriski liittyen sijoiltaanmenon suhteen tehtyihin uusintaleikkauksiin. Tulokset suosittelvat korotelinertin käyttöä.

AVAINSANAT: Lukkokuppi, Tekoniveleen sijoiltaanmeno, Pinnoite tekonivel, Korotelinert

Table of Contents

Table of Contents	6
Abbreviations	8
List of Original Publications	10
1 Introduction	11
2 Review of the Literature	15
2.1 Dislocation of THA	15
2.2 Risk factors for dislocation of THA	16
2.2.1 Patient related factors	16
2.2.2 Surgeon related factors	18
2.2.2.1 Surgical Approach	18
2.2.3 Implant related factors	19
2.3 Prevention of dislocation in primary THA.....	21
2.3.1 Surgeon experience	21
2.3.2 Component positioning.....	21
2.3.3 Large femoral heads	22
2.3.3.1 Large head MoM THAs and HRAs.....	24
2.3.4 Elevated liners.....	26
2.3.5 Dual mobility cups and articulation	27
2.3.6 Constrained cups and liners	29
2.3.7 Computer-assisted and robotic guidance in THA.....	31
2.4 Prevention and treatment of dislocation in revision THA.....	34
3 Aims of the Present Study	37
4 Materials and Methods	38
4.1 Patients.....	38
4.1.1 Study I.....	38
4.1.1.1 Study device in studies I and IV	39
4.1.2 Studies II, III and IV	40
4.2 Methods and statistical analyses	44
4.2.1 Study I.....	44
4.2.2 Study II.....	45
4.2.3 Study III.....	46
4.2.4 Study IV	48

5	Results	49
5.1	Studies based on Turku University Hospital medical records (Study I).....	49
5.1.1	Freedom Constrained liner for the treatment and prevention of dislocation.....	49
5.2	Studies based on the Finnish Arthroplasty Register (Studies II, III, IV).....	50
5.2.1	10-year survivorship of hip resurfacing arthroplasty.....	50
5.2.2	Continuum cup in primary total hip arthroplasty.....	53
5.2.3	Implant survival of constrained acetabular device based on data from the Finnish Arthroplasty Register.....	58
6	Discussion	61
6.1	Constrained acetabular device	61
6.2	Head size and hip resurfacing arthroplasty.....	66
6.3	Elevated liners.....	68
7	Conclusions.....	71
	Acknowledgements	72
	References	74
	Original Publications.....	83

Abbreviations

AOANJRR	Australian Orthopaedic Association National Joint Replacement Registry
ARMD	Adverse reaction to metal debris
ASA	American Society of Anesthesiology (Physical Status Classification System)
ASR	Articular surface replacement (DePuy Synthes)
BHR	Birmingham hip resurfacing (Smith&Nephew)
BMI	Body mass index
CAOS	Computer-assisted orthopaedic surgery
CI	Confidence interval
CIF	Cumulative incidence function
CoC	Ceramic on ceramic
CoP	Ceramic on polyethylene
CT	Computed tomography
FAR	Finnish Arthroplasty Register
HR	Hazard ratio
HRA	Hip resurfacing arthroplasty
HXLPE	Highly cross-linked polyethylene
JD	Jumping distance
LDH	Large diameter head
MoM	Metal on metal
MoP	Metal on polyethylene
NARA	Nordic Arthroplasty Register Association
NICE	National Institute for Health and Care Excellence
NJR	National Joint Registry
ODEP	Orthopedic Device Evaluation Panel
OECD	Organisation for Economic Co-operation and Development
OR	Odds Ratio
PE	Polyethylene
PJI	Periprosthetic joint infection
PROM	Patient-reported outcome measures

ROM	Range of motion
RR	Revision ratio
rTHA	Revision total hip arthroplasty
SAS	Statistical analysis system
SD	Standard deviation
THA	Total hip arthroplasty
TLC	Trilogy Longevity Constrained Liner (Zimmer, Warsaw, IN, USA)
TM	Trabecular metal

List of Original Publications

This dissertation is based on the following original publications, which are referred to in the text by their Roman numerals:

- I Karvonen M, Karvonen H, Seppänen M, Liukas A, Koivisto M, Mäkelä KT. Freedom Constrained Liner for the Treatment and Prevention of Dislocation in Total Hip Arthroplasty. *Scand J Surg.* 2017 Jun;106(2):165–172.
- II Seppänen M, Karvonen M, Virolainen P, Remes V, Pulkkinen P, Eskelinen A, Liukas A, Mäkelä KT. Poor 10-year survivorship of hip resurfacing arthroplasty. *Acta Orthop.* 2016 Dec;87(6):554–559.
- III Hemmilä M, Karvonen M, Laaksonen I, Matilainen M, Eskelinen A, Haapakoski J, Puhto AP, Kettunen J, Manninen M, Mäkelä KT. Survival of 11,390 Continuum cups in primary total hip arthroplasty based on data from the Finnish Arthroplasty Register. *Acta Orthop.* 2019 Aug;90(4):312–317.
- IV Karvonen M, Laaksonen I, Pulkkinen P, Eskelinen A, Haapakoski J, Puhto AP, Kettunen J, Manninen M, Mäkelä KT. Implant survival of constrained acetabular device in primary total hip arthroplasty based on data from the Finnish Arthroplasty Register. *J Arthroplasty.* 2020 Jan;35(1):219–223.

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1 Introduction

The main clinical indication for total hip replacement is end-stage osteoarthritis, with joint pain and stiffness that is resistant to non-operative treatments. Total hip arthroplasty (THA) is undertaken to relieve pain and improve function in individuals with advanced osteoarthritis of the hip joint. Symptomatic osteoarthritis is the most common indication for THA. In recent years in the UK, the main indications for THA have been osteoarthritis (90%), femoral neck fracture (5%), avascular necrosis (2%), dysplasia (2%), and inflammatory arthritis (1%) (Ferguson et al. 2018).

The first attempts to treat hip osteoarthritis surgically were made over 100 years ago. Professor Gluck was the first and used ivory to replace the femoral heads in hips destroyed by tuberculosis. Interpositional arthroplasty was next surgical experiment in the late 19th and early 20th centuries, when surgeons placed various tissues between the articulating surfaces of the hip (Learmonth et al. 2007). Interposition of a vitallium cup, which covered the reshaped femoral head, by Smith-Petersen in 1938 heralded a new era of arthroplasty (Smith-Petersen 1978) (Fig. 1).



Figure 1. Vitallium cup (Courtesy of the Science Museum Group).

In the 1960s, THA was revolutionized by the low friction arthroplasty developed by Sir John Charnley (Caton and Prudhon 2011) (Fig. 2). Since then modern THA has spread globally for the treatment for severe arthritis, with very good long-term results (Learmonth et al. 2007). Today, even young patients with severe hip conditions can be treated with THA to restore their quality of life, including physically demanding activities.

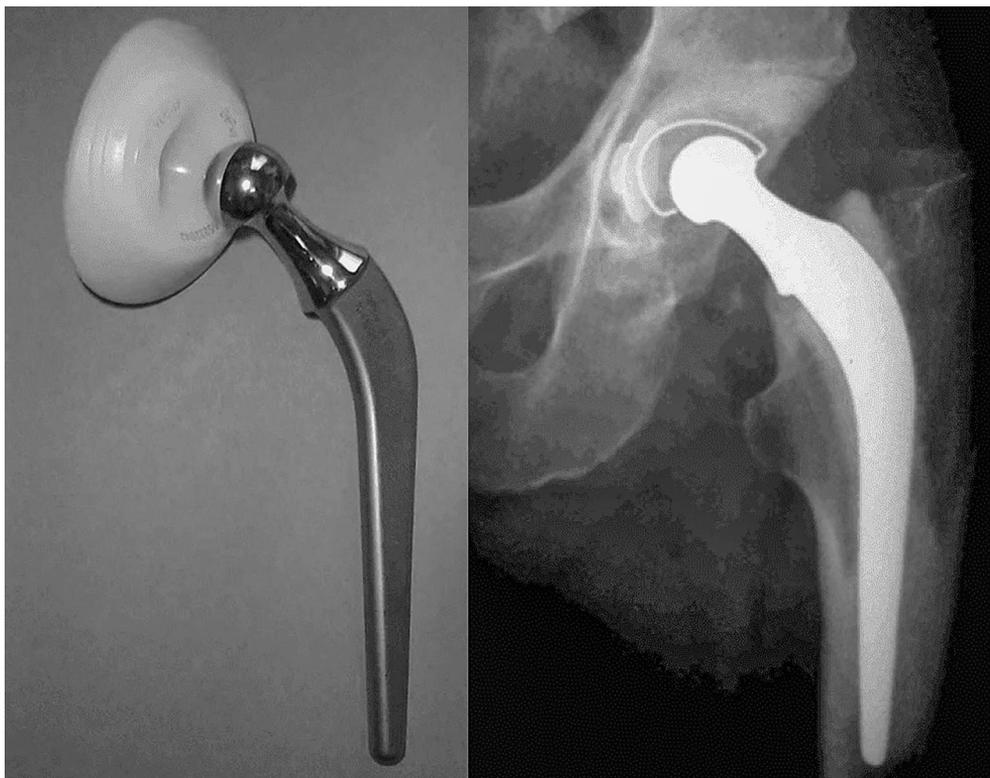


Figure 2. Charnley prosthesis with 22 mm stainless steel femoral head to reduce frictional forces.

Worldwide, more than 1 million total hip replacements are done each year (Organisation for Economic Co-operation and Development, OECD 2019). According to the FAR (Finnish Arthroplasty Register), more than 10000 primary THAs have been performed in Finland every year since 2017 (Fig. 3) (FAR). In 2017 alone, 37000 THAs were performed in Australia and 97000 in the UK (Australian Orthopaedic Association National Joint Replacement Registry 2018, National Joint Registry 2018)

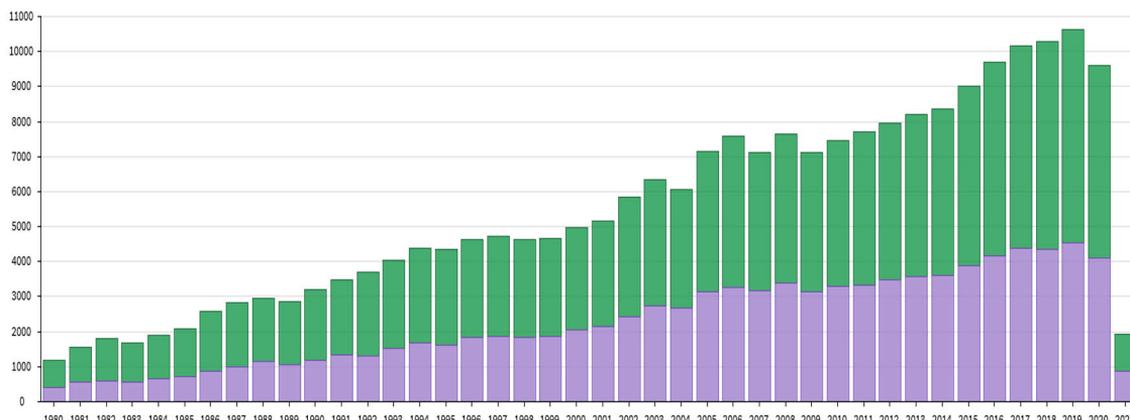


Figure 3. Annual primary THAs in Finland according to FAR (● Men, ● Women).

Modern total hip replacement can improve patient quality of life more than any other elective surgical procedure (Winter 2016). Since the pioneering work of Charnley and others in the mid-20th century, implant technology has steadily improved (Learmonth et al. 2007). Now, more than 95% of artificial hip joints survive beyond 10 years, and, despite Charnley's prediction to the contrary, many routinely do so beyond 30 years (Bayliss et al. 2017, Ferguson et al. 2018).

Advances in bioengineering technology have driven the development of hip prostheses. Better materials and design have allowed the use of larger head diameter and more durable bearings, which provide an increased range of motion (ROM) with enhanced stability and very low wear. Universal economic constraints in healthcare services dictate that further developments in THA will be governed by their cost-effectiveness (Learmonth et al. 2007). Although the era of major design innovation is probably over, incremental improvements continue. Research efforts focus on three key goals: extending implant lifespan, improving functional outcomes, and reducing complications (Ferguson et al. 2018).

The primary method used to assess the outcome of surgery is survival analysis with revision surgery as the endpoint. According to the current National Institute for Health and Care Excellence (NICE) recommendations, the revision rate of HRAs/THAs should be no higher than 5% by 10 years (<https://www.nice.org.uk/guidance/ta304/chapter/1-Guidance>). The volunteer-led Orthopaedic Device Evaluation Panel (ODEP), created in 2002, (<https://www.odep.org.uk/>) considers the revision rate data from manufacturers, registries, and independent studies, and issues a rating for each device.

According to the FAR in 2020, the most frequent reasons for THA revisions in Finland are periprosthetic joint infection (30%), dislocation (22%), femur periprosthetic fracture (17%), aseptic loosening of the acetabular component (8%),

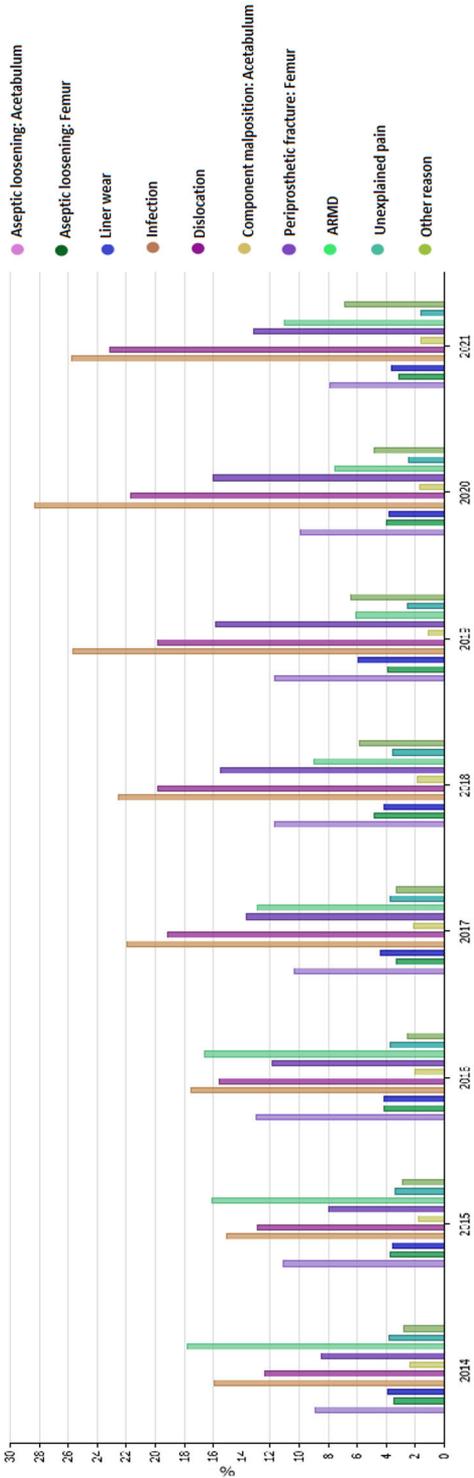


Figure 4. Main reasons for THA revision annually in 2014-2021 according to FAR.

adverse reaction to metal debris (ARMD) (6%), other reasons (6%), aseptic loosening of the femur component (4%), wearing of the liner (3%), unknown pain (2%), and malposition of the acetabular cup (2%) (Fig. 4).

To prevent THA dislocation, component-specific methods include elevated liners, large femoral heads, dual mobility liners and constrained devices. The aims of this study were to ascertain the short- and midterm survival rate of a widely used constrained device (Biomet Freedom, Warsaw, IN, USA) in primary THA based on FAR data, and to assess the failure rate of this device in revision surgery for recurrent dislocation, or as a preventive method in high dislocation-risk patients based on medical records from Turku University Hospital. Other aims were to assess the medium- to long-term survivorship of large head metal-on-metal (MoM) hip resurfacing arthroplasty (HRA) implants and their dislocation risk, and to compare implant survival and especially the rate of revision due to dislocation and the effect of elevated liners in Continuum acetabular cups with other commonly used uncemented cups, based on FAR data.

2 Review of the Literature

2.1 Dislocation of THA

Dislocation following THA continues to be one of the most common reasons for surgical revision of THA. Dislocation rates of under 1% to more than 10% have been reported after primary THA, although most studies report a prevalence of 2–5% (Woo and Morrey 1982, Callaghan et al. 2001, Von Knoch et al. 2002, Venäläinen et al. 2021). The dislocation rate after revision THA is higher than after primary THA, ranging from 7–15% (Callaghan et al. 2001, Alberton et al. 2002). According to Sadoghi et al. (2013), the most common causes for revisions in primary THA were aseptic loosening (55%), dislocation (11%), septic loosening (7.5%), periprosthetic fractures (6%). A study investigating dislocation within 1 year of primary THA found an overall rate of 1.7% (Khatod et al. 2006). Registry-based studies have reported that dislocation is among the leading causes of revision after primary THA (Hailer et al. 2012b, Kostensalo et al. 2013). Based on FAR data from 2020, 22% of THA revisions in Finland are due to dislocations.

Dislocation is a permanent risk during the postoperative life of both the patient and the prosthesis, defined by Caton and Berry in 2004 as a cumulative risk (Noyer and Caton 2017). Dislocations that occur within 2 years of surgery are “early” dislocations; “late” dislocations occur beyond the second postoperative year (Malkani et al. 2010). Dislocation may be single or recurrent. Sixty percent of dislocations occur within the first 5 weeks after operation and closed reduction is successful in 67% of patients. According earlier studies, if the hip keeps on dislocating, revision surgery for instability is needed but is successful in only 60% to 75% of patients (Bourne et al. 2004).

Over 60% of patients who sustain a dislocation have multiple occurrences, and half require revision surgery. The other half walk significantly slower, have a significantly reduced single limb support time and quality of life compared to those who have not dislocated (Kotwal et al. 2009). Unstable THAs increase hospital costs by up to 300% of the cost of a primary hip arthroplasty. The economic and human implications of this complication are important, and strategies to reduce the risk of dislocation should be adopted by surgeons and health care providers (Rowan et al. 2018).

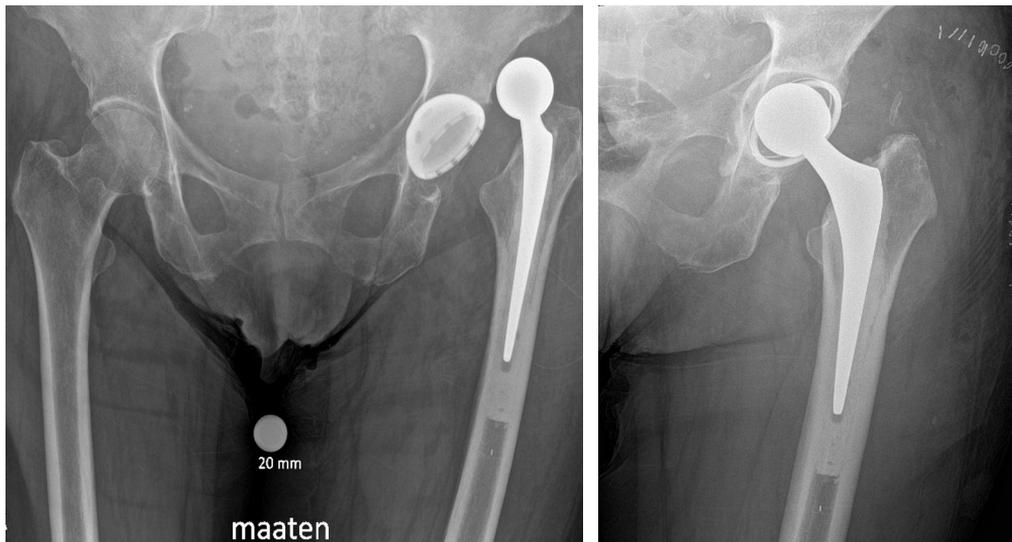


Figure 5. Dislocation treated with a cemented constrained cup.

2.2 Risk factors for dislocation of THA

Several patient- and surgery-related risk factors for dislocation have been identified. A traditional method for determining the etiology of THA instability has been to consider patient related factors, surgeon related factors, and implant related factors (Brooks 2013).

2.2.1 Patient related factors

Several patient related factors have been associated with a higher risk of THA dislocation. Older age has consistently proven to be an independent risk factor for dislocation after THA although there is no consistent cutoff age for increased instability, the cutoff ranging from 70 to 85 years of age (Malkani et al. 2010, 2017, Rowan et al. 2018). However, according to Meek et al. (2006), patients older than 85 years have a higher incidence of dislocation.

It has been shown that dislocation after THA occurs more often in patients with a body mass index (BMI) of > 30 . In a single institution study of 21,361 primary THAs performed over a 27-year period, early dislocation rates were higher for patients with a BMI of 35, with a 5% increase for each BMI unit > 35 (Wagner et al. 2016, Rowan et al. 2018). Kim et al. reported that the higher dislocation rate in obese patients was related to extra-articular soft tissue impingement during hip adduction and flexion, since the implant position was satisfactory in the group of obese patients (Kim et al. 2006).

Loss of muscle balance around the hip joint or general loss of muscle tone around a THA may contribute to instability. Cerebral, spinal, neuromuscular junction, and

muscle-tendon-bone integrity is required for normal hip function and stability. Common neurological conditions that may present in patients with pain requiring THA are post-stroke, Parkinson's disease, cerebral palsy, acquired brain injury and acquired spinal cord injury. A review by Queally et al. recommends using constrained devices for patients who are at risk of instability, such as those with cerebral palsy, spinal injury and poliomyelitis (Queally et al. 2009). A recent comparative study of patients with cerebral palsy showed no increased risk for dislocation after THA when judicious use of muscle releases and elevated and dual-mobility liners were used by experienced hip reconstruction surgeons (Houdek et al. 2017, Rowan et al. 2018).

A higher American Society of Anesthesiology (ASA) class (I–IV) has also been reported to be associated with increased dislocation risk. In a study based on FAR data the hazard ratio for dislocation revision was 2.0 (confidence interval 1.0–3.9) for ASA class III–IV compared to ASA class I (Panula et al. 2020).

Cognitive and psychiatric disorders are independent risk factors for THA dislocation (Fessy et al. 2017). Alcohol abuse is also highly associated with higher THA dislocation risk. According to a recent wide-ranging clinical study in the United States, significantly more patients in the dislocated cohort abused alcohol compared to non-dislocated patients, (3.0% vs. 1.5%, respectively) (Mohamed et al. 2020).

Lumbosacral pathology, sagittal balance, and lumbosacral mobility influences the functional position of the native acetabulum and femoral neck during deep hip movement and flexion. The surgeon should recognize a patient with confined spinopelvic mobility, as these patients demonstrate more femoroacetabular flexion, putting the patient at risk of posterior dislocation (Esposito et al. 2016). Patients who may need lumbosacral fusion before or after THA are at risk of instability. The dislocation rate of THA without spinal fusion was 1.5% compared to 3.0% and 4.1% in patients who underwent 1–2 level fusion and 3+ level fusion with subsequent THA, respectively (Buckland et al. 2017). Patients with lumbar fusion are at increased risk of post-operative dislocations requiring revision. Together, lower pelvic incidence and decreased sacral slope are associated with increased risk of dislocation in these patients (York et al. 2018).

Patients undergoing THA for hip osteonecrosis have a higher rate of postoperative instability and are twice as likely to undergo revision for instability compared to control subjects (Bergh et al. 2014, Yang et al. 2015).

Patients who have received THA for femoral neck fracture also have an elevated risk of THA dislocation compared to patients with osteoarthritis as the reason for THA. In a study based on FAR data, the hazard ratio for dislocation revision was 3.0 (95% CI 1.9–4.7) for THAs performed for femoral neck fracture compared to THAs performed for osteoarthritis (Panula et al. 2020). Preoperative rheumatoid arthritis diagnosis may also predispose the patient to elevated THA dislocation risk (Taylor-Williams et al. 2020).

2.2.2 Surgeon related factors

The surgical goals of primary THA are to recreate the center of rotation and restore leg length and combined offset. Anatomical challenges to achieving these goals should be recognized preoperatively because each factor contribute to postoperative THA instability. Femoral and acetabular component positioning is the most crucial part of avoiding postoperative dislocation of THA. The modern literature recommends patient-specific targets for component positioning with good intraoperative assessment (McCarthy et al. 2016, Rowan et al. 2018). This demands a high level of experience and technical competence on the part of the surgeon.

In a Canadian study of nearly 38,000 patients, surgeons who performed <35 THAs a year had a dislocation rate of 1.9% vs 1.3% ($p=0.006$) for surgeons with greater volumes (Ravi et al. 2014). It has been shown that for every 10 THAs performed, a surgeon's dislocation rate decreases by 50% (Hedlundh et al. 1996). Institution volume also influences dislocation, as seen when comparing high- and low-volume centers. According to Malkani et al. an indisputable measure of surgeon skill is operative time; although this does not account for case complexity, an operative time of 180 - 210 minutes was associated with a 5.0% early dislocation rate compared to 3.7% for an operative time of <90 minutes (Malkani et al. 2010).

It is the surgeon's responsibility to maintain technical competence and acknowledge their limitations in terms of volume or expertise (Rowan et al. 2018).

2.2.2.1 Surgical Approach

Registries report increased dislocation rates for the posterior approach compared to anterior, anterolateral or direct lateral approaches, but pooled data studies do not support this finding (Jolles and Bogoch 2006, Maratt et al. 2016, Mjaaland et al. 2017). However, in a study based on data from the FAR, the posterior surgical approach was significantly associated with increased risk of revision for dislocation compared to the anterolateral approach. In this study the hazard ratio for dislocation revision was 3.1 (95% CI 1.7–5.5) for the posterior compared to anterolateral approach (Panula et al. 2020). According to a study by Zijlstra et al., the posterolateral approach was associated with higher dislocation revision risk compared to straight lateral, anterolateral, and anterior approaches. However, according to Pellicci et al., by improving their posterior closure technique, two high-volume surgeons significantly reduced dislocation rates from 4% and 6.2% to 0% and 0.8%, respectively (Pellicci et al. 1998). Also, in the study by Zijlstra et al., the risk of revision for all other reasons was higher with anterior and anterolateral approaches and lowest with the posterolateral approach (Zijlstra et al. 2017).

A registry analysis of 2,061 THAs showed that acetabular component positioning was 20% more accurate with the posterior approach than with direct

lateral or anterolateral approaches (Callanan et al. 2011). In a systematic review and meta-analysis of prospective studies comparing postoperative outcomes through 90 days of anterior approach vs posterior approach in primary THA, no statistical differences in complication rates were detected between anterior approach and posterior approach (Miller et al. 2018). However, according to some recent studies, patient self-reported limping at 1–3 years postoperatively after THA with the anterolateral approach is double that with the posterolateral approach (Amlie et al. 2014, Rosenlund et al. 2017). In addition, some large-scale retrospective studies have demonstrated no difference in dislocation rates regardless of the approach used (Masonis and Bourne 2002, Chechik et al. 2013). The choice of surgical approach in primary THA should consider the preference and experience of the surgeon, as well as the preference and anatomy of the patient (Miller et al. 2018).

2.2.3 Implant related factors

The etiology of hip degeneration leading to THA, and the morphology of the native hip, will determine implant choice and reconstructive strategy.

Acetabular cup diameter has been proven to influence postoperative stability. Impingement risk grows when the femoral head diameter remains constant and the cup size grows simultaneously. Kelley et al. showed that an acetabular component outer diameter of ≥ 56 mm increased the risk of dislocation in a prospective controlled study (Kelley et al. 1998). Similar results have been reported from a retrospectively studied series of 668 primary THAs that found a higher dislocation rate with acetabular cups of >58 mm diameter (Robinson et al. 2012).

Restoring the hip center is a key target of THA surgery. Choosing the appropriate femoral component is the responsibility of the surgeon and should be based on preoperative planning and intraoperative assessment. Modular stems are a tempting option for restoring the hip center, but many have been recalled due to taper corrosion (Molloy et al. 2014, Nawabi et al. 2016, Graves et al. 2017). Others have not shown a benefit for postoperative THA stability (Colas et al. 2017, Gofton et al. 2017). Rowan et al. do not recommend routine use of modular stems in primary THA (Rowan et al. 2018).

Increased anteversion and high valgus neck-shaft angles can create challenges in restoring the hip center, combined hip offset, and length. The most notable morphologic variant is an increased likelihood of excessive femoral anteversion. Understanding this will help the surgeon determine the optimal femoral stem for such patients. To address these morphologic challenges, primary and even modular stem designs may aid in the correction and restoration of appropriate hip mechanics (Greber et al. 2017). To prevent dislocation, various femoral implant designs which can change the stem anteversion have been developed to satisfy combined

anteversion. In terms of implant design, femoral head-to-neck ratio, head diameter and head offset are all related to the impingement-free angle (Ohmori et al. 2019). Patients with coxa vara can present a challenge for hip center restoration, as conventional high offset stems and lateralized liners may not restore the combined offset. Large MoM resurfacing was previously the solution to this problem, but is no longer an option due to the high revision rate of this kind of THA (Bolland et al. 2011, Seppänen et al. 2016). However, large-diameter heads in ceramic on ceramic (CoC) THAs (≥ 40 mm) have recently shown promising clinical and radiological outcomes, although further studies are needed (Castagnini et al. 2021).

Acetabular liner morphology influences hip stability. Several implant manufacturers provide lipped or elevated liners of varying angles up to 20° to decrease the dislocation risk by increasing the jumping distance (JD). Using a 15-degree liner in the posterior quadrant with a 28-mm head increases the internal rotation ROM by 9 degrees without causing anterior dislocation (Sultan et al. 2002). Lateralized offset liners can be used to restore the hip center of rotation when the acetabular shell is medial or the reconstructed femoral offset is reduced compared to the contralateral hip or preoperative offset. In a series of 668 primary THAs with an overall dislocation rate of 1.3%, decreased postoperative offset increased the risk of dislocation (Robinson et al. 2012).

Liner wearing and tribology influences THA stability. Polyethylene wear >2 mm is a risk factor for late dislocation (Parvizi et al. 2006). Loss of component congruity due to wear with associated soft tissue laxity and/or bony loss due to osteolysis is implicated. Advances in polyethylene (PE) characteristics by increasing cross-linking have resulted in lower femoral head penetration rates (Kurtz et al. 2011). In some studies, CoC has reduced the rate of late dislocation compared with metal-on-polyethylene (MoP) (Rowan et al. 2018). However, this outcome was not found in a 13-year analysis of 1,219 of 192,275 primary THAs revised for instability in the Australian Joint Registry (Graves et al. 2014). In that registry study, there was no significant difference in dislocation rates among bearing surfaces for CoC, ceramic-on-polyethylene (CoP) and MoP.

The femoral head and acetabular cup articulate at the bearing interface. The ideal bearing interface is chemically inert *in vivo*, has a low wear rate, produces non-immunogenic wear debris, and is sufficiently tough to resist fracture. In the UK in 2017 (National Joint Registry 2018), implants with MoP bearings were used in 57% of procedures, those with CoP bearings in 33%, and those with CoC bearings in 9% of procedures (Ferguson et al. 2018). Modern highly cross-linked polyethylene (HXLPE) is more resistant than the early materials, and registry analysis has found no difference in mid-term revision rates between modern MoP, CoP, and CoC bearings (Wyles et al. 2015, Australian Orthopaedic Association National Joint Replacement Registry 2018).

2.3 Prevention of dislocation in primary THA

Risk and preventive factors for dislocation are somewhat similar, the latter being closely linked to the former. Patient selection is, of course, the most essential factor when it comes to risk of dislocation. The dislocation rate can be also reduced by surgeon experience, optimal component positioning, elevated liners, larger femoral heads, dual mobility cups and liners, constrained acetabular cups and robotic guidance in THA surgery (Rowan et al. 2018).

2.3.1 Surgeon experience

As indicated above, many factors contribute towards dislocation, and the role of the surgeon is to mitigate risk by recognizing these factors and adjusting the reconstruction strategy accordingly. Surgeons performing a high volume of THAs have better outcomes than those who performing a low volume of these procedures, including lower risk of dislocation and revision. Low-volume surgeons in particular should recognize the limitations of their skill set and refer at-risk patients appropriately (Rowan et al. 2018). Surgical resident training should also always be supervised by a senior surgeon to minimize complications and errors. Additionally, hospitals in which a high volume of procedures are done have low rates of complications, including dislocation and mortality (Laucis et al. 2016).

Restoring the hip center is a key principle of THA. Choosing the appropriate femoral and acetabular components as well as appropriate bearing surfaces is the responsibility of the surgeon and should be based on preoperative planning and intraoperative assessment (Rowan et al. 2018). Planning helps the surgeon visualize the operation after careful review of the clinical and radiographic findings. A standardized radiograph with a known magnification should be used for templating. Templating should be done by appropriate computer software. Meticulous preoperative planning allows the surgeon to perform the procedure expediently and precisely, anticipate potential intraoperative complications, and achieve reproducible results in modern hip arthroplasty (Della Valle et al. 2005). Achieving preoperative planning accurately during surgery is strongly associated with surgeon skill and experience.

2.3.2 Component positioning

Component positioning, especially of the acetabular cup, plays a significant role in preventing dislocation after THA. Lewinnek et al. proposed a safe zone for cup placement of 30–50 degrees of inclination and 5–25 degrees of anteversion as a means of minimizing postoperative dislocation (Lewinnek et al. 1978). Callanan et al. recommended that an inclination range of 30–45 degrees was more ideal (Callanan et al. 2011). The Ranawat combined anteversion test, first described in 1991 (Ranawat and Maynard 1991) is an intra-operative estimate of combined cup and stem

anteversion. Komero et al. showed that high (72°) and low (27°) combined anteversion is associated with anterior and posterior dislocation, respectively, compared to control subjects (48°) (Komero et al. 2006). Ranawat and Maynard recommended an experience based combined anteversion between 25° and 45° for women and between 25° and 35° for men (Ranawat and Maynard 1991). Dorr et al. recommended combined anteversion between 25° and 50° (Dorr et al. 2009). Whereas these concepts provide recommendations based on experience, clinical data, or virtual mathematical calculations, none of the current combined anteversion rules account for bony or soft tissue structures or functional aspects such as pelvic tilt (Weber et al. 2016).

In a systematic review, Seagrave et al. analyzed 28 articles to identify methods for measurement of cup positioning, to determine the significance of cup malpositioning influencing dislocation rates following primary THA, and to identify proposed target zones for cup anteversion and inclination to reduce the risk of dislocation (Seagrave et al. 2017). In summary, some of the articles showed that cup positioning had an influence on postoperative dislocation, whereas others were unable to pinpoint a correlation. When mean angles of anteversion and inclination were compared between dislocating and non-dislocating THAs, most of the articles did not find a statistically significant difference between these groups. Due to the variety of study designs, surgical approaches, and patient populations, it is difficult to draw broad conclusions about a definitive target zone for cup positioning in THA. The target zone for cup placement is influenced by several other factors, so the ideal target zone for each patient varies depending on these factors. "Placing the cup in a target zone may not eliminate the risk of dislocation, but it could possibly minimize this risk" (Seagrave et al. 2017). Seagrave et al. recommend that future studies investigating acetabular cup positioning and risk of dislocation should assess different surgical approaches separately, as the approach may have an influence on optimal positioning of the acetabular component (Seagrave et al. 2017).

In the 21st century, technical progress has enabled a novel approach to biomathematical combined anteversion models calculating optimal ROM by virtual hip joint movement (Widmer and Zurfluh 2004, Yoshimine 2006, Hisatome and Doi 2011). Recently, some studies have focused more on functional hip motion and the "functional safe zone" as opposed to the Lewinnek safe zone. In a study by Tezuka et al., 14% of hips within the Lewinnek safe zone were outside the functional safe zone, identifying a potential reason why hips dislocate despite having "normal" cup angles. In this study, predictive factors for falling outside the functional safe zone were increased femoral mobility, decreased spinopelvic mobility, and pelvic incidence (Tezuka et al. 2019).

2.3.3 Large femoral heads

Larger femoral head sizes are effective not only for postponing implant-implant impingement, but also for increasing the JD. The JD is the degree of lateral

translation of the femoral head center required before dislocation occurs (Fig. 6). The smaller the distance, the higher the theoretical risk of dislocation (Sariali et al. 2009). Using a larger femoral head increases the oscillation angle and JD and lowers the dislocation rate (Ohmori et al. 2019). Large femoral heads can provide greater impingement-free hip ROM, reduce the risk of dislocation by increasing the JD, and are more anatomical as their size is closer to that of the native femoral head (Shah 2019). The larger the head diameter used, the more the stability of the joint increases, because the distance required for the femoral head to disengage from the acetabular component becomes longer (Ohmori et al. 2019).

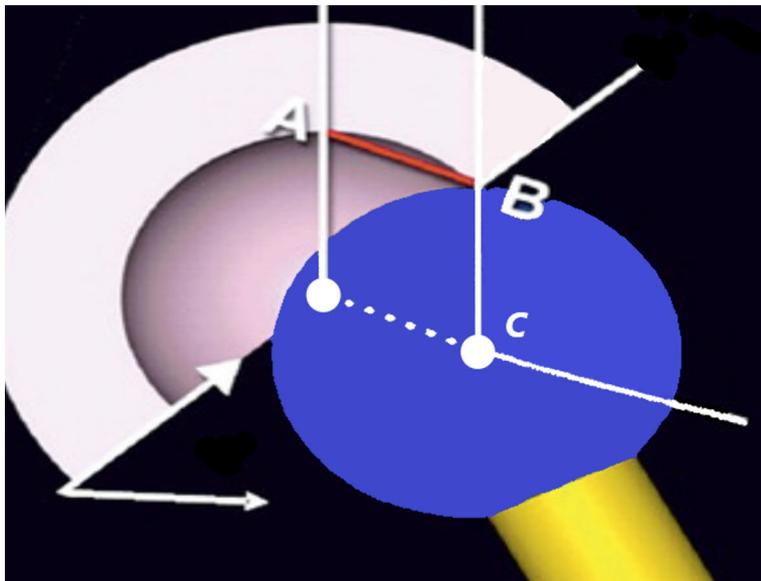


Figure 6. Jumping distance. A-B: JD, C: Femoral head center.

Larger femoral size has been associated with lower dislocation risk in national registries. Increasing femoral head size ≥ 36 mm reduced dislocation rates in a National Joint Registry report (Jameson et al. 2011). According to FAR data, the 28-mm femoral head size had a 10-fold higher risk of reoperation due to dislocation than a head size of 37 mm or more over a 12-year period (Kostensalo et al. 2013). Kelley et al. reported higher dislocation rates with 22-mm heads vs 28-mm heads, but Robinson et al. reported no difference between 32-mm and 36-mm heads (Kelley et al. 1998, Robinson et al. 2012, Tsikandylakis et al. 2018). Based on an analysis of 33,337 THAs from the FAR, 36-mm femoral heads decreased the dislocation revision risk significantly. The hazard ratio (HR) for dislocation revision was 0.5 (0.4–0.7) for 36-mm femoral head size compared to 32-mm head size (Panula et al. 2020). Several other registry and cohort studies also show that 22-mm and 28-mm

heads have higher dislocation rates compared with 32-mm and 36-mm heads (Byström et al. 2003, Amlie et al. 2010, Zijlstra et al. 2017). Computer modeling studies support the use of large femoral heads to avoid impingement and dislocation (Bunn et al. 2014). Increasing the head-neck ratio increases the hip ROM before impingement but may increase wear (Lachiewicz et al. 2016). In a prospective trial of 644 patients randomized to 28-mm or 36-mm femoral heads and followed up to 1 year, the incidence of dislocation was lower for hips with 36-mm heads (Howie et al. 2012). Burroughs et al. assessed ROM with 28, 32, 38, and 44 mm femoral heads using experimental hip models. They found that head size >32 mm provided greater ROM and virtually complete elimination of component-to-component impingement (Burroughs et al. 2005). In a cadaveric study using five head sizes of 22, 26, 28, 32, and 36 mm, Matsushita et al. reported that hip flexion and internal rotation improved in a head size-dependent manner (Matsushita et al. 2009, Shah 2019).

In THA, one should consider both prosthetic and bony impingement. Although the prosthetic impingement distance can be defined by the head diameter and neck thickness, the bony impingement distance would be expected to change in each case because each impingement point would be different according to the specific pelvic morphology (Ohmori et al. 2019).

Despite the advantages in ROM and in preventing dislocations, the use of larger femoral head sizes has been limited due to increased rates of polyethylene wear, especially while using MoP- or CoP articulate surfaces (Viceconti et al. 1996, Tarasevicius et al. 2008). Based on the existing evidence, for HXLPE bearings, a 32 mm CoCr (metal) or ceramic head appears to be a suitable choice. When using a 36 mm head with HXLPE, a ceramic head may be preferable over CoCr due to reduced risk of fretting and corrosion with the former (Shah 2019). For CoC bearings, head sizes >36 mm do not appear to provide any significant benefit over 36 mm heads. Also, large ceramic heads may lead to increased risk of squeaking (Shah 2019). However, according to data from the Australian Joint Replacement Registry (AOANJRR) for CoC bearings, head sizes 36–38 mm, and ≥ 40 mm had a lower rate of revision compared to 32 mm heads (AOANJRR 2018). According to a recent study by Castagnini et al., large-diameter heads in CoC THAs (≥ 40 mm) showed promising clinical and radiological outcomes with minimal revision rates. Squeaking is a cause of concern and should be carefully evaluated at longer follow-ups and in larger, prospective, and specifically designed case series (Castagnini et al. 2021).

2.3.3.1 Large head MoM THAs and HRAs

The trend towards larger diameter femoral heads has risen notably over the past decade. The increased size reduces the incidence of dislocation after THA. Larger heads also permit a greater ROM before impingement occurs. MoM prostheses

allow for larger and more anatomical femoral heads, having gained major popularity over the past 20 years because of this and the idea of lower bearing-surface linear wear than with MoP prostheses. According to a study by Seppänen et al., the revision rate because of dislocation in large diameter head (LDH) MoM was only 3% of all revisions, whereas in conventional THA it was 25% of all revisions at 12 years (Seppänen et al. 2018). The number of implantations peaked in 2008 consisting 21% of all primary prostheses, when analysis of registry data identified much poorer outcomes than for other types of implant (Mokka et al. 2013, Junnila et al. 2015, AOANJRR 2018). Failure of MoM -implants is due to metal ion debris generated at the bearing surface or taper junction. The debris can trigger an adverse immunological reaction (Adversed Reaction to Metal Debris, ARMD) resulting in localized bone destruction and soft tissue necrosis. The consequences of severe ARMD can be devastating.

MoM HRA and modular MoM THA both allow the use of large femoral heads, reducing the dislocation rate after primary THA (Lombardi et al. 2015). It has, however, become evident that ARMD is often associated with large-diameter head MoM THAs and HRAs. The 10-year implant survival of HRAs is 86% in Finland. The 10-year survival of the BHR in Finland is similar to that in England and Wales (91%). According to the current NICE recommendations, the revision rate of HRAs/THAs should be no higher than 5% by 10 years. Nowadays none of the HRAs achieve this goal. MoM devices are not used in Scandinavia today because of ARMD, which has proved to be a serious problem (Bolland et al. 2011, Mokka et al. 2013, Junnila et al. 2015).

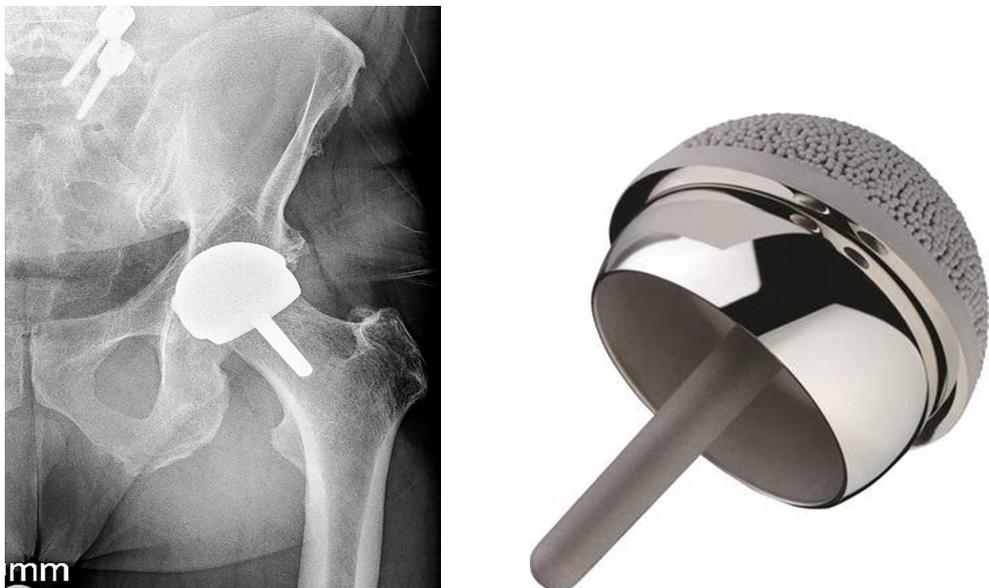


Figure 7. HRA implant (© Smith-Nephew, courtesy of Smith-Nephew).

2.3.4 Elevated liners

JD can be increased and therefore, dislocation risk reduced, by elevating the rim of the liner. A systematic review and meta-analysis by Guo et al. showed that an elevated rim liner can reduce the occurrence of dislocation after revision THA, and the risk of implant dislocation was 1.8 times higher in non elevated rim liner groups than in those with an elevated rim liner (Guo et al. 2017). Cobb et al. reported that the 2-year Kaplan-Meier probability of dislocation was 2.2% for hips with the elevated-rim liner and 3.9% for those with a standard liner (Cobb et al. 1996). This difference was significant. According to a study by Alberton et al., an elevated rim liner was significantly more stable when both components, acetabular and femur, were revised (Alberton et al. 2002).

However, the amount of build-up of the acetabular component and elevated rim should be limited by concerns of increased wear debris and restriction of motion, as well as of excessive force transmission from impingement of the neck of the femoral component on the rim of the acetabular cup (Cobb et al. 1996). Excessive augmentation or acetabular implant malpositioning with an elevated liner will cause the neck of the prosthesis to impinge and lever on the acetabular rim, forcing the head out of the cup anteriorly.

HXLPE acetabular liners were developed in an effort to reduce PE wear and the incidence of osteolysis. Recently, several studies with long-term follow-up have reported that HXLPE demonstrates superior wear resistance compared to conventional PE in primary THA (Shin et al. 2020). Highly cross-linking means using high-dose electron-beam radiation in the production of acetabular liners. This process fully cross-links broken molecular chains, leaving virtually no free radicals to promote oxidation.



Figure 8. Elevated and neutral liners.

2.3.5 Dual mobility cups and articulation

The concept of dual mobility was first introduced by G. Bousquet, A. Rambert and J. Rieu in the 1970s. The first dual mobility cup, introduced in 1979, was called NOVAE and combined two articulations, one large and one smaller, by a recruitment phenomenon increasing the JDs and thus decreasing the dislocation forces. Since 1996, 20 years after the first patent, many dual mobility cups have been developed with various designs and modes of fixation (Noyer and Caton 2017).

By using two articulations, dual mobility liners increases the JD by raising the head-neck ratio and hence the arc of motion available before impingement. Interest in dual mobility cups and liners is growing, thanks to their cost-effectiveness and effective use in high-risk patients undergoing THA and especially revision THA. (Plummer et al. 2016, Barlow et al. 2017). Dual- mobility liners are very useful and have good results in revision THA (Hailer et al. 2012a). Both uncemented modular cups and cemented monoblock cups are available, adding to their multipurpose feature.

In modern dual mobility cups and articulation surfaces, an HXLPE bearing contributes to both articulations -internally with the smaller femoral head (modern usually 28 mm), typically made of cobalt-chrome (CoCr) or ceramic, and externally with the acetabular component, which has a highly polished articulating surface of CoCr or titanium (Darrith et al. 2018). The latest generation of dual mobility cups combines: 1) a cast CoCr alloy cup covered with a bilayer coating of porous titanium and hydroxyapatite for long-term press-fit fixation with 2) an insert designed to eliminate all risks of intraprosthetic dislocation whilst keeping all of the elasticity properties of the polyethylene, which has demonstrated its medium and long-term effectiveness in preventing instability by overcoming other complications (Aslanian 2017). Modern dual mobility components use an outer head made of HXLPE, which is thought to have a lower rate of wear than previous PE components.

However, there is some concern about the long-term survival of these cups and articulations and possible original complications of these devices. The severe and known complication of this kind of articulation is intraprosthetic disassociation: the smaller femoral head remains in the acetabular component and the larger PE component lies disassociated and adjacent. This always demands a new surgical intervention. According to the literature, there is a 3.3% incidence of intraprosthetic dislocation in the older series of 22 mm heads coupled with less durable PE liners (Darrith et al. 2018). It is not known what the intraprosthetic dislocation rate is with modern 28 mm heads and more durable HXLPE liners.

According to a systematic review of the literature on primary dual mobility THAs, the incidence of aseptic loosening was 1.3%, the rate of intraprosthetic dislocation 1.1% and the incidence of extra-articular dislocation 0.5% (Darrith et al. 2018). The overall survivorship of the acetabular component and dual mobility components was 98%, with all-cause revision as the endpoint at a mean follow-up of 8.5 years. For revision dual mobility THAs, the rate of aseptic acetabular loosening was 1.4%, the rate of intraprosthetic dislocation 0.3% and the rate of extra-articular dislocation 2.2%. The survivorship of the acetabular and dual mobility components was 97% at a mean of 5.4 years. For dual mobility THAs undertaken in patients with a fracture of the femoral neck, the rate of intraprosthetic dislocation was 0.2%, the rate of extra-articular dislocation 2.3% and the survivorship 98% at a mean of 1.3 years (Darrith et al. 2018). The dual mobility cups had a lower risk of revision compared with conventional THA, based on data from the Nordic Arthroplasty Register Association (NARA) database, in 9,040 cases of hip replacements due to hip fracture (Jobory et al. 2019).

A study of the NARA database demonstrated no significant difference in the overall revision rate between dual mobility cups and MoP/CoP bearings. However, they found significant differences in the specific causes of the revisions, with the dual

mobility cups associated with a lower risk of revision due to dislocation and a higher risk of revision due to infection than the MoP/CoP bearings (Kreipke et al. 2019).



Figure 9. Cemented and uncemented dual mobility devices.

2.3.6 Constrained cups and liners

Constrained liners have a hemisphere greater than 180° that captures a bipolar or unipolar femoral head. ROM is reduced by the stability conferred by the capture of the femoral head. Constrained acetabular devices were developed to prevent dislocations after THA. However, the data on their success have been contradictory and the role of constrained cups in primary THA in preventing dislocations in high-risk patients has not been settled. Despite their advantages in terms of stability, constrained devices result in a restricted ROM and have a greater prevalence of impingement of the femoral neck on the cup. Impingement is responsible for high

stress transmission to multiple interfaces, possibly leading to liner damage, locking mechanism failure, dislocation, or loosening of the acetabular cup (Guyen 2016). The constrained acetabular device system is intended only for special situations in primary THA for patients at high risk of dislocation or revision THA to prevent further dislocations. Since constrained acetabular devices are used to resolve instability arising from various causes, they act as a mechanical substitute for poor biological support and are subjected to mechanical overload. The higher forces transmitted through the constrained articulation can contribute to reconstruction failure.

Dislocation because of component malpositioning cannot be treated only with a constrained device. Malposition of the femoral or acetabular component is associated with a high rate of failure in any constrained liner or device (Della Valle et al. 2005). It is obvious that appropriate decision-making and optimal component positioning to prevent dislocations in primary THA and dislocation revision surgery are mandatory for successfully preventing further dislocations or for the success of any constrained device. However, today there is a wide range of constrained devices, that give quite different results in terms of their survival, prevention of dislocation, ROM, and impingement.

Noble et al. retrieved the constrained components of four different designs at revision THA and examined them for the presence of rim impingement, cracks within the liner, and backside wear. Failure of the locking ring was responsible for 51% of failures, whereas 28% of revisions resulted from acetabular cup loosening, 6% from backside wear, and 22% from infection. Impingement damage of the rim of the polyethylene liner was seen in all retrievals (Noble et al. 2012). One factor explaining higher infection rates for patient treated with a constrained device might be a more fragile patient group. This is more likely to be associated with patients selection than with the implant itself, as constrained acetabular devices are used in frailer patients at increased risk of infection. Failures at the acetabular bone – prosthesis interface due to inadequate fixation of the shell and increased bone-implant interfacial stress are also well described (Cooke et al. 2003, Ito and Matsuno 2004). Long-term outcome of constrained devices with reduced ROM has demonstrated very poor results, with high re-dislocation rates and a high rate of aseptic loosening (Berend et al. 2005).

A novel constrained device (Freedom® Biomet, Inc., Warsaw, IN) that allows a substantially higher ROM before impingement compared with earlier constrained devices, has shown promising short- and medium-term results of component survival and prevention of dislocation in primary THA for high-risk patients as well as in more demanding revision surgery (Berend et al. 2006). However, evaluation of potential very long-term complications like wear, osteolysis, and loosening is still deficient.



Figure 10. Cemented and uncemented constrained devices.

The use of constrained devices in selected patients can be successful, but its use should be restricted to patients whose stability cannot be achieved by any other method. Component malpositioning should be avoided. The used device type is also essential. Constrained implants are expected to provide hip stability in the face of high stress and unusual force, but further long-term data on prevention of dislocation, component related failure, and other complications of revision surgery are still needed (Berend et al. 2006).

2.3.7 Computer-assisted and robotic guidance in THA

Various systems of computer-assisted orthopedic surgery (CAOS) in THA have been developed since the early 1990s. These include computer-assisted preoperative planning, robotic devices, navigation, and patient-specific surgical templates. Precision is enhanced more when computer navigation is elevated to the next level,

which is robotic guidance. The preoperative plan set by the surgeon is executed by the robotic tool while the surgeon manually controls the robotic arm. Robotic-guided orthopedic surgery in THA provides numerical data for cup inclination and anteversion as well as center of rotation, femoral leg length, and offset including combined anteversion of the cup and stem. Robotic guidance prevents human error, as bone preparation cannot exceed the boundaries the surgeon has set in advance. The acetabular bone preparation is done with a reamer connected to a robotic arm, which prevents the surgeon from mistakenly reaming off -line or too deep. This modern technology provides predictable and reproducible results.

A study by Kamara et al. assessed whether adopting robotic techniques improves acetabulum positioning compared to manual THA during the surgeon's learning curve. According to this study, adoption of robotic techniques delivers significant and immediate improvement in the precision of acetabular component positioning during the learning curve (Kamara et al. 2017). According to the study of Domb et al., robotic -guided techniques were more consistent than other techniques in placing the acetabular cup into the Lewinnek safe zone and within the Callanan safe zone (Domb et al. 2015). Another study by Domb et al. on robotic guidance in THA was effective in correcting the native femoral version toward a target of 15°. This could be achieved using both the anterior and posterior approach and it was not affected by BMI (Domb et al. 2017). In a study by Elmallah et al., they prospectively reviewed the use of robotic-arm assisted surgery in 224 patients. Pre-determined anteversion and inclination of acetabular cups were 15 and 40 degrees, respectively. Their results showed that the use of robotic-arm assisted surgery resulted in a post-operative mean inclination of 40 degrees and a mean anteversion of 16 degrees. Ninety-nine percent of the patients remained within the pre-designated safe zone (Elmallah et al. 2015).



Figure 11. Hip- and knee arthroplasty robot (© Stryker, courtesy of Stryker).

The planning of robotic-guided navigation based on computed tomography (CT), in addition to preoperative planning with CT images, takes time that increases both cost and radiation exposure. Although robotics help improve the accuracy of surgery in THA, broad clinical applications of these systems is hindered by the high cost, additional time during intervention, intraoperative human-machine interaction issues, and the spatially constrained arrangements of additional equipment within the operating room (Sugano 2013). In CAOS it is still important that the surgeon fully understands what they should be trying to achieve in THA for each patient. In the future, CAOS may enable the surgeon to operate more accurately and may lead to improved outcomes in THA as the technology continues to evolve rapidly (Chang et al. 2017). However, although the benefits of this technology are evident in component positioning, it has not been shown to improve patient outcomes or patient-reported outcome measures (PROM) or justify the added financial burden imposed. Cost-effectiveness has been demonstrated only for high-volume centers.

Furthermore, improvement of accuracy has only been shown among lower volume surgeons. Further research is needed to determine if this technological advancement will translate into improvements in longevity and clinical outcomes (Werner et al. 2014).

2.4 Prevention and treatment of dislocation in revision THA

The main risk factors for instability after a revision total hip arthroplasty (rTHA) are not the same as those after a primary procedure. The cause of dislocation after revision is related to multiple factors such as patient characteristics, revision etiology, component orientation, location of the hip center of rotation, limb length and status of the hip abductor mechanism and muscles around the hip. Many previous studies demonstrate that the number of previous revisions is a risk factor for further dislocation revisions (Khatod et al. 2006, Carter et al. 2011). Jo et al. noted that a history of more than two previous hip surgeries was identified as a patient -related risk factor associated with dislocation (Jo et al. 2015). A systematic review and meta-analysis by Guo et al. found that the risk of implant dislocation was 2.2 times higher in the patient groups with ≥ 3 revisions than in groups with < 3 prior revisions. This same meta-analysis also found that the risk of implant dislocation was 2.0 times higher in groups with ≥ 2 prior revisions than in groups with < 2 prior revisions (Guo et al. 2017).

Acetabular revision, femoral revision, or both is advised in patients with recurrent dislocation when component position is not satisfactory. Component alignment should be scrutinized at rTHA, and all possible attempts should be made to correct any malposition. Malposition cannot be treated only by constrained devices. The final construct, constrained or unconstrained, should allow a functional ROM without impingement, as this likely leads to mechanical failure, loosening, or both (Berend et al. 2006).

The extent of soft-tissue dissection is probably the most important variable since head size and trochanteric nonunion are related to "soft-tissue tension". Modular acetabular components with an elevated rim help to stabilize a hip undergoing a revision procedure (Alberton et al. 2002). However, often in rTHA this is insufficient. According to a study by Hernigou et al., obese patients should be counselled about the important risk of dislocation that occurs with standard liners after revision THA. Dual-mobility liners in these patients with hip revision is an efficient technique to prevent post-operative hip dislocation (Hernigou et al. 2017). Gonzalez et al. found that the risk of dislocation within the first 6 months after rTHA was substantially reduced with the use of a dual-mobility cup rather than a unipolar cup (Gonzalez et al. 2017). In a study by Wegrzyn et al., dual- mobility cups

demonstrated a low dislocation rate of 1.5% at a 7.3-year mean follow-up time in 994 rTHA procedures. Their results emphasize the ability of dual mobility cups to reduce the risk of instability even in cases of acetabular-only revisions (Wegrzyn et al. 2015). A study of the Swedish Hip Arthroplasty register hypothesized that the use of dual-mobility cups would result in a low risk of re-revision due to dislocation after rTHA in the short term (Hailer et al. 2012a).

However, it must be membered that dual mobility cups do not compensate for potential perioperative technical errors in rTHA. Optimal orientation of the dual mobility cup and restoration of the abductor mechanism and leg length should be achieved during revision. An absolute advantage of dual mobility cups is also their utility in complex revision procedures. Dual mobility cups also allow a larger femoral head size than would otherwise be possible. Cemented dual mobility cups mainly ensure satisfactory positioning of the bearing surface cup despite acetabular reconstruction (Fig. 12).

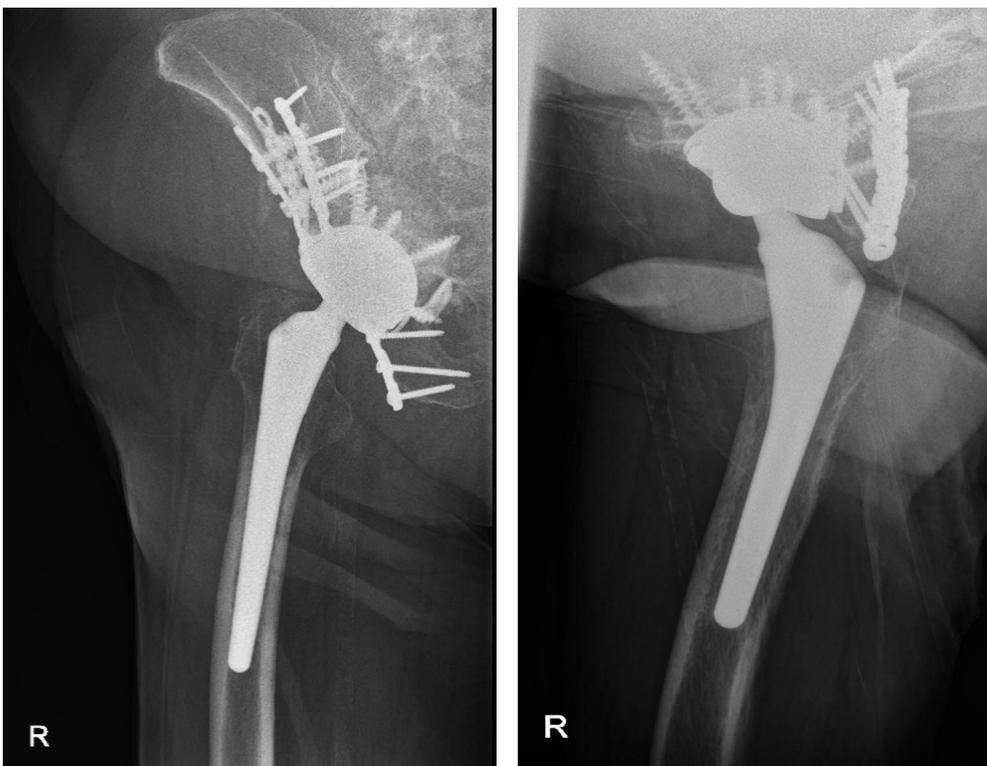


Figure 12. Cemented dual-mobility cup used in rTHA with posterior internal fixation of acetabular fracture and restoration acetabular cup with autologous bone grafting.

One strategy has been to use a constrained acetabular cup, which physically closes the acetabular insert over the femoral head after intraoperative reduction. Although this may prevent instability of the articulation, the ROM of the implant is potentially compromised (Noble et al. 2012). According to the prior literature, limiting the use of some constrained liners to salvage situations of recurrent instability (Guyen et al. 2008). Constrained acetabular cup use is supported in iterative rTHA associated with severe abductor mechanism alteration when previous attempts to stabilize the hip with a dual mobility cup have failed. An inevitable consequence with constrained liners is reduced ROM and a greater prevalence of impingement, especially with flexion and internal rotation. Forces that would otherwise lead to dislocation are transferred to the rim and the shell of the constrained component. These forces are high in cases where normal biomechanical support has decreased, like in revised THAs. Failure of the locking liner ring and loosening of the acetabular cup are the primary causes of mechanical failure with constrained liners in rTHA. Including separation of the femoral head from the constrained liner is possible (Berend et al. 2005). In conclusion in the study by Noble et al., their observations show constrained acetabular cups subject to large contact forces in service, making them vulnerable to multiple wear mechanisms in rTHAs (Noble et al. 2012). However, it must be kept in mind that these challenging revision cases could not be treated in any other way, and the demand for constrained devices is very high.

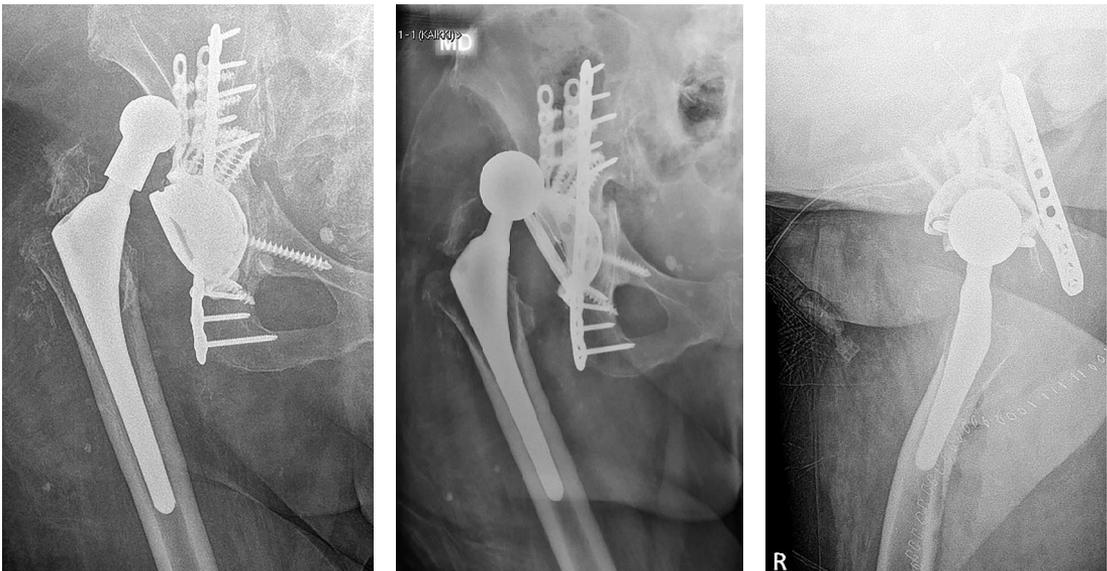


Figure 13. Complicated hip in which both dual-mobility and constrained device has failed.

3 Aims of the Present Study

The main purpose of this study was to assess preventive methods for dislocation after THA. We evaluated the failure rate of the Biomet Freedom constrained liner (Biomet, Warsaw, IN, USA) as a preventive method in high dislocation risk patients in primary THA based on FAR data, and as a preventive method or treatment for dislocation in rTHA surgery based on Turku University Hospital medical records. Further, we assessed LDH MoM HRA medium- to long-term outcomes and the reasons for revision based on FAR data. In addition, we compared implant survival of Continuum acetabular cups with other commonly used uncemented cups, with special attention to revision for dislocation and elevated liners as prevention for dislocation.

The specific aims were to investigate the following:

- Study I:** To assess the failure rate of the Biomet Freedom constrained acetabular device (Biomet, Warsaw, IN, USA) either in revision surgery for recurrent dislocation, or as a preventive method in high dislocation risk patients based on Turku University Hospital medical records.
- Study II:** To assess the medium- to long-term survivorship of LDH MoM HRA and reasons for revision based on FAR data.
- Study III:** To compare implant survival and reasons for revision for Continuum acetabular cups with other commonly used uncemented cups and the effect of an elevated liner on prevention of dislocation based on FAR data.
- Study IV:** To assess implant survival of the Biomet Freedom constrained acetabular device (Biomet, Warsaw, IN, USA) in primary THA based on FAR data.

4 Materials and Methods

4.1 Patients

4.1.1 Study I

Study I was a retrospective study based on data collected from the electronic medical record database of Turku University Hospital.

One hundred and five consecutive surgical procedures in 103 patients in which a Freedom constrained liner or cup was used in Turku University Hospital between 2007 and 2014 were assessed retrospectively. Forty-two Freedom constrained liner applications were performed as treatment for recurrent dislocations in revision THA. Eleven of the preventive constrained liner cases were used in primary THA, and 52 in revision THA. Indication for using a constrained liner in primary THA in the preventive group was neurological disorder in one case (Down syndrome), alcohol abuse in one, abductor deficiency in six, and trochanter major fracture in three cases. Indication for using a constrained liner in revision THA in the preventive group was abductor deficiency due to infection or ARMD in 19 cases, trochanter major fracture in 25, poor gluteal muscles in three, dysplastic hip in two, previous proximal femoral fracture in two cases, and alcohol abuse in one case.

Fifty-eight Freedom liners were inserted into a Regenerex cup (Biomet, Warsaw, IN, USA), 15 into a Vision cup (Biomet, Warsaw, IN, USA), 10 into a Universal cup (Biomet, Warsaw, IN, USA), 16 were cemented into a Trabecular Metal revision shell (Zimmer, Warsaw, IN, USA), four were cemented directly into the acetabulum, one was cemented into an revision shell of another manufacturer, and one into a Universal cup.

In the preventive revision group, 32 Freedom liners were inserted into a Regenerex cup, four into a Vision cup, three into a Universal cup, 10 were cemented into a Trabecular Metal revision shell, and three were cemented directly into the acetabulum.

In the recurrent dislocation group 15 Freedom liners were inserted into a Regenerex cup, 11 into a Vision cup, eight into a Universal cup, and seven were cemented into a Trabecular Metal revision shell, and one into a Universal cup. Fourteen hips had dislocated once or twice, nine hips 3–4 times, three hips 5–10 times, and 16 hips more than 10 times when the Freedom device was inserted.

4.1.1.1 Study device in studies I and IV

The Biomet Freedom constrained liner system is intended for use only in special situations where the patient has a high risk of dislocation due to a previous history of dislocation, severe joint laxity, and/or palsy of surrounding musculature and abductor muscle deficiency. The device incorporates an equatorial flat section at 15 degrees to the vertical axis along the sides of the Freedom liner and modular CoCr head, which is always 36 mm in diameter. The components are manufactured so that fluid creates a suction effect between the head and liner. The Freedom device provides 110 degrees ROM, and lever-out strength of 198 inch-lbs (90 kg) (Berend et al. 2006). The acetabular liner can be locked into a standard locking mechanism for use in primary and revision acetabular components. A cemented version is available for cementing into a well-fixed acetabular shell of differing locking design, or in cases when the locking mechanism is no longer functioning properly (Fig.14).

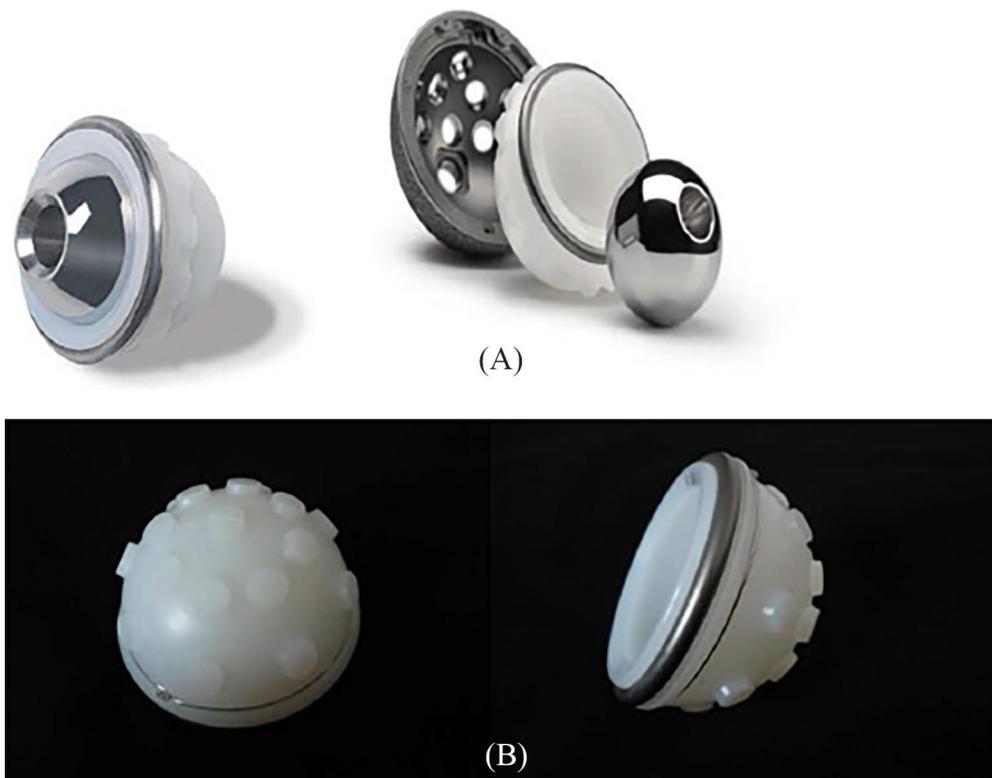


Figure 14. A) Freedom constrained liner made of ArCom isostatically molded polyethylene, and a titanium constrained ring. **B)** Freedom constrained cemented cup. (© Zimmer Biomet, courtesy of Zimmer Biomet).

4.1.2 Studies II, III and IV

Studies II, III, and IV are retrospective studies based on prospectively collected FAR data. Joint replacement registries are powerful resources for tracking the revision rate of individual implants. Since the first hip arthroplasty registry was established in Sweden 40 years ago, they have proven successful in identifying devices with high failure rates (De Steiger et al. 2011).

The FAR covers most of the total hip implants performed in Finland since 1980 (Paavolainen et al 1991, www.thl.fi/far). Orthopedic units are obligated by law to provide all the information essential for maintenance of the register to the Finnish Institute for Health and Welfare. In Finland, the data completeness for primary THA is >95%, and for revision THA 81% (FAR 2018). Dates of death are obtained from the Population Information System maintained by the Population Register Center. Since May 2014, implant identification has been performed by electronic scanning of reference codes in operating theaters, and the operative information is then sent electronically to the register. The updated data nowadays also include detailed information on items like ASA class, BMI, surgical approach, intraoperative bleeding, reason for revision, and duration of procedure.

In study II, six HRA designs used in at least 100 operations during the study period 2001–2013 were included (Table 1). There were 5,068 HRAs altogether, of which 4,474 (88%) were performed for primary osteoarthritis, 323 (6.4%) for secondary osteoarthritis, 47 (0.9%) for rheumatoid arthritis, 26 (0.5%) for other inflammatory arthritis, 68 (1.3%) for congenital dislocation of the hip, and 130 (2.6%) for other indications. The reference group consisted of 6,485 uncemented Vision/Bimetric THAs (Biomet, Warsaw, IN, USA) and ABG II THAs (Stryker, Mahwah, NJ, USA) performed during the same period. Demographic data are presented in Table 2.

Table 1. HRA designs used in ≥100 operations during the period 2001–2013 in Finland.

Implant design	N	%
BHR	2,141	42
ASR	1,051	21
ReCap	846	17
Conserve Plus	579	11
Durom	350	7
Cormet	101	2
Total	5,068	100

Table 2. Demographic data for hip resurfacing arthroplasty (HRA) and total hip arthroplasty (THA), used for reference.

	HRA	reference THA
	n = 5,068	n = 6,485
Mean follow-up (range), years	6.8 (0.0–12.7)	7.9 (0.0–13.0)
Median follow-up, years	7.0	8.8
Mean age (range), years	54 (9–86)	64 (15–97)
Males, %	67	46
Implanting period	2001–2013	2001–2013
No. of hospitals	49	65
Diagnosis, % primary osteoarthritis	88	84

In study III, based on FAR data from January 2009 to December 2017, we assessed 133,488 primary THAs. In 11,390 of these the Continuum primary cup was used. The reference group consisted of procedures using the six other most commonly used uncemented cups made of titanium alloy (n = 30,372) (Table 3). A head size other than 28 mm, 32 mm, or 36 mm, dual mobility, and constrained liners were excluded. The number of patients with bilateral hip prostheses was 4,407 and in 658 patients both hips were operated simultaneously. 498 patients had the Continuum cup in one hip and a control group cup component in the contralateral hip. Table 4. show the demographic data hip-wise separately after the data content revision in May 2014. Mortality during the study period in the Continuum group was 4% and in the control group 5%.

In the Continuum group, 36 mm femoral heads were used in 79% of cases. The corresponding proportion in the reference group was 80%. A ceramic liner was used in 14% of cases in the Continuum group and in 27% of cases in the reference group. The rest were HXLPE liners in both groups. Surgical approach data have been available from the register since May 2014, with most operations performed via the posterior approach in both groups (79% in the Continuum group and 81% in the reference group). Uncemented femoral stems were used in 71% of cases in the Continuum group compared with 83% in the reference group.

Table 3. Acetabular cups included in the study.

Cup design	N (%)
Continuum (ZimmerBiomet, Warsaw, IN, USA)	11,390 (27)
Reference group	30,372 (73)
•Exceed (ZimmerBiomet, Warsaw, IN, USA)	1,550 (4)
•G7 (ZimmerBiomet, Warsaw, IN, USA)	1,121 (3)
•Pinnacle (DePuy, Warsaw, IN, USA)	14,844 (36)
•R3 (Smith & Nephew, Andover, MA, USA)	7,289 (18)
•Trident (shell) (Stryker, Mahwah, NJ, USA)	4,279 (10)
•Vision Ringloc (ZimmerBiomet, Warsaw, IN, USA)	1,280 (3)

Table 4. Demographic data of the time period after data content revision in the Finnish Arthroplasty Register starting May 15, 2014. Values are frequency (%) unless stated otherwise.

	Continuum group	Reference group
Mean age (SD)	67 (11)	66 (11)
BMI (SD)	28 (5)	28 (5)
Male sex	3,609 (42)	7,547 (46)
Diagnosis		
•Primary osteoarthritis	7,324 (85)	13,852 (85)
•Rheumatoid arthritis	137 (2)	195 (1)
•Other ^a	1,113 (13)	2,278 (14)
Femoral head size of prosthesis		
•28 mm	29 (0.3)	107 (1)
•32 mm	1,832 (21)	3,369 (21)
•36 mm	6,713 (78)	12,849 (79)
Status at end of follow-up		
•Not revised	8,202 (96)	15,792 (97)
•Revised	372 (4)	533 (3)
Liner material		
•Ceramic	619 (7)	2,249 (14)
•Highly cross-linked polyethylene	7,955 (93)	14,041 (86)
Elevated liner		
•No	4,385 (55)	8,648 (62)
•Yes	3,570 (45)	5,393 (38)
Approach		
•Posterior	6,654 (78)	12,884 (81)
•Anterolateral (modified Hardinge)	1,667 (20)	2,864 (18)
•Anterior (Watson-Jones)	15 (0.2)	11 (0.1)
•Anterior (Smith-Peterson)	143 (2)	137 (1)
Trochanteric osteotomy performed	1 (0.01)	1 (0.01)
ASA class		
•1	1,281 (15)	2,163 (14)
•2	4,132 (49)	8,260 (52)
•3	2,992 (35)	5,308 (33)
•4	104 (1)	189 (1)
Femoral stem fixation		
•Uncemented	5,502 (65)	13,209 (81)
•Cemented	3,030 (36)	3,057 (19)

In study IV, we evaluated the FAR data. The device under study was the Freedom (Zimmer Biomet, Warsaw, IN, USA) constrained acetabular device system, which was introduced in Finland in 2006 and is currently the most commonly used constrained device in the country.

Between January 2006 and December 2017, 373 primary THAs were performed using either a cemented constrained cup (n=220) or constrained liner attached to an

uncemented cup (n=153). The uncemented cups used with the liner were Vision RingLoc (Zimmer Biomet, Warsaw, IN, USA), Regenerex (Zimmer Biomet, Warsaw, IN, USA), Exceed (Zimmer Biomet, Warsaw, IN, USA), and Trabecular Metal shell (cemented constrained cup) (Zimmer Biomet, Warsaw, IN, USA). The head size used with the constrained device is always 36 mm because of the eccentric head mold. The reference group consisted of conventional THAs with 36-mm femoral head size performed during the same period from 2006 to 2017. The groups were matched by age group (<49, 50–54, 55–59, 60–64, 65–69, 70–74, 75–79, 80+ years), sex, and diagnosis (primary osteoarthritis, rheumatoid arthritis, other) at 1:3 ratio, making a total of 1118 THAs in the reference group (Table 5). The most common cup models used in the reference group were Continuum (Zimmer Biomet, Warsaw, IN), Pinnacle (DePuy, Warsaw, IN, USA), Trident (Stryker, Mahwah, NJ, USA), Exeter (Stryker, Mahwah, NJ, USA), and Lubinus (Waldemar Link, Hamburg, Germany).

Table 5. Demographic Data. Percentage values in parentheses (%). SD, standard deviation.

Data	Constrained Acetabular Device	Reference
Mean age years and SD	71.0, SD: 12.1	70.5, SD: 12.0
Mean follow-up time in years, minimum-maximum	3.3, 0–12.4	3.8, 0–12.0
Age group		
<49	17 (4.5)	51 (4.5)
50–54	15 (4.0)	45 (4.0)
55–59	28 (7.5)	84 (7.5)
60–64	43 (12)	129 (12)
65–69	61 (16)	183 (16)
70–74	48 (13)	144 (13)
75–79	64 (17)	192 (17)
80+	98 (26)	293 (26)
Gender		
Male	163 (44)	489 (44)
Female	211 (56)	632 (56)
Diagnosis		
Primary osteoarthritis	78 (21)	234 (21)
Rheumatoid arthritis	4 (1.1)	12 (1.1)
Other	292 (78)	875 (78)
Status		
Not revised	352 (94)	1069 (96)
Revised	21 (6)	49 (4)
Operation year	2006–2017	2006–2017

4.2 Methods and statistical analyses

4.2.1 Study I

In study I, the information concerning operative reports and follow-up visits was collected retrospectively from the electronic medical record database of Turku University Hospital. The mechanical failure rate and revision rate for any reason after use of the Freedom constrained cup and liner application were assessed. Data cut-off was set at mechanical failure, and revision (preventive Freedom cup in primary THA) or re-revision (preventive Freedom cup/liner in revision THA and treatment of recurrent dislocations in THA) for any reason by 14 November 2014 (Table 6). A total of 14 patients died during the follow-up period. Data collected included demographic information, indication for using a constrained device, number of previous dislocations, reason for revision, type of revision, surgical approach, diagnosis of a neurological disease like Parkinson's and Alzheimer's or alcohol abuse, complications, re-operations, and death of the patient. The number of male patients was 53 (51%). The average age at the time of constrained component insertion was 73.4 years (range 40.1–92.2 years). The mean follow-up time was 2.5 years (range 3 days–7.5 years).

Table 6. Patient characteristics at index surgery.

	All	Freedom liner to prevent dislocations in revision THA	Freedom liner for the treatment of recurrent dislocations	Freedom liner to high dislocation risk patients in primary THA
Number of surgical procedures	105	52	42	11
Number of patients	103	52	42	9
Number of male patients	53	28	20	5

THA: total hip arthroplasty

Continuous variables were described by means and standard deviations (SDs) and categorical variables by frequencies and percentages. The associations between mechanical failure and risk factors were analyzed with logistic regression. Results were expressed by odds ratios (ORs) and 95% confidence intervals (95% CIs). The cumulative percentages for implant survival were estimated with the Kaplan-Meier technique for any reason of revision. P-values less than 0.05 were considered

statistically significant. Statistics were run on the Statistical Analysis System (SAS) for Windows, Version 9.3 (SAS Institute, Inc., Cary, NC, USA).

4.2.2 Study II

In study II, the survival of HRA devices and reference arthroplasties was assessed by Kaplan-Meier analysis. The Cox multiple regression model was used to assess differences in revision rates of the HRA devices and to adjust for any confounding factors. Revisions were linked to the primary operation through the personal identification number. The survival endpoint was defined as revision, when either one of the components or the entire implant was removed or exchanged. Revision for any reason served as an endpoint. Kaplan-Meier survival data were used to construct the survival probabilities of implants, with 95% confidence interval (CI). HRA and THA devices of patients who died or left Finland during the follow-up period were regarded as having survived until that point. The factors studied with the Cox model were HRA device, age group, sex, diagnosis, femoral head size (classified as ≤ 44 mm, 45–49 mm, 50–54 mm, and ≥ 55 mm) and hospital production volume of arthroplasties (≥ 100 or < 100 procedures).

The Cox analysis between the whole HRA group and the reference THA group showed that these factors were not useful. The sizes of the femoral heads of the reference THA group were smaller than those of the HRA group. Diagnosis and hospital volume had no effect and were censored. Female sex had no effect in the reference THA group, but the effect in the HRA group was strong and negative. Several age groups were tested, but age did not emerge as a significant factor in either group. After careful analysis, we decided to compare the HRA group and the reference group without consideration of these potentially confounding factors.

The proportional-hazards assumption of the Cox models was checked by inspecting the corresponding log-log graphs. For Cox analyses comparing the HRA brands and the reference THA group, we divided the total follow-up time into three periods (first year, second and third year combined, and fourth year onwards), because the proportional-hazards assumption was not fulfilled for the total follow-up.

Death of the patient and revision are competing risk in registry studies. We therefore repeated the analyses without the patients who died during follow-up (3.2% in the HRA group and 14% in the THA group). Furthermore, we performed competing risk analyses using Stata 14 statistical software.

Inclusion of bilateral cases in a survival analysis violates the basic assumption that all cases are independent. However, several reports have shown that the effect of including bilateral cases in studies of hip and knee joint prosthesis survival, as was done in our study, is negligible (Robertsson and Ranstam 2003, Lie et al. 2004). The Wald test was used to test the estimated hazard ratios. Differences between

groups were considered statistically significant if the p-values were less than 0.05 in a two-tailed test.

4.2.3 Study III

In study III, the average follow-up time was 3 years (0–9) in the Continuum group and 4 years (0–10) in the reference group. Kaplan –Meier survival estimates were calculated for both groups, and the log rank test was used to compare the survival curves. Revision was described as change or removal of at least one component (Table 7). To reduce the risk of selection bias we adjusted the estimated revision risks in the Cox multiple regression model by sex, age group, diagnosis, femoral head size, operated side, operation year, and fixation of the femoral stem. An additional cup revision analysis was performed, and the type of approach, ASA, BMI, and elevation status of the liner were added to the Cox model as possible confounders for cup revision for any reason as the endpoint. The analysis was done with data on primary operation following the register update in May 2014. In the Continuum elevation subgroup analysis sex, age group, diagnosis, side, stem fixation, and operation year were added to the Cox model (head size was stratified), and other than polyethylene liners were excluded. If the proportional hazards assumption for a variable was not fulfilled in the Cox model, the model was stratified by it instead. Stratification in Cox models means that the hazard functions can be estimated for all level combinations of the stratified variables, and the hazard ratios for the other variables (those that meet the proportional hazard assumption) are then optimized for all these hazard functions. Without stratification we would assume that the hazards were the same for all levels of such variables.

Table 7. Indication for revision after new indications for revision were added following the data content revision (May 15, 2014) of the FAR. Values are frequency (%).

Main reason for revision ^a	Continuum group	Reference group
Aseptic loosening		
•Cup	5 (1)	10 (2)
•Stem	15 (4)	26 (4)
Osteolysis		
•Cup	2 (1)	8 (1)
•Stem	1 (0.3)	11 (2)
Liner wear	0 (0)	2 (2)
Component breakage		
•Cup	0 (0)	1 (0.2)
•Liner	1 (0.3)	11 (2)
•Head	1 (0.3)	1 (0.2)
•Modular neck	0 (0)	1 (0.2)
Infection	100 (26)	194 (30)
Dislocation	132 (34)	153 (24)
Component malposition		
•Cup	12 (3)	23 (4)
•Stem	1 (0.3)	14 (2)
Periprosthetic fracture		
•Acetabulum	6 (2)	2 (0.3)
•Femur	73 (19)	105 (17)
ARMD	2 (1)	5 (1)
Squeaking	2 (1)	5 (1)
Unexplained pain	10 (3)	32 (5)
Leg length discrepancy repair	4 (1)	10 (2)
Other	17 (4)	24 (4)

^a No data available concerning indication for revision from 83 revisions

The primary outcome was revision for any reason and the secondary outcomes were revision for periprosthetic infection, revision for dislocation, and cup revision for any reason. Patients were censored for any event other than the outcome, or at the end of the follow-up. Since the register update in May 2014 it has been possible to assess separately which component has been changed or removed in connection with the revision. Therefore, a subgroup analysis for cup-only- revisions was performed only for the newest FAR data. In addition, a subgroup analysis was performed for Continuum cups by liner type (neutral or elevated liner) with dislocation revision as the endpoint. Survival data are presented as percentages with the 95% CI. Cox regression analysis is presented with the HR and the CI.

All analyses were performed using the SAS software (Version 9.3; SAS Institute, Cary, NC, USA).

4.2.4 Study IV

In study IV, implant survival for the constrained acetabular device and reference groups was calculated from the corresponding cumulative incidence function adjusted for patient death as a competing event for revision for any reason and revision for any aseptic reason as the endpoints. Mortality in the constrained acetabular device group as a whole was 51.7%, and in the control group, 16.3%. Therefore, we used competing risk survivorship analysis instead of Kaplan-Meier survivorship. In a Cox regression model, implant revision HRs with 95% CIs for any reason for revision were assessed. Implant revision HRs were also assessed separately for revisions performed due to dislocation and for revisions for infection.

Including stem fixation in the Cox model as a confounding factor did not change the results, and as stem fixation data were missing from 60 operations in the constrained acetabular device group (16% of all hips in the constrained device group), we decided to exclude it from the model.

Revisions were linked to the primary operation through a personal identification number. The survival endpoint was defined as revision when either one of the components or the entire implant was removed or exchanged, including isolated liner exchanges. Patients who died during the follow-up period (until December 31, 2017) were censored at that point. Mean follow-up time was 3.3 (0–12.4) years for the constrained acetabular device group and 3.8 (0–12.0) years for the reference group.

The proportional hazards assumption of the Cox models was checked by inspecting the corresponding log-log graphs. For Cox analyses comparing the constrained device group with the reference group, we divided the total follow-up time into three periods (1 to 1.5 years, 1.5 to 3 years, and the 4th year onwards), as the proportional hazards assumption was not fulfilled for the total follow-up.

Inclusion of bilateral cases in a survival analysis violates the basic assumption that all cases are independent. However, several reports have shown that the effect of including bilateral cases in studies of hip and knee implant survival is negligible (Robertsson and Ranstam 2003, Lie et al. 2004). Therefore, in this study, we included seven patients with a primary constrained acetabular device THA in both hips (14 hips altogether), 43 patients with a conventional THA in both hips (86 hips altogether), and one patient with a constrained device THA in one hip and conventional THA in the other.

The Wald test was used to test the estimated HRs. Differences between the groups were considered statistically significant if the p-values were <0.05 in a two-tailed test.

5 Results

5.1 Studies based on Turku University Hospital medical records (Study I)

5.1.1 Freedom Constrained liner for the treatment and prevention of dislocation

A total of four out of 105 Freedom constrained hips dislocated due to impingement and failure of the locking mechanism. In these four cases there was notable malpositioning of the acetabular cup, femoral stem, or both. There were also two out of 105 loosening cases. In one loosening case the uncemented Freedom liner was cemented directly into the pelvic bone, and dissociated after only two weeks. In the second loosening case, the liner attached normally with the Ringloc mechanism into an uncemented cup loosened, probably due to impingement of the remaining osteophytes. Thus, the mechanical failure rate of the Freedom device was six out of 105 (5.7%). None of the 11 preventive primary THAs failed, four out of 52 (7.7%) preventive revision THAs failed, and two out of 42 (4.8%) of the treated dislocation cases failed.

There were two infections which were treated by lavation and exchange of the modular parts, including the Freedom liner and femoral head. Five-year Kaplan-Meier survivorship of the Freedom device for any reason of revision was 74% (Fig. 15). Mean time to failure after the index Freedom operation was 0.9 years (range 14 days–2.9 years).

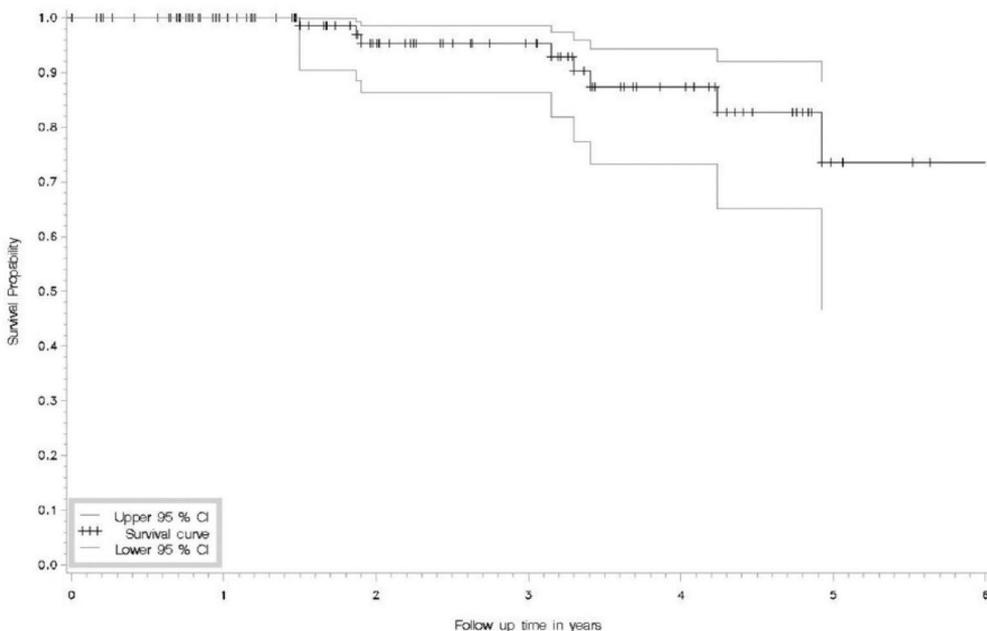


Figure 15. Kaplan–Meier survivorship of the Freedom device for any reason of revision with 95% confidence intervals.

5.2 Studies based on the Finnish Arthroplasty Register (Studies II, III, IV)

5.2.1 10-year survivorship of hip resurfacing arthroplasty

Sixty-seven percent of the HRA patients were male and the mean age of the study population was 54 (9–86) years. Primary osteoarthritis was the most common diagnosis (88%) (Table 2). The main reason for revision of HRAs was aseptic loosening of both components (40%), whereas THAs were most often revised due to dislocation (26%). Unspecified reasons for revision ("other") were recorded for 24% of HRA revisions and for 10% of THA revisions (Table 8).

Table 8. Reasons for revision. Values are n (%): (a: Including ARMD).

	HRA	reference THA
Reason for revision	n = 5,068	n = 6,485
Aseptic loosening of		
both components	215 (40)	96 (19)
the cup	53 (10)	22 (4)
the stem	18 (3)	23 (4)
Infection	17 (3)	33 (7)
Dislocation	6 (1)	132 (26)
Malposition	45 (8)	49 (10)
Fracture	49 (9)	85 (17)
Implant breakage	3 (1)	18 (4)
Other reason ^a	131 (24)	49 (10)
All	537	507

The 10-year Kaplan-Meier survival was 86% (95% CI: 84–87) for the HRA group and 92% (95% CI: 91–92) for the reference THA group (Fig. 16 and Table 9).

Table 9. Survival of HRA devices and reference THA group. Endpoint defined as revision of any component for any reason. Survival rates according to Kaplan-Meier analysis.

	n	Follow-up, years	At risk	5-year survival	At risk	8-year survival	At risk	10-year survival
		Mean (range)	5 years	(95% CI)	8 years	(95% CI)	10 years	(95% CI)
BHR	2,141	7.6 (0.0–12.7)	1,703	96 (95–97)	1,146	93 (92–94)	698	91 (89–92)
ASR	1,051	6.5 (0.0–9.8)	864	88 (86–90)	253	72 (69–76)	0	–
ReCap	846	5.5 (0.0–9.7)	546	94 (93–96)	183	91 (89–94)	0	–
Conserve Plus	579	5.3 (0.0–8.7)	428	95 (93–97)	6	–	0	–
Durom	350	6.9 (0.0–9.1)	326	95 (93–98)	103	92 (89–96)	0	–
Corin (Cormet)	101	9.1 (0.7–11.6)	95	94 (89–99)	72	92 (87–97)	46	86 (78–94)
All HRAs	5,086	6.8 (0.0–12.7)	3,848	94 (93–94)	1,724	88 (87–89)	701	86 (84–87)
Reference THAs	6,485	7.9 (0.0–13.0)	4,801	94 (94–95)	3,711	93 (92–94)	2,402	92 (91–92)

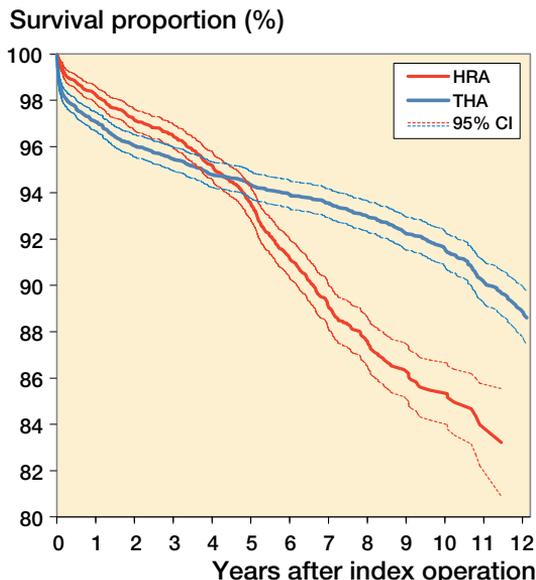


Figure 16. Kaplan-Meier survival of HRA and uncemented reference THA.

The Articular surface replacement (ASR) was associated with a higher risk of revision than the Birmingham hip resurfacing (BHR) (revision ratio (RR) = 4.0, 95% CI: 3.2–4.9; $p < 0.001$) (Table 10). The CIs for the BHR, Durom, ReCap, Conserve Plus, and Corin designs overlapped considerably, and the analysis does not permit ranking among them.

Table 10. Revision ratios (RRs) with 95% confidence intervals (CIs) for HRA devices compared to BHR. Data based on Cox regression model including implant design, sex, and femoral head diameter (categorized as ≤ 44 mm, 45–49 mm, 50–54 mm, ≥ 55 mm). Age group, hospital volume (≥ 100 or < 100 procedures) and diagnosis had no significant effect on adjustment (data not shown).

	RR	95% CI of RR	p-value
BHR (reference)	1.00		
Cornet	1.05	0.59–1.87	0.9
ASR	3.96	3.20–4.91	< 0.001
ReCap	1.21	0.88–1.67	0.2
Durom	1.02	0.65–1.58	0.9
Conserve Plus	1.30	0.90–1.88	0.2
Female (male reference)	2.12	1.66–2.70	< 0.001
Femoral head diameter, mm			
<44 (reference)	1.00		
45–49	0.70	0.54–0.92	0.01
50–54	0.61	0.44–0.85	0.003
≥ 55	0.46	0.27–0.77	0.003

Female patients had about twice the revision risk of male patients (RR=2.1, 95% CI:1.7–2.7, $p<0.001$). A femoral head diameter of less than 44 mm was independently associated with a higher revision risk.

BHR and ASR were associated with a lower revision risk than the reference THA during the first postoperative year. During the second and third postoperative years, ASR was associated with a higher revision risk than the reference THA. During follow-up from the fourth postoperative year onwards, BHR, Cormet, ASR, ReCap, and Conserve Plus were associated with a higher risk of revision than the reference THA (Table 11).

Table 11. Revision ratios (RRs) with 95% confidence intervals (CIs) in 6 HRA devices compared to uncemented reference THA. Data based on Cox regression model at different follow-up time intervals (1st year, 2nd and 3rd years, 4th year onwards).

	Follow-up interval: 1st year			Follow-up interval: 2nd and 3rd year			Follow-up: from 4th year onwards		
	RR	95% CI for RR	p-value	RR	95% CI for RR	p-value	RR	95% CI for RR	p-value
Reference THA	1			1			1		
BHR	0.48	0.32–0.70	0.0002	0.83	0.54–1.26	0.4	1.66	1.31–2.11	<0.001
Cormet	0.67	0.17–2.70	0.6	1.84	0.58–5.81	0.3	2.06	1.02–4.18	0.04
ASR	0.58	0.36–0.94	0.03	1.85	1.24–2.77	0.003	9.18	7.44–11.31	<0.001
ReCap	0.64	0.38–1.07	0.09	0.82	0.44–1.53	0.5	2.30	1.55–3.42	<0.001
Durom	0.58	0.26–1.31	0.2	1.44	0.70–2.95	0.3	1.15	0.59–2.25	0.7
Conserve Plus	1.00	0.61–1.64	1.0	0.78	0.36–1.68	0.5	1.78	1.03–3.08	0.04

5.2.2 Continuum cup in primary total hip arthroplasty

Revision for any reason

The up to 7-year survivorship for the Continuum group was 94.6% (95% CI 94.0–95.2) and for the reference group 95.6% (95% CI 95.3–95.8) for revision for any reason as the endpoint (Fig. 17). Cox regression analysis showed that the Continuum group had an increased risk of revision for any reason compared with the reference group (HR 1.3, 95% CI 1.2–1.5) (Table 12).

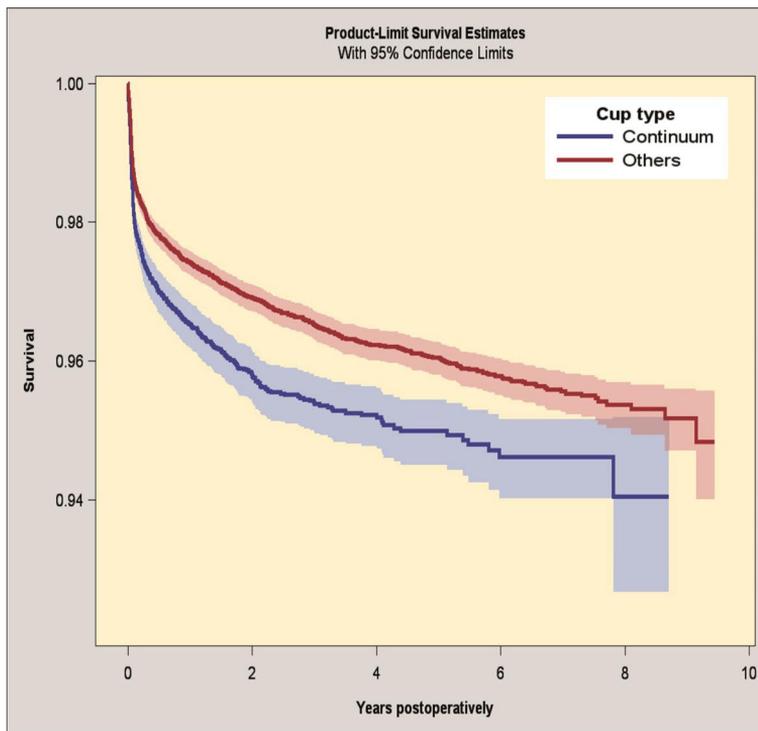


Figure 17. Kaplan– Meier survival for Continuum group and reference group with revision for any reason as the endpoint. 95% CI levels in blue and red.

Cup revision for any reason

In the cup-only- revision analysis performed with the data from May 15, 2014 to December 31, 2017, the 3-year survivorship was the same in the Continuum group as in the reference group: 99.4% vs. 99.6% (95% CI 99.2–99.6 vs. 99.5–99.7). These figures are not statistically different (Cox regression analysis HR 1.3, 95% CI 0.8–2.0) (Table 12).

Revision due to infection

The 7-year survivorship for the Continuum group was 98.9% (95% CI 98.6–99.1) and for the reference group 99.1% (95% CI 99.0–99.2), when revision because of infection was the endpoint (Fig. 18). The risk of revision for infection was the same in the groups (HR 1.0, 95% CI 0.8–1.3) (Table 12).

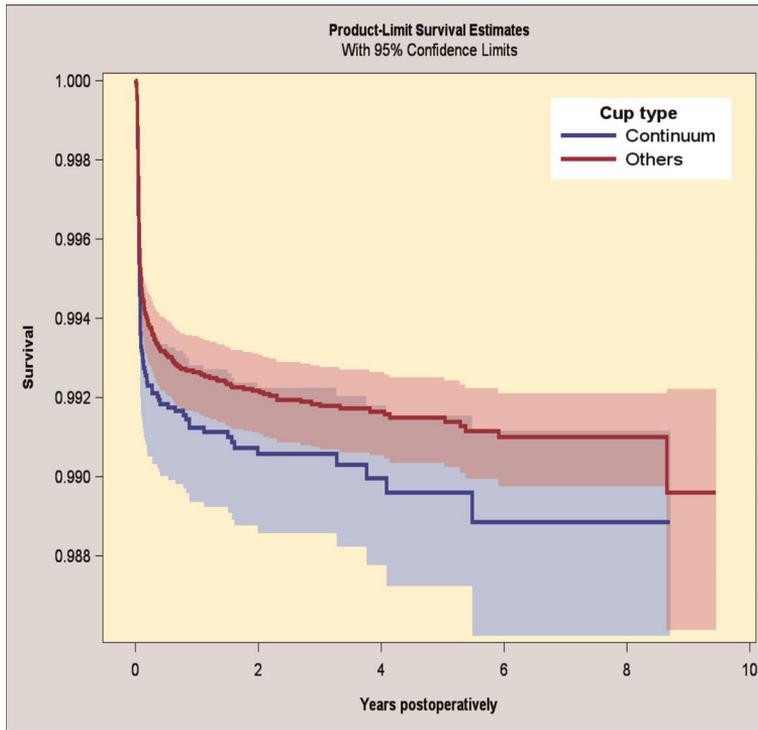


Figure 18. Kaplan– Meier survival for Continuum group and reference group with revision for infection as the endpoint. 95% CI levels in blue and red.

Revision due to dislocation

The 7-year survivorship for the Continuum group was 98.3% (95% CI 98.0–98.6) and for the reference group 99.0% (95% CI 98.8–99.1), when revision because of dislocation was the endpoint (Fig. 19). The Continuum group had an increased risk of revision for dislocation (HR 1.9, 95% CI 1.5–2.3) compared with the reference group (Table 12).

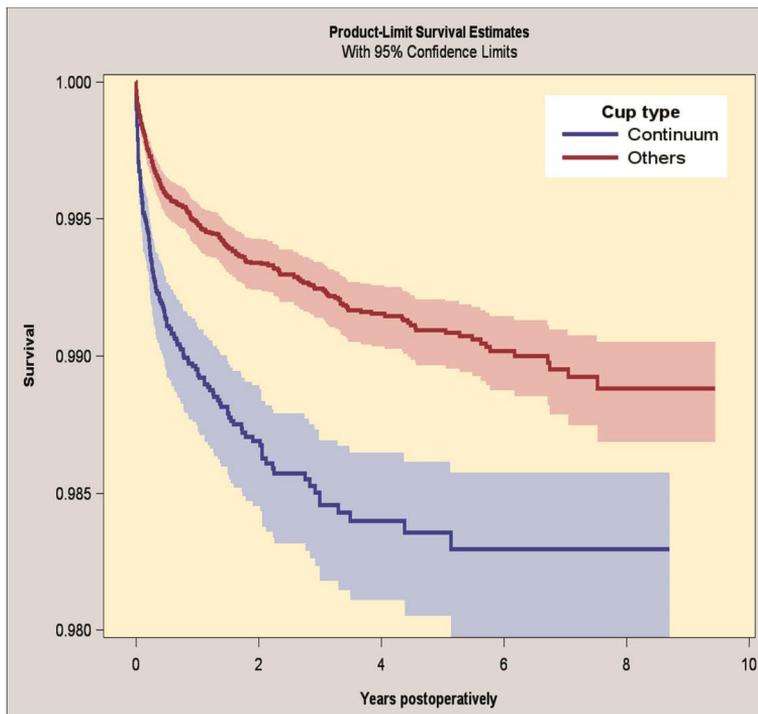


Figure 19. Kaplan– Meier survival for Continuum group and reference group with revision for dislocation as endpoint. 95% CI levels in blue and red.

Table 12. Revision risk according to the Cox regression model (adjusted for age group, gender, diagnosis, femoral head size, operated side, operation year group, and fixation of femoral stem) with revision for any reason, revision for infection, revision for dislocation, and any cup revision as the endpoints.

Group	HR	95% CI
Revision for any reason		
Reference group	1.0	
Continuum group	1.30	1.2–1.5
Revision for infection		
Reference group	1.0	
Continuum group	0.99	0.8–1.3
Revision for dislocation		
Reference group	1.0	
Continuum group	1.9	1.5–2.3
Cup revision as the endpoint		
Reference group	1.0	
Continuum group	1.3	0.8–2.0

Subgroup analysis: Continuum THA with or without liner elevation

The 5-year survivorship for the Continuum group with elevated liners was 98.9% (95% CI 98.4–99.2) and for the Continuum group with neutral liners 97.8% (95% CI 97.3–98.2), when revision because of dislocation was the endpoint (Fig. 20). After adjustments of the statistical data, the Continuum group with neutral liners had a higher risk of revision for dislocation compared to the Continuum group with elevated liners (HR 1.7, 95% CI 1.2–2.5).

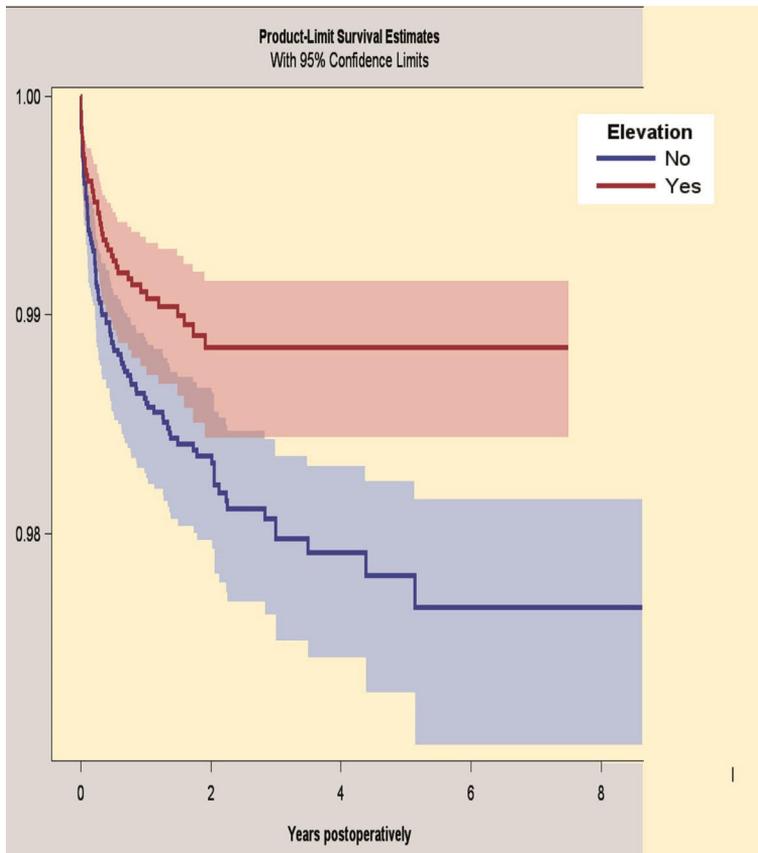


Figure 20. Kaplan–Meier survival by subgroup analysis of Continuum THA with or without elevated liner. Endpoint: revision for dislocations. 95% CI levels in blue and red.

5.2.3 Implant survival of constrained acetabular device based on data from the Finnish Arthroplasty Register

Revision for any reason

The 8-year survivorship of the constrained acetabular device group was 94% (95% CI: 91–96) and that of the reference group 93% (95% CI: 89–97) (Fig. 22). Overall, there were 21 revisions in the constrained acetabular device group and 49 in the reference group. The reasons for revision are listed in Table 13. During the first 1.5 years, the constrained acetabular device group had a similar risk of revision (HR 0.92, 95% CI 0.48–1.75, $p=0.8$) to the reference group. From 1.5 to 3 years, the constrained acetabular device group had an increased risk of revision (HR 6.35, 95% CI 1.86–21.7, $p=0.003$) over the reference group. From the fourth year onwards, the constrained acetabular device group had a similar risk of revision (HR 2.02, 95% CI 0.33-12.44, $p=0.4$) to the reference group (Table 14).

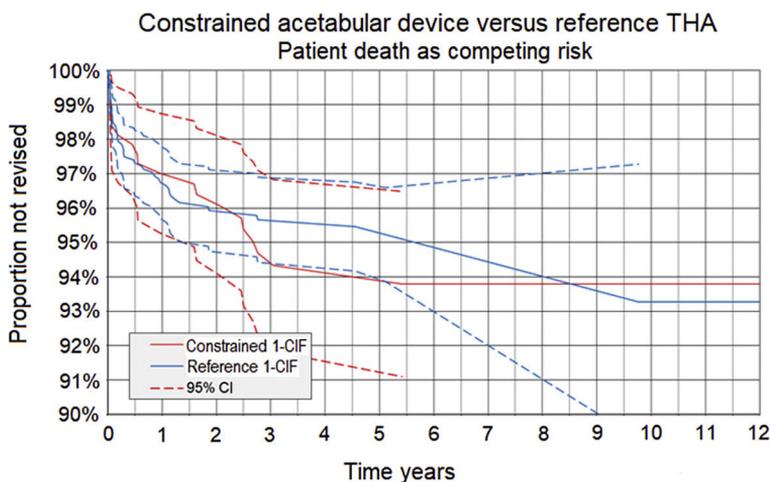


Figure 22. Implant survival for the constrained acetabular device and reference groups with revision for any reason as the endpoint, using patient death as competing risk. 95% CI shown around the curves in blue (reference group) and red (constrained acetabular device group). CI, confidence interval; THA, total hip arthroplasty; CIF, cumulative incidence function.

Table 13. Reason for revision. Values are n (%).

Reason for revision	Constrained acetabular device	Reference
Aseptic loosening (femur and acetabulum)	0 (0)	2 (4)
Aseptic loosening (acetabulum)	2 (10)	3 (6)
Aseptic loosening (femur)	1 (5)	3 (6)
Infection	10 (48)	11 (22)
Dislocation	1 (5)	12 (24)
Component malposition	1 (5)	2 (4)
Periprosthetic fracture	3 (14)	8 (16)
Other reason	2 (10)	2 (4)
Missing data	1 (5)	6 (12)
Total	21 (100)	49 (100)

Table 14. HR for the constrained acetabular device and reference groups with revision for any reason as the endpoint.

Group	HR	95% CI	p value
All revisions from 0 to 1.5 y			
Constrained acetabular device group (vs reference group)	0.92	0.48–1.75	0.8
All revisions from 1.5 to 3 y			
Constrained acetabular device group (vs reference group)	6.35	1.86–21.70	0.03
All revisions from fourth year onwards			
Constrained acetabular device group (vs reference group)	2.02	0.33–12.44	0.4

Follow-up time has been divided into three parts (0 to 1.5 years, 1.5 to 3 years, and from the fourth year onwards) because the proportional hazards assumption of the Cox model was not fulfilled. HR, hazards ratio; CI, confidence interval.

Revisions due to dislocation

The constrained acetabular device group had a similar risk of revision due to dislocation (HR 0.27, 95% CI 0.03-2.05, $p=0.2$) compared with the reference group. There was one revision due to dislocation in the constrained acetabular device group and there were 12 in the reference group.

Revisions due to any aseptic reason (infections excluded)

The 8-year survivorship of the constrained acetabular device group was 97% (95% CI 95-99) and that of the reference group 94% (95% CI 90-98) with any aseptic revision as the endpoint (Fig. 23).

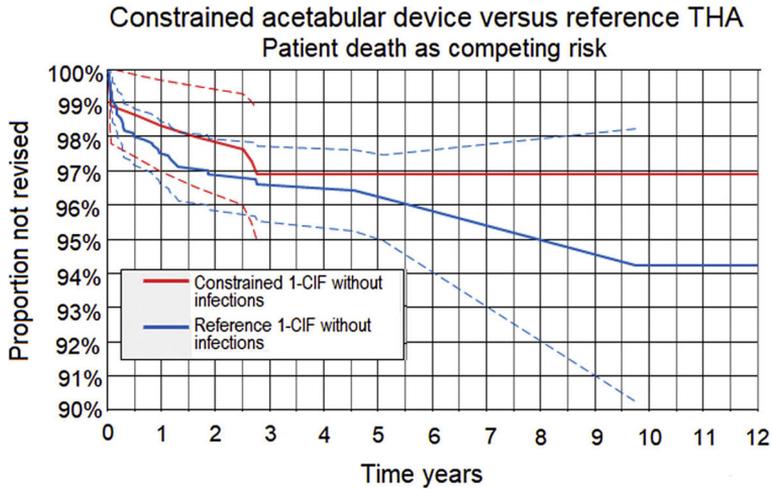


Figure 23. Implant survival for the constrained acetabular device and reference groups with revision for any mechanical reason as the endpoint (revisions for infection excluded), using patient death as competing risk. 95% CI levels shown around the curves in blue (reference group) and red (constrained acetabular device group) (CIF = Cumulative Incidence Function).

Revisions due to infection

There were 10/373 revisions due to infection in the constrained acetabular device group and 11/1118 in the reference group. The constrained acetabular device group had an increased risk of revision due to infection (HR 2.99, 95% CI 1.27-7.04, $p=0.01$) compared with the reference group. However, the mortality was significantly higher in the constrained acetabular device group, which indicates that the patients in this study group are more fragile than in the control group.

6 Discussion

Recurrent instability after THA is a challenge for the arthroplasty surgeon. Rates of dislocation after revision or primary hip arthroplasty for patients at risk of instability are still ranging from 6% to 20% despite various surgical solutions proposed (Callaghan et al. 2001, Carter et al. 2011). There are various methods, such as constrained acetabular devices, elevated liners, and larger femoral head size, to decrease the risk of dislocation.

6.1 Constrained acetabular device

Constrained acetabular liners are used to resolve instability due to various causes, they thus act as a mechanical substitute for poor biological support and are subjected to mechanical overload. The higher forces transmitted through the constrained articulation can contribute to reconstruction failure. The four modes of failure of a constrained device are failure of fixation to the pelvis, liner dissociation, biomaterial failure, and femoral head dislocation (Cooke et al. 2003, Yun et al. 2005). Impingement is a common underlying cause in each mode of failure, and may occur with every constrained liner (Noble et al. 2012). The femoral head is captured deeper into the polyethylene, leaving the femoral neck vulnerable to contact against the comparatively elevated liner rim. High forces lead to liner dissociation and femoral head dislocation depending on the design. The repetitive impingement forces that occur within a reduced arc of motion generate polyethylene fatigue fractures and locking mechanism failure (Yun et al. 2005).

The Freedom constrained device in studies I and IV was first introduced in Finland in 2006. Since then, this device has shown reasonable results especially in hip revision arthroplasty and is currently used worldwide (Siegmetz et al. 2009, Jafari et al. 2010, Davies et al. 2011, Skyttä et al. 2011). However, peer-reviewed long-term research reports on the device are still scarce. Recently, in addition to their use in revision arthroplasty, there has been an increase in the use of constrained acetabular devices in primary THA for high-risk patients, based only on moderate evidence.

Noble et al. retrieved 57 constrained components of four different designs at revision THA and examined them for the presence of rim impingement, cracks in

the liner, and backside wear. Failure of the locking ring was responsible for 51% of failures, whereas 28% of revisions were the result of acetabular cup loosening, 6% backside wear, and 22% infection (Noble et al. 2012). Impingement damage to the rim of the polyethylene liner was seen in all retrievals. Our results were in line with these findings, but this study of Noble et al. consisted mainly of other constrained devices.

In study I there were eight out of 105 Freedom failures of which four were dislocations due to impingement and failure of the locking ring with severe malpositioning of the acetabular cup or femoral stem, two due to liner loosening, and two due to infection. In two loosening cases, one Freedom liner attached normally with the Ringloc mechanism into an uncemented cup loosened, probably due to impingement of the remaining osteophytes. In the second loosening case the uncemented Freedom liner was cemented directly into the pelvic bone, and dissociated only after 2 weeks.

There are several reports of constrained liners that were cemented into the shell and subsequently dissociated from the cement (Bremner et al. 2003, Shapiro et al. 2003, Callaghan et al. 2004). Failures at the acetabular bone–prosthesis interface due to inadequate fixation of the shell and increased bone-implant interfacial stress and pull-out forces are also well described (Cooke et al. 2003, Ito and Matsuno 2004).

The mechanical failure rate of the Freedom constrained liner in study I, (six out of 105 (5.7%) at a mean follow-up of 2 years) compares favorably to other reported series of comparable constrained devices. Although in recent study Freedom device has used mainly in revision cases. According to Berend et al. (Berend et al. 2006), the success rate of a Freedom constrained liner in a follow-up on average of 9 months was 99% when treating dislocation of primary THA (one dislocation out of 81 THAs) and 93% for patients for whom a constrained device was placed during revision for recurrent instability. Four out of 82 ,Trilogy[®] Longevity[®] Constrained (TLC) liners (Zimmer, Warsaw, IN, USA), inserted for primary (n = 10) or revision (n = 72) THA failed in a study by Munro et al. (Munro et al. 2013), with a mean follow-up of 34 months. Three of the liners failed due to dislocation, and one for aseptic loosening of the cup. Andersen et al. (Andersen et al. 2013) reported that four TLC constrained devices out of 32 inserted for recurrent dislocation failed due to dislocation, and one due to cup loosening at 1.8-year follow-up. Zywiell et al. studied the Trident constrained liner (Stryker Orthopaedics, Mahwah, NJ, USA) in 33 revision THAs with a previous history of dislocation, and 10 revision THAs with intraoperative instability. Thirty-nine of the 43 hips required no further re-operation of the acetabular component and/or liner over the study period, for an overall survival rate of 91% at a mean follow-up of 49 months (Zywiell et al. 2011).

Berend et al. demonstrated the relationship between preoperative history of dislocation and recurrent dislocation rate using the S-ROM constrained liner.

Recurrent dislocation occurred in 14% of patients without a history of dislocation and in 28% of patients with a previous history. When the constrained device was inserted due to diagnosis of recurrent dislocation, the re-dislocation rate was 29% (Berend et al. 2005). In study I the failure rate of the Freedom device, used as treatment for dislocation was only two out of 42 (4.8%), although there were 16 hips with a history of more than 10 previous dislocations. Della Valle et al. (Della Valle et al. 2005) reported a re-recurrent dislocation rate of 20% in patients undergoing Duraloc liner insertion for recurrent dislocation. In the same report, they demonstrated that isolated exchange of the liner to a constrained mechanism without optimizing additional factors that may contribute to instability, like malposition of the femoral and acetabular component, is associated with a high rate of failure (Della Valle et al. 2005). We agree that appropriate decision-making and optimal component positioning in dislocation revision surgery is mandatory for the success of preventing further dislocations using any device.

Hernigou et al. (Hernigou et al. 2010) compared primary THA performed on patients with neuromuscular disease with a constrained device (Groupe lepine, Genay, France) in 164 hips and with conventional heads in 132 hips. At a minimum follow-up of 5 years, the dislocation rate in the constrained group was 2% and in the conventional group 25%. None of the preventive primary THA cases in our Freedom study I failed, which supports the findings of Hernigou et al. (Hernigou et al. 2010). However, the constrained device was not the same in these two studies. Furthermore, most of our cases were abductor deficiency or trochanter major fracture patients compared to neurological patients in the previous study. At any rate, given the high dislocation rate after THA in neurological and muscle deficiency patients, the use of preventive constrained liners should probably be further encouraged in these patient groups.

A major concern with any locking ring-style constraining device is that recurrent dislocation almost always requires open reduction and revision. Some reports have indicated that closed reduction of dislocated constrained THAs is possible in some cases at least using S-ROM (McPherson et al. 1999, Miller and Zura 2001, Harman et al. 2003), or the Trilogy liner (Sonohata et al. 2012). Harman et al. (Harman et al. 2003) showed that six patients who had a successful closed reduction remained stable without any additional dislocations 7–72 months after reduction. Sonohata et al. (Sonohata et al. 2012) reported that the Trilogy hip remained stable for 10 months, until the patient died due to unrelated causes. These data suggest that closed reduction of constrained polyethylene liners can be successful without predisposing patients to additional dislocations. In Freedom study I, we tried to treat three out of six failed Freedom hips initially with a closed reduction, two of which were successful. Later on, however, all three cases needed revision surgery due to continued dislocation issues. Clyburn et al. (Clyburn et al. 2003) reported a cadaveric

biomechanical evaluation that, with recurring dislocation, the torque to dislocate was reduced. They recommended consideration of revision surgery if dislocation occurs. Our study I data, support this recommendation.

A limitation of our retrospective Freedom study I is that it lacks a control group. We did not have a defined list of indications for using a constrained liner. Some of our revision patients had complex acetabular and femoral reconstructions and multiple medical comorbidities. Some of the general complications (i.e., infection) were not related to the use of the constrained liners. The downside of constrained devices include limitations of ROM and an increased risk of impingement between the femoral neck and the constrained liner, potentially transferring high stresses at the bone –implant interface. This may change the mechanism of failure from dislocation to loosening and wear (Noble et al. 2012). The follow-up time in our study was relatively short and evaluation of potential long-term complications like wear, osteolysis, and loosening was not possible.

Furthermore, assessment of function or quality of life was not included, because this was not routinely recorded at subsequent follow-up visits. The strength of our Freedom study I, is that we were able to assess the outcome of an entire cohort of patients with a single constrained device in one specialized joint arthroplasty center. We are aware of only one previous retrospective study on the dislocation rate of the Freedom device (Berend et al. 2006).

In Freedom study IV, we found that the 8-year survivorship of the constrained acetabular device group was equal to that of the reference group with revision for any reason as the endpoint. There was only one dislocation revision in the constrained acetabular device group compared with 12 in the matched reference group, although the difference between the groups was not statistically significant. There was no difference in the overall revision risk between the constrained acetabular device group and the reference group during the first 1.5 years, when most of the revisions occurred. To our knowledge, our study IV is the first published prospective, register-based cohort study assessing the use of a constrained acetabular device (Freedom, Zimmer Biomet, Warsaw, IN, USA) in primary THA. Nonetheless, the results of study IV, based on high-quality national register data are in line with these previous findings that the constrained acetabular device works well in preventing revision operations in high-risk patients undergoing primary THA.

In Freedom study IV, we found no difference in overall revision rate between the constrained acetabular device group and the reference group during the first 1.5 years of follow-up, when most (77%) of the revisions occurred. From 1.5 to 3 years postoperatively, the adjusted revision risk of the constrained acetabular device group was higher than that in the reference group; the difference is probably attributable to the overall low number of revisions during this time -only 11 out of all 70. From the

fourth year onwards, the revision risk returned to being similar between the study groups.

There was only one revision for dislocation in the constrained acetabular device group compared with 12 in the matched reference group in the present study. In general, constrained acetabular devices are used for patients with a high risk of instability. This indicates that a constrained acetabular device may help to lower the dislocation revision rate compared with conventional primary THA in patients at high dislocation risk, even though the difference in dislocation risk between the study groups was not statistically significant.

There was no difference in the 8-year survivorship between the two groups after excluding infections as the cause of revision. It has been stated previously that constrained implants may have an increased prevalence of impingement of the femoral neck on the cup, leading to liner damage, locking mechanism failure, dislocation, and loosening (Guyen 2016). In Freedom study IV, we did not find any evidence to support this assumption. Overall, there were only two revisions for aseptic loosening of the cup in the constrained acetabular device group compared with five in the reference group, and the difference was not statistically significant. Patients in the constrained acetabular device group were frailer than those in the reference group, even after matching, which is indicated by the high mortality rate (51.5% vs 16.3%, respectively). Therefore, one should be cautious in extrapolating our results to younger patients with a longer life expectancy. However, in general, these devices are not routinely used in younger and fitter patients with higher physical demands.

Interestingly, in Freedom study IV, the constrained acetabular device group had a statistically significantly increased risk of revision because of infection compared with the reference group (HR 2.99, $p=0.01$). We theorized that this is more likely to be associated with patient selection than with the implant itself, as constrained acetabular devices are used in frailer patients at increased risk of infection. Unfortunately, we were not able to adjust the data for comorbidities, which are a well-known risk factor for deep infection (Pedersen et al. 2010). Furthermore, the current approach of including bilateral hip cases may in theory be biased when studying the rate of revision due to infection, as there is a potentially higher risk of the contralateral THA developing a periprosthetic joint infection (PJI) when a patient has a current THA with confirmed PJI and is potentially septic. However, we consider this bias to be of theoretical importance only.

We acknowledge that Freedom study IV has several limitations. As with any register research, we were limited to the data the register provides. There are several factors we did not have access to that might influence instability, such as alcoholism, spinal fusion, abductor deficiency, neurological disease, high BMI, or dementia. As mentioned earlier, patient selection regarding constrained acetabular devices tends

to lean on more fragile patients. By matching the study groups, we were able at least somewhat to reduce these confounding factors. Also, we were not able to assess the patients' radiographs. Furthermore, we were only able to use revision as the outcome. Some of the patients might have suffered pain or had other problems with their implant without having a revision, for example, due to poor general health. Moreover, our results are based on a single constrained acetabular device (Freedom, Zimmer Biomet, Warsaw, IN, USA) and are not generalizable to other constrained designs. A strength of our study is the independent population-based cohort design with prospective collection of data and large sample size. The FAR has a high degree of completeness and coverage and thereby provides a representative study population.

6.2 Head size and hip resurfacing arthroplasty

Larger femoral head size has been well documented to decrease the risk of dislocation due to increased JD and was one of the theoretical advantages in LDH MoM THA and HRA. However, as is now well known, MoM arthroplasties have a higher risk of revision due to metal wear related problems.

In HRA study II, the 10-year implant survival of HRAs was 86% in Finland. The 10-year survival of the BHR in Finland is similar to that in England and Wales (91%). According to the current NICE recommendations, the revision rate of HRAs/THAs should be no higher than 5% by 10 years. None of the HRAs in this study achieved this goal.

The cumulative rate of revision of all HRAs by 10 years in Australia was 9.8%, and that of conventional THAs was 6.8% (AOANJRR 2013). The cumulative rate of revision of all HRAs by 10 years in England and Wales (NJR 2013) was 13%, and that of uncemented THAs was 7.7%. Our data support these findings: the overall long-term survival of conventional THAs is higher than that of HRAs. Lately, based on NJR data it has been suggested that there is no advantage in using resurfacing implants over THA, even in younger patients (Jameson et al. 2015). In a previous report based on data from 2001–2009 (Seppänen et al. 2012), has concluded that HRA had comparable 4- to 8-year survivorship to that of THA at the national level. It is now evident that this conclusion was not valid in 8- to 10-year follow-up.

The 10-year cumulative rate of revision of the BHR is 6.9% in Australia (AOANJRR 2013) and 9.0% in England and Wales (NJR 2013). Our registry results on BHR are similar. Excellent implant survival results have been published for the BHR based on data from single centers. In single center studies from developing clinics, 10-year survival has been 92% to 97% (Daniel et al., Matharu et al. 2013). The 10-year overall survival rates based on independent single centers have varied between 87% and 95% (Coulter et al 2012, Holland et al. 2012, Murray et al. 2012,

Reito et al. 2014). However, survival rates have constantly been worse for female patients, with 10-year survival rates of no more than 67% for women in younger age groups (Murray et al. 2012)

There has been concern about local adverse tissue reactions associated with the use of the BHR, as with other HRA devices. An ARMD prevalence of 6.9% in male patients and 8.8% in female patients has been reported for the BHR (Reito et al. 2014). Bisschop et al. reported a 28% prevalence of CT-verified pseudotumors in BHR patients by 3 years. In the current study, the revision risk for BHR was similar to that for other HRA devices except ASR. The revision risk for the BHR compared to uncemented THAs increases from the fourth postoperative year onwards. The survival rate of BHRs beyond 10 years may deteriorate further compared to conventional THAs due to revisions indicated by ARMD.

The 7-year cumulative rate of revision of the ASR was 24% in Australia (AOANJRR 2013) and the 10-year rate was 30% in England and Wales (NJR 2013). These results are in line with ours. ASR was recalled by the manufacturer in September 2010. An 8-year implant survival of 96% with revision for any reason as the endpoint was reported from single-center data by Vendittoli et al. (2013) for the Durom HRA. This extraordinary finding has not been verified in population-based registry studies. The 10-year cumulative rate of revision of the Durom was 10% in Australia (AOANJRR 2013) and 9.4% in England and Wales (NJR 2013). These data are in accordance with our results (8% at 8 years). Durom was recalled by the manufacturer in 2008 due to high early revision rates. An 11-year implant survival of 93% with revision for any reason as the endpoint was reported from single-center data by Gross et al. (2012) for the Corin Cormet HRA. The cumulative revision rate for adverse wear failure was 1% (Gross and Liu 2013). The 10-year cumulative rate of revision of the Corin Cormet HRA was 19% in both Australia (AOANJRR 2013) and England and Wales (NJR 2013). Our results (14% at 10 years) are in accordance with these population-based findings.

According to single-center data, the implant survival rate of the ReCap HRA is 94% over 6 years (van der Weegen et al. 2012), 96% over 7 years (Gross and Liu 2012), and 100% over 7 years (Borgwardt et al. 2015). The 7-year cumulative percent probability of revision of the ReCap was 12% in Australia (AOANJRR 2013) and 9% in England and Wales (NJR 2013). Again, our results (9% at 8 years) are in accordance with previous population-based findings. Five-year survival rates of 98% (Amstutz et al. 2007) and 95% (Zylberberg et al. 2015) have been reported for the Conserve Plus HRA, based on single-center data. The 10-year survival rate of the Conserve Plus cup was 98% with aseptic loosening as the endpoint (Hulst et al. 2011) and 89% for the Conserve Plus HRA with revision for any reason as the endpoint (Amstutz et al. 2010). The 10-year cumulative rate of revision of the Conserve Plus was 14% in England and Wales (NJR 2013). In Finland, the Conserve

Plus HRA is not in common use and follow-up times are short, but we did find a 5-year survival rate for the Converse Plus of 95%, which is comparable to that of other HRA devices.

In HRA study II, as well as in the previous report, aseptic loosening was the most common reason for revision—53% and 51% of all revisions, respectively (Seppänen et al. 2012). The most common reason for HRA revision in Australia has been loosening/lysis (33%), followed by metal-related pathology (24%) and fracture (21%) (AOANJRR 2013). In England and Wales, the most common reason for HRA revision was pain, followed by aseptic loosening and other indications (NJR 2013). The variation in indications for revisions between registries indicates that the definitions of the indications are ambiguous. Pain only or ARMD were not coded as reasons for revision in the previous pre-registry notification form of the FAR. Revisions performed for ARMD were coded as performed for "other reason". There were 131 HRA revisions (24% of all revisions) performed for "other reason" in the current study, compared to 8% in the previous report (Seppänen et al. 2012). These data have been available since the reformation of the registry on May 19, 2014. In our HRA study, the dislocation revision rate was very low, accounting for only 1% of all revisions.

The revision rate in women has reportedly been about twice that in men (AOANJRR, NJR 2013). However, based on data from the Australian registry, adjustment for femoral head size eliminates female sex as an independent risk factor (Prosser et al. 2010). However, the NARA group found that femoral head diameter alone had no effect on the early revision rate (Johanson et al. 2010). We found that the HRA revision rate for women is twice as high as for men. We also found, in HRA study II, a higher risk of revision in the group with the smallest femoral head diameter. Perhaps somewhat surprisingly, a high hospital production volume was not associated with a reduced risk of revision.

Since our study design was observational, it was vulnerable to omission of variables, which may have confounded our findings. Potentially important variables such as comorbidity and socioeconomic status were not available. In addition, important clinical information (radiological data, patient-reported outcome measure data, and data on blood metal ion concentrations) was not available.

6.3 Elevated liners

Study III shows that use of the Continuum THA is associated with a slightly higher risk of revision compared to other uncemented titanium alloy cups. The Continuum study group and the reference group had a similar risk of revision due to infection, but the risk of revision due to dislocation was higher in the Continuum group.

Further, the use of elevated liners in Continuum THA reduced the risk of revision for dislocation compared with neutral liners.

Continuum cups with a neutral liner have been associated with a reduced JD of the femoral head and possibly with a resulting higher dislocation risk (Pakarinen et al. 2020). In an earlier large register study based on Australian and Swedish data, the revision risk due to dislocation was not assessed separately, although the overall revision risk of TM cups was increased compared with the other uncemented cups (Laaksonen et al. 2018). We found that the risk of revision due to dislocation of the Continuum THA was increased compared with reference THAs. In the subgroup analysis of the Continuum group we found that cups with a neutral polyethylene liner were associated with a 1.7-fold dislocation revision risk compared to Continuum cups with an elevated liner. This is in line with the previous finding by Pakarinen et al. (2020).

Elevated liners were first introduced by Charnley in the early 1970s to reduce the tendency for posterior dislocation by providing more coverage (Charnley 1979). The improved stability in primary THA from using an elevated rim liner was first reported in 1996 and, although these liners are widely used, there is only limited clinical evidence to support their use (Cobb et al. 1996, Sultan et al. 2002, Carter et al. 2011). Also, the benefit of routine use of elevated-rim liners in instances in which the acetabular component otherwise is positioned satisfactorily has been questioned (Krushell et al. 1991). In addition, there might be potentially harmful side effects. The elevated liners may predispose the neck of the prosthesis to impinge on the acetabular rim, forcing the head out of the cup anteriorly, but such a risk has not been confirmed in clinical studies (McCollum and Gray 1990, Sultan et al. 2002). Despite these suspicions, elevated liners have not been associated with increased revision rates during 5 years of follow-up (Cobb et al. 1997). Also, the use of lipped liners with modular uncemented acetabular components has been associated with a decreased rate of revision due to instability after primary THA, according to a register study from New Zealand (Insull et al. 2014). Our data support these findings: we did not observe any trend toward an elevated risk of revision due to increased wear. It is nevertheless prudent to remember that these problems may appear in a longer follow-up.

Our Continuum study has some limitations. First, we were not able to assess radiographs to evaluate preoperative bone loss. It is possible that Continuum cups have been used in more demanding cases. However, Continuum being the second most used uncemented cup during our study time does suggest that it is used routinely for primary THA. Second, we were able to analyze only factors included in the register dataset. It is possible that patients might have comorbidities that could influence their dislocation risk that we are not aware of. Third, we were only able to use revision as the outcome. Some of the patients might have experienced pain,

dislocations, or other implant-related problems without having a revision, for example, due to poor general health contraindicating risky revision surgery.

In summary, elevated liners, large diameter femoral heads and constrained devices are all very useful for preventing THA dislocations. In Freedom studies I and IV we found that this constrained acetabular device works well in patients undergoing primary THA with high instability risk or even more demanding cases in rTHAs. In HRA study II with LDH MoM HRAs, the dislocation revision rate was only 1% of all revisions but 26% of all revisions in the reference THA group. However, ARMD is major problem with LDH MoM HRAs and THAs. In Continuum study III we found that the elevated rim liner prevents well revisions for dislocations compared to the neutral rim liner.

7 Conclusions

Our study leads to the following conclusions:

- I. We found that the mechanical failure rate of a Freedom constrained device in revisions and in high risk patients was 5.7% over a mean follow-up of 2.5 years. These results encourage us to continue using the device for the treatment and prevention of dislocation in THA.
- II. We found that the 10-year implant survival of HRAs is 86% in Finland. According to new recommendations from NICE, an HRA/THA should have a revision rate of 5% or less at 10 years. None of the HRAs studied achieved this goal. However, there were only a very few revisions performed for dislocation.
- III. We found that if the Continuum cup is used, our results support the use of an elevated, rather than neutral rim liner to reduce the risk of revisions for dislocations.
- IV. We found that the 8-year survivorship of the Freedom constrained acetabular device group was equal to that of the conventional THA group with revision for any reason as the endpoint. Our current national register-based results indicate that this constrained acetabular device works well in patients undergoing primary THA with high instability risk.

Acknowledgements

This dissertation was done at the Department of Orthopaedics and Traumatology of Turku University Hospital and University of Turku during years 2016–2021. This study was financially supported by the EVO grants of Turku University Hospital and by the Finnish Arthroplasty Association.

I want to express my deepest gratitude to my supervisor, Professor Keijo Mäkelä. Your professional skills with scientific research and clinical work are unparalleled. Your forward going attitude is what a scientific field and supervisor needs. Your enormous work with The Finnish Arthroplasty Register is outstanding. Without you, this dissertation would not have been possible. Thank you.

I am greatly thankful to my other supervisor, Inari Laaksonen. Inari's sharp intelligence and great humour has helped me forward with this thesis. Your capability with scientific work is amazing. Thank you for donating your time to my research.

I want to thank the reviewers of this thesis, Adjunct Professor Minna Laitinen and Adjunct Professor Jyrki Nieminen. Your criticism has been constructive and precise. It is my honor to be able to get feedback from these highly respected and experienced surgeons.

The co-authors of the original studies, Matias Hemmilä, Inari Laaksonen, Matti Seppänen, Hanna Karvonen, Antti Eskelinen, Antti Liukas, Ari-Pekka Puhto, Jukka Kettunen, Mikko Manninen, Petri Virolainen, and Ville Remes are greatly acknowledged for their contribution to the studies. This dissertation would not have been possible without biostatisticians Mari Koivisto, Pekka Pulkkinen, Markus Matilainen and FAR data manager Jaason Haapakoski.

I want to express my gratitude to the head of the department, Ville Äärimaa. Ville has supported me in my clinical and scientific career. You are indomitable and a persistent boss.

Matti Seppänen, Hannes Keemu, Miika Stenholm, Matias Hemmilä, Petteri Unkuri, Juha Helminen and Joonatan Pappinen, you are the best workmates I can imagine. Your hardworking attitude is incomparable and it is easy to lead with guys like you. It is always a great privilege to work with your supportive and humorous atmosphere. Thank you. I also want to thank my former colleagues in Prote, Jari

Mokka and Mika Junnila. You are very skillfull surgeons. Without Jari, I wouldn't be an arthroplasty surgeon.

I want to express my gratitude to all my colleagues in the Department of Orthopaedics and Traumatology. Kari Isotalo, your stance is unequalled. I also want to express my warmest thanks to the Anesthesiologists, nurses and staff in the operating theatre in Tyks Orto and Traumatology, Joint Replacement Ward, Outpatient Ward and Traumatology Ward.

I owe the deepest gratitude to all my friends. I want to thank you for all our history and good times. Lohtajan Veikot, thanks for keeping me down to earth and thanks for keeping it real. I want to thank my training partners in Finnfighter's gym for all these years, especially Jarkko Mäkelä. OSS! Wednesday trainings during lunch time, are invaluable to my mental health.

I will always be grateful for my parents-in-law Eeva and Risto Neuvo. Thank you for taking care of our kids when Hanna and I have been busy as well as for all the other support in our life.

My parents Anna-Maija and the late Valto, words cannot express my appreciation. You gave me a loving, safe, happy and supportive childhood. I also want to express my sincere thanks to my sister Maisa for showing me stylish rebellion and for sharing cherished times with our families. My brother Matti, our brotherhood is unique. You have been my paragon and support. May the ever-continuing sport contests and repairing projects remind us of our true selves also in the future.

Finally, my utmost gratitude goes to my beloved wife, faithful Hanna. Thank you for always keeping up joy of life. Thank you for the continuing and tireless support and love. Thank you for being my wife. You and our children, the headstrong Iina, witty Amanda and dexterous Väinö, are the most important things in my life. I am forever grateful of you.

Turku, January 2022

Mikko Karvonen

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ISBN 978-951-29-8769-6 (PRINT)
ISBN 978-951-29-8770-2 (PDF)
ISSN 0355-9483 (Print)
ISSN 2343-3213 (Online)

