NATIONAL JOINT REPLACEMENT REGISTRY

AOA

AUSTRALIAN

ORTHOPAEDIC

ASSOCIATION

Lay Summary Hip and Knee Replacement

REPORT 2016

CELEBRATING 15 YEARS OF DATA



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Introduction

This summary explains the major findings of the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) 2016 Annual Report for Hip, Knee and Shoulder Arthroplasty (replacement). This is the major clinical report produced by the Registry each year.

The Lay Summary provides a clear and concise explanation of the published findings to all who may be interested.

The Australian Orthopaedic Association (AOA) believes this is especially important because of the high level of community interest in the Registry and the need to ensure that reports are accessible to all.

The full version of the 2016 Annual Report on Hip, Knee and Shoulder Arthroplasty is available in the Publications section of the Registry website. For the first time, the AOANJRR has included Shoulder Arthroplasty in the Annual Report, which this year is based on the analysis of 1,123,643 primary and revision procedures (498,660 hip, 592,577 knee and 32,406 shoulder). This is the total number of hip, knee and shoulder replacement operations recorded by the Registry with a procedure date up to and including 31 December 2015. It is 107,740 additional hip, knee and shoulder procedures compared to the 2015 Annual Report.

In addition to the Annual Report and this Lay Summary, there are a further 11 supplementary reports published by the Registry on the website https://aoanjrr.sahmri.com/annual-reports-2016

A brief history of the Registry origins

The AOA launched the National Joint Replacement Registry in 1999. It was initially for hip and knee replacement only. This was a complex system to set up and therefore it took almost three years to fully implement the Registry across Australia. The Registry now receives information from over 300 hospitals. Since mid-2002, the Registry has received information on almost all hip and knee replacements undertaken in Australia.

In November 2007, the Registry commenced collecting data on additional types of joint replacement. Data collection on shoulder arthroplasty was established later than hip and knee arthroplasty. The first year of full national data collection for shoulder procedures was 2008. Additional types of joint replacement include elbow, wrist, ankle and spinal disc replacement. Information on these procedures is presented in the supplementary reports previously mentioned and does not appear in this report.

Supplementary Reports

- Demographics of Hip, Knee and Shoulder Arthroplasty
 Details the age and gender profile of people receiving hip, knee or shoulder replacement and includes information on the reasons for undergoing replacement surgery.
- 2. Cement in Hip and Knee Arthroplasty

Details the use of the different types of cement in hip and knee replacement surgery.

- Mortality of Hip and Knee
 Arthroplasty
 Details the risk of dying following the different types of
- following the different types of hip and knee replacement surgery.
- Revision of Hip and Knee Arthroplasty
 Details the outcome of revisions of hip and knee replacements.
- Metal on Metal Bearing
 Surface in Total Conventional
 Hip Arthroplasty
 Details the outcome of metal
 on metal bearings when used
 with large (greater than 32
 mm) femoral heads.
- Metal and Ceramic Bearing Surface in Total Conventional Hip Arthroplasty
 Details the outcome of all metal on ceramic bearings.

Supplementary Reports cont.

Outcome of Classes No Longer Used - Hip and Knee Arthroplasty

Details the outcome of classes of hip and knee replacement that are no longer used and therefore do not appear in the main report.

8. Demographics and Outcomes of Elbow and Wrist Arthroplasty

Details the age and gender profile of people receiving elbow and wrist surgery. The report includes information on the reasons for undergoing these different types of joint replacement as well as some early information on the outcome of these operations.

Demographics and Outcomes of Ankle Arthroplasty

Details the age and gender profile of people receiving ankle joint replacement. The report includes information on the reasons for undergoing ankle replacement as well as some early information on the outcome of this operation.

10. Demographics of Spinal Disc Arthroplasty

Details the age and gender profile of people receiving spinal disc replacement and includes information on the reasons for undergoing this operation.

- 11. Analysis of State and Territory Health Data – All Arthroplasty 1993/1994 – 2013/2015
- 12. Investigations of Prostheses with Higher than Anticipated Rates of Revision

Each year the Registry identifies prostheses that have a higher than anticipated rate of revision. This is a series of reports providing detailed information on each of the prostheses identified in the 2016 Annual Report.

The purpose of the Registry

The AOA started the Registry to improve the results of joint replacement surgery in Australia. Generally, this type of surgery is very successful, but as with all areas of healthcare, there is always room for improvement.

One of the most serious consequences of a less than successful operation is the need to have a revision (redo) operation. The Registry has worked hard to ensure that the number of these operations is kept to a minimum. It does this by identifying those things that work best and highlighting what can be improved.

Prior to establishing the Registry, Australian orthopaedic surgeons felt they had a lack of detailed information on the results of the many different procedures and types of joint replacement available. In particular, surgeons require information to compare the effects of the many different factors known to influence the results for their patients.

Surgeons have a large choice of different types of artificial joints that they can use to replace damaged and painful joints. There are also different techniques, which can be used to put these artificial joints in place. Surgeons know that there is variation in the results depending on the patient, the nature of the patient's problem, which joint is being replaced, the way the operation is performed and the type of artificial joint replacement used.

"The Registry provides information to assist in deciding the best type of artificial joint replacement to use in any particular situation."

The Registry is able to compare all of these different factors simultaneously. In doing so, it provides information to assist in deciding the best type of artificial joint replacement to use in any particular situation. The Registry is able to detail the results for different classes (or categories) of artificial joints and different types of artificial joints in each of the classes. It can also determine if patient age, gender and/or the reason a joint replacement is performed, affects the result.

It is important to emphasise that this is not the only information used to determine what the best approach should be. When providing advice to patients, surgeons will also rely on their training and experience as well as information from medical journals, other registries elsewhere in the world, conferences and courses they may attend, as well as learning from other surgeons.

When surgeons interpret information from the Registry they use their knowledge and experience to put that information into context. The Registry does not decide or recommend the best joint replacement for a particular patient. This can only ever be made by the surgeon in consultation with the patient. In this way, all factors can be carefully taken into consideration.

How the Registry works

The Registry collects a small amount of confidential information on each joint replacement operation undertaken in Australia, with the exception of those people who choose not to have their information collected by the Registry. The information collected includes details of the patient, the reason for the surgery, the joint that was replaced and whether it was on the right or left side. Information on the type of artificial joint replacement and the individual components used in the operation are also collected.

"Currently the Registry monitors and has information on over 1.1 million joint replacement operations."

As previously mentioned, if a problem occurs following a joint replacement one of the possible outcomes is that the operation is redone. This is referred to as a revision procedure. The Registry is notified about the revision, records this information

and links it to the first (or primary) operation. By doing this it is able to determine how many initial primary procedures have been revised, the reason for the revision, how long after the original surgery, and which of the components (if any) were replaced.

How the Registry presents the results

The fact that the Registry is a national database means it reports on the results of a very large number of operations, which improves the value of the information. Currently the Registry monitors and has information on over 1.1 million joint replacement operations.

The Registry presents the results in different ways. The clearest and most important way is by graphs with tables referred to as 'cumulative percent revision' tables. These graphs are called 'Kaplan-Meier estimates of survivorship'. The term 'survivorship' refers to the survivorship of the prosthesis. In other words, whether or not all or part of it has been removed or replaced. When measuring survivorship the length of time it takes before the revision operation is measured and so the Registry then knows the survivorship for any time point since the original first operation.

The graphs are used to look at and compare the difference between the results using plotted curves on each graph and between different graphs and how this changes with time.

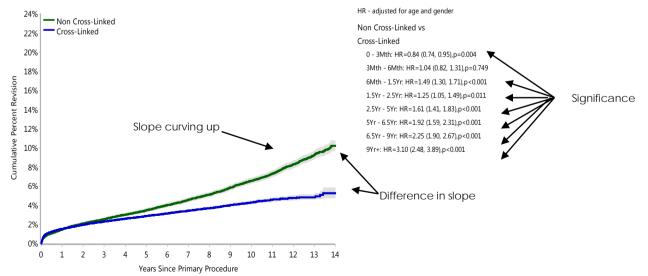


Figure LS1 Example of a graph with Kaplan-Meier estimates of survivorship. (from the Registry Annual Report)

When looking at the plotted lines the difference between the results for the factors being compared can be seen by comparing the plotted curves on each graph and between different graphs. The more the curve slopes upwards the greater the number of revision operations that have been required. In general, the greater the difference in the slopes of the graph the more important the difference.

On the right hand side of each of these graphs is a series of numbers. The most important of these are the HR (hazard ratio) and the p (probability) value. The hazard ratio is an indication of the risk of revision. For example, if the HR=3, this means that there is a three times greater risk of being revised compared to the situation to which it is being compared.

The 'p' value is a very important number. It is a measure of the likelihood of a real difference rather than the difference just occurring by chance. In statistical terms, this is called 'significance'. The difference is regarded as significant (in other words likely to be true) if a p value is smaller than 0.05. A p value of 0.05 means that there is a 1 in 20 chance that the difference is not true. A p value of 0.001 means that there is only a 1 in 1,000 chance that the difference is not true. In other words, it is even more certain that the difference is real.

Figure LS2 Example of a hazard ratio from a Registry graph

```
HR adjusted for age and gender

Non Cross-Linked vs Cross-Linked Polyethylene

0-3Mth: HR=0.84 (0.74, 0.95),p=0.004
3Mth-6Mth: HR=1.04 (0.82, 1.31),p=0.749
6Mth-1.5Yr: HR=1.49 (1.30, 1.71),p<0.001
1.5Yr-2.5Yr: HR=1.49 (1.05, 1.49),p=0.011
2.5Yr - 5Yr: HR=1.61 (1.41, 1.83),p<0.001
5Yr - 6.5Yr: HR=1.92 (1.59, 2.31),p<0.001
6.5Yr - 9Yr: HR=2.25 (1.90, 2.67),p<0.001
9Yr+: HR=3.10 (2.48, 3.89),p<0.001
```

The 'hazard ratio' (HR) is used to explain survivorship (also called survival data). The values in the brackets are the lower and upper limits of occurrence of the HR ratio. For instance, the first entry in Table LS2 above (highlighted in green) referring to the 0-3 month period, has a lower limit of 0.74 and an upper limit of 0.95. The HR value of 0.84 is the arithmetic mean (average) value of the upper and lower limit.

When the Registry compares two different factors, such as Non Cross-Linked to Cross-Linked Polyethylene to see if there is a difference, it also takes into account whether that difference is only evident for part of the time, or if the difference is there from start to finish i.e. over the entire period that the two factors are being compared.

The length of time after the initial operation when differences become evident is an important piece of information in helping to determine why there is a difference. There are many reasons why some things may differ soon after surgery and these reasons often change as the time after surgery increases. What can also happen is that the extent of difference can vary with time; sometimes the difference is greatest early, and other times the difference may increase as time progresses.

In order to clearly present these data, the Registry reports hazard ratios and their significance in particular time periods. These periods vary and are calculated based on the degree of difference. If more than one time period is reported it means that the difference was not constant and varied with time.

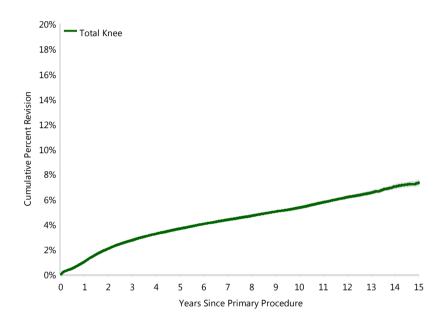
Using Figure LS2 as an example, the HRs have been divided into eight time periods: the time from the joint replacement to three months after the surgery, then three months following the surgery, six months, and so on. Each of these periods may have a different meaning. If we examine the period between six months and one and a half years (highlighted in blue) non cross-linked polyethylene has a higher rate of revision compared to cross-linked polyethylene (p<0.001). The hazard for revision is 1.49 times higher for non cross-linked polyethylene compared to cross-linked polyethylene and, with 95% confidence, the true hazard for non cross-linked polyethylene will lie between 1.30 and 1.71 times higher.

The Registry also reports data in cumulative percent revision tables. These tables give the number of revisions as a percentage of the number of operations at particular times i.e. 1 year, 3 years etc. The numbers are simply the values on the graph at the specific time points.

Figure LS3 Example of a table and corresponding graph

(KT12 Cumulative Percent Revision of Primary Total Knee Replacement (Primary Diagnosis OA) from the 2016 Registry Annual Report)

Knee Class	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	7 Yrs	10 Yrs	15 Yrs
Total Knee	17213	482373	1.0 (1.0, 1.1)	2.7 (2.7, 2.8)	3.6 (3.6, 3.7)	4.4 (4.3, 4.4)	5.3 (5.2, 5.4)	7.3 (7.1, 7.6)
TOTAL	17213	482373						



This Table shows the lower and upper limits of the cumulative percentage as the values in the brackets. So, at one year the cumulative percentage is 1.0, and is the calculated mean (or average) from the upper limit of 1.1 and the lower limit of 1.0.

On occasion, the Registry provides only cumulative percent revision tables and does not provide the graphs. This is usually when the results of a large number of different replacements in one category are being presented. The reason the graphs are not provided for each of the different replacements is simply a space issue. It would make the report too large.

When examining the tables variation in the outcome of the different prostheses that are listed can be seen. It is important to understand that just because a prosthesis combination has a higher cumulative percent revision than other prosthesis combinations, it does not necessarily mean that the combination is not as good. It is possible that this difference in the number of revisions between the prostheses has occurred by chance rather than being a true difference. In reality, most of the combinations have equally good results.

The Registry lists individual prostheses that have been identified as having two or more times the rate of revision when compared to all other prostheses that are similar in design. This difference also has to be significant (likely to be true). These prostheses are detailed in the final chapter of the Annual Report, which is titled 'Prostheses with a Higher than Anticipated Rate of Revision'. Summary data is presented in this chapter but a complete analysis of each of these prostheses can be found in the Investigation reports published in the supplementary reports section on the website.

There are many reasons why an individual prosthesis may have a higher rate of revision. Only some of these are related to the prosthesis. Prostheses identified in the higher than anticipated rate of revision group are prostheses that have been individually reviewed by a group of joint replacement specialists who believe that the particular prosthesis should be highlighted in the report. Identification by the Registry also initiates a process whereby the Australian regulatory body, the Therapeutic Goods Administration (TGA), assesses each of the individually identified prostheses to determine if they are still safe to use.

Who funds the Registry

The Commonwealth Government through the Department of Health, fund the Registry. The Government and the Department have been very supportive of the Registry. They provided the initial funding to establish the Registry and have maintained its funding since the Registry started.

2016 Annual Report for Hip, Knee and Shoulder Arthroplasty

When the Registry prepares the Annual Report each year, not only does it update important information that it has reported previously, but it also provides some new information. There are a number of new things being reported in this year's report. The first, includes a closer look at the results for both hip and knee replacement operations in younger patients (those aged less than 55 years). The second new part provides the results of surgery up to 15 years after the initial operation. The third section that is new includes some early reporting on the health of patients. A number of years ago the Registry started collecting two additional items of information on the health of patients at the time of surgery. The first is the American Society of Anaesthesiologists – Physical Status Classification (ASA score). This is a measure of a patient's general health, completed by all anaesthetists prior to any operation. They report this as a patient belonging to a particular category. The higher the number of the category the more general health problems that particular patient has. The other measure is Body Mass Index (BMI). This is an assessment of the weight of the patient. The reason that the Registry decided to collect this information is because both ASA and BMI are known to affect the results of joint replacement surgery. The Registry is reporting information on how both ASA and BMI vary in patients receiving hip, knee and shoulder replacement for the first time.

The remainder of the report includes an additional year of information on the results previously reported by the Registry. As with previous reports, there is a section on the outcome of those devices that have reached 10 years (now also including 15 years), as well as sections on Primary Hip Replacement, Primary Knee Replacement, Primary Shoulder Replacement and Prostheses with Higher than Anticipated Rates of Revision.

The Primary Hip, Knee and Shoulder chapters are each divided into three sections: Introduction, Partial and Total. There are some additional analyses included in these sections that have not been previously provided and there are some analyses that have been removed. When this has occurred, the information that was previously provided has been updated and provided within a supplementary report. Therefore, anything we have reported previously is still available and based on the most recent data. A good example of this is the metal on metal bearing surface for primary total conventional hip replacement. Although common a number of years ago, procedures using this bearing surface are now rarely done. This section was moved out of the main report last year and is now provided in a supplementary report, which is updated each year.

The section on Prostheses with Higher than Anticipated Rates of Revision includes hip, knee and shoulder procedures. These are the prostheses that, for whatever reason, have a higher rate of revision compared to all the other prostheses in the same class. These prostheses have been identified by the Registry on the advice of the independent orthopaedic experts that have reviewed and discussed the data on these devices.

Ten and Fifteen Year Prosthesis Outcomes

This year, the Registry is reporting on the outcome of 71 different hip prostheses combinations of femoral and acetabular prostheses with at least 10 year data. Prostheses with 10 year data account for 62.3% of all primary total conventional hip procedures being undertaken in Australia. The percentage of procedures that have reached 10 years and have ended up being revised varies from 1.9% to 45.8%. There are 36 (50.7%) hip prostheses combinations that have a 5.0% or less chance of being revised at 10 years. This is regarded as an excellent result for these 36 different hip replacements.

A similar analysis was undertaken for primary total knee replacement. The Registry identified 46 total knee replacement combinations with data for 10 years or more. This group accounts for 78.9% of all the total knees reported to the Registry. The percentage of procedures that have reached 10 years and have ended up being revised varies from 2.9% to 11.0%. Of these, 15 (32.6%) have a cumulative percent revision of less than 5.0% at 10 years.

For the first time a number of prostheses (7 hip and 14 knee) have information that extends out to 15 years. Most of the devices have performed well. For the hip replacements the percentage of procedures that have been revised at that time varies between 4.3% and 12.4%. Four of the hip prostheses have been revised less than 6.5%, and one less than 5%. For the knee replacements the percentage of procedures that have been revised at 15 years varies between 4.5% to 11.5%. Seven of the knee prostheses have a percent revision of less than 6.5% and one less than 5%.

Primary Total Hip Replacement in Younger Patients

It is known that the results of both hip and knee replacement surgery varies depending on the age of the patient at the time of surgery. Younger patients, those less than 55 years, are known to require revision operations more often than patients who are older. It is for this reason that surgeons often recommend that patients wait as long as possible before they have their joint replaced. Every surgeon knows that there are some younger patients who are having so much trouble that it is not really possible for them to wait until they are older. The reason that we have focused on the younger patients this year is to provide information on the best ways to get the best results if surgery has to be undertaken in a younger patient.

We know that the number of hip and knee replacements undertaken each year is increasing. It has been said in the past that part of the reason for this is because younger patients are having these operations more often. This does not appear to be the case. The proportion of younger patients (less than 55 years) having hip and knee replacements has not really increased very much for hips and it has actually gone down slightly for knees.

The likelihood of a person less than 55 years having a revision operation following a total hip replacement at 10 years is 5.8% and 9.9% at 15 years. This is a little higher than we see for older patients. There are various reasons why younger patients may require this revision surgery. The Registry has noticed some differences in the results depending on these reasons but these are not major differences.

There are quite a few different choices that a surgeon has with respect to the type of hip replacement that might be done and the way it is fixed into the bone. There does not seem to be a lot of variation in the results with the different classes of devices that are commonly used today. There are some differences when the results of specific devices are compared. Some appear to have less risk of being revised.

The Registry also looked at resurfacing hip replacement and found that this type of hip replacement works much better in men than women. The Registry has highlighted this finding now for many years.

Primary Total Knee Replacement in Younger Patients

Younger patients having total knee replacements are required to have them revised a little more often than younger patients having hip replacements. The chance of a younger patient having a revision operation after a total knee replacement is 10.9%, at 10 years and 15.7% at 15 years. Men have a slightly higher chance of needing a revision and this is due to an increased chance of getting an infection in the knee after the replacement has been done. However, the risk of this occurring is still small. It is not known why men, particularly younger men, have an increased chance of getting an infection. The Registry has identified a number of things about the general features of the prostheses that are used, or the way in which they are inserted, which can help to reduce the chance of being revised. As with the hip replacement prostheses, there is some variation in the results when different devices are compared. Some prostheses are associated with better results than others.

Hip Replacement

The Registry considers three different categories of hip replacement. These are primary partial, primary total and revision hip replacement. Each of these categories is divided into a number of different classes. These are described in the Annual Report at the start of the section on hip replacement.

There were 44,710 hip replacements reported to the Registry in 2015. This is an increase of 2.6% compared to the number undertaken in 2014. The majority of hip replacements are undertaken in private hospitals (59.7%).

Primary partial hips account for 15.5% of all hip replacements reported to the Registry since it commenced data collection. Primary total hips account for 72.9% and revision hips 11.6%.

Due to the staged introduction of the Registry, the first year that the Registry recorded complete national data was 2003. Since that time, the number of hip replacements reported to the Registry has increased each year. The number of hip replacements undertaken in 2015 was 64.9% more than undertaken in 2003.

However, there are differences in the rate of increase depending on the category of hip replacement. The number of primary partial hip replacements, which are almost always done for fractured neck of femur (broken hip), has increased by 28.9% since 2003. The number of primary total hips, which are most often done due to severe arthritis, has increased by 81.7% during the same time. The increase in revision hip replacement was the lowest of all categories and comparing 2003 to 2015 the number of revision hip procedures increased by 21.8%.

The proportion of hip procedures that are undertaken each year that are revision operations is called the revision burden. The aim of any intervention to improve the outcome of joint replacement is to reduce the revision burden. In 2011, the Registry reported an increase in the revision burden. This was largely due to the high revision rate of large head metal on metal hip replacements and in particular the ASR XL prostheses. In 2012, we noticed a decrease in the revision burden and this has now decreased further still. In 2011, the revision burden was 12.6%; in 2012, it was 11.8%; in 2013, it was 10.6%; and in 2015, it had decreased to 10.2%. This is the lowest revision burden for hip replacement ever reported by the Registry.

The Registry data continues to show that in general Australian surgeons have increasingly used approaches to hip replacement and hip replacement prostheses identified by the Registry as being associated with an improved result. This is particularly evident in recent years with increased use of prostheses known to have excellent outcomes over a long period, and decreased use of those that are known to have a less satisfactory result. It is anticipated that the effect of these changes will have a progressively beneficial impact on the revision burden in coming years.

Primary Partial Hip Replacement

Most partial hip replacements are used to treat broken hips. In particular, elderly patients with a broken hip involving a complete fracture at the base of the femoral head (ball of the hip joint) which is significantly displaced (moved out of position). This is commonly referred to as a subcapital fractured neck of femur.

The Registry has previously reported that the risk of further revision surgery following the treatment of broken hips with primary partial hip replacement is dependent on a number of factors. These include the age at time of surgery, class of partial hip replacement, method of fixation, and the type of prosthesis used.

There are three main classes of partial hip replacement: unipolar monoblock prostheses, unipolar modular prostheses and bipolar prostheses. Each has their place in the management of broken hips.

The use of partial hip replacement has been decreasing in recent years. The only type of partial hip replacement to show an increase in use is bipolar hips. This is a good outcome as these prostheses are reported by the Registry as having a lower rate of revision compared to other partial hip prostheses.

When the Registry first started collecting data, unipolar monoblock prostheses were the most common type of partial hip prostheses used. Although still quite common, their use has declined considerably in recent years, with a 50% reduction in use over the last 10 years. They are now used mainly in very elderly patients who are almost certainly not very mobile. It is in this group that the monoblock prostheses are least likely to run the risk of needing a revision operation, therefore the risk in this group is small.

Unipolar modular and bipolar replacement have a lower risk of revision in the 'younger' elderly population (below 85 years). Bipolar prostheses are revised less frequently than unipolar modular prostheses when individuals are less than 75 years of age.

The use of cement fixation reduces the risk of revision by approximately half, regardless of the class of partial hip replacement. Consequently, there has been a dramatic increase in recent years in the use of cement fixation when partial hips are used. However, the vast majority of partial hip replacements will do well, whether they are cemented or not.

Primary Total Hip Replacement

There are two main classes of primary total hip replacement. The first and most common is total conventional hip replacement, which involves replacing the femoral head (ball of the hip joint) as well as the acetabulum (socket of the hip joint). The second is a total resurfacing hip replacement. Although the socket is replaced in a similar way to a conventional hip, it differs in that only the surface of the femoral head is replaced rather than the whole head.

Overall, resurfacing hip replacement has a greater rate of revision compared to primary total conventional hip replacement. In recent years, the use of total resurfacing hip replacement has continued to decline. In 2015, it declined further, accounting for 0.8% of all primary total hips.

Factors that affect the outcome of primary total resurfacing hip replacement include the type of prostheses used, as well as the gender and age of the patient. Women have a significantly higher rate of revision. This difference has resulted in this procedure being done almost exclusively in males. Men have an age related rate of revision. Older males over the age of 65 years have a higher rate of revision in the first six months after surgery.

It appears that there are a number of reasons for the difference in outcomes related to gender. The first relates to the size of the patient. Smaller femoral head sizes do not do as well when a resurfacing procedure is done, and women on average, have smaller femoral head sizes. It also appears that women still have a higher rate of revision following a resurfacing hip replacement when a larger head size is used, but the reason for this is not clear. Currently, Australian surgeons rarely undertake resurfacing procedures in female patients. Only 1.9% resurfacing operations were performed on women in 2015.

The Registry has identified many factors that affect the outcome of primary conventional hip replacement. These can be divided into patient and prostheses factors.

Patients with osteoarthritis have better outcomes compared to patients having a total hip replacement for a different reason. Generally, it can be said that women have a slightly lower rate of revision compared to men. In the long term, the rate of revision decreases as the age at the time of the initial surgery increases. This is more apparent in women than men.

As has been done in previous years, a number of important prostheses characteristics that influence outcome have been highlighted again in this year's report. These include the method of fixation, the use of an exchangeable femoral neck, and the bearing surface of the hip prosthesis.

Primary total conventional hip replacements vary in the approach used to fix the prostheses to bone. There are three main types of fixation: cemented, cementless and hybrid fixation.

Cemented fixation is when the femoral and acetabular prostheses are fixed to bone using a hard setting plastic called methyl methacrylate (bone cement). Cementless fixation is when the femoral and acetabular prostheses are fixed to bone using macro fixation initially, which is followed by bone ingrowth into the surface of the prostheses, which gives a biological fixation. Macro fixation is achieved by shaping the bone and placing a slightly oversized prosthesis into the cavity produced by that shaping. Prostheses are designed to be specifically used with cemented or cementless fixation. The other main approach to fixation is hybrid fixation. This involves cementing the femoral component and using an acetabular component that is cementless. There is also an approach used which is termed reverse hybrid where the acetabular component is cemented and the femoral component is cementless. This method of fixation is rarely used in Australia.

For a number of years, the Registry has identified that there is an age related effect associated with the method of fixation. In general, older patients do better with hybrid or cement fixation and younger patients do better with hybrid or cementless fixation.

This year the Registry is again highlighting the increased rate of revision associated with the use of an exchangeable femoral neck. The Registry has previously identified this class of prostheses as having a higher rate of revision compared to other conventional hip replacements. The neck is the part of the femoral component that protrudes outside of the femur. It is usual that the stem and neck are all one piece, i.e. the neck is fixed to the femoral stem.

An exchangeable neck consists of the stem and neck as separate pieces, which are put together after the femoral stem is placed in position inside the femur. As the femoral head connects to the femoral component by the neck, the supposed advantage of an exchangeable neck is that it enables the surgeon to slightly vary the position of the head after the stem has been placed in position. This is not possible if the neck and stem are in one piece.

As the Registry has previously reported, our analysis shows that the use of an exchangeable neck is associated with twice the rate of revision. As in previous years, the Registry is also reporting that the rate of revision was higher regardless of the type of bearing surface used, and if the metals in the stem and the neck did not match. There is a much higher rate of revision if the stem and neck combination was titanium and cobalt chrome, compared to a titanium and titanium combination. All prostheses with exchangeable necks, which the Registry has more than five years follow up, show an increased rate of revision. Those with a metal mismatch have a higher rate of revision.

Last year, the Registry reported for the first time the results of a number of different types of hip replacements that have special features. These included mini femoral stems, as well as constrained and dual mobility acetabular components. The Registry has reported the results of these devices again this year.

Mini stems are very short cementless femoral stems, where fixation to the bone is over a smaller area entirely in the top of the femur. This is in contrast to the standard femoral stem that usually extends almost half way down the length of the femur. Currently mini femoral stems remain a relatively new technology and are not commonly used. They represent less than one percent of all total conventional hip procedures. This initial analysis does not identify any difference in the overall revision rate compared to standard femoral stems. There is a difference in the reasons for revision, with the mini stems requiring revision because they have become loose twice as often as the standard stem. However, the rate of revision does vary depending on the mini stem used.

As mentioned last year a constrained acetabular prosthesis is a special prosthesis. Unlike normal acetabular prostheses, it has a mechanism to lock the femoral head inside the acetabular socket so that there is a reduced chance of dislocation. It is not surprising to find they are used in different types of clinical situations compared to usual acetabular prostheses. In particular, they have been used more commonly in situations known to have a higher risk of dislocation. They do seem to have some beneficial effect because there is no difference in the rate of revision when a constrained acetabular

prosthesis is used, when it would be expected that the risk of revision would be increased when used in that patient. However, when a constrained cup is used in younger patients (aged 70 years or less) do not do as well compared to older patients. They have over three times the rate of revision. When total hip replacement is used to manage a broken hip (fractured neck of femur), a constrained acetabular prosthesis is associated with a smaller risk of revision.

Another type of special acetabular prostheses is the dual mobility acetabular prosthesis. The reason it is called dual mobility is because the femoral head moves or articulates with a polyethylene liner. This is unlike the common situation where the polyethylene liner is fixed to the acetabular shell. In this case, the liner in the dual mobility is designed to articulate with the metal shell i.e. there is dual mobility. The purpose of the dual mobility design is similar to the constrained acetabular prosthesis, in that it is designed to reduce the risk of dislocation. Similar to constrained acetabular prostheses, there is a high proportion of dual mobility acetabular prostheses used for unusual reasons, compared to standard acetabular prostheses. At five years, there is no difference in the revision rate of dual mobility acetabular prostheses compared to standard acetabular prostheses. This is true for both the diagnoses of osteoarthritis and fractured neck of femur.

This year the Registry has again undertaken an extensive analysis on outcomes related to the use of different bearing surfaces used in primary total conventional hip replacement. The bearing surface is the articulating surface and this varies depending on the material used to make the articulating surface on both the acetabular and femoral sides.

The acetabular articulating surface may be metal, ceramic or polyethylene. The polyethylene may be non-cross linked (also called non XLPE) or cross-linked (also called XLPE). Cross-linked means that an additional manufacturing process has been used that increases the bonding of the molecules within the polyethylene. It has been shown in laboratory testing that increasing the cross-linking, increases the resistance to wear when this material is used in hip replacement.

The femoral articulating surface may be metal, ceramic, or a third option called ceramicised metal, which is available mainly from one company. Consequently, there are a number of possible combinations that make up the different bearing surfaces. These include metal on polyethylene (non cross-linked and cross-linked) ceramic on polyethylene (non cross-linked and cross-linked), ceramic on ceramic, and metal on metal. Ceramicised metal femoral heads have only been used in sufficient numbers to assess when combined with cross-linked polyethylene.

There are a small number of procedures where the bearing surface is ceramic on metal. Large head (over 32 mm) metal on metal bearings and ceramic on metal bearings are now rarely used. They have not been included in the main report. However, the information on these bearing surfaces is still available in two separate supplementary reports, which have been listed at the start of this summary. As the Registry has reported since 2008, large head metal on metal bearings continue to have a much higher rate of revision compared to other bearings. This is because they produce metal particles at a higher rate compared to other bearing surfaces. These particles cause an inflammatory reaction which can damage the bone and muscles around the joint replacement.

Although ceramicised metal on cross-linked polyethylene has the lowest reported cumulative percent revision at seven years, the Registry has explained that this result should be interpreted with caution. This is for a number of reasons; the Registry is not confident that this result is due to the bearing. While there is no doubt that it is a perfectly satisfactory bearing, there is not enough evidence in the current data to suggest that it is the best. A complicating factor is that this bearing has only been used with a small number of different femoral stems and acetabular cups and shells from the same company. Many of these are well performing stems and acetabular components that are likely to be contributing in a major way to the lower revision rates seen with this bearing, when compared to other bearings.

In recent years, there has been increasing use of cross-linked polyethylene. The use of this material has been associated with a significant reduction in the rate of revision in primary total conventional hip replacement. This is due to a reduced rate of revision for both dislocation and loosening/lysis. The reduced rate of revision for dislocation is due to an increased use of larger head sizes (32mm or greater) in cross-linked polyethylene procedures.

These larger head sizes can be used because there is a lower rate of wear with this polyethylene. As mentioned earlier, when a larger head size is used, the hip replacement is more stable and so there is a lower rate of revision for dislocation. The reduced rate of revision for loosening and lysis is thought to be due to the lower wear rate. Loosening and lysis is most often due to an inflammatory reaction that occurs following the production of small wear particles. Theoretically, a reduced wear rate means less particles and therefore less inflammation. The reduction in loosening is supportive of a lower wear rate for cross-linked polyethylene.

Cross-linked polyethylene has a lower rate of revision compared to non cross-linked, regardless of whether a metal, ceramic or ceramicised metal femoral head is used. In addition to the overall analysis of all prostheses, the Registry has also undertaken analyses on five different acetabular prostheses - each have been used in large numbers with both cross-linked and non cross-linked polyethylene. Three of the five prostheses, have a lower rate of revision when cross-linked polyethylene is used. The other two do not show any difference. This is further evidence supporting a reduced revision rate when cross-linked polyethylene is used, but it does raise the question of whether this is true for all types of cross-linked polyethylene.

The Registry has undertaken a detailed analysis of ceramic on ceramic bearings. In particular, the different types of ceramic. The Registry has previously reported that the outcome of ceramic bearings is partly related to head size. Smaller heads less than 32mm have a higher rate of revision compared to all larger head sizes. There is no difference in how often a ceramic head is revised when 30-32mm heads are compared to larger head sizes. However, there is only a short follow up on the heads sizes over 36 mm.

There are three different types of ceramic: Zirconia, Alumina and Zirconia, and a combined Alumina, referred to as Mixed Ceramic. Zirconia is an older type of ceramic that is no longer used. The Registry was able to show that the change to the more modern mixed ceramic has been an improvement over the use of both Zirconia and Alumina ceramics.

Knee Replacement

As with hips, the Registry considers three different categories of knee replacement: primary partial, primary total, and revision knee replacement. Each of these categories is further divided into a number of different classes. These are described in the Annual Report at the start of the section on knee replacement.

There were 57,860 knee replacements undertaken and reported to the Registry in 2015. This is an increase of 5.9% compared to the number reported in 2014. The majority of knee replacements reported to the Registry up to the end of 2015 (70.7%) were undertaken in private hospitals.

Primary partial knee replacement accounts for 8.4% of all knee replacements reported to the Registry since it commenced data collection. Primary total knees account for 83.5% and revision knees 8.2%.

Since 2003 (which, as previously mentioned was the first year that the Registry collected full national data), the number of knee replacements undertaken each year has increased. In 2015, there was a 101.5% increase in the number of knee replacements compared to 2003. However, the rate of change differs depending on the category of knee replacement. Primary total knee replacement has increased by 130.4% since 2003, and revision knees by 82.9%. However, primary partial knees have decreased by 35.4%. Almost all primary knee replacements, whether they are partial or total, are undertaken for osteoarthritis.

The proportion of knee procedures that are revision procedures, has been decreasing since the Registry was implemented. Between 2004 and 2015 the percentage of knee replacements that are revisions decreased from 8.8% in 2004 to 7.4%.

Primary Partial Knee Replacement

The Registry identifies five classes of primary partial knee replacement. Most are used in small numbers and two are no longer used in Australia. A partial knee replacement is a replacement that only replaces part of the knee joint.

The most used partial knee replacement is the unicompartmental knee. This replaces the femoral and tibial joint surfaces on either the inner or outer side of the knee (most commonly the inner side of the knee). Its' use accounts for 93.1% of all primary partial knees. Other types of partial knee replacement are partial resurfacing and patella/trochlear knee replacements. There are also two types of partial knee replacement that are no longer used in Australia. This is because the results were not very good. They are the unispacer and bicompartmental knee replacement. The results of these two prostheses are available in the supplementary report under the heading of 'Outcome of Classes No Longer Used - Hip and Knee Arthroplasty'.

Partial resurfacing involves the use of special buttons to replace damaged areas of the knee joint surface. They account for 0.5% of all partial knee replacements. The Hemicap is the only partial resurfacing prosthesis currently available. Over the last few years, the Registry has reported that this prosthesis has a higher rate of revision compared to other partial knee replacements. These findings have been confirmed again this year.

Patella/trochlear prostheses replace the joint surfaces of the knee cap, both on the underside of the knee cap, and on the top of the femur in the groove where the knee cap runs. This area of the femur is referred to as the trochlear. This is the second most used partial knee replacement and accounts for 6.0% of all partial knees. There are a range of different patella/trochlear prostheses available for use. Patella/trochlear replacement is used in relatively small numbers and generally in very special circumstances. Age is a risk factor for revision. The rate of revision in patients younger than 65 years of age is significantly higher than patents 65 years or older. Men have a slightly higher rate of revision compared to women. There is variation in the outcome depending on the type of patella/trochlear prosthesis used.

Primary unicompartmental knee replacement has a higher rate of revision than primary total knee replacement. Age is a major factor affecting the outcome of unicompartmental knee replacement. The younger the patient, the more likely it is that the procedure will be revised early. At 15 years following a unicompartmental knee replacement, 21.0% have been revised. Almost 32.0% of patients less than 55 years of age at the time of their surgery have been revised within 14 years.

Unicompartmental knee replacement may be undertaken on the medial (inner), or lateral (outer) side of the knee. Medial unicompartmental knee replacement is much more common and accounts for 95.4% of all unicompartmental knee replacements. There is no difference in the outcome when medial and lateral unicompartmental knee replacements are compared. The outcome of unicompartmental knee replacement does vary depending on the type of prosthesis used.

Primary Total Knee Replacement

A primary total knee involves the removal and replacement of the joint surface of the femur and the tibia on both the medial (inner) and lateral (outer) sides. A single femoral prosthesis and a single tibial prosthesis are used. The tibial prosthesis may be one component, but is more commonly two. Usually, a metal tray fits over the cut surface of the tibia, with a plastic insert that fits inside the tray and articulates with the single femoral replacement. A primary total knee replacement may, or may not have the under surface of the patella replaced.

Primary total knee replacement has the lowest rate of revision compared to all other types of primary knee replacement. Men have a slightly higher rate of revision compared to women. The most important patient factor identified by the Registry that influences the rate of revision, is age at the time of surgery; the younger the patient the higher the subsequent rate of revision. Patients under 55 years of age at the time of surgery, have a 14.9% chance of being revised at 15 years. The rate of revision declines as patients get older, and in patients aged over 75 years, for those that live another 14 years only, 3.3% end up being revised.

There is only a small variation in the outcome of knee replacement related to the type of fixation used. Hybrid fixation has the lowest rate of revision but the difference is not major. Cemented fixation has a lower rate of revision compared to cementless fixation, but again the difference is not very large. However, there are some differences depending on the intrinsic stability of the knee replacement (see below). Minimally stabilised knees do best if at the very least the tibial component is cemented. Posterior stabilised knees do best when both the tibial and femoral components are cemented.

An important difference between hip and knee replacement is the intrinsic stability of the joint. As the hip is a ball inside a socket joint, there is a lot of stability because of the shape. This is not the case with knee replacement, where two relatively flat surfaces articulate with each other. The stability of the knee joint is much more dependent on surrounding soft tissues and in particular ligaments that hold these joint surfaces in place and in the correct alignment. Quite often in patients receiving a knee replacement, one or more of these ligaments may already be damaged. In order to address this issue, primary total knee replacement can vary depending on the additional built-in stability that may be required. In certain circumstances, it is necessary to use a replacement that is designed to substitute for one or more of the damaged ligaments.

Most knee replacements used do not require any additional stabilising, other than substituting for the anterior cruciate ligament. These are referred to as minimally stabilised knee replacements. The next most common group is posterior stabilised. These have additional stability built into the knee replacement, so that the prosthesis substitutes for the posterior cruciate ligament as well. The vast majority of knee replacements used are either minimally or posterior stabilised prostheses. Minimally stabilised prostheses have a slightly better outcome than posterior stabilised prostheses. However, there is some difficulty in being too definite about this, as posterior stabilised prostheses may be used more often in difficult cases. If a case is more difficult, it has the potential to be revised more often.

Other important ligaments around the knee are the medial and lateral collateral ligaments. These can also be substituted by what is often referred to as constrained knee replacements. These are not often required in primary operations. There is one final group of knee replacement when considering stability,

and these are hinged knees. These are mostly often used when there is absolutely no ligament stability left in the knee. Their use is very rare for primary knee replacement.

Another general difference in the design of primary total knee replacement, is the way the tibial insert is designed to move on the surface of the tibial tray. It may either be fixed to the tray (fixed insert), or designed to move (mobile insert). Mobile inserts either rotate, slide, or do both. For a number of years the Registry has reported that in general, fixed inserts have a lower rate of revision. However, a number of prostheses with mobile inserts do have similar rates of revision as fixed inserts. This remains the current situation.

In previous reports, we provided information on the use of cross-linked polyethylene in total knee replacement. This year we have repeated and extended that analysis. Comparing the outcome of cross-linked to non cross-linked polyethylene across all knee replacements, there appears to be a benefit when cross-linked polyethylene is used. However, in primary total knee replacement cross-linked polyethylene is not used as often as non cross-linked polyethylene. There is also considerable variation between the type of prostheses and the type of polyethylene used.

As a consequence, any difference seen when comparing the overall result of cross-linked to non cross-linked may be due to the type of prostheses, rather than the type of polyethylene. To try and overcome this problem, the Registry has undertaken analyses of specific designs of total knee replacement that have used both cross-linked and non cross-linked polyethylene. Only prostheses that had a minimum of 2,500 procedures in at least one of the polyethylene groups, and a follow-up time of five or more years, were used in this analysis. There were a number of different primary total knee prostheses that met this requirement.

The results were similar to last year, in that the data confirms that there is no disadvantage to using cross-linked polyethylene, and that in certain situations there may be a benefit i.e. in some but not all minimally stabilised prostheses. The Registry has not been able to show that there is any benefit in posterior stabilised prostheses.

We have also done a follow up analysis on the outcome of computer navigation in primary total knee replacement. Computer navigation is computer-assisted surgery, which was first used over 10 years ago. It involves the use of intraoperative computer monitoring in an attempt to more accurately position the knee replacement prosthesis. It is known that accurate positioning of the prosthesis is a very important factor in determining the result of the operation. The current information from the Registry suggests that there may be a small advantage, particularly in younger patients, as there is a small reduction in the rate of revision for loosening in this group.

There is another technique which surgeons are using in an attempt to improve the positioning of the knee prostheses. This is known as Image Derived Instrumentation (IDI). This technique involves obtaining accurate images of the knee joint preoperatively, so that the instruments used to achieve the alignment can be specifically made for that patient. The Registry has looked at the early results of this technique and there is no difference in the rate of revision at three years compared to when IDI is not used.

Hip and Knee Prostheses with a Higher than Anticipated Rate of Revision

The Registry reports on the results of individual prostheses in the different classes. There is variation in the revision rates for different types of prostheses in each class. Many of these differences are not statistically significant.

However, the Registry does identify individual prostheses that have a statistically significant higher rate of revision that is more than twice that of all other prostheses in the same class. These prostheses lay outside the expected norm and are often referred to as outliers. These outliers are identified in the final chapter of the 2016 Annual Report.

This information highlights to surgeons, orthopaedic companies and regulatory bodies worldwide, that something unexpected is happening with respect to the outcome of these prostheses. It enables consideration to be given as to the possible reasons for this difference, and whether it is worthwhile or appropriate to continue to use these prostheses.

It is important to emphasise that there may be many reasons why the revision rate is twice that of other prostheses. Some of these may not necessarily be related, or specific to the identified prostheses. The data related to each of these prostheses have been considered by an expert group of orthopaedic surgeons who have recommended these prostheses be identified and therefore be considered further as to whether or not they should continue to be used.

This year the Registry has identified 118 prostheses, or prostheses combinations (71 hip and 47 knee). There were 10 total conventional hip prostheses and no total knee prostheses identified for the first time.

The identified prostheses are listed in one of three groups. There are those that have a higher rate of revision but are no longer used in Australia. These are listed to provide ongoing information on the rate of revision and because it enables comparison of other prostheses, to the no longer used group.

The second group, is prostheses that are being re-identified but are still used. This list identifies that the prosthesis continues to have a higher than anticipated rate of revision, but it also provides information on its continued use. Most identified or re-identified prostheses decline in use. This is usually evident only after the first year because almost a full year of use has occurred prior to the identification in a previous Annual Report.

The third group are newly identified prostheses that are currently used and identified for the first time.

The Registry identification of prostheses with a higher than anticipated rate of revision has resulted in many of these prostheses being withdrawn from national and international markets. Only summary information is provided in the Annual Report. However, the full detailed analysis for each of these prostheses is available from the Registry website.

Summary

The purpose of the Australian Orthopaedic Association National Joint Replacement Registry is to provide high quality independent data on the results of joint replacement in Australia.

The Registry provides this information to surgeons, and all other stakeholders, to assist them to make informed judgments on the best approach to joint replacement surgery.

It is hoped that this summary, explaining the major findings of the 2016 Annual Report, is useful to people who are seeking additional information on joint replacement surgery; particularly those that are considering or have already undergone the operation. Registry information can be very complicated, as many factors interact to influence the outcome of the surgery. The intention of making this information available to everybody is to assist in promoting informed discussion about the outcome of joint replacement surgery, particularly between patients and their treating surgeons.