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ORIGINAL ARTICLE

No differences in outcomes between cemented and uncemented acetabular components after 12–14 years: results from a randomized controlled trial comparing Duraloc with Charnley cups

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Abstract
Background Even though there are multiple studies documenting the outcome of the Charnley low-friction arthroplasty as well as abundant studies on uncemented arthroplasties, there is a dearth of comparative studies of the uncemented acetabular component and a cemented component. In this study we aimed to document the long-term clinical and radiographic outcome as well as component survival in a randomized controlled trial.
Materials and methods Two hundred fifteen patients (240 hips) were randomly allocated to receive a cemented Charnley cup or uncemented Duraloc 1200 cup. All patients received cemented Charnley stems and were evaluated clinically and radiographically after 6 months, and 2, 5, and 10 years.
Results Harris Hip Scores improved from 48.3 [95% confidence interval (CI) 45.0–51.6] to 90.2 [95% CI 87.9–92.6] in the Charnley group and from 49.3 [95% CI 86.9–91.3] in the Duraloc group at 6 months. After 10 years, the Charnley group's Harris Hip Score was 89.8 [95% confidence interval (CI) 87.0–92.6], and the Duraloc group's score was 87.3 (95% CI 84.1–90.6). In the radiographic analysis after 10 years, there was no statistical difference in the prevalence of radiographic signs of loosening. Nine cups were revised in the Charnley group, and five cups were removed in the Duraloc group. The difference was not statistically significant. There was no statistical difference between the cups when aseptic loosening was the end-point, nor in survival analyses.
Conclusions There is no statistically significant difference in clinical or radiological outcome between the Charnley cup and the Duraloc after 10 years, and no difference in implant survival after 12–14 years. The uncemented Duraloc cup is as good as the cemented Charnley cup after 10 years.

Keywords Hip · Acetabulum · Cemented · Uncemented · Randomized

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Introduction

Hip arthroplasty is a highly successful procedure for alleviating pain and improving overall hip function in arthritis and other destructive hip joint conditions [1]. However, the method of fixation for hip replacement components has remained a matter of controversy [2, 3].

The cemented all-polyethylene acetabular component has been regarded as a gold standard, and multiple reports confirm survival of 85–92% after 16–25 years [4–6] and revision rates of 2–17% after 17–30 years [7–10] when aseptic loosening is the end-point. However, results are worse for younger patients, and rates of revision increase with longer follow-up [5].

The uncemented acetabular component has been regarded as a viable alternative to the cemented cup [2], and the

hemispheric porous-coated cup inserted with press-fit technique has emerged as the most commonly used component [11]. Multiple series have demonstrated low rates of revision when aseptic loosening is the end-point, but revision due to osteolysis and polyethylene wear remains a problem [12–15]. Survival of the shell after 8–12 years is reported to be 100% in several studies when aseptic loosening is the end-point [12, 16–19], whereas survival of the acetabular component may be 64–80% when liner exchange, osteolysis, and wear are end-points [12, 14, 16, 20]. In a study of a first-generation porous-coated cup (PCA) with 15–17 years follow-up, 17% of the cups had been revised due to loosening with or without osteolysis [21], whereas a recent 20-year study found 96% survival of shell and 17% liner revision rate [15].

As the acetabular component of the Charnley arthroplasty has remained virtually unchanged for close to 40 years, there is an abundance of clinical studies documenting the results of the cemented acetabular component. A recent PubMed search yielded more than 400 studies on the Charnley arthroplasty, but only 8 were comparative studies [22–29], and only 1 compared the Charnley with a modern hemispheric porous-coated press-fit cup [30]. This was a radiostereometric study in 21 patients which found no difference between the Charnley cup and the Harris Galante cup in terms of fixation.

Thus there is a lack of good evidence with regards to the comparative outcome of the modern porous-coated cup and the traditional cemented all-polyethylene cup. Randomized controlled studies provide the best evidence, and in this report we convey the results of a randomized controlled trial comparing the Duraloc cup with a conventional Charnley cup with 10–14 year follow-up to help resolve the lack of evidence from direct comparisons of these two hip arthroplasty techniques.

Patients and methods

Between April 1994 and June 1997, 215 patients treated at one clinic consented to take part in the study, which was conducted at a county hospital with an annual case load of 300 total hip replacements. According to the inclusion criteria, patients were eligible for participation in the study if they suffered from noninflammatory degenerative disease of the hip including osteoarthritis, posttraumatic arthritis, psoriatic arthritis, and gout. They were also eligible if they suffered from joint diseases of inflammatory origin such as rheumatoid arthritis and juvenile rheumatoid arthritis as well as systemic lupus erythematosus. The upper age limit was 75 years, but there was no lower age limit. Previous prosthetic replacement was a contraindication to participation, but osteotomies and internal fixations were not. Twenty-five patients consented for both of their hips, resulting in a total of 240 hips enrolled. Patients were given sequential enrollment numbers, but the assignment of patients to treatment groups was randomly chosen using a table of random numbers. The randomization was concealed until after surgery had been initiated. In order to reduce potential bias, patients were not told which acetabular implant they received until their 2-year follow-up visit, which was covered in the preoperative consent form.

Patients were grouped in accordance with the Charnley classification (Table 1) to allow stratification according to presence of comorbidities and condition of other joints [31]. Surgery was performed using a direct lateral approach [32] by five orthopedic surgeons. The femoral component was cemented using third-generation cementing techniques with vacuum mixing, retrograde filling of the canal, and pressurization prior to insertion of the femoral component [33]. Cement containing gentamycin and a Charnley stem (DePuy, Leeds, UK) with 22.225 mm head diameter was used in all cases.

For the uncemented group, the Duraloc 1200 cup (DePuy, Leeds, UK), a hemispherical modular cup consisting of a titanium shell with a porous-coated surface, was used. The surface has a mean pore size of 250 μm. The Duraloc 1200 cup was considered a second-generation cup because it had a minimum polyethylene thickness of 6 mm, dome-loading of the polyethylene, and an improved locking mechanism designed not to interfere with liner–shell conformity [34]. The shell had a central hole for the insertion device and 12 holes for screw fixation. An ultrahigh-molecular-weight polyethylene (UHMWPE) liner (Enduron; DePuy, Leeds, UK) with a 10° posterior lip was used in all cases.

The Charnley cup (DePuy, Leeds, UK) used for the other group was an all-polyethylene cup with a flange. The Ogee cup was used in 101 cases and the Low Posterior Wall cup was used in 19 cases. The surgeon cut the flange

Table 1 Charnley classification including modification of group B

A	Single-joint arthropathy and no significant medical comorbidity
B	One other joint in need of an arthroplasty, or an unsuccessful or failing arthroplasty in another joint
B1	Contralateral hip in need of arthroplasty, but untreated
B2	Contralateral hip has been successfully treated with an arthroplasty
C	Multiple joints in need of arthroplasty, multiple failing arthroplasties or significant medical or psychological impairment

to fit the rim of the acetabulum, which provided increased pressure to the cement, augmenting cement penetration into the bone of the acetabulum. Surgery was performed under laminar air flow.

For prophylaxis against thromboembolic events, dalteparin (Fragmin®), a low-molecular-weight heparin, 5000 IE was given subcutaneously on the night before surgery, 4–8 h postoperatively, and daily for the length of the stay. Cefuroxim (Zinacef®) was given routinely in the study period as prophylaxis for infection. Patients were screened for urinary-tract infection prior to surgery and treated appropriately if bacteriuria was detected. Postoperatively, patients were allowed restricted weight bearing on the day after surgery. All patients were encouraged to use two crutches for at least 6 weeks.

The objectives of the study were to assess the safety and efficacy of the implants by means of clinical evaluation by means of Harris Hip Score (HHS), and radiological evaluation after 6 months, and 2, 5, and 10 years, as well as adverse event reporting. Though not part of the original study protocol, we conducted an implant survival analysis as well. No subgroup analysis was performed.

Patients were seen by their surgeon 6 weeks after surgery and by a physiotherapist 6 months, and 2, 5, and 10 years after surgery. The physiotherapist was specifically trained to evaluate hip replacement patients. The patients, but not the physiotherapist, were blinded as to which implant had been used in order not to bias the subjective part of the evaluation. The physiotherapist obtained a Harris Hip Score [35] at each visit. Radiographs were obtained at all visits and analyzed by a radiologist not directly involved in the study but very competent in this field. Radiographic changes that were noted included radiolucencies, bone resorption, cortical hypertrophy, cement fracture, and migration of components in the femoral zones of Gruen [36] and acetabular zones of DeLee [37]. No measure of polyethylene wear and no formal quantification of osteolysis was performed as this was not a part of the original study protocol.

All patient charts were examined during the summer of 2008, and censoring dates were set to July 31, 2008 for patient and implant survival. Thus, the follow-up was 12–14 years in the survival analysis. During the chart review we collected information that was not included in the protocol, including duration of surgery, bleeding, and any secondary use of antibiotics that might indicate complications not routinely recorded in the research protocol.

Statistical analysis

Two-sample *t*-tests were used for comparing continuous data. Chi-square and Fisher exact test were used to compare categorical variables. Survival data were analyzed using Kaplan–Meier plots and log-rank test. Logistic regression analysis was employed to explore possible risk factors for prosthetic infection. Results are considered statistically significant when *p*-values are below 0.05 or when the 95% confidence intervals do not overlap. In 25 cases two arthroplasties were included in the study, and these were analyzed as independent cases for reasons outlined in the "Discussion."

Ethics

This study was initiated prior to the institution of a Institutional Review Board at our hospital. However, the procedures were conducted in accordance with the Declaration of Helsinki and the study has been evaluated by the present research ethics committee, which did not have any objections. All patients provided informed consent prior to surgery.

Results

There were 58 men and 157 women enrolled in the study, with mean body mass index (BMI) of 26.50 kg/m^2 (SD 3.4 kg/m^2) and 26.87 kg/m^2 (SD 4.5 kg/m^2), respectively. There was a statistically significant difference between the Charnley and Duraloc group in the distribution of hips between class A and B in the Charnley classification (Table 2; $p = 0.049$), with the Charnley group having more B1 patients and the Duraloc group more A patients. There was no statistically significant difference in other preoperative characteristics or baseline demographics (Table 3) between the groups. Operative time was significantly longer for Charnley (71 min) than for Duraloc

Table 2 Preoperative characteristics of the patients according to group

Diagnosis	Charnley	Duraloc
Osteoarthritis	93	94
Congenital hip dysplasia[a]	24	18
Posttraumatic arthritis	2	4
Rheumatoid arthritis	1	3
Avascular necrosis	0	1
Class	**Charnley**	**Duraloc**
A	46	66
B1	40	24
B2	29	25
C	5	5

[a] Mild dysplasia not necessitating advanced acetabular procedures

Table 3 Baseline values of patient demographics

	Charnley			Duraloc		
	Mean	95% Confidence interval		Mean	95% Confidence interval	
Age (years)	65	64	66	66	65	67
Gender[a] (%)	76	68	84	71	63	79
Harris Hip Score	47	45	50	49	47	52
Body mass index (kg/m^2)	27	27	28	27	26	27

[a] Proportion female

(66 min) ($p = 0.033$), but there was no significant difference in bleeding (636 versus 602 ml) ($p = 0.295$).

Follow-up

During the entire study period, 53 hips were lost due to the death of the patient, 24 in the Charnley group and 29 in the Duraloc group. However, only 25 patients died before their 10-year appointment, representing 12 cases in the Charnley group and 14 cases in the Duraloc group (Fig. 1). We were able to locate all patients in the study, but 31 patients were not able to attend their 10-year appointment, mostly because of ill health. Furthermore, 31 femoral revisions were performed, 17 in the Charnley group and 14 in the Duraloc group. For this reason, 71 patients in the Charnley group and 80 patients in the Duraloc group were available for 10-year Harris Hip Score and radiographic analysis.

Bilateral cases

The preoperative characteristics of the bilateral cases are shown in Table 4. The patients who were included in the study with two hips had a statistically significant lower BMI than the unilateral patients in the Duraloc group, but not in the Charnley group.

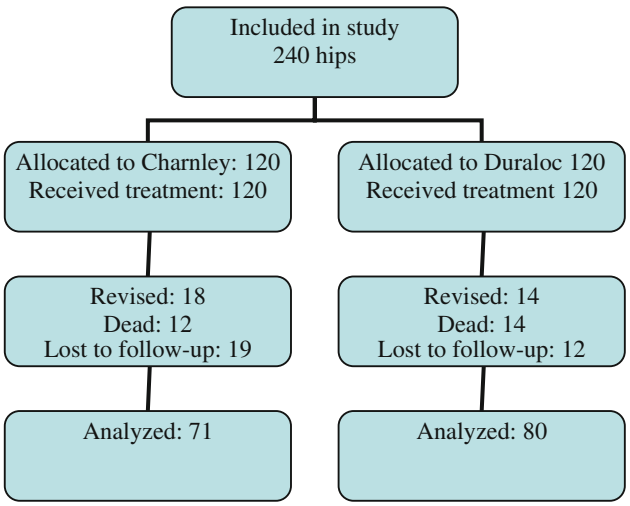

Fig. 1 Flow diagram illustrating the flow of hips through the study. Numbers for revision include femoral revisions

Table 4 Baseline characteristics of the unilaterally and bilaterally operated cases in the Charnley (91 and 29) and Duraloc (99 and 21) groups

Acetabulum	Mean	95% Confidence interval for mean	
		Lower bound	Upper bound
Charnley			
Baseline HHS			
Unilateral	46.7	43.8	49.5
Bilateral	49.8	43.3	56.3
Total	47.4	44.8	50.0
Age (years)			
Unilateral	65.5	64.0	67.0
Bilateral	63.9	60.8	67.0
Total	65.1	63.7	66.4
BMI (kg/m^2)			
Unilateral	27.4	26.4	28.3
Bilateral	25.3	24.1	26.5
Total	26.9	26.1	27.7
Duraloc			
Baseline HHS			
Unilateral	48.2	45.3	51.1
Bilateral	55.2	50.0	60.3
Total	49.4	46.9	52.0
Age (years)			
Unilateral	66.2	64.8	67.7
Bilateral	64.4	60.8	68.1
Total	65.9	64.6	67.3
BMI (kg/m^2)[a]			
Unilateral	27.1	26.3	27.9
Bilateral	24.5	23.0	26.0
Total	26.7	25.9	27.4

[a] Significant difference as evidenced by nonoverlapping confidence intervals

Table 5 Mean Harris Hip Score including confidence intervals (95%) for both interventions

	Charnley			Duraloc		
	CI			CI		
	Mean	Lower	Upper	Mean	Lower	Upper
Preoperative	48.3	45.0	51.6	49.3	46.3	52.4
6 months	90.2	87.9	92.6	89.1	86.9	91.3
2 years	92.7	89.6	95.8	94.0	92.4	95.7
5 years	93.9	91.6	96.2	91.4	89.3	93.5
10 years	89.8	87.0	92.6	87.3	84.1	90.6

Harris Hip Score

There was a significant difference between preoperative and postoperative scores for both groups ($p < 0.0005$). The Harris Hip Score improved from a baseline score of 47.7 to 87.7 at 6 months in the Charnley group, and from 49.4 to 88.2 in the Duraloc group. The difference between the intervention groups was not statistically significant at any time point (Table 5). There was a clear but not statistically significant decline in Harris Hip Score after 5 years in both groups, with the decline starting earlier for the Duraloc hips. Based on the function part of the Harris Hip Score, there was a reduction in function for both groups starting at 2 years of follow-up (Fig. 2). The pain component of the Harris Hip Score remained stable for both groups.

Revisions

A total of 13 acetabular components were revised during the study (5.4%), 9 in the Charnley group and 4 in the Duraloc group, which was not statistically significant ($p = 0.12$; chi-square). In the Charnley group, three cups were revised due to aseptic loosening, one due to dislocation, and five due to prosthetic infection.

The five hips that became infected were treated with two-stage revision after 5, 11, 14, 24, and 48 months. While the difference in the rate of prosthetic infection between the groups was not quite statistically significant ($p = 0.06$; Fisher's exact test), further exploration of the reasons for the disproportionately high rate of infection in the Charnley group revealed that the mean operating time was longer in the infected group (83 versus 68 min; $p = 0.065$) and the patients that became infected were significantly older (71.2 versus 65.4 years, $p = 0.035$) than the patients who did not become infected. There was a significant association between secondary use of antibiotics and later prosthetic infection ($p = 0.001$). Only 1 of the 188 cases who did not have a urinary infection developed a hip infection, whereas 4 of the 41 cases with urinary infection later sustained a prosthetic infection. In logistic regression analysis, secondary use of antibiotics for any reason significantly increased risk of having a later prosthetic infection by 12.5 (CI 95% 1.2–133), after correction for age, gender, comorbidities (Charnley class), surgeon, and study group (Charnley versus Duraloc).

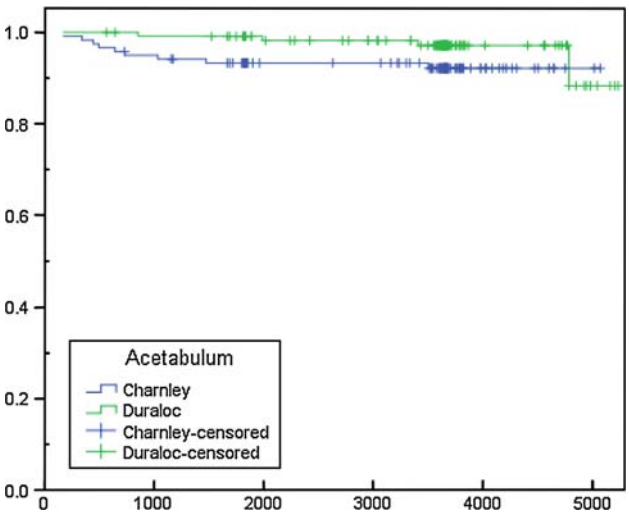

Fig. 2 Survival in days of Charnley and Duraloc acetabular components with revision for any reason as end-point

Of the four revised cups in the Duraloc group, no cups were revised due to aseptic loosening. Three cups were removed in conjunction with revision of a loose stem, and one cup that did not show signs of being loose was removed during revision for instability. There were no isolated exchanges of liner, but the liner was changed *en passant* in conjunction with femoral revision in nine cases in the Duraloc group. If these liner exchanges were included among the revisions, 13 Duraloc cups were revised (11%) versus 9 Charnley cups (8%), a difference that was still not statistically significant ($p = 0.37$; chi-square).

Implant survival

Survival of the implants was determined using Kaplan–Meier survival analysis (Fig. 2) using revision for any reason as end-point, except liner exchange *en passant*. The curves (Fig. 2) indicate a slightly better survival for the Duraloc cup for the first 12 years, but the log-rank test between the implants was not significant (Mantel-Cox; $p = 0.09$).

Dislocation and other complications

In the Charnley group, four patients had dislocations which were treated by closed reduction. One patient was later revised due to recurring instability from loosening of the

femur. In the Duraloc group, ten patients had dislocations, one of which was later revised because of recurring instability from loosening of the femur. Another patient in the Charnley group and two in the Duraloc group reported instability, but they did not have documented dislocation necessitating reduction. Thus a total of 17 patients reported instability, 5/120 in the Charnley group (3.3%) and 12/120 (10.0%) in the Duraloc group ($p = 0.098$).

There were 33 complications that were not treated surgically, 15 in the Charnley group and 18 in the Duraloc group ($p = 0.32$; Table 6). In the retrospective chart review, 52 cases (24 in the Charnley group and 28 in the Duraloc group) were identified in which a second course of antibiotics was given, of which 41 cases were given antibiotics indicating a urinary infection and 11 cases were other antibiotics indicating a range of infection types.

Radiographic results

For the acetabular component, 71 radiographs in the Charnley group and 80 in the Duraloc group were obtained. In the Charnley group, three patients had radiolucencies of 1 mm in zone A. One patient had changes in zones A and C, while three patients had changes in all three zones. In the Duraloc group, one patient had radiolucencies in zone A. There was no migration of the cup in any of the groups. Thus, 7/71 patients had some evidence of loosening of the cup in one or more zones in the Charnley group, while only 1/80 in the Duraloc group had any evidence of loosening ($p = 0.024$).

Discussion

Both groups improved their Harris Hip Score significantly after surgery, and the magnitude of improvement compared well with what is usually seen after total hip arthroplasty [18, 38]. The difference in Harris Hip Score between the implants was 2.4 points after 5 years and 2.5 points after 10 years, in favor of the Charnley cup. The study probably did not have sufficient power to detect a difference of this magnitude as statistically significant. Harris Hip Scores between 90 and 100 are regarded as excellent, and we feel that a clinically relevant difference between treatment groups would have to be 5 points. In the study by Kalairajah [38], the mean HHS was 89 and the standard deviation was 13.3. In a study designed to detect a 5% effect size with 80% power and 95% certainty and a standard deviation of 13.3, one would need 87 subjects in each treatment group. In our study, loss of patients due to revision, death, and ill health was underestimated, resulting in somewhat small samples.

The observed decline in HHS from 5 years in the Charnley group and from 2 years in the Duraloc group is in accordance with what is usually seen. When splitting the Harris Hip Score into a pain component and a functional component, it can be seen that the arthroplasties remain pain free even though function declines. For this reason, we feel that the decline in HHS corresponds to a decline in general health due to aging of the patients, which has been reported in some [23] but not all [39] earlier studies. This supports the previous findings that call for a separate instrument to assess activity level of the arthroplasty patient beyond what is measured by the Harris Hip Score [40].

There was a large discrepancy in the frequency of infection which warrants more investigation. Five of the 240 arthroplasties became infected (2.1%), but all occurred in the Charnley group. There was a significant association between urinary infection and later deep infection of the hip, which is consistent with findings in previous reports [41–43]. However, since we do not have information on the infecting agent, it is not possible to suggest a causal relationship between urinary-tract infection and subsequent prosthetic infection. However, the finding is interesting and may suggest an underlying predisposition for infection. In any case, the finding certainly represents a cautionary reminder concerning perioperative instrumentation of the urinary tract. On a slightly different note, it may be argued that the patients who became infected should be removed from the survival analysis, but we have elected to keep them, since infection is an important aspect of implant survival in the clinical setting.

The radiographic analysis indicated that 9.9% of the Charnley cups and 1.2% of the Duraloc cups had some signs of loosening. However, since none of them had changed position, they were not deemed to be definitely loose. In our study, we included any sign of loosening larger than 1 mm noted by the radiologist in the analysis, and many of these signs were probably very subtle. This

Table 6 Complications reported in the study that were not treated surgically

	Charnley	Duraloc
Cardiovascular	0	1
CNS (stroke)	0	2
Pulmonary embolism	1	3
Hematemesis	1	0
Respiratory	1	0
Weakness of muscles	3	5
Wound problems	6	5
Other	3	2

CNS, central nervous system

may have exaggerated the number of cups with radiographic signs of loosening, but the relationship between radiographic signs and loosening is complicated, as radiographically loose cups may function well clinically whereas painful, loose cups do not always display definite signs of loosening radiographically. Furthermore, we have not studied wear and osteolysis, which are known to affect predominantly uncemented cups. For this reason, our findings may underestimate problems with uncemented cups.

There are limitations to any long-term study of this nature. Because of death and deterioration in general health, only 59% in the Charnley group and 67% in the Duraloc group were available for clinical and radiographic evaluation at the 10-year mark. While it is has been shown that the results in patients lost to follow-up are worse than patients who stay in clinical studies [44], we were able to determine reason for loss to follow-up for almost all of our patients, with the vast majority of those who declined a follow-up visit doing so because of advanced comorbid diseases and not because of poor function of the hip. In addition, our overall follow-up rate was similar to other long-term studies of hip function [18, 19, 41], even though our patient population was significantly older. The generalizability of the study is felt to be good as the study was conducted at a nonacademic center, included most patients under 75 years of age, and the surgery was performed by general orthopedic surgeons.

The lack of precise recording of comorbidities is also a limiting factor. Indices of comorbidities have previously been shown to predict functional outcome as well as complications after total hip arthroplasty [45–51]. The Charnley score is not a dedicated comorbidity instrument and might not be sensitive enough to record subtle nuances in patient health status, which could have contributed to a better understanding of the large discrepancy in infection rates between the two study groups. Another limitation is the lack of a formal account for patient activity level [40, 52]. Level of activity is important as it is of primary interest to the patients for performing recreational activities [53] as well as for improving physical fitness, although increased level of activity correlates with wear and potential failure of an implant [54–56]. The Harris Hip Score contains assessment of physical function, but it does not quantify what the patient actually does, only what he or she is capable of doing. Dedicated scales have been developed for the sole purpose of estimating level of activity before and after total hip arthroplasty (THA), but these scales were not available for use in this study [56–59].

The issue of bilateral procedures is controversial since the presence of two procedures in one patient violates the assumption of independent observations on which many statistical tests rely [60]. However, other authors have discussed this and found that inclusion of bilateral procedures did not alter the results [61, 62]. In a recent study from the Finnish Arthroplasty Register, 27% of the cases analyzed were bilateral cases, and inclusion of bilateral cases in the analysis was considered appropriate, even though the statistical technique (Cox regression) formally requires independent observations. In out study, 21% of the cases were bilateral. We did find statistically significant differences in preoperative BMI, which raises the question of whether other unknown confounders might influence the results. However, the issue of bilaterality was not addressed in the study protocol. The presence of an arthroplasty in the contralateral hip was not an exclusion criterion for the study, nor was there any criterion excluding patients with poor function of the contralateral hip. For these reasons, we find it justified to include the patients who had two arthroplasties during the study and treat them as independent cases.

While the Charnley cup has remained unchanged since the inception of this study, uncemented cups have undergone a continuous process of change. As screw-holes are believed to transmit increased stress to the polyethylene, in addition to providing a potential pathway for polyethylene debris, a shell with 12 screw-holes is now rarely used in primary surgery. Furthermore, the polyethylene used in this study has largely been replaced by cross-linked polyethylene (PE) or alternative bearings, and there is an international trend moving toward larger head sizes. Nevertheless, the Charnley low-friction arthroplasty continues to be regarded by many as a gold standard against which new implants are compared [63].

In conclusion, our 10-year results confirm previous reports from noncontrolled studies that survival of an uncemented hemispherical porous-coated cup as well as the cemented all-polyethylene cup is excellent. With no statistically significant differences in outcomes or survival between the two implants, surgeons should choose the system that they are either more familiar with in terms of surgical technique or that would most benefit the individual patient. Further studies might indicate whether one implant will perform better than the other in the long term.

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Conflict of interest The authors declare that they have no conflict of interest.

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