

Bespoke Implant Report for:

DePuy

Corail Collared vs. Collarless (ex MoM)

Comprising PRIMARY hips implanted up to:
NJR Database extract:

09 October 2017
08 December 2017

Produced on:

29 December 2017

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This report has been produced by the National Joint Registry of England, Wales and Northern Ireland (NJR). It summarises usage and outcomes associated with DePuy Corail Collared Standard Offset Stem (KA) vs. Collarless Standard Offset Stem (KS) used in primary hips (excluding metal on metal bearings), based on data collected by the NJR. Details of the stems in this report are contained in the appendices.

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Implant Usage

| Totals Recorded in NJR | Corail Collared Standard (KA) | Corail Collarless Standard (KS) |
|------------------------------------|-------------------------------|---------------------------------|
| First usage in the NJR: | 05-Jun-2003 | 13-May-2003 |
| Last usage in this dataset: | 09-Oct-2017 | 09-Oct-2017 |
| Maximum implantation time (years): | 14.3 | 14.4 |
| Mean implantation time (years): | 3.7 | 5.5 |
| Procedures | 62048 | 58173 |
| Patients | 56686 | 53068 |
| Centres | 288 | 344 |
| Consultants | 980 | 1273 |
| Implanting Surgeons | 1632 | 2070 |

| Group | Year of implantation | | | | | | | | | | | | | Total |
|--|----------------------|------|------|------|------|-------|-------|-------|-------|-------|-------|-------|------|--------|
| | Pre-2006 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | |
| Corail Collared Standard (KA) | 406 | 481 | 846 | 1514 | 2895 | 4175 | 5355 | 6319 | 6745 | 7922 | 8877 | 9322 | 7191 | 62048 |
| Corail Collarless Standard (KS) | 2117 | 2028 | 3297 | 4787 | 5254 | 6241 | 6238 | 5935 | 5411 | 5303 | 4759 | 4001 | 2802 | 58173 |
| Total | 2523 | 2509 | 4143 | 6301 | 8149 | 10416 | 11593 | 12254 | 12156 | 13225 | 13636 | 13323 | 9993 | 120221 |

Patient / Procedure Details

Patient Details

| | Corail Collared Standard (KA) | Corail Collarless Standard (KS) |
|--------------------------------------|----------------------------------|------------------------------------|
| Total Procedures | 62048 | 58173 |
| Total Patients | 56686 | 53068 |
| Demographics | | |
| Mean age | 67.7 | 65.4 |
| < 50 | 5.8% | 7.9% |
| 50 – 59 | 15.3% | 18.4% |
| 60 – 69 | 32.6% | 36.5% |
| 70 – 79 | 32.6% | 28.6% |
| ≥ 80 | 13.6% | 8.6% |
| Median BMI | 28 | 28 |
| % BMI information available | 66.8% | 59.3% |
| Underweight (BMI < 18.5) | 0.8% | 0.7% |
| Normal (18.5 ≤ BMI < 25) | 20.6% | 19.3% |
| Overweight (25 ≤ BMI < 30) | 38.5% | 39.5% |
| Obese I (30 ≤ BMI < 35) | 25.6% | 26.0% |
| Obese II (35 ≤ BMI < 40) | 10.7% | 10.8% |
| Obese III (BMI ≥ 40) | 3.8% | 3.7% |
| % Male | 33.9% | 35.9% |
| ASA Grades | | |
| P1 - Fit and healthy | 15.2% | 18.0% |
| P2 - Mild disease not incapacitating | 70.6% | 70.3% |
| P3 - Incapacitating systemic disease | 13.8% | 11.4% |
| P4 / P5 | 0.5% | 0.3% |
| Indications | | |
| Osteoarthritis | 92.99% | 93.78% |
| Rheumatoid Arthritis | 1.17% | 1.37% |
| Other Inflammatory Arthropathy | 1.98% | 2.34% |
| Previous Trauma | 3.11% | 1.39% |
| Avascular Necrosis | 1.33% | 1.87% |
| Other | 1.21% | 1.48% |

Total of indications may exceed total number of implants, since more than one indication can be listed per case.

Revision and Survivorship

Reasons for Revision

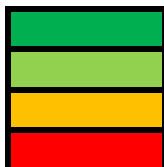
Reasons for revision of primary procedures in which the implant was used.

| Reason for Revision | Corail Collared Standard (KA) | | Corail Collarless Standard (KS) | | p value |
|--------------------------------|-------------------------------|---------------------|---------------------------------|---------------------|------------------|
| | Revised [†] | Revised / Expected* | Revised [†] | Revised / Expected* | |
| Pain | 80 | 0.79 | 164 | 1.14 | 0.008 |
| Dislocation / Subluxation | 196 | 0.92 | 265 | 1.07 | 0.123 |
| Adverse Soft Tissue Reaction | 32 | 0.95 | 61 | 1.03 | 0.747 |
| Infection | 154 | 0.97 | 195 | 1.03 | 0.591 |
| Aseptic Loosening - Stem | 142 | 0.85 | 288 | 1.10 | 0.013 |
| Aseptic Loosening - Socket | 72 | 1.09 | 89 | 0.94 | 0.337 |
| Periprosthetic Fracture Stem | 54 | 0.40 | 231 | 1.55 | <0.001 |
| Periprosthetic Fracture Socket | 10 | 0.83 | 17 | 1.13 | 0.562 |
| Malalignment Stem | 34 | 0.86 | 52 | 1.12 | 0.235 |
| Malalignment Socket | 62 | 1.05 | 76 | 0.97 | 0.668 |
| Wear Of Acetabular Component | 45 | 1.04 | 67 | 0.98 | 0.772 |
| Lysis Stem | 15 | 0.80 | 40 | 1.10 | 0.323 |
| Lysis Socket | 16 | 1.16 | 27 | 0.92 | 0.514 |
| Implant Fracture Stem | 7 | 0.68 | 15 | 1.28 | 0.202 |
| Implant Fracture Socket | 30 | 0.87 | 53 | 1.09 | 0.373 |
| Implant Fracture Head | 3 | 1.24 | 4 | 0.87 | 0.699 |
| Dissociation of Liner | 30 | 0.92 | 46 | 1.06 | 0.564 |
| Other / reason not recorded | 47 | 0.81 | 85 | 1.15 | 0.065 |
| Total Revised | 817 | 0.86 | 1386 | 1.11 | <0.001 |

† multiple reasons may be listed for one revision procedure

* Logrank comparison, adjusted for Patient Gender, Age Group, and indications (OA/non-OA)

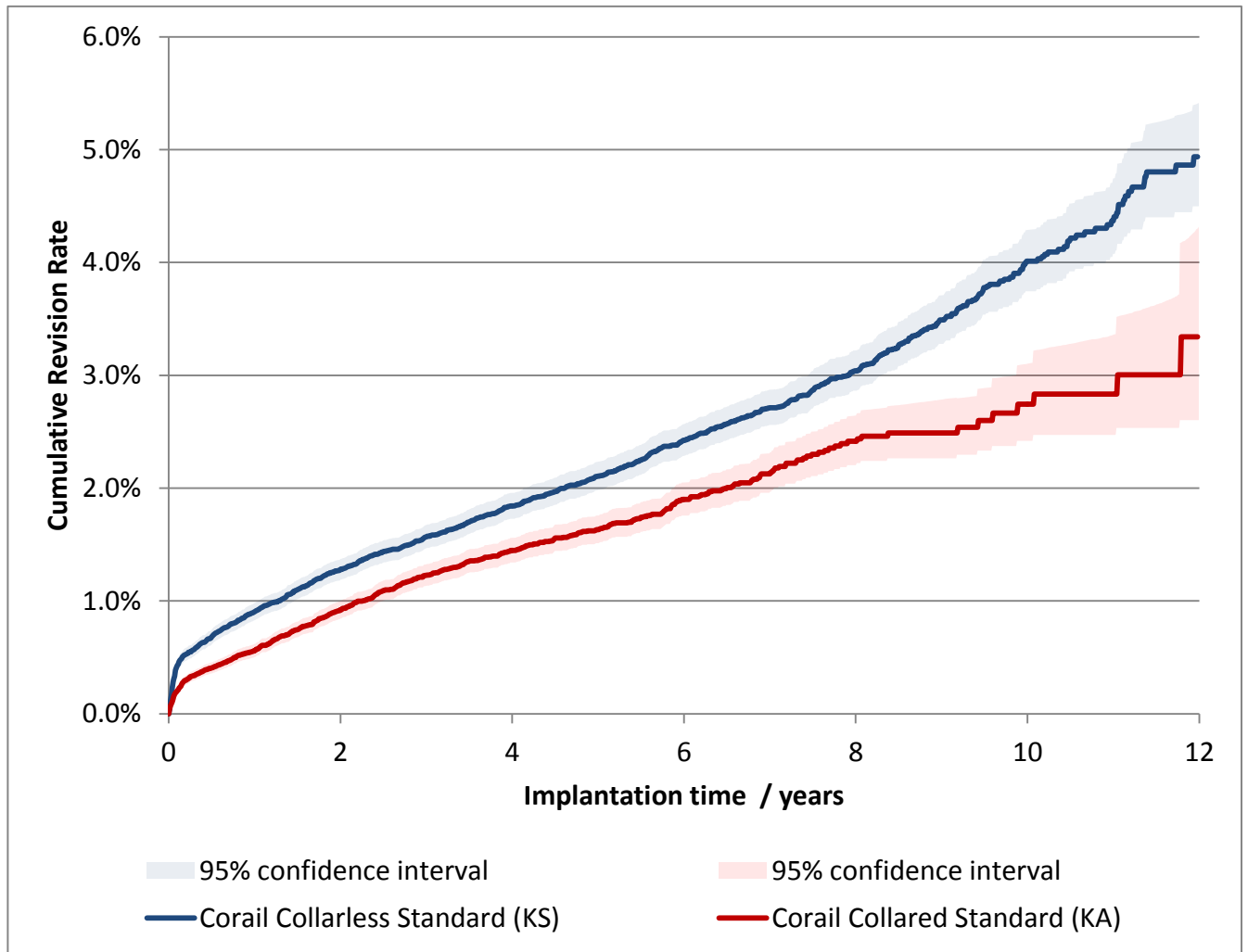
- Significantly better, p < 0.001
- Significantly better, p < 0.05
- Significantly worse p < 0.05
- Significantly worse p < 0.001



| Components Revised | Corail Collared Standard (KA) | | Corail Collarless Standard (KS) | |
|--|-------------------------------|------------|---------------------------------|------------|
| | Count | Percentage | Count | Percentage |
| Femoral only | 174 | 21.3% | 454 | 32.8% |
| Acetabular only | 249 | 30.5% | 339 | 24.5% |
| Both femoral and acetabular | 270 | 33.0% | 434 | 31.3% |
| Neither femoral nor acetabular revision recorded * | 124 | 15.2% | 159 | 11.5% |

* includes isolated head and/or liner exchange

Endpoint: Revision for any reason



Stratified Log-rank test, with observed and expected number of revisions

| Adjustment | Corail Collared Standard (KA) | | Corail Collarless Standard (KS) | | p-value |
|------------|-------------------------------|----------|---------------------------------|----------|---------|
| | Observed | Expected | Observed | Expected | |
| Unadjusted | 817 | 965.5 | 1386 | 1237.5 | <0.001 |
| Adjusted | 817 | 954.8 | 1386 | 1248.2 | <0.001 |

Cox Proportional Hazards model for revision risk ratio of Corail Collared Standard (KA) / Corail Collarless Standard (KS)

| Adjustment | Hazard Ratio (95% CI) | p-value |
|------------|-----------------------|---------|
| Unadjusted | 0.75 (0.69 - 0.82) | <0.001 |
| Adjusted | 0.76 (0.70 - 0.83) | <0.001 |

Adjustment includes Patient Gender, Age Group, and indications (OA/non-OA)

Revision and Survivorship

Cumulative Revision Rate

Endpoint: Revision for any reason

| Period /years | Corail Collared Standard (KA) | | Corail Collarless Standard (KS) | |
|---------------|-------------------------------|-----------------------|---------------------------------|-----------------------|
| | At Risk | Revision Rate | At Risk | Revision Rate |
| 0 | 62,048 | - | 58,173 | - |
| 1 | 51,833 | 0.56% (0.50% - 0.62%) | 53,550 | 0.90% (0.83% - 0.98%) |
| 2 | 42,058 | 0.92% (0.85% - 1.00%) | 48,763 | 1.28% (1.19% - 1.37%) |
| 3 | 33,039 | 1.23% (1.13% - 1.33%) | 43,352 | 1.57% (1.47% - 1.67%) |
| 4 | 25,093 | 1.45% (1.34% - 1.56%) | 37,433 | 1.84% (1.73% - 1.96%) |
| 5 | 18,520 | 1.63% (1.51% - 1.76%) | 31,690 | 2.11% (1.98% - 2.23%) |
| 6 | 12,523 | 1.90% (1.76% - 2.05%) | 25,530 | 2.42% (2.28% - 2.57%) |
| 7 | 7,722 | 2.13% (1.96% - 2.31%) | 19,272 | 2.71% (2.56% - 2.87%) |
| 8 | 4,337 | 2.41% (2.20% - 2.64%) | 13,538 | 3.04% (2.86% - 3.22%) |
| 9 | 2,166 | 2.49% (2.26% - 2.78%) | 8,861 | 3.49% (3.28% - 3.71%) |
| 10 | 1,154 | 2.74% (2.42% - 3.10%) | 5,125 | 4.01% (3.75% - 4.29%) |
| 11 | 586 | 2.83% (2.47% - 3.36%) | 2,733 | 4.37% (4.05% - 4.71%) |
| 12 | 212 | 3.34% (2.60% - 4.30%) | 1,191 | 4.94% (4.50% - 5.41%) |
| 13 | | (-) | 152 | 5.62% (4.90% - 6.97%) |
| 14 | | (-) | | (-) |
| 15 | | (-) | | (-) |

Cumulative revision rate with 95% confidence intervals

Rate is only reported for times where more than 40 remain at risk

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Appendix A1

| Catalogue Number | Description | Number Implanted |
|------------------|---------------------------------|------------------|
| 3L92498 | Corail Collared Stem K8A 115mm | 3484 |
| 3L92499 | Corail Collared Stem K9A 130mm | 5573 |
| 3L92500 | Corail Collared Stem K10A 140mm | 11233 |
| 3L92501 | Corail Collared Stem K11A 145mm | 16277 |
| 3L92502 | Corail Collared Stem K12A 150mm | 13252 |
| 3L92503 | Corail Collared Stem K13A 155mm | 6524 |
| 3L92504 | Corail Collared Stem K14A 160mm | 3374 |
| 3L92505 | Corail Collared Stem K15A 165mm | 1602 |
| 3L92506 | Corail Collared Stem K16A 170mm | 588 |
| 3L92508 | Corail Collared Stem K18A 180mm | 130 |
| 3L92521 | Corail Collared Stem K20A 190mm | 11 |

Appendix A2

| Catalogue Number | Description | Number Implanted |
|------------------|-----------------------------------|------------------|
| 3L92507 | Corail Collarless Stem K8S 125mm | 3930 |
| 3L92509 | Corail Collarless Stem K9S 130mm | 5126 |
| 3L92510 | Corail Collarless Stem K10S 140mm | 10079 |
| 3L92511 | Corail Collarless Stem K11S 145mm | 14850 |
| 3L92512 | Corail Collarless Stem K12S 150mm | 12799 |
| 3L92513 | Corail Collarless Stem K13S 155mm | 6099 |
| 3L92514 | Corail Collarless Stem K14S 160mm | 3107 |
| 3L92515 | Corail Collarless Stem K15S 165mm | 1414 |
| 3L92516 | Corail Collarless Stem K16S 170mm | 537 |
| 3L92518 | Corail Collarless Stem K18S 180mm | 221 |
| 3L92520 | Corail Collarless Stem K20S 190mm | 11 |