Introduction

Total hip and total knee arthroplasties are some of the most frequently performed surgical procedures.\textsuperscript{1} Many factors affect the survivorship of these procedures, such as implant geometry, materials, surface finish and type of bearing, as well as surgical approach, cementing technique, surgeon experience and patient characteristics.

For several decades, bone cements have been used for anchoring and fixing artificial joints, helping improve survivorship in both hip and knee arthroplasty.\textsuperscript{1-3} In primary total hip arthroplasty (THA), the percentage of patients receiving cemented prostheses varies between countries, in the UK 58\% of hips were cemented (30\% total hips and 28\% hybrid where only the hip stem was cemented).\textsuperscript{4} In total knee arthroplasty (TKA) the cementing of prostheses is much more common in England, Wales, Northern Ireland, and Isle of Man, with almost 85\% being cemented, and 95\% in Sweden in 2014.\textsuperscript{1,4,5} Antibiotic-loaded cements have been developed to help reduce the risk of developing deep infection.\textsuperscript{6,7} These cements are widely used, for example making up more than 90\% of cemented hip arthroplasties in the Swedish Hip Arthroplasty Register.\textsuperscript{3}

National joint registries provide valuable generalizable information on revision rates and survivorship of orthopaedic implants. Typically they include large cohorts, with data reported from all surgeons and centers, irrespective of surgeon experience level. The National Joint Registry for England, Wales, Northern Ireland and Isle of Man (NJR) has been in operation since 2003 and in that time has collected data on almost 890,681 total hip replacements of which 58\% of procedures were cemented (30\% total hips and 28\% hybrid where only the hip stem was cemented).\textsuperscript{4} For the knee, procedures using all DePuy Synthes cups and stems were considered. The ASR family of implants was excluded from the analysis. For the knee, the analysis considered DePuy Synthes (Total Knee System LCS\textsuperscript{TM}) Low Contact Stress rotating knees and SIGMA\textsuperscript{®} Knee implants, with partial knees being excluded.

Of the procedures included in the supplier feedback dataset, 29,562 hips and 53,432 knees used a combination of DePuy Synthes implants and DePuy Synthes cements. Due to the low number of procedures that used plain cements, SMARTSET GMV Gentamicin and CMW 3 Gentamicin, these were excluded from our analysis, yielding a total of 27,966 THAs and 52,240 TKAs that used antibiotic cements.

Materials and Methods

DePuy CMW 1 Gentamicin, DePuy CMW 2 Gentamicin and SMARTSET\textsuperscript{TM} GHV Gentamicin Bone Cements are self-curing, radiopaque, polymethyl methacrylate based cements, containing gentamicin antibiotic, used for securing a metal or polymeric prosthesis to living bone in arthroplasty procedures in which infection by gentamicin sensitive organisms is a potential risk. The bone cements have no intrinsic adhesive properties, but rely instead on close mechanical interlock between the irregular bone surface and the prosthesis. Each bone cement is supplied as a two-component system, consisting of separate, sterile liquid and powder components, which are mixed together at the point of use to produce the cement.

DePuy CMW 1 Gentamicin and SMARTSET GHV Gentamicin are both high viscosity bone cements that are intended for either digital or syringe application. DePuy CMW 1 Gentamicin was originally designed for use in total hip arthroplasty whereas SMARTSET GHV Gentamicin was designed with a longer working time making it suitable for use in Total Knee Arthroplasty. Both cements can be used for the hip and knee and is down to surgeon preference.

DePuy CMW 2 Gentamicin is a fast setting cement designed for digital application to small joints such as the patella of the knee and the hip acetabulum. It is generally not suitable for fixation of the femoral component in total hip arthroplasty due to its fast setting time.

Analysis population

Product specific data for cemented procedures using either implants or cements manufactured by DePuy Synthes were downloaded from the NJR on December 11, 2017.\textsuperscript{12} For the hip, procedures using all DePuy Synthes cups and stems were considered. The ASR family of implants was excluded from the analysis. For the knee, the analysis considered DePuy Synthes (Total Knee System LCS\textsuperscript{TM}) Low Contact Stress rotating knees and SIGMA\textsuperscript{®} Knee implants, with partial knees being excluded.

In addition to the NJR's publicly available reports, data is also available from a supplier feedback dataset, downloaded by DePuy Synthes from the NJR on December 11, 2017.\textsuperscript{12} This additional information provides detailed data on DePuy Synthes bone cements and is the focus of this commentary.
This analysis is done by cement type, where any procedure that reported use of that cement is included. Therefore, a single procedure may appear in multiple cement groups.

Statistical analysis
Kaplan-Meier (KM) survivorship analyses were conducted on DePuy Synthes Bone Cements used in combination with DePuy Synthes hip and knee implants, with an endpoint of revision for any reason. Estimates are shown together with 95% Confidence Intervals (95% CI) annually after the primary operation.13 Our analysis was discontinued after 40 cases were at risk.

Details of the class of all-cemented primary hip and knee procedures performed between April 1, 2003 and December 31, 2016 were published in the 14th annual report of the National Joint Registry for England, Wales and Northern Ireland.9 Kaplan-Meier survivorship estimates are shown up to 13 years after the primary operation.

Primary total hip arthroplasty (THA): Results and Discussion
Within the DePuy CMW 1 Gentamicin dataset, 214 revisions for any reason were recorded from 9,842 cases within 14 years. The Kaplan-Meier survivorship was calculated to be 98.60% (95% CI 98.31 - 98.84%) at 5 years, 96.75% (95% CI 96.19 - 97.23%) at 10 years and 94.66% (95% CI 93.65 - 95.52%) at 13 years. For DePuy CMW 2 Gentamicin, there were 272 revisions for any reason recorded from 19,929 cases at 14 years, correspondingly 5, 10 and 13 year survivorship of 98.52% (95% CI 98.29 - 98.71%), 97.10 (95% CI 96.60, 97.53%) and 95.87% (95% CI 94.93 - 96.63%), respectively. For the SMARTSET GHV Gentamicin Bone Cement, 128 revisions were recorded from 5,097 procedures within 12 years. Survivorship was calculated to be 97.83% (95% CI 97.34 - 98.22%), 96.65% (95% CI 95.96 - 97.23%) and 95.30% (95% CI 93.77 - 96.46%) at 5, 10 and 12 years, respectively (Figure 1).

These results suggest that for all three cements, the survivorship after primary total hip arthroplasty is similar at 13 years to the class of all-cemented procedures published in the NJR annual report 2017, which has a reported Kaplan-Meier survivorship estimate of 95.66% (95.46 - 95.86%) at 13 years.9 Likewise, other national registries published long-term 10-year survivorship of all-cemented primary hip arthroplasties that support these findings. The Australian Orthopaedic Association National Joint Replacement Registry reported a 10-year survivorship of 96.3% (95.30 - 97.10%) for procedures performed between 1999 and 2016,14 the New Zealand Joint Register published a 10-year survivorship of 94.60% and a 13-year survivorship of 91.30% for procedures registered between 1999 and 2016,15, and the Swedish Hip Arthroplasty Register reported a 10-year survivorship of 94.3% (95% CI 94.0 - 94.6%) for the timespan between 2005 and 2014.16 Finally, 10-year survivorships in Denmark and Norway for the period 1995 to 2006 were reported by the Nordic Arthroplasty Register Association as 92.9% (95% CI 92.4 - 93.4%) and 93.5% (95% CI 93.2 - 93.9%) respectively.17

Espheaug and co-workers published data for PALACOS® R Gentamicin cement from the Norwegian Arthroplasty Register, depicting a Kaplan-Meier estimated 10-year survivorship of approximately 93.5%.18

The finding that the SMARTSET GHV Gentamicin Bone Cement performs similarly to the PALACOS R Gentamicin cement, is supported by the results of a two-year prospective, randomised, radiostereometric analysis (RSA) trial that showed no statistically significant difference in THA stem fixation with use of plain SMARTSET HV and PALACOS R at 2-year and 5-year follow-up.19,20

Figure 1. Kaplan-Meier (KM) survivorship of DePuy CMW Cements used in combination with DePuy Synthes implants in primary total hip arthroplasty (THA). DePuy CMW 1 Gentamicin, DePuy CMW 2 Gentamicin and SMARTSET GHV Gentamicin Bone Cements are compared to the class of all-cemented procedures registered in the NJR.9 Shadings indicate the 95% confidence interval (CI). KM survivorship displayed until 40 primary procedures remain at risk. Class data displayed to latest published annual time point.

Primary total knee arthroplasty (TKA): Results and Discussion
After TKA with DePuy CMW 1 Gentamicin Bone Cement, 227 revisions were recorded from 13,466 cases within 14 years. Survivorship was 98.57% (95% CI 98.34 - 98.77%) at 5 years, 97.66% (95% CI 97.29 - 97.98%) at 10 years and 97.30% (95% CI 96.80 - 97.72%) at 13 years, respectively. For DePuy CMW 2 Gentamicin Bone Cement, 184 revisions were recorded from 12,348 cases within 14 years, with corresponding 5, 10 and 13 year survivorships of 98.23% (95% CI 97.91 - 98.49%), 97.26% (95% CI 96.70 - 97.72%) and 96.48 (95.57 - 97.21%) respectively. For the SMARTSET GHV Gentamicin Bone Cement, there were 532 revisions recorded from 27,937 cases within 13 years. The survivorship at 5, 10 and 13 years were 98.00% (95% CI 97.80 - 98.17%), 97.12% (95% CI 96.83 - 97.38%) and 96.70% (95% CI 95.97 - 97.30%), respectively (Figure 2).
Summary and Conclusion

National Joint Registries have been used for many years and provide a useful means to compare the outcomes of different procedures and products in all types of hospital setting. The NJR is one of the largest of its kind and allows analysis of up to date outcome data from current surgical practices, in particular for modern cementing technique in THA.

Survivorship of DePuy Synthes implants combined with DePuy Synthes Bone Cements documented in the NJR were high. Overall, around 97% of the hip and knee replacement procedures were revision-free out to 10 years follow-up and are consistent with the new 2014 NICE guideline of a 5% revision rate at 10 years being acceptable for THA. Additionally, the results presented here are comparable to the ones reported for the classes of all-cemented procedures in the NJR.

Other national registries have published survivorship after hip and knee replacement procedures. Compared to the rates observed in the UK, Australia, New Zealand and Sweden seem to have slightly lower survivorship, although the THA results fall within the current NICE recommendation. Sibanda et al. discussed several possible explanations for these differences which they suggested may be attributable to the applied definition of a revision, or might arise from discrepancies in data capturing methods.

The analysis performed for this commentary has some limitations. First, these results are based on NJR registry data from DePuy Synthes implants combined with DePuy Synthes cements only. Second, as with other registry data, the results are based on procedures performed in a single country only. Additionally, the data generated is observational, so causality cannot be proven. However, the National Joint Registry for England, Wales and Northern Ireland comprises a large population and has a high level of participation which provides a degree of confidence in the validity of the findings from it.
References

5. Swedish Hip Arthroplasty Register, Annual Report 2014, p54, Figure 'All Cemented Implants'. Available from: https://registercenter.bldb.core.windows.net/JPn/Annual-report-2014-Bvjpjl.pdf
17. Havelin LI et al., The Nordic Arthroplasty Register Association: a unique collaboration between 3 national hip arthroplasty registries with 280,201 THRs, Acta Orthopaedica 2009; 80 (4): 393–401

The data used for this analysis was obtained from the NJR Supplier Feedback System. All analyses of NJR data were undertaken by DePuy Synthes. The Healthcare Quality Improvement Partnership (“HQIP”) and the National Joint Registry (“NJR”) take no responsibility for the accuracy, currency, reliability and correctness of any data used or referred to in this report, nor for the accuracy, currency, reliability and correctness of links or references to other information sources and disclaims all warranties in relation to such data, links and references to the maximum extent permitted by legislation.

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