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Original research

Observed effect of femoral component undersizing and a collarless design in the development of radiolucent lines in cementless total hip arthroplasty

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A B S T R A C T

Background: The objective of this study was to determine the prevalence of radiolucent lines (RLLs) around the femoral component in a cohort of patients who underwent well-functioning cementless total hip arthroplasty (THA).

Methods: A cohort of unrevised Corail (DePuy Synthes, Raynham, MA) femoral components (n = 636) were analyzed at a median follow-up of 6.0 years (interquartile range: 5.2-6.8) with the Oxford Hip Score (OHS) and radiographs. Two independent observers assessed the radiographs for the presence of RLLs.

Results: The overall prevalence of RLLs in zone 7 was 13% (83/636). Patients with RLLs in zone 7 had an average OHS of 40.3 (15-48), and those who did not have RLLs in zone 7 had an average OHS of 38 (6-48), $P = .07$. Both groups had an average pain score of 1.6 out of 5, $P = .5$. The prevalence of RLLs in zone 7 was much less in the collared femoral components (2.6% prevalence) than in the collarless components (23.6% prevalence), but there was heterogeneity between these 2 groups preventing comparison. Logistic regression analysis of only the collarless components identified undersizing as the only predictive (odds ratio = 2.6) factor for RLL development in zone 7.

Conclusions: Undersizing the Corail stem is strongly predictive of developing RLLs in zone 7. Preoperative templating for the appropriate size is critical. We observed more RLLs in zone 7 with the collarless design Corail, but a comparison study with the same bearing couple is needed to investigate this further.

Introduction

The Corail (DePuy Synthes, Raynham, MA) is the most popular cementless femoral component in the UK for total hip arthroplasty (THA) [1]. It has excellent survivorship data from the design surgeons [2-4], from Registry data [5] and from independent centers [6], including our own unit which reported an aseptic loosening incidence of 15 out of 4802 population (0.31%) at a mean follow-up of 5.5 years [7]. In this article, we report on data from the 4 subtypes named KA (standard offset with collar), KLA (high offset with collar), KS (standard offset without collar), and KHO (high offset without collar).

Long-term radiographic outcome of this implant has previously been reported by the design group [4,8,9]. They describe patterns of radio-opaque lines, which are considered healthy indicators of a

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responsive biological interface in a well-fixed implant. They describe a pattern of radiolucent lines (RLLs) in Gruens [10] zone 1 and/or zone 8 which are also benign as they represent the tensile forces in that area. However, RLLs beyond these 2 zones are concerning, especially in zone 7, the area of maximal compression.

The senior author has exclusively used the Corail implant for all THA for 13 years and at the time of publication has a series of approximately 6000. Implant survivorship is good [7]; however, there are a subset of patients with a discordance between good clinical scores and radiographs with RLLs in all 4 proximal zones (Fig. 1a and b). The primary aim of this study was to determine the number of this subset of patients. The secondary aims were to identify possible risk factors for developing this pattern and whether or not there is a relationship between the presence of RLLs and the Oxford Hip Score (OHS) [11].

Material and Methods

Operative technique

This has evolved over the years and particularly so during the catchment period for the patients in this study. The changes are summarized in Figure 2, but the technique has been particularly influenced by the introduction of cross-linked polyethylene (XLPE), the introduction of a femoral component collar, and by an increasing emphasis on achieving primary mechanical stability of the femoral component. The common features to all cases in this study are that none were preoperatively templated, all had posterior approach, all had a Pinnacle (DePuy Synthes, Raynham, MA) cementless cup, and all were performed by the senior author or a member of his team trained in his technique at that time.

Study design

After obtaining local institution audit approval (Audit reference number 5422), specific outpatient clinics were established to invite patients back for an additional follow-up. Eight hundred patients were identified, 200 from each Corail subtype, starting at the first performed, and excluded if they were older than 70 years at the time of surgery. Age exclusion was chosen to increase the yield of patients with good activity levels, to truly test if any RLL seen was asymptomatic. Six hundred thirty-six patients attended in total, and the clinics were completed over a period of 17 months.

At the clinic, each patient had an anteroposterior and lateral view radiograph of the replaced hip, completed an OHS assessment, and met with an arthroplasty care practitioner for clinical evaluation.

Grading of the radiographs

After all clinics were completed, 2 experienced external orthopedic surgeons visited the unit, agreed upon radiographic evaluation criteria, and independently evaluated 50% of the radiographs each. The radiographic report consisted of 3 questions (Appendix 1):

1. Are there radiolucent lines? (Radiolucent line defined as any radiolucency at the bone-implant interface)
2. If radiolucent lines are present, what Gruen zones are involved?
3. Is the stem undersized? (Correct size definition = One size less than metaphyseal cortical fit on templating)

Statistical analysis

Data analysis was carried out using SPSS (version 22.0, IBM SPSS Statistics for Windows, Armonk), and all relevant data were assessed for normality. Normally distributed data are presented as mean with ranges, while skewed data are presented as median and interquartile range. Continuous data were analyzed using independent samples *t*-test, or nonnormally distributed data were analyzed using the nonparametric alternative (Mann-Whitney *U*-tests). Significance level was set at $P \leq .05$.

Prevalence data are presented as percentage of its appropriate group. Clinical outcome and radiographic outcome are compared using Chi-square analysis. Contributory factors of RLLs were identified by multivariable analysis.

Results

Group demographics

From the beginning in 2005 until mid-2007, only collarless implants were used. As such, as seen in Table 1, the median follow-up for the collarless cohort (KS and KHO) is longer than that for the collared cohort (KA and KLA) by approximately 2 years. Each of the

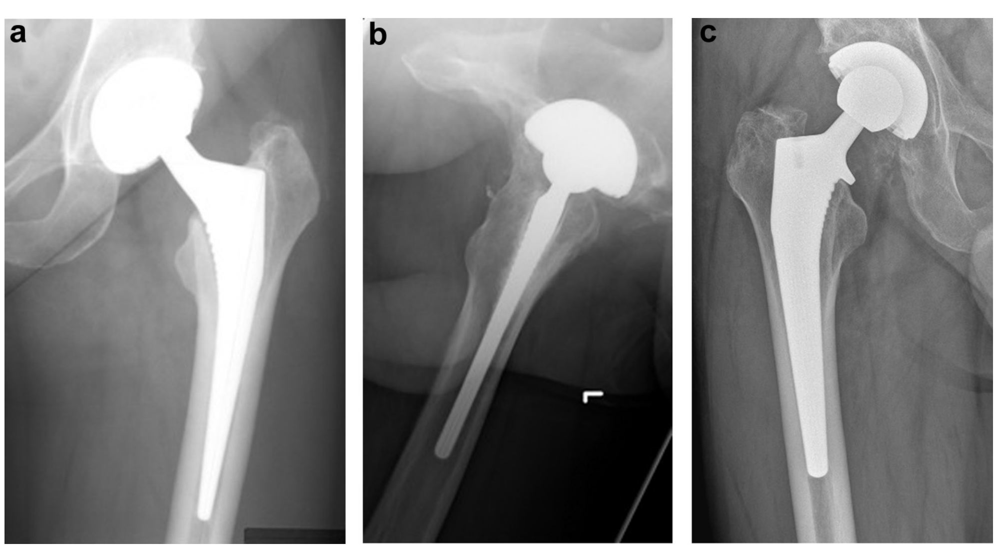

Figure 1. Plain radiograph comparison of a KS collarless (a and b) and KA collared (c) corail cementless femoral component, both at ten years after implantation, and both in patients with no pain. Note in 1a and 1b the radiolucent lines in Gruen zones 1,7,8 and 14.

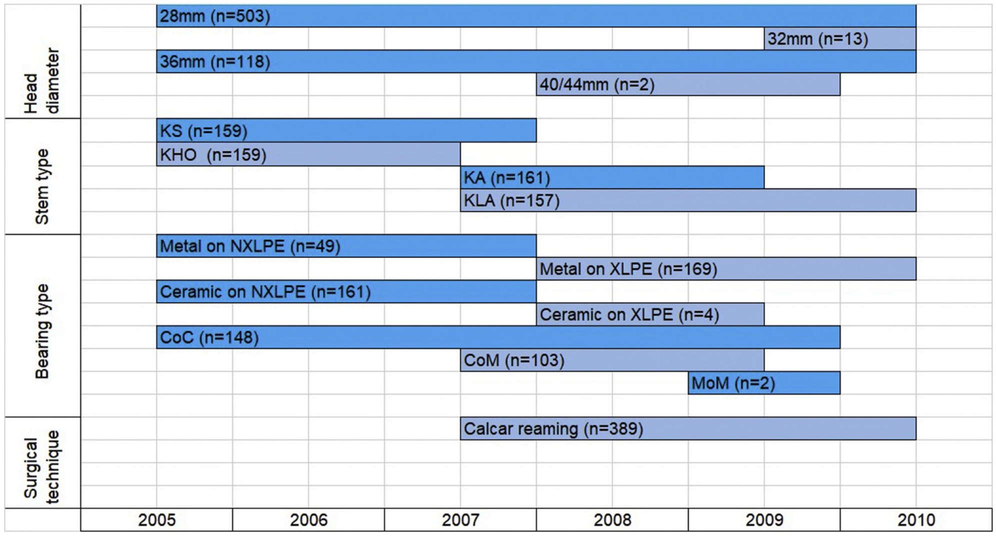

Figure 2. Implant choices and operative technique changes during the catchment period of the study. Only reviewed stems (n = 636) included. NXLPE, non cross-linked polyethylene; XLPE, cross-linked polyethylene; CoC, ceramic on ceramic; CoM, ceramic on metal; MoM, metal on metal..

4 subtypes was similar in terms of number, age, and stem size, and all were paired with the Pinnacle acetabular component. There were more males in the high-offset groups (KHO and KLA). The most striking difference however is in the bearing choices. In 2005, non—cross-linked polyethylene (NXLPE) was predominant, but after XLPE was first used in our unit in 2007, it was quickly adopted exclusively. As 2007 also marked the time the senior author moved away from collarless implants, there was an unintentional dichotomy created: a collarless group with NXPLE and a collared group with XLPE. Ceramic-on-metal (CoM) bearings were essentially unique to the collared cohort and were used for only a limited period because of their higher failure rate [12,13].

Radiographic report on latest follow-up radiographs

Six hundred thirty-six radiographs were analyzed at a median follow-up of 6.0 years (interquartile range: 5.2 to 6.8), and the results of the RLL prevalence overall and by stem subgroup are displayed in Table 2. The overall prevalence of any RLL in any zone is 41%, with no significant difference between the subtypes of each cohort, $P = .08$. However, any pattern of RLLs involving zone 7 was much more prevalent in the collarless cohort (23.6%) than in the collared cohort (2.6%), $P < .001$ (Table 2). Of the 8 collared cases displaying zone 7 RLL, there were 2 CoM bearings. Of the 75 collarless cases displaying zone 7 RLLs, 53 contained NXLPE.

Comparisons of clinical and radiographic outcome

OHS and pain level (OHS question 1) were skewed because most patients had a satisfactory functioning THA with a high OHS and a low pain score. The median (interquartile range) OHS for patients with RLL in all 4 proximal zones was 43 (36-47), and for those with no RLL, it was 41(33-46), $P = .11$. Sixty-eight percent of patients with RLLs in all 4 proximal zones reported no pain, and 10% reported moderate pain. Sixty-six percent of patients without RLLs reported no pain, and 6% reported moderate pain, $P = .3$.

Statistical analysis for predictors of RLLs involving zone 7

Statistical analysis could not be performed on the total 636 components because there were 2 very different groups: one collared with predominantly XLPE and one collarless with predominantly NXLPE. The 2 groups had to be considered separately. The collared group did not have a high enough incidence (8 cases in 318) of RLLs in zone 7 to perform statistical analysis. The collarless group did have a high enough incidence (75 cases in 318) to

Table 1
Demographics of study participants.

Implant / Variable	KS (n = 159)	KHO (n = 159)	KA (n = 161)	KLA (n = 157)
Median follow-up in years (IQR)	7.0 (6.0-7.0)	6.5 (6.2-6.9)	5.4 (5.1-5.8)	5.1 (4.7-5.5)
Median patient age in years at time of surgery (IQR)	65 (62-68)	65 (62-68)	64 (58-68)	63 (58-67)
Median stem size (IQR)	11 (9-12)	11 (10-13)	10 (9-12)	11 (10-12)
Pinnacle acetabular component, %	100	100	100	100
Female, number (%)	102 (64.6%)	61 (38.4%)	135 (84.0%)	53 (33.7%)
Bearing type, n (% per stem)				
Metal on NXLPE	25 (15.7%)	24 (15.1%)	3 (1.9%)	2 (1.3%)
Metal on XLPE	0	0	84 (52.2%)	80 (51.0%)
Ceramic on NXLPE	77 (48.4%)	84 (52.8%)	0	3 (1.9%)
Ceramic on XLPE	0	0	1 (0.6%)	0
CoC	57 (35.8%)	50 (31.4%)	5 (3.1%)	36 (22.9%)
CoM	0	1 (0.6%)	67 (41.6%)	35 (22.3%)
MoM	0	0	1 (0.6%)	1 (0.6%)

CoC, ceramic on ceramic; CoM, ceramic on metal; IQR, interquartile range; MoM, metal on metal.

Table 2
Prevalence outcome from the radiographic analysis of the 636 femoral components at latest follow-up.

Radiographic report	All stems n = 636	Collarless cohort			Collared cohort			
		Total (n = 318)	KHO (n = 159)	KS (n = 159)	Total (n = 318)	KA (n = 161)	KLA (n = 157)	*P* value[a]
RLL any zone	260 (40.9%)	141 (44.3%)	80 (50.3%)	61 (38.4%)	119 (37.4%)	53 (32.9%)	66 (42.0%)	.08
RLL only zone 1 and/or 8	137 (21.5%)	35 (11.0%)	24 (15.1%)	11 (6.9%)	103 (32.4%)	45 (28.0%)	58 (36.9%)	<.001
Any RLL pattern involving zone 7	83 (13.1%)	75 (23.6%)	50 (31.4%)	25 (15.7%)	8 (2.6%)	2 (1.2%)	6 (3.8%)	<.001
Undersized by 2 sizes or more	58 (9.1%)	25 (7.9%)	17 (10.7%)	8 (5.0%)	33 (10.4%)	20 (12.4%)	13 (8.3%)	.27

[a] Comparing collarless and collared cohorts using the Chi-square test.

perform statistical analysis and showed a similar prevalence in both males (24.5%) and females (22.7%) with a mean age of 64 years for the 75 cases with zone 7 RLLs and also 64 years for the 243 cases without zone 7 RLLs. Multivariable analysis was conducted on the collarless group with the variables NXLPE (210 yes), undersized by 2 sizes or more (25 yes), and follow-up time in years (Table 3).

Discussion

We examined 636 Corail stems at a median follow-up of 6 years. The clinical scores were on average excellent, and no patient was identified de novo as requiring revision. Despite this, 83 patients had radiographs showing a pattern of RLLs involving compressive zone 7. From this group of 83 patients, 8 had a collared stem and 75 had a collarless stem. Because this is an observational study only, we cannot conclude that the collar is protective against osteolysis, but our findings strengthen that suspicion. That is, although the collared group was exposed to 2 osteolytic risk factors, the incidence of zone 7 RLLs remained very low. The first of these risk factors was CoM bearings, which comprised 34% of all bearings in the collared group. We now know that this bearing is associated with osteolysis and early failure, and hence, it is no longer used [12]. The second risk factor was that 10.4% of the collared stems were undersized by 2 or more sizes. Our multivariable analysis suggested that undersizing has an odds ratio of 2.6 ($P = .03$) for development of RLLs in zone 7. Undersizing has also been linked to an increased risk of revision, with Jameson et al [13] reporting a higher 5-year revision rate for Corail Pinnacle with smaller stem sizes in male patients (sizes 8 to 10, hazard ratio = 1.82, $P < .001$) than midrange. Preoperative templating of stem size was not used in either cohort in this study, and unsurprisingly the proportion of undersized stems was high and the same in both cohorts. Templating provides the surgeon with a target that prevents innappropriate intraoperative acceptance of an undersized stem that has primary stability secondary to varus malalignment or distal fixation alone from metaphyseal-diaphyseal mismatch. Avoidance of undersizing is therefore clearly important with the Corail both to reduce the overall incidence of RLLs, as shown in this study, and to reduce the risk of revision [13]. Consequently, we now always preoperatively template the size of the stem.

Our belief that the collar is protective against osteolysis is open to debate. Wangen et al [14] have reported only a 2% prevalence of RLLs in all 4 proximal zones in a cohort of 109 collarless Corail (KS) at a mean follow-up of 10 years. Notably though, in that series, the incidence of stem undersizing was only 2.5% as opposed to 8% and 10%, respectively, in our 2 cohorts. Conversely, 25- to 30-year observational data from the design group identify a trend toward better clinical scores with the collar [15]. From a survivorship perspective, the use of a collar is now supported by registry data. The UK [16] and Australian [17] joint registries show a reduction in revision rate of 29% and 35%, respectively, when compared with collarless uncemented THA. This becomes evident in the first few months after surgery and remains significant out to 10 years. This would indicate that the collar protects against early failures, in other words failure due to fracture and failure due to lack of osteointegration. Khan et al [18] looked at the UK National Joint Registry data specifically for fractures and identified a 55% reduction in risk of revision with a collared vs collarless Corail. Furthermore, more recent data from the UK National Joint Registry [19] indicate that the KA Corail stem delivers a survival performance that is very similar to that of a cemented THA in the first year. When the collar is used correctly with the calcar mill, it not only protects against subsidence but also provides rotational stability [20]. This protects the proximal femur from early periprosthetic fracture, and we hypothesize that it also protects the proximal part of the Corail stem during the early phase of osteointegration.

Today the argument for using XLPE is probably unassailable [21-23], and it may be that the higher proportion of zone 7 RLLs seen in our collarless group is due to NXLPE. It is interesting to note however that our multivariable analysis did not associate NXLPE and zone 7 RLL development (odds ratio: 1.3, $P = .42$).

A direct comparison study of collared and collarless components with the same bearings would answer this question.

As this was an audit as opposed to a research study, there are a number of major limitations. First, the simultaneous change to the collared stem and XLPE makes it difficult to determine which is responsible for the reduced incidence of RLL in zone 7. In addition, because the 2 cohorts were sequential, there may be other confounding factors that we are not aware of. For simplicity, we defined an RLL as any radiolucency at the bone-implant interface, but clearly, lines within any zone can differ in terms of their appearance surface area and extent and would be better defined by computerized tomography. Our patient selection excluded patients older than 70 years and those patients who had undergone revision, which clearly creates a selection bias. In addition, only 80% of each selected group attended. Finally, we do not have information on the natural history of the RLLs, particularly beyond the 7-year time period, which was the limit of this study. This is important

Table 3
Results of multivariable analysis on the collarless cohort with respect to the presence of any RLL involving zone 7.

Variable	Odds ratio	95% CI	*P* value	Interpretation
Non–cross-linked polyethylene	1.3	0.7-2.2	.42	NXLPE is not a significant factor for development of RLL in zone 7
Undersized ≥2 sizes	2.6	1.1-6.2	.03	If a femoral component is undersized ≥ 2 sizes, it is 2.6 times more likely to develop RLL in zone 7
Follow-up years	0.6	0.4-0.9	.01	RLL in zone 7 is seen in those with shorter follow-up

CI, confidence interval.

future work, and we are now in the process of carrying out 10-year patient reviews, which will include a more detailed analysis of radiographs from 1 year, 5-7 years, and 10 years.

Conclusions

Careful preoperative templating should eliminate significant undersizing, and this study has shown that when a Corail stem is within one size of planned, it has less chance of developing RLLs in zone 7, which may also improve survivorship [13]. This study cannot prove that using a collared version of the Corail stem reduces the incidence of RLLs, but our observations certainly identify the need for a long-term comparative study.

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Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.artd.2019.11.009.

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