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JRI Orthopaedics Limited

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JRI products brands, overview

JRI orthopaedics was formed in 1970 as Joint Replacement Instrumentation Ltd by Mr Ronald Furlong F.R.C.S. consultant orthopaedic surgeon from St Thomas's Hospital London. The company changed its name to JRI Orthopaedics Ltd in 2010 following a rebranding exercise. JRI is wholly owned by Orthopaedic Research UK (ORUK), formally Furlong Research Charitable Foundation, an independent charity that funds orthopaedic research. All profits generated by JRI, after operational costs, are gift aided to ORUK.

Company administration and finance are based in the London office. Manufacturing is based in the modern Sheffield facility, alongside Research, Product Development, Customer Service, Marketing, Warehousing and Distribution.

Cemented implants

Furlong Modular Stem – A full report can be found in document 'ER1 – cemented' in Appendix 1.

Designed by Mr Ronald Furlong, the femoral stem is a Muller type design which is a straight double tapered, highly polished collarless prosthesis, now made of High nitrogen alloyed stainless steel. The stem was launched in 1979 as a monoblock matt finished titanium stem. In 1987 it was changed to a modular design and in 1989 the surface finish was changed to polished. In 1992 the product range was extended with a 316LVM option. In 2001 these were superseded by the currecnt high nitrogen stainless steel alloy version. In 2003 the titanium stems were discontinued.

JRI Cemented Acetabular cup - A full report can be found in document 'ER1 – cemented' in Appendix 1.

Designed by Mr Ronald Furlong, the acetabular cup is a monoblock device available in a variety of sizes for use with cement and is made of Ultra High Molecular Weight Polyethylene (UHMWPE) with an integral radiopaque stainless steel X-ray wire. The design has remained unchanged since 1979, the internal diameter (I/D) of the cup accommodates head diameters of 28mm, 32mm and 36mm. The 36mm I/D cups are only available in CLP 75®, JRI's highly cross linked Polyethylene. See NICE technical Report for more details on CLP 75®

Uncemented Implants

Furlong H-A.C. A full report can be found in document 'ER2 - Furlong H-A.C.' in Appendix 1

The Furlong® H-A.C. stem was developed by Mr Ronald Furlong F.R.C.S. and first implanted in 1985. The stem was designed specifically as an uncemented stem and was the first femoral prosthesis in the world to utilise Hydroxyapatite-ceramic (H-A.C.) coating. Mr Furlong pioneered the use of H-A.C. in hip replacement surgery specifically to improve long term survivorship, reduce aseptic loosening and reduce mortality due to cement. The unique stem design enables stable primary mechanical fixation to be achieved. Secondary physiological fixation is achieved through osteointergration with the H-A.C. (Supravit®), Supravit® is unique to JRI and has properties that differentiate it

from other forms of H-A.C. See section on Supravit® below. The stem is a straight collared prosthesis, made of Titanium alloy Ti-6Al-4V and fully coated with Surpavit®. It is intended for use WITHOUT cement, fixation being achieved through bone ingrowth and union of the coating and the host bone and is available in various sizes to accommodate anatomical variations of the femur. The Furlong H-A.C. won a 1993 Queen's Award for Technological Achievement.

Furlong Active Stem – A full report can be found in document 'ER3 Furlong Active' in Appendix 1

The Furlong® Active Femoral Stem is a double tapered collarless prosthesis made of titanium alloy Ti-6Al-4V and fully coated with Supravit® hydroxyapatite ceramic. First implanted in 2004, it is intended for use without cement, fixation being achieved through bone ingrowth and union of the coating and the host bone.
The Furlong® Active stem design is been based on the Furlong® H-A.C. stem which has extensive clinical use and has proven its biomechanical stability and biocompatibility. The changes in geometry were designed mainly to improve the load transfer and improve any areas of potential stress shielding
The range of Furlong® Active stems have been designed with both spigot length/offset and stem length increasing with stem size.

Furlong Evolution - A full report can be found in document 'ER3 Furlong Active' in Appendix 1

The Furlong® Evolution femoral stem was developed as a bone preserving design. It is made from titanium alloy Ti-6Al-4V and fully coated with Supravit® hydroxyapatite ceramic coating. The stem was developed with input from 12 surgeons led by Professor Justin Cobb at Imperial College London. Based on the Furlong H-A.C. the stem retains the rectangular cross section proximally, the cone transition into the distal stem and Supravit® Zoned H-A.C. coating. The stems are all 100mm length and are available collared and collarless. The shape of the stem, the instrumentation and the operative technique have been developed to allow the implant to be more easily inserted whilst removing less bone compared to the Furlong® H-A.C.

Furlong Threaded Cup – A full report can be found in document 'ER5 – H-A.C. cups' in Appendix 1

The Furlong Threaded cup was designed by Mr Ronald Furlong and first implanted in 1985. Primary fixation of a threaded cup is achieved by direct tapping of a buttress thread into the acetabulum. It is intended for use without cement, fixation being achieved through bone ingrowth and union of the coating and the host bone. It is made from titanium alloy Ti-6Al-4V and coated with Supravit® H-A.C. coating. Fixation of the liner is achieved through use of a 5 degree taper lock mechanism. Ceramic and UHMWPE liners are available for use with the cup in a variety of bore sizes. Hooded liners are available in UHMWPE to provide additional security against dislocation.

Furlong H-A.C. CSF Cup - A full report can be found in document 'ER5 – H-A.C. cups' in Appendix 1

The Furlong CSF cup was designed by Mr Ronald Furlong and first implanted in 1991. Primary fixation of a CSF cup is achieved by a press fit at the equator of the cup, in addition the use of 3 screws has been recommended. It is intended for use without cement, fixation being achieved through bone ingrowth and union of the

coating and the host bone. It is made from titanium alloy Ti-6Al-4V and coated with Supravit® hydroxyapatite ceramic coating. Fixation of the liner is achieved through use of a 5° taper lock mechanism.

Ceramic and UHMWPE liners are available for use with the cup in a variety of bore sizes. Hooded liners are available in UHMWPE to provide additional security against dislocation.

The Furlong H-A.C. CSF *Plus* cup A full report can be found in document 'ER5 – H-A.C. cups' in Appendix 1

The CSF *Plus* cup was developed based on the proven principles of the CSF cup but with enhancements to the fixation surface. A 'Two' cup system was developed to utilise the simplest and most effective means of fixing the bearing liners, either Ceramic or Polyethylene.

Primary fixation of a CSF Plus cup is achieved by a pressfit at the equator of the cup. It can be used without screws if preferred. It is intended for use without cement, fixation being achieved through bone ingrowth and union of the coating and the host bone. Extensive clinical use has proven its biomechanical stability and biocompatibility. It is made from titanium alloy Ti-6Al-4V and coated with Supravit zoned H-A.C. coating (Appendix 3, H-A.C. coatings).

Ceramic bearing CSF *Plus* cups - Fixation of the ceramic liner in the cup is achieved through use of an 18 degree taper lock mechanism. These cups accept Biolox® Delta ceramic liners only. The advent of these next generation ceramics, enables the use of large diameter heads with thinner ceramic liners.

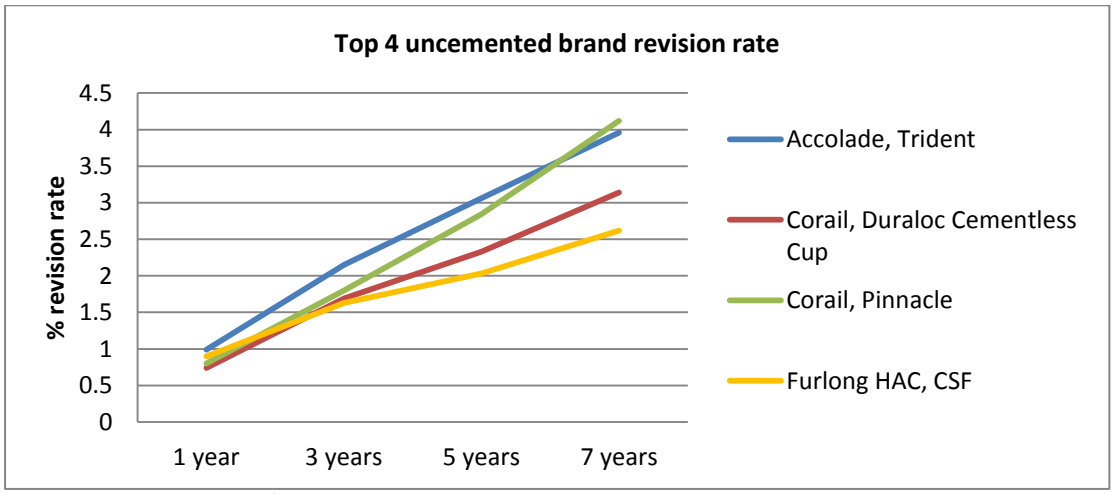
Polyethylene bearing CSF *Plus* cups - Fixation of the liner in the cup is achieved through use of a 5 degree taper lock mechanism. The screw holes can be plugged to prevent transfer of Polyethylene particles. The cup and all plugs are made from titanium alloy Ti-6Al-4V and coated with Supravit®. The cups accept CLP 75® (Appendix 3, CLP 75)®, JRI's highly cross linked polyethylene liners. Hooded liners are also available to provide additional security against dislocation.

JRI technology evidence report

The excellent clinical results of the Furlong H-A.C. brand documented in numerous peer reviewed papers[1][2][3] are also reflected in the latest edition of the England and Wales NJR 2012. The Furlong H-A.C. stem/ CSF cup has the lowest revision rate of all of the uncemented hip brands at 7 years in the NJR 9th annual report [4].

Uncemented stems and uncemented cups					
Accolade, Trident	13,712	0.99% (0.83-1.19)	2.15% (1.86-2.48)	3.06% (2.56-3.64)	3.96% (2.70-5.82)
Corail, Duraloc Cementless Cup	3,990	0.74% (0.51-1.06)	1.69% (1.32-2.18)	2.33% (1.85-2.95)	3.14% (2.45-4.03)
Corail, Pinnacle	54,019	0.80% (0.73-0.89)	1.80% (1.67-1.95)	2.84% (2.61-3.10)	4.12% (3.51-4.85)
Furlong HAC, CSF	13,940	0.90% (0.75-1.07)	1.63% (1.43-1.87)	2.03% (1.79-2.31)	2.62% (2.28-3.00)
Furlong HAC, CSF Plus	8,896	1.10% (0.89-1.35)	1.74% (1.43-2.11)	-	-
SL-Plus Cementless Stem, EPF-Plus	3,890	1.24% (0.93-1.65)	2.83% (2.31-3.45)	4.12% (3.36-5.05)	-
Taperloc Cementless Stem, Exceed	6,986	1.00% (0.78-1.28)	1.54% (1.21-1.98)	2.22% (1.36-3.60)	-

Table 1 NJR England and Wales, 9th Annual Report showing revision rates of most commonly used uncemented THR's



Graph 1, NJR England and Wales, 9th Annual Report showing revision rates of most commonly used uncemented THR's

It is important to consider that there are several different uncemented technologies, which do not all have the same success rates:

- Porous coated
- Grit blasted
- Sintered beads
- Trabecular metal
- Titanium coated
- H-A.C. coated – Atmospheric conditions
- H-A.C. coated – Vacuum conditions

In addition, implant geometry and the ability through optimisation of this and surgical technique to achieve stable initial fixation, are important factors in achieving long term survivorship.

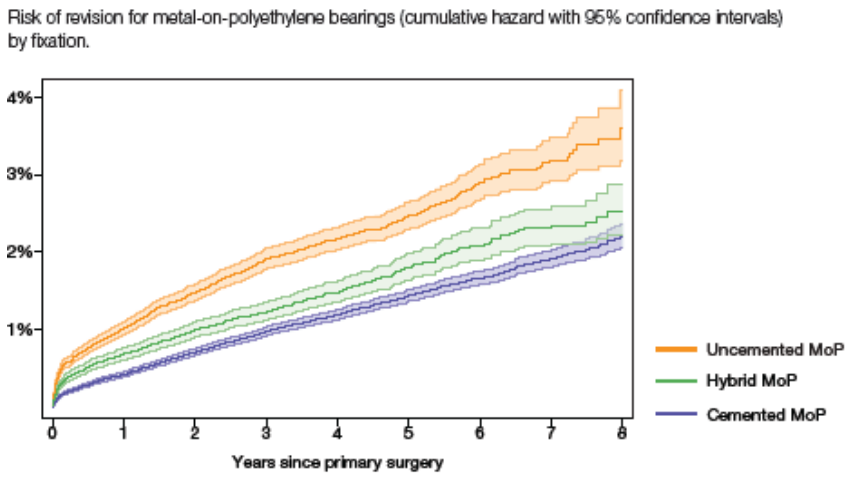
JRI uses H-A.C. coating applied in a Vacuum (see Appendix 3)

The National Joint Registry of England and Wales has been collecting data since 2003. Reviewing the data available from the NJR 9th annual report, the market shift towards uncemented implants has been driven by the Corail/Pinnacle THR by DePuy, which has 48% of the Stem market and 33% of the Cup market. Considering that the combined revision rate of the Corail/Pinnacle is 40% higher at 7 years than the Furlong® H-A.C./CSF, care should be taken not to allow the results of the market leading implant to unduly influence judgment on the success rate of uncemented total hip implants.

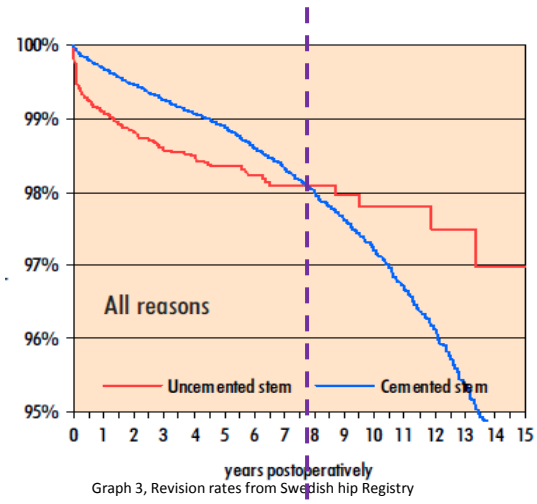
NJR Versus Swedish hip registry and the Australian Joint registry

The early years of the Swedish Hip Registry [5] and the Australian Joint Registry [6] showed a similar trend to that shown on the NJR 9th Annual report. When comparing the revision rates of cemented versus uncemented all three registries clearly showed a significantly higher revision rate for uncemented However, the Swedish hip registry demonstrates that the revision rates of cemented and uncemented crossed over after 8 years (Graph 3) . The Australian Joint registry states that cementless has a higher rate of revision compared to cemented in the first month but after six years the rate of revision for cemented is significantly higher than cementless.

The United Kingdom population was estimated to be 63.2 million in 2011, up 7 per cent (4.1 million) from 2001 and 50 per cent (21.1 million) from 1911. This is the largest decennial percentage change in population since the 1961 Census [7]. There are now over 14 million people in the UK aged 60 and above and the number is expected to pass the 20 million mark by 2031. Current UK estimates from the Office for National Statistics for female life expectancy at birth are 82.3 years and 78.2 years for men and projected to rise to 87 and 83.3 respectively by 2033 [8]. Patients receiving a THR at the age of 75 can have a reasonable expectation of requiring their replaced hip to function well for at least 10 years.



Graph 2 NJR England and Wales, 9th Annual Report



Graph 3, Revision rates from Swedish hip Registry

JRI data taken from the NJR up to December 2012 (Appendix 2)

JRI THR's

- 34,968 registered cases where JRI products have been used
- 3,248 cases when a JRI stem was used with another manufacturers cup
- 1,940 cases when a JRI cup was used with another manufacturers stem

Femoral stems

- 27,046 Furlong H-A.C. stems
- 601 Active stems
- 1,816 Cemented Stems
- 202 Evolution Stems

Acetabular cups

- 15,042 CSF
- 11,473 CSF Plus
- 1,914 Cemented Cups
- 1,306 Threaded Cups

Table 2 shows the combination of cup and stem brands entered onto the NJR up to December 2012.

	CSF	**CSF Plus**	**Total**
Evolution	2	200	202
Furlong Active H-A.C.	319	226	545
Furlong H-A.C.	14587	10965	25552
Total	14908	11391	26299

Table 2, JRI implant combination chart entered in the NJR up to December 2012

Table 3 shows how JRI uncemented implants compare with Cemented, Hybrid and Uncemented THR's in the NJR 9th annual report. As shown, the revision rates for all of the categories for revision for JRI uncemented are less than all the uncemented, the majority of the hybrid and 2 of the 6 categories of the cemented.

Fixation	Pain	Dislocation/ Subluxation	Infection	Aseptic loosening	Lysis	Periprosthetic fracture
All Cemented	0.46	0.87	0.78	0.86	0.17	0.27
All Hybrid	0.67	1.23	0.73	0.81	0.2	0.56
All uncemented	1.57	1.37	0.95	1.85	0.26	0.8
JRI uncemented	0.66	1.37	0.47	1.43	0.12	0.56

Table 3, revision rates for different fixation types, incidence per 1000 life years

Consideration: The NJR collects data on the reason for revision, often multiple reasons are given and regularly the reasons can be as a consequence of, rather than the cause of the revision. i.e if a patient is revised for a periprosthetic fracture, one can assume that the implant would become loose and cause pain.

Survival rates of Furlong H-A.C./ CSF cup and Furlong H-A.C./ CSF *Plus* cup

Furlong H-A.C. and CSF cup survival rates at 9 years

Case Processing Summary

Bearing	Total N	N of Events	Censored	
			N	Percent
COC	1582	52	1530	96.7%
COP	6096	99	5997	98.4%
MOP	6535	150	6385	97.7%
Overall	14213	301	13912	97.9%

Table 4, survival rates calculated with Kaplan Meier survival analysis

Furlong H-A.C. and CSF *Plus* survival rates at 5 years

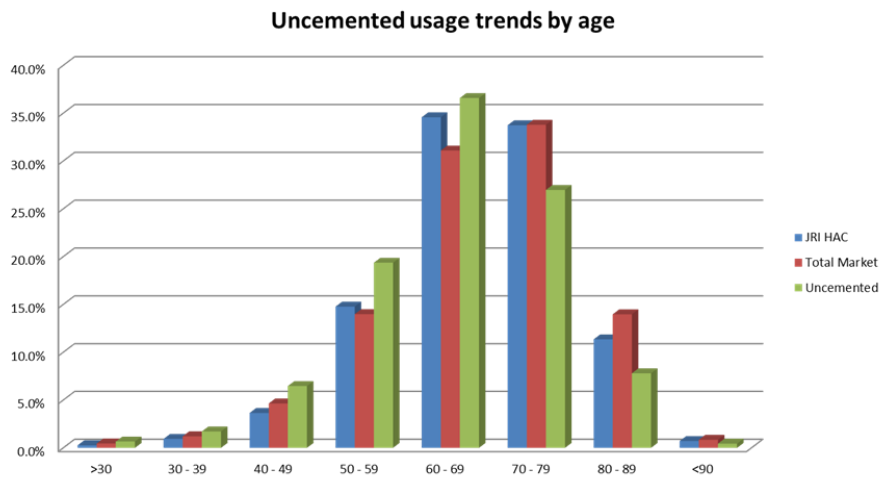
Case Processing Summary

Bearing	Total N	N of Events	Censored	
			N	Percent
COC	7135	96	7039	98.7%
COP	1222	17	1205	98.6%
MOP	2494	40	2454	98.4%
Overall	10851	153	10698	98.6%

Table 5, survival rates calculated with Kaplan Meier survival analysis

JRI uncemented usage trends by age

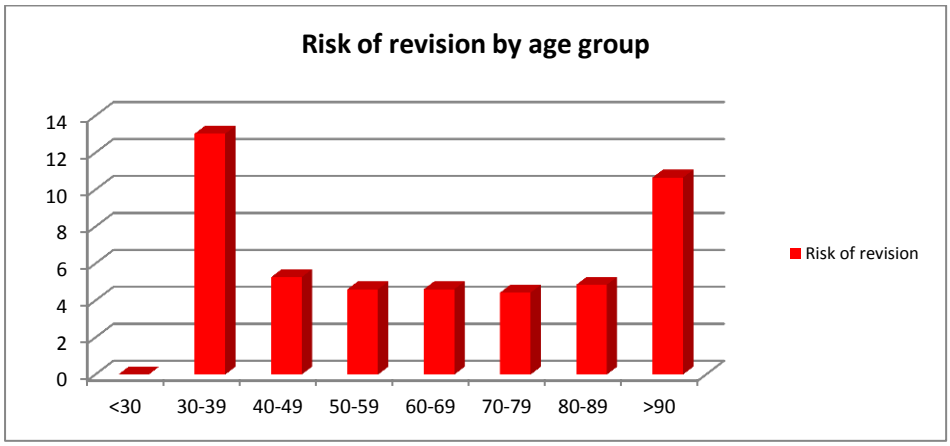
Surgeons who implant Furlong CSF/CSF Plus tend to use the same implant in most of their patients irrespective of age, health and life expectancy as can be demonstrated in the graph below. Looking at the percentage split over the patient age group of all procedures and comparing JRI H-A.C. implants as a whole it can be observed that it follows the general trend.



Graph 4, uncemented rates

Risk of revision by age group

The risk of revision for a Furlong H-A.C. THR is consistent between the age groups. The two outlying groups are patients between 30 and 39 and patients over 90. There were only 5 revisions in the over 90 group 2 for dislocation and 2 for periprosthetic fracture. 45% of patients receiving a Furlong THR are aged between 70 and 90 years old. Graph 5 demonstrates no significant increase in the risk of revision for those patient groups.



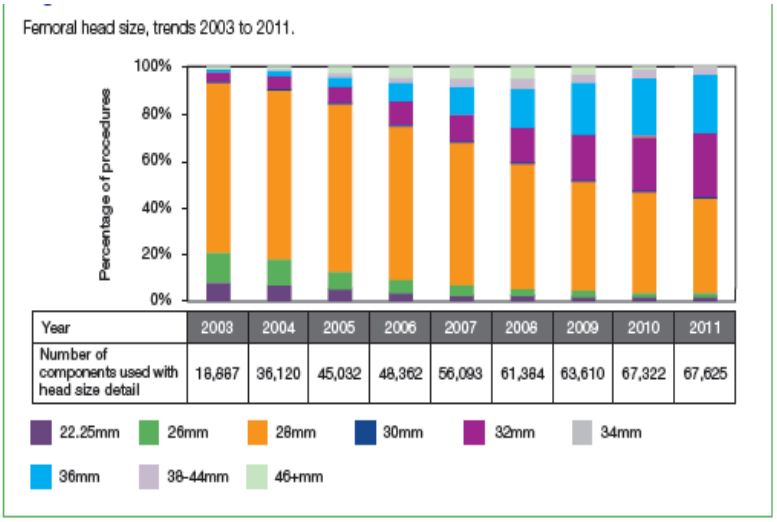
Graph 5, risk of revision per age group, incidence per 1000 life years

Femoral head diameter and liner composition

The NJR 9th annual report clearly shows a trend toward larger head sizes (Graph 5). The perceived benefits are to reduce the risk of dislocation and to increase the range of motion.

- CSF acetabular cups were developed for use with Biolox® Forte liners which are only compatible with 28mm heads.

- CSF *Plus* acetabular cups were developed for use with Biolox® Delta Ceramic liner; 28, 32, 36 and 40mm heads can be used in this cup.

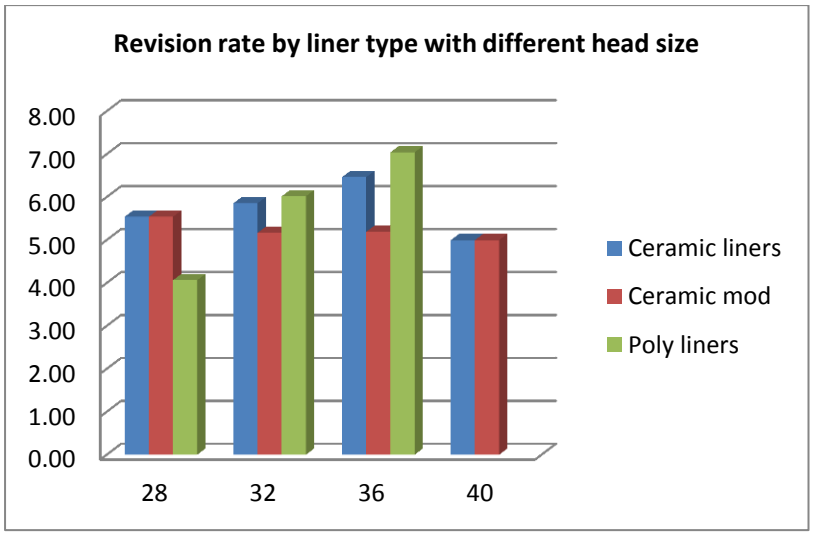


To compare head size and their influence on revision rates the two variants of acetabular cups have been combined, this also applies to the polyethylene version. See compatibility chart for further details [9], [10].

Graph 6, NJR femoral head size trends

Revision rate by liner type with different head size

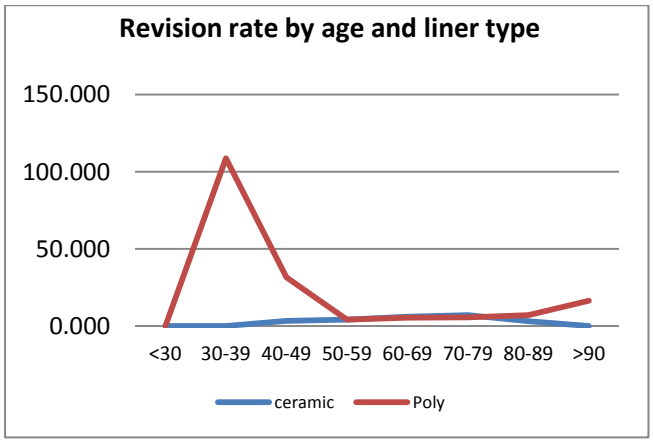
It can be observed that the revision risk increases with head size for polyethylene bearing cups. The ceramic liners also seem to follow the same pattern until you factor in the early incidences of liner fractures associated with malposition of the liner are taken into account. The issue with malposition of the liner was common to all manufacturers on the introduction of Biolox® Delta ceramic liners. The problem was identified early and addressed. The incidence of ceramic liner fractures has all but ceased, one fracture was reported in 2011 and none reported in 2012 (Appendix 4). Removing these cases, the inverse trend for revision of ceramic heads can be observed. Shown as 'Ceramic Mod' in Graph 7.



Graph 7, revision rate by liner type with different head size, incidence per 1000 life years

Revision rate by Liner type and age group

JRI bearings articulate against either ceramic or polyethylene acetabular liners. Graph 8 compares all ceramic and all polyethylene bearings and looks at the incidence of revision per 1000 life years in different age groups. The number of patients available for study in the lower age group gives a spurious reading, although it would be valid to assume that using polyethylene bearing in patients under 50 would result in a higher than average revision rate. The interesting results demonstrate that the risk of revision increase after the age of 70 when using a poly liner instead of a ceramic liner.



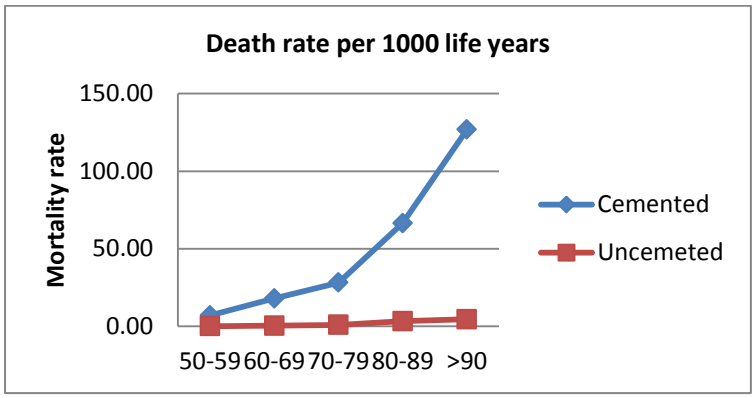
Graph 8, revision rate by age and liner type, incidence per 1000 life years

Mortality rates between cemented and uncemented implants

Although difficult to attribute death of the patient to the type of implant used, we have looked at the percentage mortality rate within the first 30 days post op and have also looked at the incidence of death per 1000 life years. One would expect there to be slight differences when comparing cemented and uncemented implants due to the surgeon's assessment of activity level, health and expected life expectancy. Table 6 shows a slightly higher death rate for patients receiving a cemented JRI THR in comparison to JRI Uncemented. Graph 9 demonstrates a significant difference in life expectancy when considering the incidence per 1000 life years.

		% death rate upto 30 days post op			
		60-69	**70-79**	**80-89**	**>90**
JRI Cemented	implanted	312	830	493	25
	Died	1	4	8	0
	% Death	0.32%	0.48%	1.62%	0.00%
JRI Uncemeted	implanted	8972	8462	2704	138
	Died	14	31	32	2
	% Death	0.16%	0.37%	1.18%	1.45%

Table 6, percentage death rate up to 30 days post op.



Graph 9, comparison of death rates for cemented and uncemented implants, incidence per 1000 life years

Trunion design (Appendix 3, trunion design)

JRI introduced modular implants in 1985 with the introduction of the Furlong H-A.C. femoral prosthesis. The original trunion design utilised a 14/16 taper, this design was changed to a 12/14 taper in 1989 on the introduction of ceramic heads and has remained unchanged since. The trunion is a 'full' engagement trunion, meaning a complete engagement of the inside of the head on the trunion of the stem. 'Micro tapers', as introduced by other manufacturers have the internal surface of the head sitting on the 'shorter' trunion. A 'full' trunion engages the whole of the internal head surface resulting in a larger contact area. The logical assumption is, if there is a greater area of contact it should allow a more stable interface. To date, through our internal complaints system, not one incidence of 'trunionosis' has been reported. We believe that this is due to the trunion design but no comparative studies have been conducted to date to substantiate this hypothesis.