

# CeraNews | TO THE POINT

HEALTH ECONOMICS & POLICY

OUTCOMES RESEARCH

IMPLANT MATERIAL



## SUPPLEMENT REGISTRIES



## Clear Trends Are Favoring Ceramics



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The latest figures speak for themselves. According to the six most important national registries, the use of ceramic components in arthroplasty is on the rise. In 2020, 48.8% of all primary total hip replacements registered in the NJR\*, around 60% in the AOA NJRR\*, 89.3% in the EPRD\*, 61% in the NZJR\*, around 26% in the SAR\*, and 71.1% in the AJRR\* were performed with ceramic femoral heads. This accounts for an increase of more than 3.8% in the NJR, about 2% in the AOA NJRR, 0.4% in the EPRD and 2.1% for the AJRR compared to the previous year. The use of ceramic-on-polyethylene (CoP) bearings has generally increased in 2020. According to the NJR, hybrid CoP figures have grown in particular, making this the most often utilized construct in 2020. Correspondingly, the use of metal femoral heads has again declined in 2020.

Recurrent dislocation, infection, periprosthetic fracture and aseptic loosening are still the main complications with these products leading to revision. On the other hand, according to the NJR, revision rates for CoP bearings remain consistently low or equivalent to other bearings across all fixation types for up to ten years. The NJR shows that good results were obtained with CoC and CoP bearings in young patients. The AOA NJRR also shows that CoXLPE has a lower rate of revision compared to MoXLPE after the first two weeks. According to the EPRD, CoC shows the lowest short- and mid-term failure rates among all bearing surfaces. Obviously, the good clinical results support the observed trends.

We can say that statistics show more than promising figures for ceramic bearings. New applications such as dual mobility can benefit from the excellent biocompatibility and extraordinary wear resistance of advanced ceramics. The number of dual mobility bearings implanted has steadily increased over the years. According to the AJRR, the use of dual mobility in primary and revision hip replacements has continued to increase and in 2020 accounted for 10.5% of all bearings used in elective primary surgeries and for more than 25% of all revision procedures. The NJR is currently the only registry reporting the use of ceramic heads with dual mobility constructs, and nearly one-third of the total dual mobilities implanted in a primary procedure in 2020 had a ceramic head. The Australian registry reports a lower revision rate for dislocation with this solution, in comparison with all other acetabular prostheses.

\*  
 AJRR: The American Joint Replacement Registry  
 NJR: The National Joint Registry, which covers England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey  
 AOA NJRR: The Australian Orthopaedic Association National Joint Replacement Registry  
 EPRD: Endoprothesenregister Deutschland  
 NZJR: The New Zealand Joint Registry  
 SAR: The Swedish Arthroplasty Register



## Foreword

Analysing registry data can be complex due to differences in the definitions used, which are dependent on the culture, healthcare systems, response patterns, priorities, and needs. The International Society of Arthroplasty Registries (ISAR) is working on the harmonisation of definitions, data collection and reporting across registries. The aggregation of data for procedures recorded by different registries aims to enable international comparisons and to identify issues with medical devices.

This CeraNews issue extracts and summarizes the data and trends related to the usage of bearing materials and especially ceramic bearings, and the reasons for revision and trends in total hip replacement using the data on hip procedures from the annual reports 2021 of six registries selected for their historical perspective and data collection.

The analysis is limited to the most commonly used materials, *i.e.* ceramic and metal (cobalt chrome) for femoral heads; (cross-linked) polyethylene and ceramic for inserts. The bearing types considered are therefore ceramic-on-ceramic, ceramic-on-polyethylene and metal-on-polyethylene.

### **Ceramic - No differentiation between the ceramic materials**

The only registry that differentiates between ceramic materials is the AOA NJRR which is in its analysis examines only the newest generation materials, mixed ceramic and cross-linked polyethylene. Therefore, the following analysis was generalized to ceramic without distinguishing between alumina and mixed ceramics.

### **Polyethylene – The classification according to the irradiation dose is not harmonised across the registries**

The only registry that differentiates polyethylene according to irradiation dose is the German registry, whereas, at the other extreme, the NJR makes no differentiation at all. This summary tries to reflect the results of modern prosthetics as closely as possible.

### **Dual Mobility – Increasing attention by registry annual reports**

Dual mobility constructs were until recently sparsely used. They have gained increasing interest in the last decade and most registries considered reporting their use, but only the AOA NJRR and NJR annual reports show revision rates. NJR is the only registry that between differentiates dual mobility constructs by head material (*i.e.* CoCr and ceramic).

# Fixation and Bearings in Hip Replacement

Despite some distinct differences among countries, there is a continuing overall trend toward uncemented and especially hybrid fixation at the expense of the all-cemented procedures. Larger head sizes and dual mobility constructs are also gaining in popularity. Ceramic femoral heads more and more supplant metal femoral heads.

The following overview is based on the 2021 Annual Reports of the registries of Australia, Germany, New Zealand, Sweden, the USA as well as registry for England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey.

## THR Fixation: More Hybrid, Less Cement

### NJR

In 2020, 23.0% of total hip replacement (THR) procedures in England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey were performed and classified in the registry as cemented fixation, 35.8% as uncemented and 39% as hybrid fixation.<sup>1</sup>

### AOA NJRR

There is a continuing trend in favor of uncemented fixation in Australia, making up for 60.8% in 2020 vs. 51.3% in 2003. The percentage of hybrid fixation rose slightly from 34.8% in 2003 to 36.8% in 2020, while the numbers for cemented fixation decreased significantly, from 13.9% in 2003 to 2.4% in 2020.<sup>2</sup>

### EPRD

In Germany, considering the procedures recorded into registry dataset with the type of fixation, uncemented fixation remains the clear favorite despite a slight reduction from 78.6% in 2019 to 77.9% in 2020. Hybrid fixation increased from 15.2% in 2019 to 16.8% in 2020.<sup>3</sup>

### AJRR

In the United States, uncemented femoral stem fixation remains clearly the preferred option. In 2020, it was used in 94.2% of the procedures.<sup>4</sup>

### NZJR

The usage of cemented hip replacement has fallen to 5.3% in 2020. There is an increasing trend toward hybrid fixation, while uncemented is still the most popular procedure.<sup>5</sup>



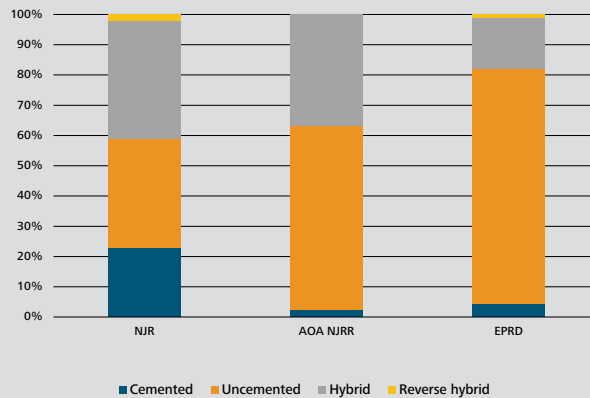
 SAR

Fully cemented fixation has continuously decreased in Sweden since 2000 and accounts for 50% of all procedures in all age groups in 2020. In the group of patients age below 65, the uncemented fixation has become the preferred option. The majority of the patients under 54 undergoes THA with uncemented fixation. The proportion of reversed hybrids has decreased since 2012 and the SAR reports an increase of hybrid fixation since 2010 from about 1.5% to 7.1% in 2020.<sup>6</sup>

*Figure 1a (left): Distribution of fixation methods in primary hip replacement in 2020: in Australia, Germany, as well as England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey.*



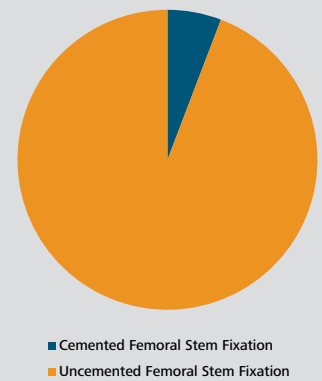
**Fixation in THR: A comparison**



*Figure 1b (right): Distribution of femoral stem fixation methods in primary hip replacement in 2020 in the USA.*



**Stem Fixation in THR: AJRR**



Evaluation of the data by CeramTec based on NJR Annual Report 2021 Page 51 Table 3.H2<sup>1</sup>, AOA NJRR Annual Report 2021 Page 83 Figure HT3<sup>2</sup>, EPRD Annual Report 2021 Page 19 Table 5<sup>3</sup>, and AJRR Annual Report 2021 Page 41 Figure 2.25<sup>4</sup>.

## Bearing Size and Material Distribution: A Trend towards Larger Head Sizes

There is a trend towards 32mm femoral heads according to the considered European registries and NZJR, whereas the AOA NJRR and AJRR report a larger usage of the 36mm bearings.

The NJR and AOA NJRR Annual Reports 2021 provide information on the size as well as the material of femoral heads used in THR allowing for analysis of the combinations. It should be mentioned that the AOA NJRR only considers procedures involving mixed ceramic bearings as of 2017 for the primary THA analysis. The intention behind is to deliver an analysis reflecting the modern surgical praxis.

### NJR

In 2020, the most common head size as recorded by the NJR was 32mm, followed by 36mm and 28mm. There is a decline of the usage in 28mm heads and smaller across all fixations. CoP with 32mm and 36mm is showing increased usage over the years.<sup>1</sup>

### AOA NJRR

The Australian registry distinctly looks at the usage of "mixed ceramic" components like BIOLOX<sup>®</sup>delta in THR. 36-38mm mixed ceramic/mixed ceramic bearings accounted for 73.8% of all primary THR procedures with this bearing surface in patients diagnosed for osteoarthritis in the period 2003-2020.<sup>2</sup>

### EPRD

In Germany, the most common head size was 32mm in 2020. It was used in 52.7% of all primary THRs. However, an increase in the numbers for 36mm femoral heads can be observed over the years. They are used in 41.4% of the cases vs. 33% in 2015. 28mm heads account for 5.0% of all primary THR.<sup>3</sup>

### AJRR

The share of 36mm heads in primary elective THR grew from 49% in 2012 to 59% in 2020. The usage of 32mm heads decreased slightly from 20.2% in 2019 to 18.7% in 2020. The treatments with head sizes larger than 40mm grew slowly from 5.4% in 2013 to 7.7% in 2020.<sup>4</sup>

### NZJR

New Zealand shows a trend toward 36mm heads since 2017, with 32mm remaining the most often used head size.<sup>5</sup>

 SAR

The use of 32mm heads continues to increase, while the use of 36mm heads shows a reduction during the last two years. 36mm heads were used in 10% of the cases in 2020.<sup>6</sup>

Figure 2a (left): Cumulative head size distribution of ceramic bearings in England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey.

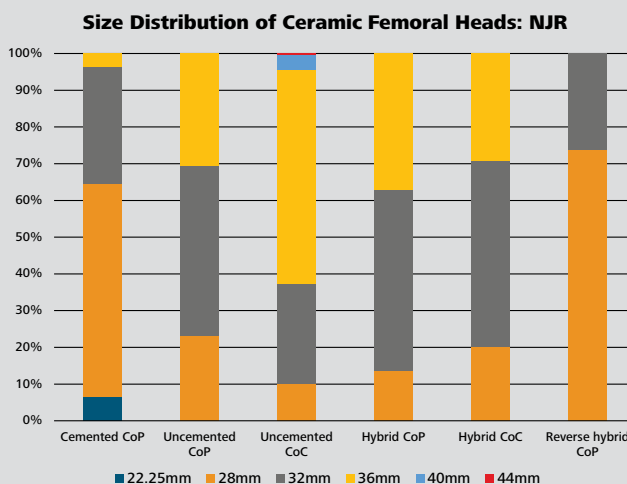
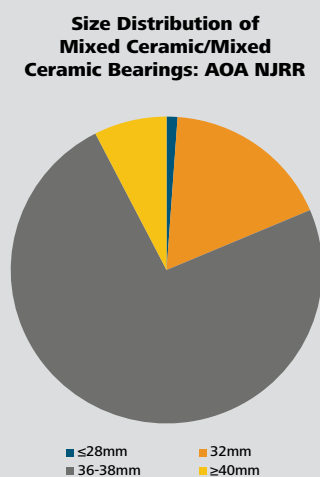


Figure 2b (right): Cumulative head size distribution of mixed ceramic/mixed ceramic bearings in Australia.



Evaluation of the data by CeramTec based on the NJR Annual Report 2021 Page 79 Figure 3 H10 (b, e, f, h, i, k)<sup>1</sup>, and the AOA NJRR Annual Report 2021 Page 128 Table HT33<sup>2</sup>.

## Distribution of Ceramic and Metal Heads in THA

The following analysis focuses exclusively on hip procedures involving ceramic and metal heads which are the most common head materials in THA. Other materials like ceramised metal have not been considered.

### NJR

2020 was the tipping point for ceramic femoral heads according to the NJR: Their use reached 50%, up from 17.9% in 2004. Correspondingly, the use of metal femoral heads decreased from 82.1% in 2004 to 50% in 2020.<sup>1</sup>

### AOA NJRR

A steady increase in the use of ceramic heads can be observed since 2014. Consequently, a decrease in the usage of metal heads has been recorded by the registry in the same period.<sup>2,7-12</sup>

### EPRD

In Germany, the trend toward ceramic femoral heads is still increasing. They were used in 92.5% of the procedures in 2020. Metal femoral heads are used meanwhile in "only" 7.5% in 2020.<sup>3,13-18</sup>

### AJRR

In the United States, the percentage of ceramic femoral heads in THR has continuously been rising from 40.4% in 2012 to 78.6% in 2020. Accordingly, AJRR reports a continuous decline of the usage of metal heads and explains this trend with the surgeons' concern about fretting corrosion.<sup>4</sup>

### NZJR

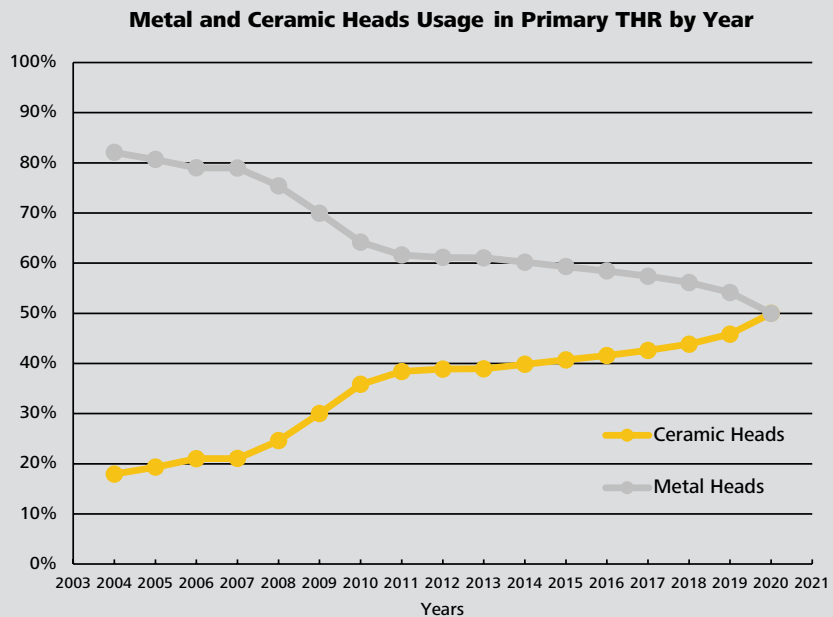
According to the NZJR Annual Report 2021, the use of ceramic femoral heads continuously increased since 2013. Their percentage surpassed that of the metal heads in 2017.<sup>5</sup>

### SAR

In Sweden, the use of ceramic femoral heads has continuously increased over the years. However, metal still remains the most used head material in hip procedures.<sup>6</sup>

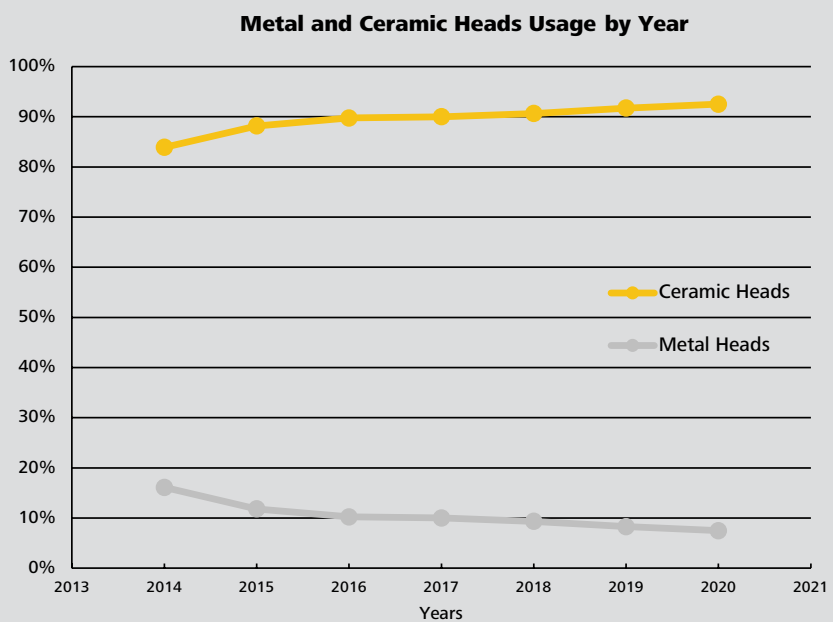


**Figure 3: Percentage of metal and ceramic femoral heads in primary THR by year in England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey.**



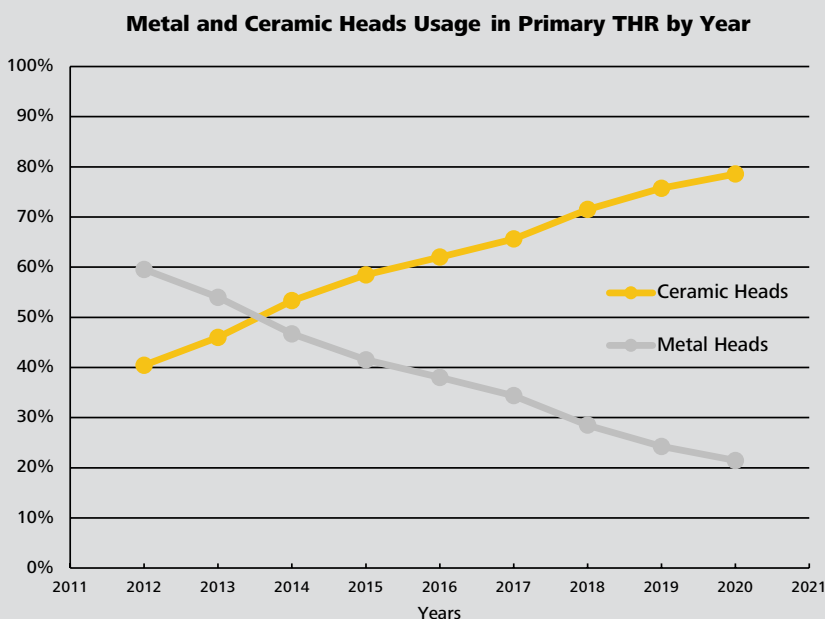
Evaluation of the data by CeramTec based on NJR Annual Report 2021 Page 51 Table 3.H2<sup>1</sup>. The hip procedures with ceramic and metal heads only have been included in the analysis.<sup>1</sup>

**Figure 4: Percentage of ceramic and metal femoral heads by year in Germany.**



Evaluation of the data by CeramTec based on EPRD Annual Reports 2014 to 2021 (For operation year 2014, the number indicates percentage of all primary hip replacements. For operation years 2015 to 2020, the numbers indicate percentage of all primary THR)<sup>3, 13-18</sup>. The hip procedures with ceramic and metal heads only have been included in the analysis.

**Figure 5: Percentage of metal and ceramic femoral heads in primary THR by year in the USA.**



Evaluation of the data by CeramTec based on AJRR Annual report 2021 Page 38 Figure 2.20<sup>6</sup>. The hip procedures with ceramic and metal heads only have been included in the analysis.

## Bearing Surfaces: Ceramic-on-Polyethylene the Preferred Option

The most implanted combinations in hip replacement are CoP, CoC and MoP. In most countries, CoP has become the preferred bearing option in THA.

### NJR

The use of CoP bearings increased from 15.9% in 2012 to 44.2% in 2020 in England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey. The use of MoP bearings has decreased from 81.5% in 2004 to 50% in 2020. CoC bearings were implanted in 5.8% of the procedures in 2020.<sup>1</sup>

### AOA NJRR

In Australia, almost the totality, 96.8%, of the bearings implanted in 2020 consisted of mixed ceramic- and metal-on-cross-linked polyethylene, and mixed ceramic-on-mixed ceramic. The latter is defined as "modern bearing surfaces" by the registry. The hard-on-soft bearings with a ceramic head account for approximately half of the bearing surfaces implanted. CoC with mixed ceramic consisted of 99.7% of all primary total conventional hip procedures. When polyethylene was used, in 97.3% of the procedures in 2020, was XLPE. The usage of metal heads and CoC is gradually decreasing.<sup>2,7-12</sup>

### EPRD

In Germany, the use of CoP bearings continuously grew from 68.2% in 2014 to 84.3% in 2020. There was a corresponding decrease in the use of CoC bearings from 15.7% to 8.4% and for MoP bearings from 16.1% to 7.3%.<sup>3,13-18</sup>

### AJRR

Between 2012 and 2020 the share of CoP bearings doubled to 79.6% in the USA. In the same period MoP dropped down from 61.4% to 20.4%.<sup>4</sup>

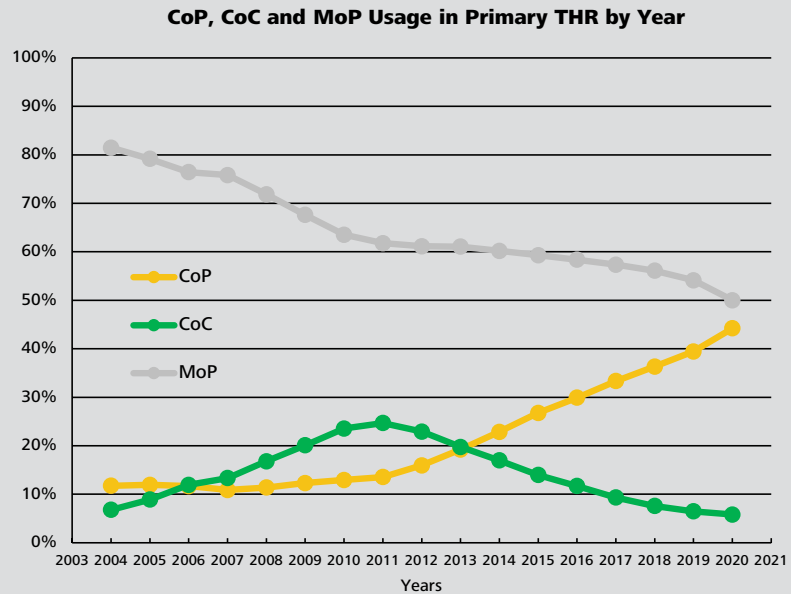
### NZJR

In New Zealand, the CoP bearing surface continues to increase from 42% of the total in 2017 to 54% in 2020.<sup>5</sup>

### SAR

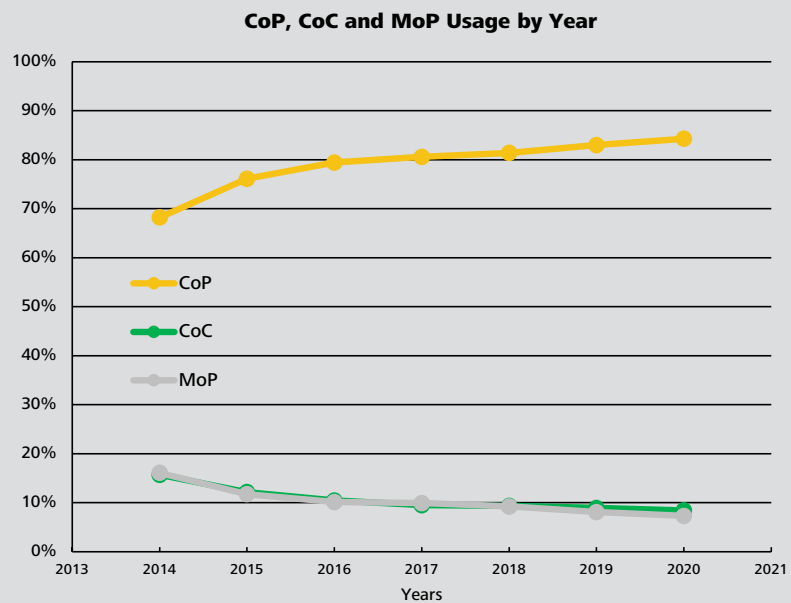
In Sweden, the use of CoP has increased from 21% in 2019 to 26% in 2020. According to the SAR Annual Report 2021, the proportion of MoP in 2020 is about 73%.<sup>6</sup>

**Figure 6: Usage of CoP, CoC and MoP bearings in primary THA by year in England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey.**



Evaluation of the data by CeramTec based on the NJR Annual Report 2021 Page 51 Table 3.H2<sup>1</sup>. The hip procedures with CoP, CoC and MoP only have been included in the analysis.

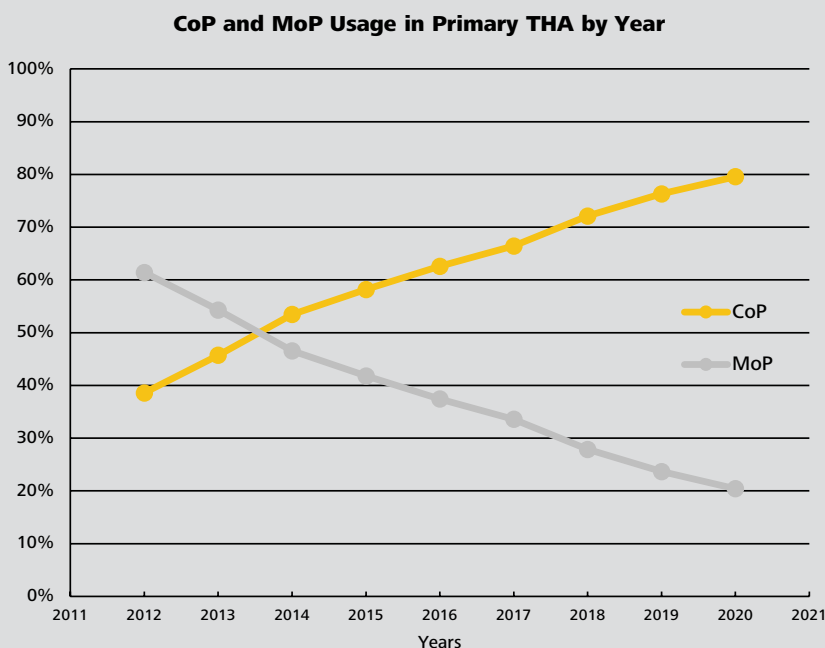
**Figure 7: Usage of CoP, CoC and MoP by year in Germany.**



Evaluation of the data by CeramTec based on the EPRD Annual Reports 2014 to 2021. For the operation year 2014, the number indicates percentage of all primary hip replacements; for operation years 2015 to 2020, the numbers indicate percentage of all primary THRs<sup>3, 13-18</sup>. The hip procedures with CoP, CoC and MoP only have been included in the analysis.



**Figure 8: Usage of CoP and MoP bearings in primary THA by year in the USA.**



Evaluation of the data by CeramTec based on the AJRR Annual Report 2021 Page 39 Figure 2.22<sup>4</sup>. The hip procedures with CoP and MoP only have been included in the analysis.





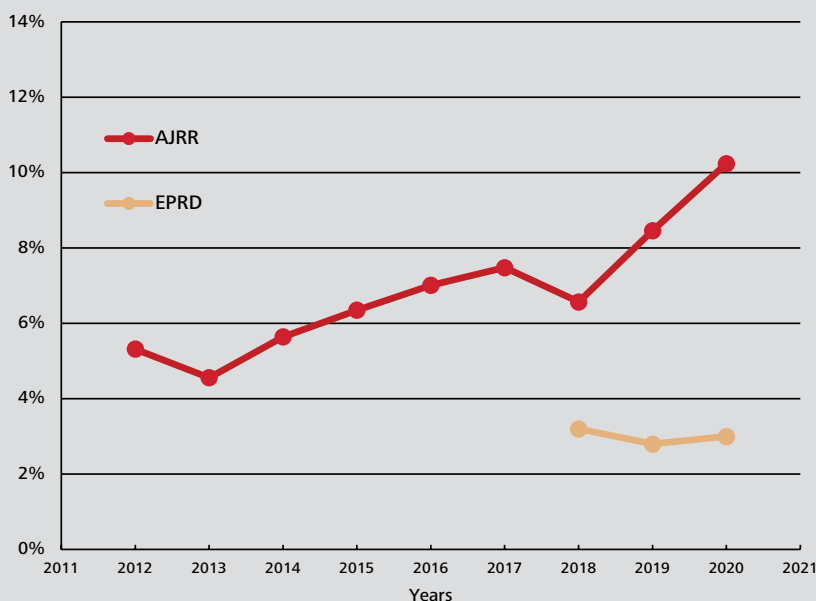
## Ceramicised Metal-on-Polyethylene: Adoption in Different Countries

In the USA, the use of CMoP has nearly doubled between 2012 and 2020 from 5.3% to 10.2%.<sup>4</sup> No significant change was recorded in Germany where approximately 3% of primary THRs are performed with CMoP femoral heads since 2018.<sup>3,17,18</sup> The NZJR<sup>5</sup>, the SAR<sup>6</sup> and the NJR<sup>1</sup> do not include CMoP bearings in their annual reports. However, a study analyzing the British dataset shows that 9,237 CMoP bearings with an uncemented acetabular component were used between January 1, 2004, and July 28, 2016.<sup>19</sup>

Figure 9: Usage of CMoP bearings in primary THA by year in Germany and the USA.



Ceramicised Metal-on-Polyethylene Usage in Primary THA by Year



Evaluation of the data by CeramTec based on the EPRD Annual Report 2019 to 2021<sup>3,17,18</sup>, AJRR Annual Report 2021 Page 39 Figure 2.22<sup>4</sup>.

## Dual Mobility Constructs: Growing Usage in Primary and Revision THR

The usage of dual mobility bearings has steadily increased over the years.<sup>1-4</sup> The data about dual mobility bearings are reported by NJR, AOA NJRR, EPRD, AJRR, and SAR registries.

### NJR

Before 2013, dual mobility was scarcely used. An increase from less than 0.1% in 2004 to 2.2% of all primary THR in 2020 can be observed, of which nearly one-third is performed with a ceramic head (CoPoM: 28.6%, MoPoM: 71.4%). Dual mobility bearings are mostly used in cases of fractured femoral neck, accounting for 8.4% of these cases in 2020.<sup>1</sup>

### AOA NJRR

In Australia, the annual use of dual mobility constructs is increasing. Their use grew by 19.6% since 2019. Compared to other acetabular prostheses, dual mobility implants are used most frequently for fractured femoral neck, tumor and failed internal fixation.<sup>2</sup>

### EPRD

The German EPRD first included dual mobility bearings in the analysis of the Annual Report 2019. In 2020, this implant type accounted for 1.4% of all bearings in primary THA, whereas in acetabular revision a dual mobility cup was chosen in 29.3 % of cases.<sup>3,17,18</sup>

### AJRR

In the United States, the use of dual mobility in both primary and revision hip replacement has continued to increase and accounted for 10.5% of all bearings used in elective primary surgeries in 2020, up from 5.32% in 2012. Dual mobility was used in over 25% of all revision procedures in 2020. This type of construct is used in all patient age groups: 9.4% of the patients under 50 years received a dual mobility bearing.<sup>4</sup>

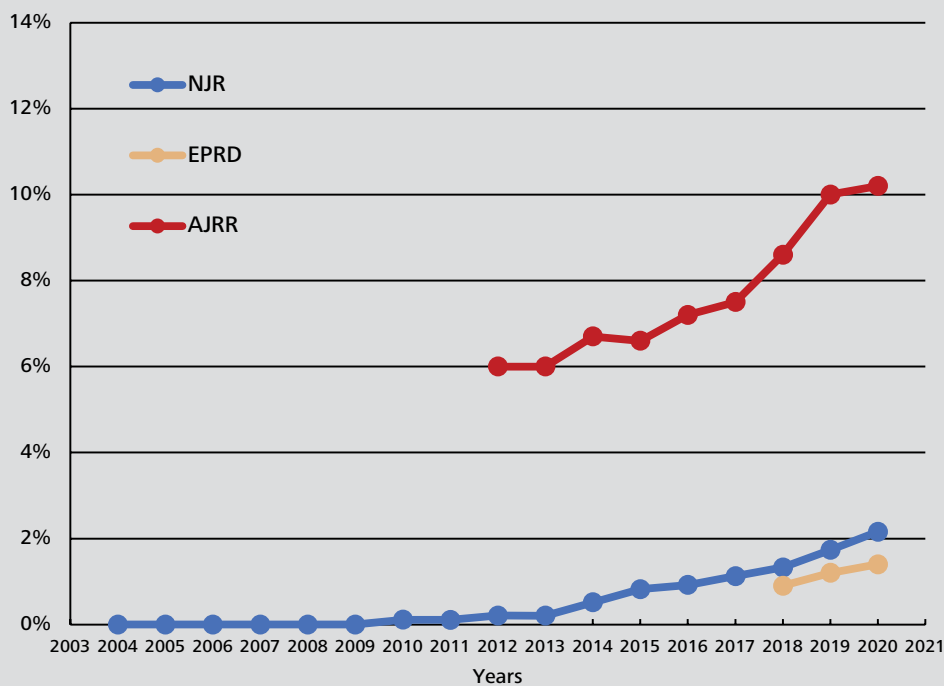
### SAR

In Sweden, dual mobility was used mainly for revisions, in almost every third first-time revision and in 46.5% of all multiple-time revisions with cup exchange or at insertion after an earlier extraction.<sup>6</sup>

Figure 10: Annual use of dual mobility bearings in primary THR in the NJR, EPRD, and AJRR.



### Dual Mobility Usage in Primary THA by Year



Evaluation of the data by CeramTec based on the NJR Annual Report 2021 Page 51 Table 3.H2<sup>1</sup>, EPRD Annual Report 2019 to 2021<sup>3,17,18</sup>, and AJRR Annual Report 2021 Page 39 Figure 2.22<sup>4</sup>.

## Failure Modes in THA

Naming the most common reasons for revision, the national registries use slightly different terminologies. There are also some differences in the ranking of the main reasons between the countries. (Aseptic) loosening, infection, dislocation and (periprosthetic) fractures are found at the top of the lists with varying order. Revision due to the fracture of implant components is considered a very rare event.

### Reasons for Revision: Loosening, Infection, Dislocation, Periprosthetic Fracture

- 1. Aseptic loosening
- 2. Dislocation
- 3. Periprosthetic fracture
- 4. Infection

#### NJR

Since 2003, the NJR has recorded a total of 1,251,164 primary hip replacements. Of these, 3% (37,444) are associated with a first revision in the Annual Report 2021. The three most common reasons for single-stage revision in the last five years are aseptic loosening (38.5%), dislocation/subluxation (18.9%), periprosthetic fracture (17%).<sup>1</sup> Revision for infection accounts for 7.7% of single-stage revisions. However, over 80% of two-stage revisions are related to infection. It is worth to mention that the reasons for revision in the NJR are not mutually exclusive. For this reason, the percentages may not add up to 100%.

- 1. Dislocation/Instability
- 2. Infection
- 3. Periprosthetic fracture
- 4. Loosening

#### AOA NJRR

Since the introduction of the AOA NJRR in 1999, the most common reasons for revision for all primary conventional THRs with primary diagnosis osteoarthritis in Australia are prosthesis dislocation/instability (22.5%), infection (22.3%), (periprosthetic) fracture (21.5%) and loosening (21.1%).<sup>2</sup>

- 1. Loosening
- 2. Infection
- 3. Periprosthetic fracture

#### EPRD

The German EPRD provides data on reasons for revision based on procedures performed during a year. In 2020, loosening (24.7%), infection (15.8%), periprosthetic fracture (13.4%) were the most frequent causes for revision.<sup>3,13-18</sup>

- 1. Infection and inflammatory reaction
- 2. Instability
- 3. Aseptic loosening

#### AJRR

Infection and inflammatory reaction (20.1%) remain the most common reason for all revisions recorded in the US registry, followed by instability related codes (18.3%) and aseptic loosening (15.9%).<sup>4</sup>

1. Loosening  
2. Dislocation  
3. Unexplained pain  
4. Deep infection  
5. Fracture femur

1. Loosening  
2. Infection  
3. Dislocation/instability  
4. Periprosthetic fracture

NZJR

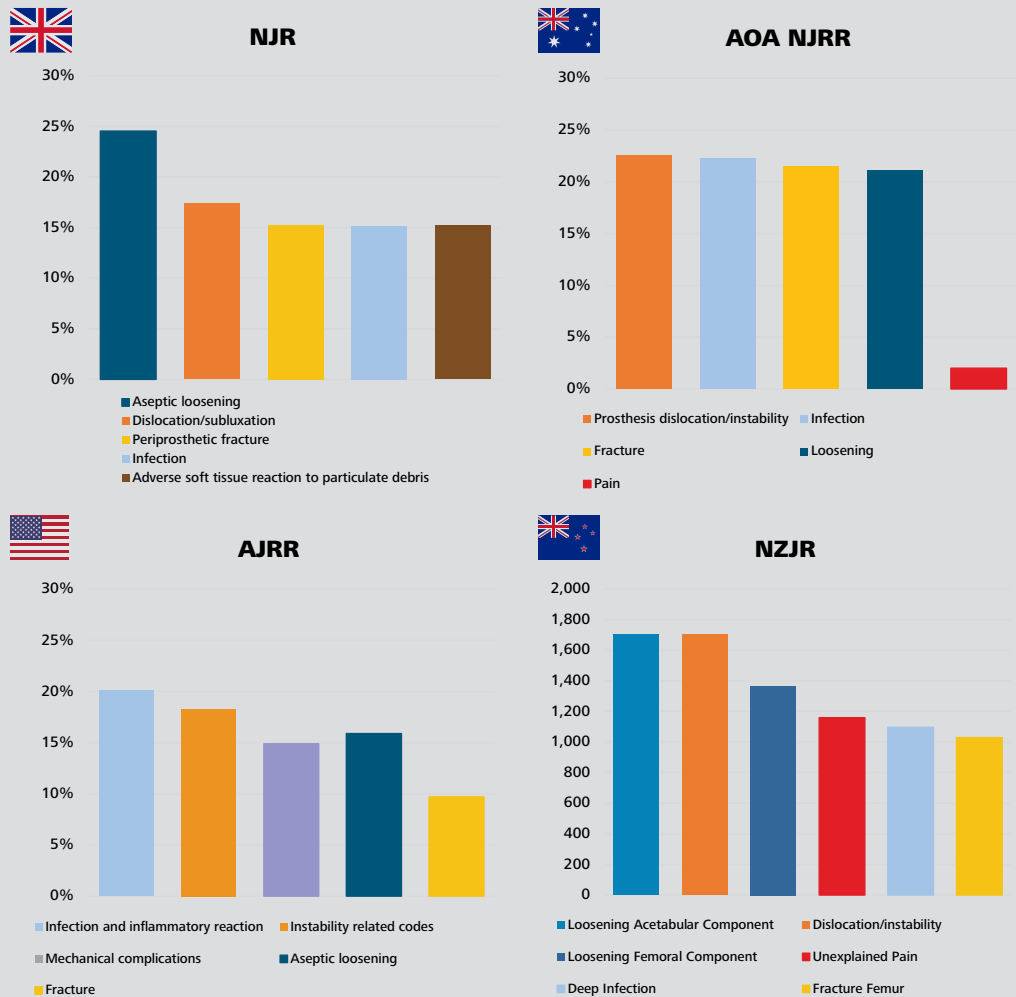
Since 1999, the five main reasons for revision after THR procedures in New Zealand are: loosening (of the acetabular and femoral component, respectively), dislocation/instability, unexplained pain, deep infection and femoral fracture.<sup>5</sup>

SAR

According to the SAR Annual Report 2021, the most common reasons for revisions in three-year periods 2018 to 2020 are: loosening, infection, dislocation/instability, periprosthetic fracture/pseudoarthrosis as well as wear of cup or liner.<sup>6</sup>

Figure 11: The most common reasons for revision in England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey, Australia, USA and New Zealand.

The Most Common Reasons for Revision



Evaluation of the data by CeramTec based on NJR Annual Report 2021 Page 100<sup>1</sup>, AOA NJRR Annual Report 2021 Page 96 Table HT15<sup>2</sup>, AJRR Annual Report 2021 Page 55 Table 2.36<sup>4</sup>, NZJR Annual Report 2021 Page 21.<sup>5</sup>



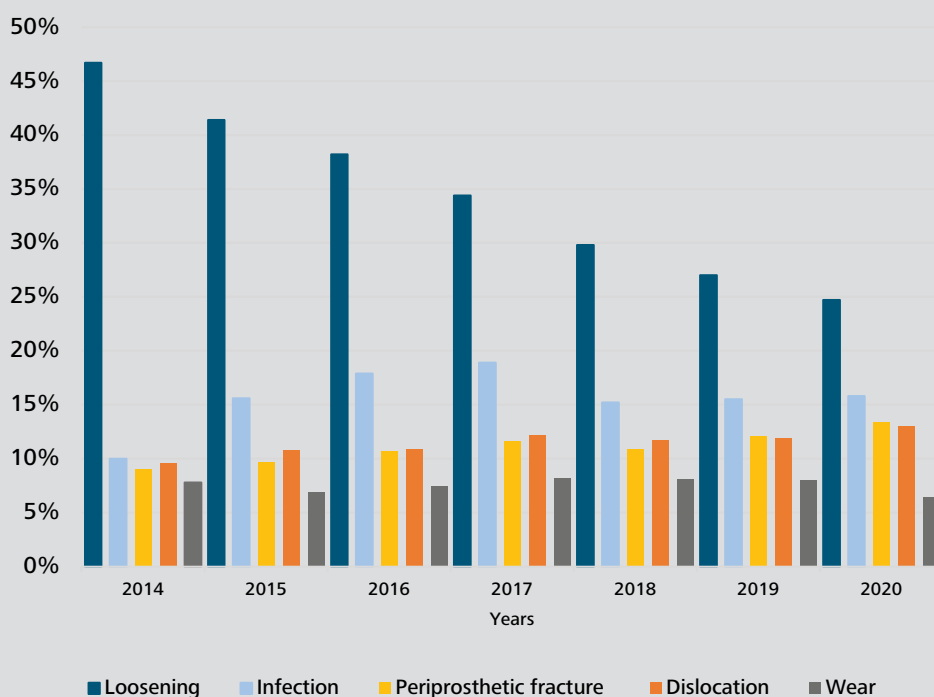
## Trends in Reasons for Revision: Infections on the Rise?

In Germany, the revision rate due to loosening has been decreasing year by year. The rates for revision for infection have increased from 10% in 2014 to 18.9% in 2017, then dropped off to 15.8% in 2020. Similarly, revision rates due to infection documented by the AJRR fluctuate between 11.3% and 25.7% over the years 2012 to 2020 (AJRR Annual Report 2021 Page 56 Figure 2.39).<sup>4</sup> A similar trend can be observed in New Zealand where the revision rate due to infection increased from 8.7% in 2012 to 18.8% in 2020.<sup>5</sup> The revision rate due to fracture of the femur steadily increased from 9.1% in 2013 to 20.9% in 2020. On the other hand, the rate of revision for unexplained pain decreased from a peak of 20.7% in 2011 to the lowest point recorded by the registry in the last decade equal 9.5% in 2020.

Figure 12: Reasons for revision by year in Germany.



### Reasons for Revision by Year: EPRD

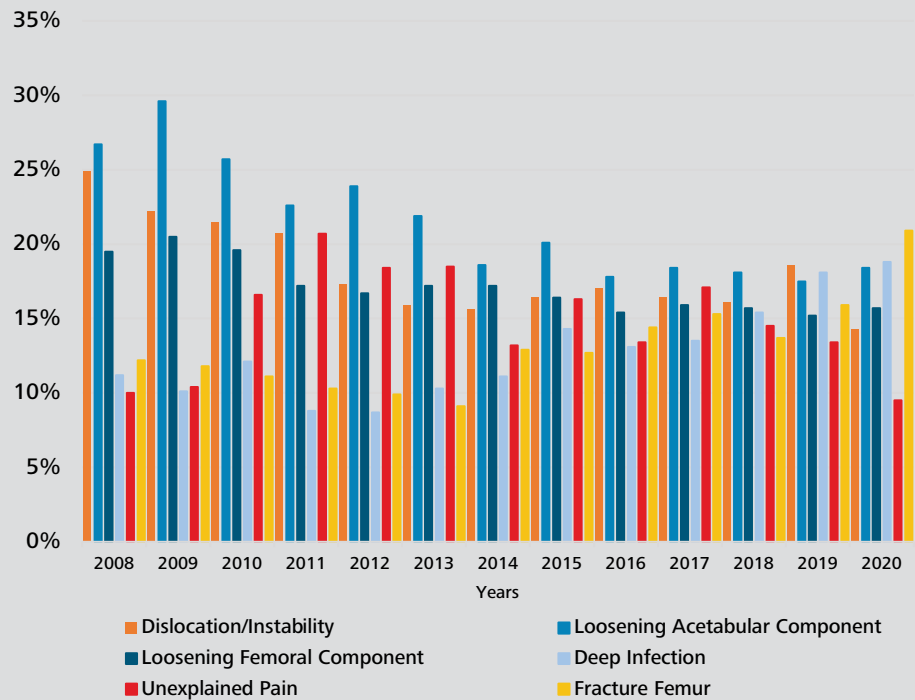


Evaluation of the data by CeramTec based on EPRD Annual Report 2014 to 2020<sup>3, 13-18</sup>.

Figure 13: Reasons for revision in New Zealand.



### Reasons for Revision by Year: NZJR



Evaluation of the data by CeramTec based on Figure on Page 22 in the NZJR Annual Report 2021<sup>5</sup>.

## Revision Rates: Best Outcomes for Ceramic Bearings

### NJR

According to the NJR, the revision rates for CoP bearings remain consistently low or similar to other bearings across all fixation options for up to ten years. The NJR shows that the relatively good results obtained with CoC and CoP bearings in young patients are "remarkable".<sup>1</sup>

For the combination of uncemented fixation and a CoC bearing, there is a clear correlation with head size: the larger the head, the lower the revision rate of the construct. Combined with hybrid fixation, the long-term revision rate of CoC bearings is lower than that of CoP and MoP. In this fixation group, CoC bearings with 36mm heads had a higher revision rate than 32mm and 28mm heads ( $P=0.009$ ).<sup>1</sup>

With MoP and CoP, large head sizes appear to be associated with higher failure rates particularly for 36mm heads with cemented fixation. According to the NJR, for patients above 75 years, CoP bearings combined with cemented and hybrid fixation possibly generate the lowest failure rates.<sup>1</sup>

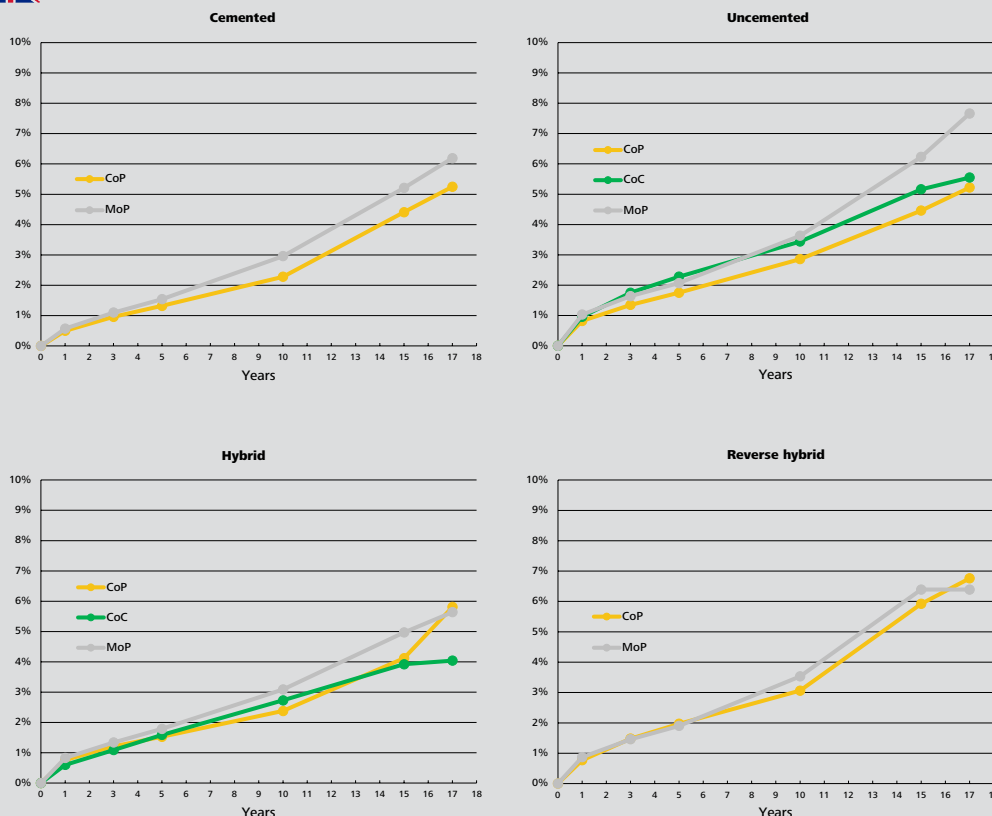
The NJR does not differentiate between polyethylene types by irradiation. One study linked a total of 290,770 THR from the registry with the manufacturing characteristics of the polyethylene inlays: Highly cross-linked polyethylene is associated with a marked reduction in the cumulative risk of revision for aseptic loosening when compared to non-irradiated polyethylene in cemented acetabular components.<sup>20</sup> It is also stated in the NJR Annual Report 2021: The trajectory of revision rates for polyethylene-containing bearings appears to differ beyond ten years, which may represent the increased use of highly cross-linked polyethylene over time.<sup>1</sup>



Figure 14: Cumulative revision rates in primary hip replacement with CoP, CoC and MoP bearings in combination with different fixation methods in England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey.



## Revision Rates in Primary THR by Fixation and Bearing Type



Evaluation of the data by CeramTec based on the NJR Annual Report 2021 Page 65 Table 3.H5<sup>1</sup>.

### AOA NJRR

In Australia, CoXLPE shows a lower rate of revision than MoXLPE already after two weeks (HR=0.93 (0.89,0.98), p=0.003). According to Australian registry analysis, the revision rate of CoC is not statistically different from MoXLPE (HR=1.01 (0.97, 1.05), p=0.613). The lowest revision rate of revision is given by ceramicised metal heads coupled with XLPE liners, which is statistically different from MoXLPE (after 3 months: HR=0.69 (0.63,0.76), p<0.001). However, the registry urges caution in the interpretation of this result as in the previous reports since "This bearing is a single company product, used with a small number of femoral stem and acetabular component combinations. This may have a confounding effect on the outcome, making it unclear if the lower rate of revision is an effect of the bearing surface or reflects the limited combinations of femoral and acetabular prostheses."

As far as the head size is concerned, the 32 mm XLPE associated with a lower rate of revision in comparison with the smaller and larger heads (XLPE <32mm vs. XLPE 32mm after three

months: HR=1.14 (1.07, 1.22),  $p < 0.001$ ; XLPE >32mm vs. XLPE 32mm: Entire Period: HR=1.07 (1.02, 1.13),  $p = 0.005$ ).

In contrast, for CoC bearings with mixed ceramic, there is no significant difference in the rate of revision between 36/38mm and 32mm head sizes (HR=1.02 (0.87, 1.18),  $p = 0.842$ ). Further, also the revision rates of 36-38mm and  $\geq 40$ mm head sizes are also not statistically different over the entire period (HR=0.87 (0.72, 1.05),  $p = 0.143$ ).

However, the 28mm head sizes are associated with a higher revision rate within the first three months (HR=2.74 (1.59, 4.72),  $p < 0.001$ )<sup>2</sup>.

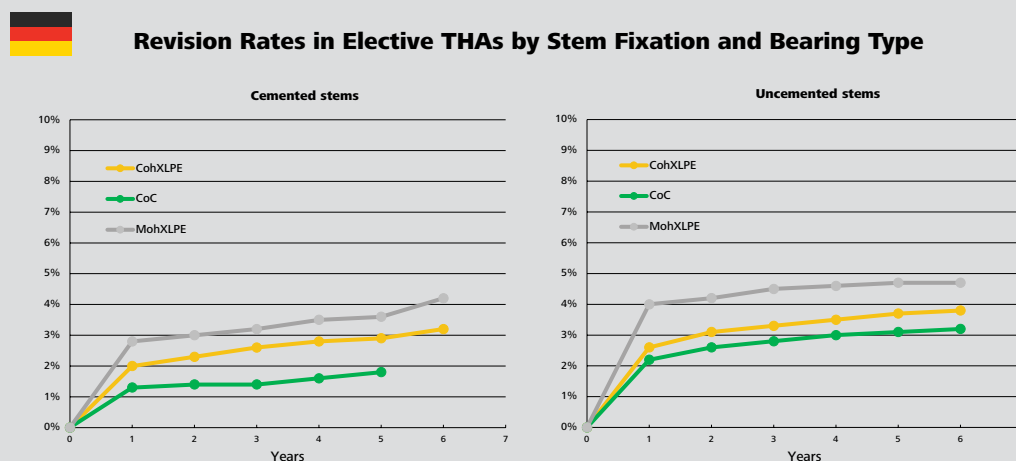
The Australian Annual Report shows that the cumulative incidence of dislocation/instability at 1 year is 1.7% for CoC bearing with a head size less than or equal to 28mm, while it is 0.4% for 32mm, 0.3% for 36-38mm and 0.2% for head sizes greater than or equal to 40mm.<sup>2</sup>

## EPRD

In Germany, among all bearing couples, CoC shows the lowest short- and mid- term failure rates. The revision rate of MohXLPE bearings is higher than that of CoC and CohXLPE in both cemented and uncemented stem fixation groups.

Looking at infection-related revision, CoC bearings also show the lowest short- and mid- term rates in the uncemented stem fixation group. In the cemented stem fixation group, CoC bearings correlate with lower infection rates than other bearings except MoM. In elective as well as non-elective THR, the larger the head diameter, the lower the probability of failure in the early phase.<sup>3</sup>

*Figure 15: Cumulative revision rates in elective hip replacement by stem fixation with CohXLPE, CoC and MohXLPE in Germany.*



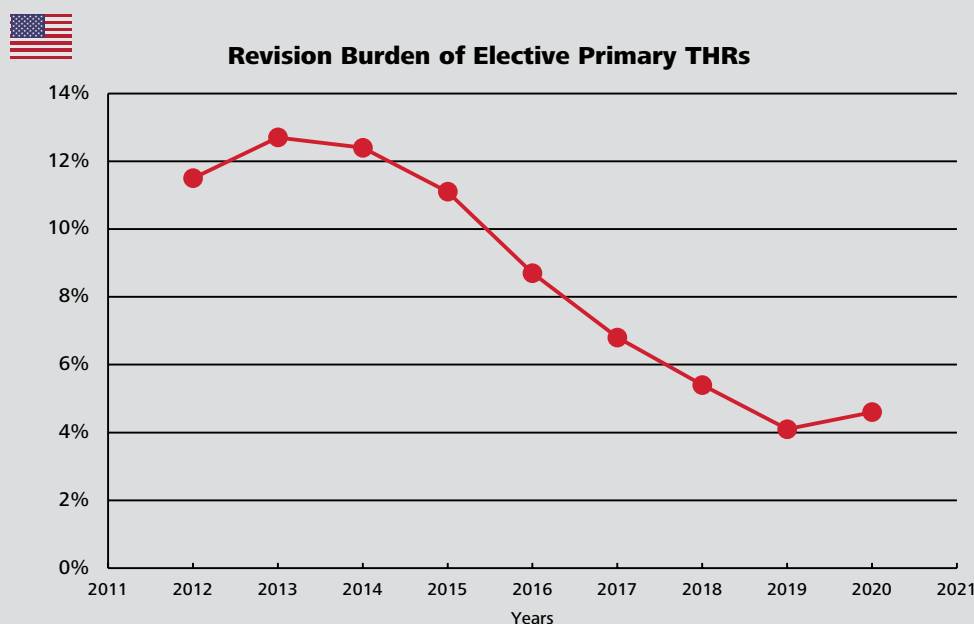
Evaluation of the data by CeramTec based on EPRD Annual Report 2021 Page 40 Table 37<sup>3</sup>.



 **AJRR**

In the USA, 4.6% of all THR procedures were revisions. There was a steep decline of this number from 12.7% in 2013 to 4.1% in 2019 followed by a slight increase in 2020. Head size and bearing surface material are identified as risk parameters for revision<sup>21</sup>. Uncemented femoral stem fixation and CoXLPE bearings with a 36mm head size have become the predominantly used combination in the United States. This might have contributed to the observed decrease. The Annual Report states that improvements in techniques and implants as well as material selection may reduce the risk of revision.<sup>4</sup>

*Figure 16: Revision burden of elective primary THRs in the USA.*



Evaluation of the data by CeramTec based on AJRR Annual Report 2021 Page 59 Figure 2.43<sup>4</sup>.

 **NZJR**

The New Zealand registry uses two very specific statistical terms for revision rates that are not found in the other registries:

**Observed component years:** the number of registered primary procedures multiplied by the number of years each component has been in place.

**Rate/100 component years:** equivalent to the yearly revision rate expressed as a percentage figure derived by dividing the number of prostheses revised by the observed component years multiplied by 100.

Regardless of the fixation method, the NZJR shows that the revision rate for CoC bearings is lower than that for CoP and MoP. The revision rate for CoP is also lower than that of MoP.



When adjusted by fixation types, the CoC bearing has the lowest revision rate in the uncemented and the hybrid fixation group.<sup>5</sup>

**Table 1: Revision data by bearing type in New Zealand. January 1999 – December 2020.**

Surfaces	Number of Operations	Observed Component Years	Number Revised	Rate/100 Component Years	Exact 95% Confidence Interval	
CoC	15,167	120,212.9	629	0.52	0.48	0.57
CoP	42,323	252,659.8	1,577	0.62	0.59	0.66
MoP	86,976	696,402.9	4,687	0.67	0.65	0.69

Evaluation of the data by CeramTec based on the NZJR Annual Report 2021 Page 52<sup>5</sup>.

**Table 2: Revision data by bearing type and fixation in New Zealand. January 1999 – December 2020.**

Fixation and Bearing	Number of Operations	Observed Component Years	Number Revised	Rate/100 Component Years	Exact 95% Confidence Interval	
<b>Cemented</b>						
CoP	856	7,125.0	51	0.72	0.53	0.93
MoP	25,934	230,873.5	1,523	0.66	0.63	0.69
<b>Uncemented</b>						
CoC	11,802	95,159.3	517	0.54	0.50	0.59
CoP	27,914	163,038.7	1,024	0.63	0.59	0.67
MoP	17,569	132,324.4	975	0.74	0.69	0.78
<b>Hybrid</b>						
CoC	3,365	25,053.6	112	0.45	0.37	0.54
CoP	13,553	82,496.2	499	0.60	0.55	0.66
MoP	43,473	333,204.9	2,180	0.65	0.63	0.68

Evaluation of the data by CeramTec based on the NZJR Annual Report 2021 Page 52<sup>5</sup>.

## Patient in Focus: Current Trends

### Patient-Reported Outcome Measures (PROMs)

PROMs calculate the health gains after surgical treatment from a patient perspective. This can contribute to the analysis of revision rates, identifying patients with persistent pain or disability as well as measuring patient satisfaction after surgery. Therefore, many registries and hospitals have started to record PROMs data. There is a growing demand for feasible methods and instruments to collect comprehensive PROMs and to enable data comparison between the registries.

#### NJR

Patient reported outcome PROMS including pain and function data have been collected nationally by NHS Digital since 2009 for all patients receiving a primary hip or knee replacement. This information has not been included in the NJR Annual Reports yet, but shall be addressed in future annual reports.<sup>1</sup>

#### AOA NJRR

The Australian registry conducted a pilot program to determine the feasibility of collecting PROMs from patients undergoing hip, knee or shoulder arthroplasty in 2017 involving 44 hospitals. The national roll-out of PROMs data collection started in 2020. For THR patients, the validated PROMs reported in 2020 include the EQ-5D Utility Index. This summary score is generated from the five domains of the EQ-5D survey: usual activities, mobility, pain, depression/anxiety and quality of life. Its values span from 0 ('a state as bad as being dead') to 1 ('full health'). Another included score, the EQ VAS Health, is a measure of patient-reported health 'today', ranging from 0 ('worst health imaginable') to 100 ('best health imaginable'). The Oxford Score provides joint-specific values of pain and function, ranging from the worst possible 0 to a maximum of 48, complemented by preoperative expectations and patient-perceived improvement at 6 months. For both surgeon-level and hospital-level of patients' proportion who indicated that they were satisfied, the overall rate of satisfaction for THR was 87%, respectively.<sup>2</sup>

## Patient in Focus: Current Trends

**Table 3: Preoperative and postoperative PROMs for primary total conventional hip replacement (primary diagnosis OA) from AOA NJRR Annual Report 2021.**

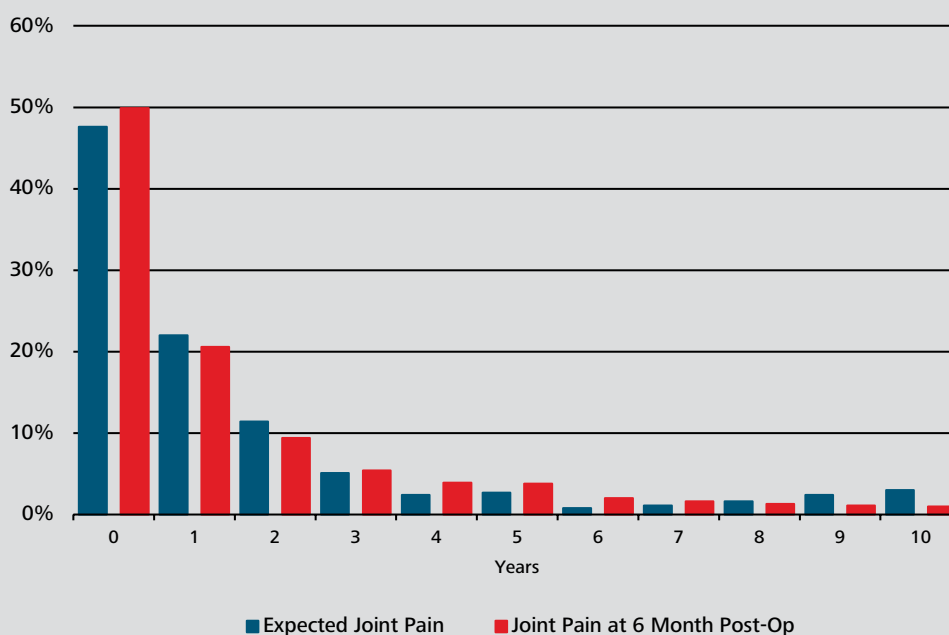
	Preoperative		Postoperative		Mean Difference (95% CI)
	N	Mean±SD	N	Mean±SD	
EQ VAS Health	7602	66.85±20.09	4606	80.99±16.12	14.13 (13.56, 14.70)
EQ-5D Utility	7675	0.35±0.35	4644	0.8±0.24	0.45 (0.44, 0.46)
Oxford Score	7585	20.42±8.89	4621	41.52±7.31	21.10 (20.84, 21.36)

Evaluation of the data by CeramTec based on AOA NJRR Annual Report 2021 Page 32 Table P2 & Page 43 P3<sup>2</sup>.

**Figure 17: Comparison of expected joint pain and actual joint pain at 6 months after primary conventional THR in Australia.**



**Expected Joint Pain vs Actual Joint Pain for Patients Undergoing Primary Total Conventional Hip Replacement (Primary Diagnosis OA)**



Evaluation of the data by CeramTec based on AOA NJRR Annual Report 2021 Page 52 Figure P29<sup>2</sup>.

**AJRR**

290 sites out of 1,152 (25.2%) have submitted PROMs until December 31, 2020, marking a 39% increase compared to the previous Annual Report. Based on the HOOS JR. score, 93% of the patients achieved a meaningful improvement after elective primary THR.



The HOOS JR., PROMIS-10, and VR-12 scores are the main instruments used by the AJRR to record PROMs after hip replacement.<sup>4</sup>

#### NZJR

The NZJR was one of the first joint registries to collect PROMs data. The validated Oxford Hip outcome questionnaires have been sent out on a random selection basis since July 2002 achieving an annual response rate of 20%. It was agreed that in the future, the questionnaires should be sent to all registered patients six months following surgery and after that at five-year intervals.

The NZJR uses the Oxford-12 questionnaire which includes 12 questions with score points ranging from 4 to 0. The maximum score of 48 indicates normal function, 0 stands for most severe disability. At six months after surgery, 84% of the participants have an excellent or good score. The average numbers are 42.37, 41.94, 41.37 and 40.75 at five, ten, fifteen and twenty years, respectively, after surgery.<sup>5</sup>

#### SAR

In Sweden, the PROM-routine for hip replacement started as a pilot project in one region in 2002. Until 2020, more units jointed, than PROMs were registered for more than 50% of the primary surgeries. In 2017, EQ-5D-5L was used to get health-related quality of life. Since 2012, the SAR started "Supported Osteoarthritis Self-Management Program", and in 2013 a question of smoking was added. At one, six, and ten years after the latest surgery, the same PROM-questionnaire with the addition of one question is sent to the patient.<sup>6</sup>

Latest registry data confirm former findings and existing trends. Hybrid fixation is gaining popularity. The same is true for dual mobility, especially in the treatment of fractured neck of femur. There is a modest comeback for hip resurfacing: While the use of the metal-on-metal version is restricted to patients meeting very strict selection criteria, the newly introduced ceramic-on-ceramic resurfacing could become a game changer.

### Dual Mobility

AJRR, AOA NJRR, EPRD, NJR, and SAR are reporting the usage of dual mobility bearings, which have steadily increased over the years.<sup>1-4</sup> In Australia, dual mobility prostheses show a lower rate of revision for dislocation than all other acetabular prostheses.<sup>2</sup> The American registry reports that dual mobility constructs were mostly used in patients younger than 50 years, accounting for 9.4% of the cases.<sup>4</sup> According to the NJR, the CoPoM dual mobility bearing shows lower revision rates than the MoPoM combination but without significant difference.<sup>1</sup> According to the EPRD Annual report 2020 and 2021, the modular and dual mobility cup systems have increased their share from 0.4 % to 1.2 % in the period 2015-2020.<sup>17,18</sup>

### Hip Resurfacing

Metal-on-metal resurfacing is still restricted to carefully selected patients. Women are mostly excluded from this procedure. Ceramic resurfacing procedures are recorded in the NJR and AOA NJRR. According to the NJR, currently performed CoC and MoP resurfacing procedures will be reported as a new category in future reports although the numbers are likely to remain too small for meaningful analysis for some years.

In the Australian registry, 177 CoC hip resurfacing procedures are documented, showing a cumulative revision rate of 0.6 (0.1, 4.2) at 1 year. This number is lower than that of MoM resurfacing at 1 year.<sup>2</sup> The 2020 Annual Report states that 'metal related pathology is the most common reason for revision after 7 years'.<sup>12</sup> Using ceramic instead of metal should therefore potentially minimize the major risks and contraindications for hip resurfacing. In New Zealand, the use of MoM-resurfacing has continuously increased from 70 procedures in 2016 to 122 procedures in 2020.<sup>5</sup>

### Hybrid Fixation

According to the NJR, hybrid fixation has become the most popular choice for hip replacement for the first time.<sup>1</sup> Hybrid fixation combined with CoP is the most frequently utilized construct in 2020 documented by the NJR. CoC bearings with hybrid fixation have a lower long-term revision rate than other combinations.<sup>1</sup> The percentage of hybrid fixation documented in Australia has increased slightly from 34.8% in 2003 to 36.8% in 2020. For patients aged 75 years or older the revision rate is lower when either hybrid or cemented fixation is used, with the analysis restricted to modern prostheses.<sup>2</sup>



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## Abbreviations, Tables and Figures

**AJRR:** The American Joint Replacement Registry

**AOA NJRR:** The Australian Orthopaedic Association National Joint Replacement Registry

**CI:** Confidence Interval

**CMoP:** Ceramicized Metal-on-Polyethylene

**CoC:** Ceramic-on-Ceramic

**CoM:** Ceramic-on-Metal

**CoP:** Ceramic-on-Polyethylene (including both conventional polyethylene and cross-linked polyethylene)

**CoPoM:** Ceramic-on-Polyethylene-on-Metal (Dual Mobility - only used by the NJR)

**CoXLPE:** Ceramic-on-Cross-Linked Polyethylene

**CohXLPE:** Ceramic-on-Highly Cross-Linked Polyethylene (only used by the EPRD)

**DM:** Dual Mobility

**EPRD:** Endoprothesenregister Deutschland (The German Arthroplasty Registry)

**EQ-5D:** European Quality of Life 5 Dimensions

**EQ-5D-5L:** European Quality of Life 5 Dimensions 5 Level Version

**EQ VAS Health:** EuroQol-Visual Analogue Scales

**HOOS JR. Score:** Hip Disability and Osteoarthritis Outcome Score for Joint Replacement Score

**HR:** Hazard Ratio

**MoM:** Metal-on-Metal

**MoP:** Metal-on-Polyethylene (including both conventional polyethylene and cross-linked polyethylene)

**MoPoM:** Metal-on-Polyethylene-on-Metal (Dual Mobility - only used by the NJR)

**MoXLPE:** Metal-on-Cross-Linked Polyethylene

**MohXLPE:** Metal-on-Highly Cross-Linked Polyethylene (only used by the EPRD)

**NHS:** The National Health Service

**NJR:** The National Joint Registry, which covers England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey

## Abbreviations, Tables and Figures

**NZJR:** The New Zealand Joint Registry

**OA:** Osteoarthritis

**PROMs:** Patient-Reported Outcome Measures

**PROMIS-10:** Patient-Reported Outcomes Measurement Information System-10

**SAR:** The Swedish Arthroplasty Register (Merger of the Swedish Hip Arthroplasty Register and the Swedish Knee Arthroplasty Register)

**SD:** Standard Deviation

**THA:** Total Hip Arthroplasty

**THR:** Total Hip Replacement

**VR-12:** The Veterans RAND 12 Item Health Survey

**Figure 1a (left):** Distribution of fixation methods in primary hip replacement in 2020: in Australia, Germany, as well as England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey.

**Figure 1b (right):** Distribution of femoral stem fixation methods in primary hip replacement in 2020 in the USA.

**Figure 2a (left):** Cumulative head size distribution of ceramic bearings in England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey.

**Figure 2b (right):** Cumulative head size distribution of mixed ceramic/mixed ceramic bearings in Australia.

**Figure 3:** Percentage of metal and ceramic femoral heads in primary THR by year in England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey.

**Figure 4:** Percentage of ceramic and metal femoral heads by year in Germany.

**Figure 5:** Percentage of metal and ceramic femoral heads in primary THR by year in the USA.

**Figure 6:** Usage of CoP, CoC and MoP bearings in primary THA by year in England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey.

**Figure 7:** Usage of CoP, CoC and MoP by year in Germany.

**Figure 8:** Usage of CoP and MoP bearings in primary THA by year in the USA.

**Figure 9:** Usage of CMoP bearings in primary THA by year in Germany and the USA.

## Abbreviations, Tables and Figures

**Figure 10:** Annual use of dual mobility bearings in primary THR in the NJR, EPRD, and AJRR.

**Figure 11:** The most common reasons for revision in England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey, Australia, USA and New Zealand.

**Figure 12:** Reasons for revision by year in Germany.

**Figure 13:** Reasons for revision in New Zealand.

**Figure 14:** Cumulative revision rates in primary hip replacement with CoP, CoC and MoP bearings in combination with different fixation methods in England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey.

**Figure 15:** Cumulative revision rates in elective hip replacement by stem fixation with CohXLPE, CoC and MohXLPE in Germany.

**Figure 16:** Revision burden of elective primary THRs in the USA.

**Figure 17:** Comparison of expected joint pain and actual joint pain at 6 months after primary conventional THR in Australia.

**Table 1:** Revision data by bearing type in New Zealand. January 1999 – December 2020.

**Table 2:** Revision data by bearing type and fixation in New Zealand. January 1999 – December 2020.

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