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■ TRAUMA

More re-operations after uncemented than cemented hemiarthroplasty used in the treatment of displaced fractures of the femoral neck

AN OBSERVATIONAL STUDY OF 11 116 HEMIARTHROPLASTIES FROM A NATIONAL REGISTER

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Using data from the Norwegian Hip Fracture Register, 8639 cemented and 2477 uncemented primary hemiarthroplasties for displaced fractures of the femoral neck in patients aged > 70 years were included in a prospective observational study. A total of 218 re-operations were performed after cemented and 128 after uncemented procedures. Survival of the hemiarthroplasties was calculated using the Kaplan-Meier method and hazard rate ratios (HRR) for revision were calculated using Cox regression analyses. At five years the implant survival was 97% (95% confidence interval (CI) 97 to 97) for cemented and 91% (95% CI 87 to 94) for uncemented hemiarthroplasties. Uncemented hemiarthroplasties had a 2.1 times increased risk of revision compared with cemented prostheses (95% confidence interval 1.7 to 2.6, p < 0.001). The increased risk was mainly caused by revisions for peri-prosthetic fracture (HRR = 17), aseptic loosening (HRR = 17), haematoma formation (HRR = 5.3), superficial infection (HRR = 4.6) and dislocation (HRR = 1.8). More intra-operative complications, including intra-operative death, were reported for the cemented hemiarthroplasties. However, in a time-dependent analysis, the HRR for re-operation in both groups increased as follow-up increased.

This study showed that the risk for revision was higher for uncemented than for cemented hemiarthroplasties.

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The treatment of displaced fractures of the femoral neck in elderly patients remains controversial. Several recent studies have reported better clinical outcome for hemiarthroplasty compared with screw fixation for these fractures.[1-4] However, there is no consensus on whether to use a cemented or an uncemented hemiarthroplasty. In Norway most hemiarthroplasties used for displaced fractures of the femoral neck are cemented (around 79%) and the remainder are uncemented implants with porous and/or hydroxyapatite coating.[5]

A recent randomised study of 220 hemiarthroplasties found no differences in mortality, complications or functional outcome when comparing contemporary cemented and uncemented implants.[6] The study was not powered sufficiently to detect differences in the incidence of re-operations. Two systematic reviews found less pain and better function after cemented than uncemented hemiarthroplasties.[7,8] However, most of the uncemented implants in these studies were older uncoated designs.

The Norwegian Hip Fracture Register (NHFR) was initiated in 2005 to provide epidemiological data on hip fractures and to improve the management of patients with hip fractures by evaluating different methods of treatment.[9] The aim of the present observational study was to compare the rates of re-operation within six years of cemented and uncemented hemiarthroplasty in patients with a displaced (Garden type 3 and 4[10]) fracture of the femoral neck reported to the register.

Patients and Methods

The NHFR contains data from more than 46 000 operations for patients with a fracture of the hip between January 2005 and the end of 2010.[5] Information on patient characteristics, fracture type and treatment is collected using a one-page questionnaire that is completed by the surgeon at operation. Both primary operations and re-operations are registered, and re-operations are linked to the index operation using the national identification number assigned to each individual. The

Table I. Baseline characteristics of patients

	Cemented hemiarthroplasty (n = 8639)	Uncemented hemiarthroplasty (n = 2477)	p-value
Mean age at fracture (yrs) (range)	83.5 (70 to 104)	83.8 (70 to 103)	0.067*
Female (n, %)	6450 (*74.7*)	1825 (*73.7*)	0.322†
ASA‡ class (n, %)			0.394†
1	345 (*4.0*)	85 (*3.4*)	
2	2912 (*33.7*)	872 (*35.2*)	
3	4727 (*54.7*)	1346 (*54.3*)	
4	515 (*6.0*)	142 (*5.7*)	
5	4 (*0.0*)	2 (*0.1*)	
Data missing	136 (*1.6*)	30 (*1.2*)	
Cognitive impairment (n, %)			< 0.001†
Yes	2173 (*25.2*)	705 (*28.5*)	
Uncertain	962 (*11.1*)	273 (*11.0*)	
No	5281 (*61.1*)	1457 (*58.8*)	
Data missing	223 (*2.6*)	42 (*1.7*)	

* independent *t*-test
† Pearson chi-squared test
‡ ASA, American Society of Anesthesiologists

Table II. Type of implants

Cemented hemiarthroplasty (n = 8639)		Uncemented hemiarthroplasty (n = 2477)	
Name	**Number (%)**	**Name**	**Number (%)**
Exeter/V40 (Stryker)	2907 (*33.6*)	Corail (DePuy)	1869 (*75.5*)
Charnley (DePuy)	2085 (*24.1*)	Filler (Biotechni)	361 (*14.6*)
Spectron (Smith and Nephew)	1066 (*12.3*)	SL-PLUS (Smith and Nephew)	158 (*6.4*)
Lubinus SP II (LINK)	825 (*9.5*)	HACTIV (Biomed)	37 (*1.5*)
Titan (DePuy)	809 (*9.4*)	Other	52 (*2.1*)
Charnley Modular (DePuy)	796 (*9.2*)		
Other	151 (*1.7*)		

definition of a re-operation is any further procedure undertaken for complications and includes closed reduction for dislocation and soft-tissue procedures.[9] Those requiring with conversion to total hip replacement (THR) were reported separately to the Norwegian Arthroplasty Register and added to the NHFR. All patients were followed until the time of re-operation, the time of death, or emigration, or until censoring on December 31, 2010. Records with information on time of death and emigration were obtained from the Norwegian Register of Vital Statistics. The recording of data in the NHFR has the approval of the Norwegian Data Inspectorate. All patients provided informed consent that was entered into their hospital medical record. Cognitive function was defined by the surgeon based on the medical records or with help from relatives. Comorbidity was recorded according to the classification of the American Society of Anesthesiologists (ASA).[11]

As of 23 May 2011, there was information on 46 046 primary operations for a fracture of the hip registered in the NHFR. Displaced fractures of the femoral neck constituted 17 875 operations. Of these, 12 500 were treated with a hemiarthroplasty. Only patients > 70 years of age were included, leaving 11 758 patients. Unipolar hemiarthroplasties were rarely used (n = 259) and consequently they were excluded. Plain bone cement, without antibiotics, was used infrequently (n = 62) and these were also excluded. Finally, patients with missing information on type of fixation (cemented or uncemented) (n = 321) were excluded. A total of 11 116 displaced fractures treated with a cemented (n = 8639) or uncemented hemiarthroplasty (n = 2477) remained for analysis.

More patients were cognitively impaired in the uncemented than in the cemented group (707 (28.5%) *versus* 2173 (25.2%); p < 0.001, Pearson chi-squared test). There were no other significant differences between the two groups in terms of age, gender or ASA score (Table I). The mean duration of surgery was 78 minutes (SD 23) for cemented and 62 minutes (SD 21) for uncemented implants (p < 0.001, *t*-test). The types of arthroplasty in the two groups are shown in Table II. The Exeter-UHR (Stryker, Selzach, Switzerland) and Charnley-Hastings (DePuy) were the most frequently used cemented implants, with bipolar heads. The Corail stem (DePuy, Leeds, United Kingdom) was the most frequently used uncemented implant and was

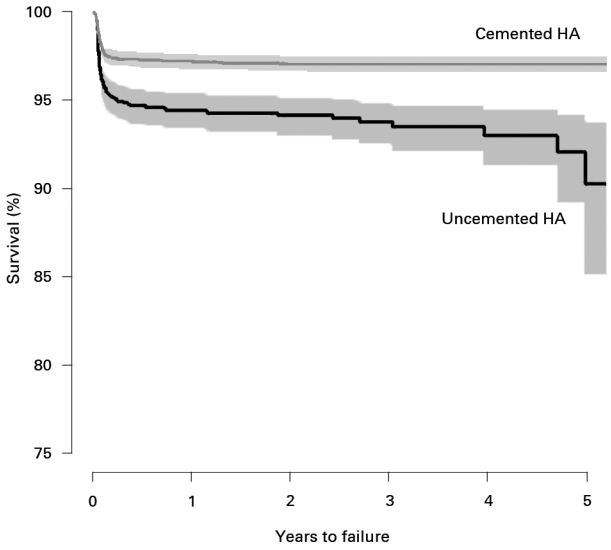

Fig. 1

Adjusted survival with 95% confidence intervals for patients with cemented and uncemented hemiarthroplasty (HA) with all re-operations as the endpoint.

commonly used with the Bipolar self-centering head (DePuy) (935 out of 2477) or the Landos Bipolar Cup (DePuy) (819 out of 2477).

Statistical analysis. The Pearson chi-squared test was used for comparison of categorical variables in independent groups. The independent *t*-test (Student's *t*-test) was used for continuous variables in independent groups. The survival of implants with any re-operation as the endpoint was calculated with Kaplan-Meier analyses with 95% confidence intervals (CIs).[12] Cox regression models were used to adjust for potential confounders, such as differences in age, gender, comorbidity (ASA classification), and cognitive impairment (dysfunction, no dysfunction and uncertain) in the two treatment groups with follow-up from zero to six years.[13] Furthermore, the Cox model was used to construct adjusted survival curves at mean values of the covariates and to calculate differences in re-operation risk between the two groups with different reasons for re-operation as the endpoints. For re-operation of any cause we calculated time dependent curves for the hazard rate ratio (HRR) based on scaled Schoenfeldt residuals.[14] In the regression models, the category of cemented prostheses was used as the reference, to which the other categories were compared. We did not adjust for patients who were operated on both sides, since we have previously shown that this will not alter the conclusion for the entered covariates.[15] All continuous variables were presented with 95% CIs. All tests were two-sided and the results were considered statistically significant at a p-value of < 0.05. The analyses were performed with use of PASW Statistics software, version 18.0 (SPSS Inc., Chicago, Illinois) and the statistical program R version 2.12.2.[16]

Results

The mean follow-up was 1.65 years (1 to 5), and the median follow-up, as calculated using the reverse Kaplan-Meier method of Schemper and Smith,[17] was 1.4 years (0 to 6). In all 218 re-operations were performed after cemented hemiarthroplasties and 128 after uncemented hemiarthroplasties The one-year implant survival was 97% (95% CI 97 to 98) for cemented and 94% (95% CI 93 to 95) for uncemented hemiarthroplasties. The five-year survival was 97% (95% CI 97 to 97) and 91% (95% CI 87 to 94) for the cemented and uncemented hemiarthroplasties, respectively. Figure 1 shows the Cox survival curves with adjustments for age, gender, comorbidity and cognitive function. Further, Cox regression analyses with the same adjustments revealed that uncemented hemiarthroplasties had a 2.1 times increased risk of re-operation with up to six years follow-up compared with cemented hemiarthroplasties ($p < 0.001$) using any re-operation as the endpoint (Table III). HRR with one year follow-up was 2.0 (95% CI 1.6 to 2.5). The increased risk of re-operation for uncemented prostheses was due to more peri-prosthetic fractures (HRR 17 (95% CI 6.3 to 44)), aseptic loosening of the prosthesis (HRR 17 (95% CI 4.7 to 58)), haematoma (HRR 5.3 (95% CI 2.5 to 11)), superficial infection (HRR 4.6 (95% CI 1.7 to 12)), and dislocation (HRR 1.8 (95% CI 1.1 to 2.8)).

The time-dependent risk of re-operation in patients with an uncemented hemiarthroplasty is presented in Figure 2. The HRR for re-operation after uncemented hemiarthroplasty was increased by the first month post-operatively compared with the cemented hemiarthroplasties. After two months post-operatively this relative risk seemed to increase constantly.

The types of re-operations performed are shown in Table IV. The most frequent re-operation was a soft-tissue procedure for haematoma or infection, a procedure that often included a concomitant change of the bipolar head.

Table V presents the intra-operative complications. There was a total of 399 complications (4.6%) in the cemented group and 86 (3.5%) in the uncemented group ($p = 0.032$, Pearson chi-squared). Cardiac and respiratory problems were common in the cemented group. Among the 8639 cemented hemiarthroplasties, there were 26 intra-operative deaths (0.3%) and 15 (0.2%) cases of cardiac arrest. Intra-operative fracture was the most frequent complication for uncemented hemiarthroplasties; only one of 2477 patients (0.04%) died during surgery (Table V). In all 23 of 27 patients who died during surgery were ASA grade 3 or 4. The one-year mortality was 25.6% and 26.5% for patients with cemented and uncemented hemiarthroplasties respectively (adjusted Cox: HRR 0.98, $p = 0.51$).

Discussion

In the present study uncemented HAs had twice the risk of re-operation at six years follow-up compared with cemented HAs in elderly patients with displaced femoral neck fractures. This difference was caused by an increased

Table III. Number of re-operations with 0- to 6-year follow-up according to type of fixation of the hemiarthroplasty. More than one reason may exist for each re-operation. The table also shows hazard rate ratios (HRR) of re-operations in uncemented hemiarthroplasty relative to cemented hemiarthroplasty. HRRs were adjusted for differences in gender, age, American Society of Anesthesiologists class, and cognitive impairment (CI, confidence interval)

	Cemented hemiarthroplasty		Uncemented hemiarthroplasty		
Re-operations	**Number**	**Reference**	**Number**	**HRR (95% CI)**	**p-value**
All re-operations	174	1	93	2.09 (1.68 to 2.60)	< 0.001
Superficial infection	7	1	9	4.59 (1.71 to 12.3)	0.003
Deep infection	119	1	43	1.27 (0.90 to 1.80)	0.177
Haematoma	12	1	18	5.27 (2.54 to 11.0)	< 0.001
Dislocation	59	1	30	1.78 (1.15 to 2.76)	0.010
Peri-prosthetic fracture	5	1	22	16.6 (6.27 to 43.9)	< 0.001
Implant loosening	3	1	13	16.5 (4.71 to 58.1)	0.001
Pain	2	1	1	1.72 (0.16 to 19.0)	0.659
Other, unspecified	22	1	11	1.51 (0.16 to 3.39)	0.319

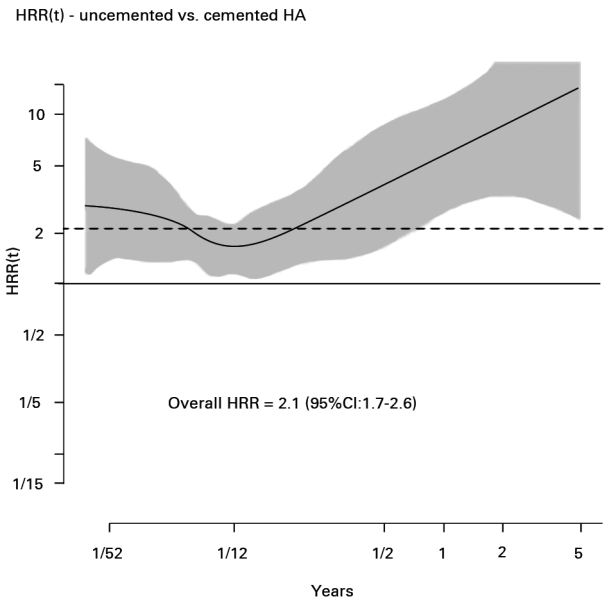

Fig. 2

Time-dependent hazard rate ratios (HRRs) of re-operation, with 95% confidence intervals, for cemented compared with uncemented hemiarthroplasties. The horizontal dotted line indicates overall HRR for uncemented hemiarthroplasty compared with cemented. The horizontal line represents the risk of re-operation in cemented prostheses. Both the x-axis and the y-axis are logarithmic. The curves show an increased overall HRR for re-operation.

risk of re-operation for peri-prosthetic fracture, implant loosening, haematoma formation, superficial infection, and dislocation. On the other hand, intra-operative complications were more frequent with cemented hemiarthroplasties. The most serious complications, including intra-operative death and cardiac arrest, were almost exclusively reported for the cemented procedures. However, the one-year mortality was similar for the two groups.

Figved et al[6] found similar rates of complication with one year follow-up when comparing cemented and uncemented hemiarthroplasties. In that study the uncemented Corail stem was used in the uncemented procedures. The study was not, however, sufficiently powered to detect differences in rare adverse effects between the two groups. The uncemented Corail hemiarthroplasty has low rates of revision and was also the most frequently used implant in a Norwegian nation-wide study.[18] However, in the latter study most patients had osteoarthritis and were < 60 years of age. This finding does not necessarily apply to osteoporotic patients > 70 years of age with a fracture.

Deep infection was a frequent reason for re-operation in our study. This may be explained by the age and comorbidities in our patients; both factors being associated with an increased risk of infection.[19] There were few re-operations for superficial infection but still significantly more in the uncemented group; and there was a trend towards more re-operations for deep infection in the uncemented group ($p = 0.18$). A recently published study on infection after hemiarthroplasty and THR also found an increased revision risk in uncemented implants.[20] Another study from the Norwegian Arthroplasty Register on THRs undertaken between 1987 and 2009 found an increasing risk of re-operations because of infection and the most pronounced increase was found for uncemented THRs.[21] Antibiotic-loaded bone cement has been shown to protect against infection in earlier studies, and one explanation for the increased risk of infection after uncemented THRs can be the absence of cement.[22,23]

Peri-prosthetic femoral fracture, peri-operative and at any time post-surgery, is a well-known complication to of an uncemented implant.[24] The femurs of older patients with a fracture are often osteoporotic (Dorr type C[25]). The uncemented hemiarthroplasties used most commonly in our country are straight tapered stems designed for a metaphyseal fixation. This type of fixation can be difficult to achieve in elderly patients, with an increased risk of peri-operative fracture in the attempt to achieve fixation.

Even if the cemented hemiarthroplasties had fewer re-operations in our study, the number of intra-operative complications found after cemented procedures is a concern. In a recently published randomised controlled trial, Parker, Pryor and Gurusamy[26] found no difference in general complications when comparing cemented and uncemented

Table IV. Type of re-operation according to hemiarthroplasty fixation

Type of re-operation (n, %)	Cemented hemiarthroplasty (n = 218)	Uncemented hemiarthroplasty (n = 128)
Total hip replacement*	24 (*11*)	9 (*7.0*)
Bipolar hemiarthroplasty	10 (*4.6*)	22 (*17*)
Girdlestone procedure	19 (*8.7*)	7 (*5.5*)
Drainage of haematoma or infection	92 (*42*)†	53 (*41*)‡
Open reduction of dislocated hemiarthroplasty	21 (*9.6*)§	15 (*12*)¶
Closed reduction of dislocated hemiarthroplasty	11 (*5.0*)	5 (*3.9*)
Other	26 (*12*)	17 (*13*)

* reported to the Norwegian Arthroplasty register
† procedure included change of bipolar head in 70 patients
‡ procedure included change of bipolar head in 17 patients
§ procedure included change of bipolar head in 11 patients
¶ procedure included change of bipolar head in nine patients

Table V. Intra-operative complications according to hemiarthroplasty fixation

Type of complication (n, %)	Cemented hemiarthroplasty (n = 399)	Uncemented hemiarthroplasty (n = 86)	p-value*
Intra-operative death	26 (*0.3*)	1 (*0.04*)	0.020
Cardiac arrest	15 (*0.2*)	0 (*0*)	0.038
Bradycardia	16 (*0.2*)	0 (*0*)	0.032
Angina/myocardial infarction	17 (*0.2*)	2 (*0.08*)	0.218
Hypotension	18 (*0.2*)	2 (*0.08*)	0.186
Respiratory failure (with cementing)	22 (*0.3*)	0 (*0*)	0.012
Intra-operative femoral fracture	74 (*0.9*)	51 (*2.1*)	< 0.001
Bleeding	15 (*0.2*)	5 (*0.2*)	0.770
Insufficient anaesthesia	49 (*0.6*)	6 (*0.2*)	0.042
Technical problem with cement	53 (*0.6*)	0 (*0*)	< 0.001
Difficult reduction of hemiarthroplasty	23 (*0.3*)	3 (*0.1*)	0.187
Malposition of femoral stem	6 (*0.07*)	1 (*0.04*)	0.611
Other	65 (*0.8*)	15 (*0.6*)	0.414
Total number of complications	399 (*4.6*)	86 (*3.5*)	0.032

* Pearson chi-squared test

hemiarthroplasties. However, 400 patients were included in their study and this is probably an insufficient number to detect differences in rare adverse effects. A Cochrane review comparing cemented and uncemented arthroplasties concluded that adverse reactions to cement occur, but could not find any other significant differences in the incidence of complications.[8] In the present study there were more cardiovascular and respiratory complications during the cemented procedures. Intra-operative death almost exclusively occurred during cemented procedures. These serious intra-operative complications could have been caused by the cementing that has been referred to as the bone cement implantation syndrome.[27] A distal venting hole in the femur has been found to reduce the intramedullary pressure during cementing.[28] This may reduce the serious complications related to cement if used in elderly and frail patients. Several studies have investigated the mortality rate after hemiarthroplasty. Based on concern from the National Patient Safety Agency in United Kingdom that reported 26 deaths after hip fractures treated using cemented implants,[29] Timperley and Whitehouse[30] evaluated the evidence for the use of cemented hemiarthroplasties. One of their conclusions was the need for national hip fracture databases in order to evaluate and optimise the treatment of patients with a fracture of the hip. They also concluded that there is good evidence in the literature supporting the use of cemented hemiarthroplasties.

A study from the national joint replacement registry in Australia found an increased mortality for patients after undergoing cemented hemiarthroplasty on the first post-operative day.[31] However, this difference was reversed with longer follow-up. Parvizi, Ereth and Lewallen[32] found an increased short-term mortality after cemented arthroplasties in the first 30 days. On the other hand, results from the National Hip Fracture Database in the United Kingdom showed a slightly better peri-operative survival until discharge for patients undergoing a cemented arthroplasty compared with those undergoing an uncemented procedure.[33] Most studies with longer follow-up have not found any difference in mortality between the two types of treatment.[6,8,26] One reason for the reversion of the early increased mortality risk after cemented hemiarthroplasty found in some studies could be that the patients with uncemented implants had more re-operations and thus ran the risk of new complications and death as a consequence of repeated surgery. Even though the most serious intra-operative

complications occurred more frequently in the cemented group, the risk of intra-operative death (0.3%) and major cardiovascular events (0.8%) reported was still low. Most patients with a fracture of the hip, at least the ones with serious peri-operative complications in our study, are old and frail with a short life-expectancy. Taking the reduced risk of later re-operations into account, and the finding that mortality one year post surgery is not different in the two groups, the rate of complications, which are related to the cement, is probably acceptable.

The mortality rates after hemiarthroplasty, both short- and long-term are very high, independent of the method of fixation. Several studies have addressed the importance of good peri-operative treatment in order to reduce the mortality for these old and frail patients. Foss et al[34] found a tendency towards lower in-hospital mortality after surgery for a fracture of the hip when anaesthetists performed daily ward rounds. However, the study was not powered to detect statistically significant differences. In another study Fisher et al[35] found reduced morbidity and mortality for those patients receiving shared care from consultants in geriatric medicine. In order to improve survival and to facilitate rapid recovery after surgery for a fracture of the hip, treatment of these patients in specialised ortho-geriatric wards with multidisciplinary co-operation should be considered.

Nevertheless, the mortality, and in particular the short-term mortality, after uncemented and cemented hemiarthroplasty must be further investigated. In order to examine the adverse effects in the two groups, a large number of patients would be required. Ideally, a large randomised controlled trial (RCT) would be the best way to eliminate confounding variables. However, re-operations and peri-operative complications are infrequent, and a RCT would need a very high number of patients to detect significant differences between treatment groups. Such studies are difficult to perform and rare in the orthopaedic literature. One concern in the present study is the higher rate of cognitively impaired patients in the uncemented group. However, an earlier study from our registry found a lower rate of re-operation after undisplaced fractures of the femoral neck in cognitively impaired patients compared with cognitively fit patients.[36] Therefore, the higher rate of re-operation after uncemented hemiarthroplasty in the present study is probably not due to differences in cognitive state between the two groups.

In the NHFR, all re-operations should be reported. Nevertheless, there may be an under-reporting especially of minor complications and re-operations due to superficial infection and closed reduction of dislocation. Another limitation is the relatively short follow-up, and the number of re-operations will probably rise for both groups with longer follow-up. The strength of our study is the high number of patients included, and that the findings represent the results that can be achieved from orthopaedic surgeons on a national level.

In the treatment of displaced femoral neck fractures in elderly patients the results of both cemented and modern uncemented bipolar hemiarthroplasties were satisfactory with a rate of re-operation of about 5% within the first post-operative year. However, more re-operations were encountered after uncemented hemiarthroplasty whereas the cemented procedures were associated with more serious cardiovascular intra-operative complications. Even though the overall number of these intra-operative complications was low, this is worrying, and must be addressed during surgery.

Supplementary material

A further opinion by Mr C. Mauffrey is available with the electronic version of this article on our website at www.boneandjoint.org.uk/site/education/further_op

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