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## Peri-operative mortality after hemiarthroplasty related to fixation

## Study based on the Australian Orthopaedic Association National Joint

## **Replacement Registry**

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#### Abstract

<u>Background and purpose</u>: The appropriate fixation method for hemiarthroplasty of the hip as it relates to implant survivorship and patient mortality is a matter of ongoing debate.

<u>Methods</u>: We analyzed approximately 25,000 hemiarthroplasty cases from the AOA National Joint Replacement Registry. Deaths at 1 day, 1 week, 1 month, and 1 year were compared for all patients and among subgroups based on implant type.

<u>*Results:*</u> Patients treated with cemented monoblock hemiarthroplasty had a 1.7 times higher day 1 mortality compared to uncemented monoblock components (p<0.001). This finding was reversed by 1 week, 1 month and 1 year post surgery (p<0.001). Modular hemiarthroplasties did not reveal a difference in mortality between fixation methods at any time-point.

<u>Interpretation</u>: This study demonstrates lower (or similar) overall mortality with cemented hemiarthroplasty of the hip.

#### Introduction

The frequency of hip fractures is increasing with our ageing population with an annual incidence of between 1.4-5 per 10<sup>3</sup> per year (Lonnroos et al. 2006, Icks et al. 2008, varez-Nebreda et al. 2008). Health model projections have estimated that 6.3 million hip fractures will occur annually worldwide within the next 40 years (Cooper et al. 1992), imposing a significant economic health burden. There is a large reported perioperative mortality rate in this population, ranging from 2.4 to 8.2% at 1 month (Parvizi et al. 2001, Radcliff et al. 2008), and over 25% at 1 year (Elliott et al. 2003, Jiang et al. 2005). Furthermore, it was recently reported that the current mortality rate is higher now than 25 years ago (Vestergaard et al. 2007a). It is today largely accepted that displaced intracapsular fractures are best treated with arthroplasty rather than internal fixation (Keating et al. 2006, Leighton et al. 2007). However, in the at-risk population, multiple comorbidities are common, and the best component fixation is in question.

Bone cement implantation syndrome is a well described complication of cemented hip arthroplasty. It is characterized by a systemic drop in systolic blood pressure, hypoxemia, pulmonary hypertension, cardiac dysrhythmias, and occasionally cardiac arrest and death (Rinecker 1980, Orsini et al. 1987, Parvizi et al. 1999). The prevailing theory to explain the pathophysiology of this phenomenon is embolism of fat, marrow contents, bone, and to some degree methylmethacrylate to the lung (Rinecker 1980, Elmaraghy et al. 1998, Parvizi et al. 1999, Koessler et al. 2001). An increased pulmonary insult with fat microemboli has been demonstrated (by mostly randomized controlled trials) during insertion of a cemented femoral stem compared to uncemented implants (Orsini et al. 1987, Ries et al. 1993, Christie et al. 1994, Pitto et al. 1999), presumably due to increased intramedullary femoral canal pressures in the cemented group (Kallos et al. 1974, Orsini et al. 1987). These pressures can be reduced by the use of distal venting holes in the femur during stem insertion (Engesæter et al. 1984). It has previously been shown via single institutional review that patients undergoing cemented hip arthroplasty have a higher intraoperative mortality rate relative to uncemented arthroplasty, presumably due to a reduced incidence of fat embolism in the latter group (Parvizi et al. 1999). The increased mortality risk was also present at 30 days in the treatment of acute fractures with cemented arthroplasty, also from a single institutional review (Parvizi et al. 2004). Although cement-related mortality is rare (Dearborn and Harris 1998, Parvizi et al. 1999, Parvizi et al. 2001, Parvizi et al. 2004, Weinrauch et al. 2006), it is a devastating complication, often reported via observational studies or literature reviews. Proponents of uncemented hip arthroplasty often cite this concern to support their reluctance to use cemented hip arthroplasty in both elective procedures and fracture management. However, there have been many different types of studies that have been unable to identify any increased mortality risk with the use of cement (Lausten and Vedel 1982 (observational), Emery et al. 1991 (RCT), Lo et al. 1994 (observational), Khan et al. 2002a,b (literature review), Parker and Gurusamy 2004 (literature review)) and others have shown a decrease in mortality at 30 days when cement is used (Foster et al. 2005).

Results of cemented hip hemiarthroplasty offer improved rate of return to baseline function, reduced post-operative pain, and superior long-term survivorship relative to

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uncemented arthroplasty (Khan et al. 2002a,b, Parker and Gurusamy 2004). We reasoned that failure to return to baseline function after hemiarthroplasty may be another risk factor for peri-operative mortality (Hannan et al. 2001, Braithwaite et al. 2003). Lower revision rates for cemented prostheses and increased mortality at revision surgery also further contribute to reducing the overall mortality risk. We evaluated the relationship between the method of fixation of hip arthroplasty and peri-operative mortality using a large national joint replacement registry.

#### Patients and methods

Data pertaining to patient age, implant type, fixation method, and patient location were obtained from the Australian Orthopaedic Association (AOA) National Joint Replacement Registry (NJRR). Mortality information was obtained by patient matching with the National Death Index (NDI) from the Australian Institute of Health and Welfare. The outcome of interest was mortality at 1 day, 1 week , 1 month, and 1 year post surgery. Data were then stratified by implant type to examine the effect of cement fixation within monoblock and modular implant procedures.

The AOA NJRR identified patient selection differences for implant type based on demographic data. As patient comorbidities are not captured in the AOA NJRR, these demographics were used as a surrogate measure for different patient populations in an effort to adjust for bias in the comparison of fixation method. We hypothesized that monoblock components were typically reserved for more elderly, lower demand patients

with more comorbidities, and modular prosthesis implants were used in healthier patients with expected longer survival.

Data in the AOA NJRR are collected at the time of surgery using a standard paper based form, with methods described in more detail elsewhere (Conroy et al. 2008, AOA 2009,). Each hospital subsequently forwards these forms to the Registry for data entry. Forms with incomplete or inconsistent data are followed up by the Registry with the hospital concerned. Cases where forms have not been completed are identified by verification of Registry data using government hospitalization separation data.

#### **Statistics**

Mortality rates were compared between cemented and uncemented prostheses using a time dependent cox-proportional hazard model. For each model the assumption of proportional hazards was checked analytically by inspecting the log(-log(survival))) versus log of survival time graph. Time points were selected a priori based on clinical importance and hazard ratios were then calculated for each selected time period. All analyses were adjusted for age and sex as measured at the primary procedure date. All analyses were performed in SAS Version 9.1 (SAS Institute Inc., Cary, NC).

#### **Ethics**

Local ethical approval was not required from our institution as this study was purely data driven and used de-identified national data. A formal request was made to the Australian Orthopaedic Association (AOA) National Joint Replacement Registry (NJRR) for access to the national de-identified data.

#### Results

#### Patient demographics:

There were 12,804 patients treated with uncemented hemiarthroplasty, and 12,935 treated with cemented hemiarthroplasty. No statistically significant differences in demographic characteristics between the methods of fixation were detected among the different groups **(Table 1)**.

#### Peri-operative mortality:

Kaplan Meier survival estimates by days post-operative are shown in **Figure 1** and hazard ratios are detailed in **Table 2**. There was an increased risk of peri-operative mortality in patients treated with uncemented hemiarthroplasty at 1 week (p = 0.02), 1 month (p = 0.03), and 1 year (p < 0.001) post-operatively. Conversely, there was a greater risk of peri-operative mortality in the first post-operative day in patients treated with cemented components (p < 0.001), suggesting that at-risk patients are more likely to succumb early if cement is used. However, most patients receiving cemented components were treated with modular components (9,301/12,935 – 72%), whereas most patients receiving uncemented components received a monoblock prosthesis (10,362/12,804 – 81%). We therefore were interested in further characterizing the role of fixation method in different patient groups to identify the true effect of cement on mortality.

#### Cemented vs. uncemented monoblock components:

There were 10,362 patients treated with uncemented monoblock implants, and 3,634 patients received cemented monoblock implants. The mortality rate was higher at day 1 when cemented monoblock implants were used (p < 0.001). This has been further detailed per day for the first post-operative week in **Table 3.** However, this difference was no longer statistically significant at 1 week or 1 month between groups. By 1 year, the death rate had reversed with a favorable survival among patients treated with cemented implants (p < 0.001) (**Figure 2, Table 4**).

As comorbidities increase with age, we hypothesized that if cement was a risk factor for perioperative mortality, the relationship would be more evident in the elderly patients treated with cemented hemiarthroplasty. To evaluate this relationship, we further analyzed this cohort of patients stratified by age treated with cemented vs. uncemented hemiarthroplasty. Although numbers were relatively small (see **Table 1**), this analysis showed that elderly patients (>70) have a more favorable survivorship at 1 year when cemented monoblocks are compared to uncemented monoblocks (**Fig. 2a**; p = 0.005 & p < 0.001). In the older age group (>80), there was a higher 1 day mortality rate when using cement (p<0.001), but this difference disappeared by 1 week (p=0.5) and 1 month (p=0.9) and reversed by 1 year (p<0.001) where cemented implants had a more favorable mortality rate.

Cemented vs. uncemented modular components:

There were 2,442 patients treated with uncemented modular components, while 9,301 received cemented implants. There was no statistically significant difference in mortality at any time between the methods of fixation of modular implants (Figure 3, Table 5).

### Discussion

We found a decreased mortality at 1 year following a cemented procedure compared to uncemented procedures. At the outset of this study, it was our hypothesis that there would be similar mortality rates for cemented and uncemented hemiarthroplasty using a large, nationwide joint registry database. The fact that the data reveal a lower overall mortality rate at later times with cemented monoblock procedures was surprising. Together with the fact that implant survival from the AOA NJRR is increased for cemented as compared to uncemented implants into the mid-term (AOA 2009), as well as previous work demonstrating improved functional outcome and pain scores with cemented implants (Khan et al. 2002a,b, Parker and Gurusamy 2004), it is becoming increasingly difficult to justify the continued preference of some surgeons for uncemented implants.

The strength of this study lies in the large numbers available for analysis. Due to high data completion rates and stringent data validation protocols by the AOA NJRR, the data are robust and easily lend itself to this type of analysis.

There are many possible explanations for our findings. Firstly, a weakness of this study is that selection of implant fixation was not randomized. In that regard, other patient

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factors may have influenced surgeon decision to avoid cement, which may not have been adequately adjusted for in our analysis. For example, it has been shown that preexisting cardiac disease is an independent risk factor for cement-related mortality (Parvizi et al. 2004). Other risk factors for increased peri-operative mortality with hip fracture include age, sex, and comorbidities (Hannan et al. 2001, Jiang et al. 2005, Vestergaard et al. 2007b, varez-Nebreda et al. 2008). The Australian Orthopaedic Association National Joint Replacement Registry does not collect comorbidity data, and in that regard we could not rule out the possibility that selection bias for fixation method influenced overall patient mortality. Our subcategorization of procedures into modular and monoblock components was an effort to control for this variable with a surrogate measure, as monoblock components are typically used in the frail elderly for quicker surgery and less functional demand on the component post-operatively. In a separate analysis, we found that there was a favorable survival rate at 1 year in patients 71-80 and >80 when cemented monoblock implants were used vs. uncemented monoblock components. Reasons for this are unclear, but may relate to selection of fixation method based on patient variables not captured by the AOA NJRR. For example, it is possible that elderly patients receiving cemented monoblock components are generally in better health than those treated with uncemented monoblock hemiarthroplasty, and are felt to be less likely to succumb to cement-related drop in systolic blood pressure intraoperatively. Alternately the opposite may be true as for hip prostheses generally fitter (younger, healthier) individuals receive cementless prostheses. There is also considerable state-to-state variability in preference for fixation method (AOA 2009), as well as individual hospital trends, which likely reflect different training and philosophies

across the country. Further subanalysis of the relationship of these variables makes broad conclusions difficult as patient numbers decrease with further sub categorization.

The cause of death was also not investigated in this study, and we therefore could not directly link mortality to surgery-related issues. Certainly 1 day and 1 week mortality are likely to be associated with peri-operative factors. Consistent with our study, Foster et al. (2005) found a higher 30 day mortality rate in uncemented (9%) vs. cemented (1%) hemiarthroplasties in a retrospective review of 244 patients, despite similar ASA grades in either group.

Parker and Gurusamy (2004) reported their meta-analysis on the outcome of cemented hip arthroplasties vs. uncemented components for hip fracture, and found that mobility and pain at 1 year post-operatively was better in the cemented group. There was no difference in peri-operative mortality in their analysis. This report included over 1900 patients, although still substantially smaller than our study. The same findings were corroborated in a separate meta-analysis of 18 publications addressing cemented vs. uncemented arthroplasty for hip fractures (Khan et al. 2002b). Khan's group further compared 121 uncemented Austin-Moore hemiarthroplasty patients to 123 cemented Thompson implants done at 2 hospitals (Khan et al. 2002a). Patients treated with uncemented Austin-Moore implants had more pain, worse function in terms of walking and dependence on walking aids, and reduced capacity to perform activities of daily living as compared to patients with cement fixation. There was no statistically significant difference in mortality or non-fatal medical complication rates related to type of fixation

used. There were more intra-operative fractures (3/121 uncemented vs. 0/123 cemented), more dislocations (3/121 vs. 0/123), and a higher failure rate (numbers not reported) in uncemented vs. cemented patients. In a single institution audit, Singh and Deshmukh (2006) reported an overall increased reoperation and revision rate using uncemented Austin-Moore implants vs. cemented Thompsons hemiarthroplasties. Patients treated with cemented implants also had a higher overall satisfaction rate relative to the uncemented stem. In a small randomized study comparing cemented Thompson's to uncemented Austin-Moore's implants (Emery et al. 1991), pain and dependence on walking aids was less if the femoral component was fixed with cement. There was no difference in mortality or peri-operative complications in either group. In a retrospective review of 107 patients treated with Thompson's hemiarthroplasty for displaced femoral neck fractures, Sikorski and Millar (1977) failed to demonstrate an increased rate of mortality, myocardial infarction, cerebrovascular incident, cardiac failure, or post-operative hypotension whether or not cement was used. Similar findings have been reported with other cemented vs. uncemented implants (Lausten and Vedel 1982, Lo et al. 1994).

Although pulmonary fat embolization is much less common with uncemented components, embolic events do occur (Orsini et al. 1987, Ries et al. 1993, Pitto et al. 1999), and this likely is related to increased intramedullary pressures during instrumentation of the femoral canal (Kallos et al. 1974, Orsini et al. 1987). Wenda et al (1995) has demonstrated that reaming the intramedullary canal produces pressures averaging 835 mm Hg, and that only 200 mm Hg are required for fat intravasation and

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embolization. This compares with maximum pressures of approximately 846 mmHg demonstrated with introduction of cement into the femoral canal in a dog model by Orsini et al (1987). In fact, there are a few case reports outlining peri-operative fat embolism syndrome and mortality due to fat embolization with uncemented hip arthroplasty (Arroyo et al. 1994, Gelinas et al. 2000). It is also known that intraoperative complications are higher with uncemented hemiarthroplasty, including iatrogenic femoral fracture (Foster et al. 2005, Weinrauch et al. 2006). A randomized controlled trial looking at prevalence of fat and bone marrow emboli to lung based on right atrium blood sampling showed similar prevalences in cemented and uncemented components (Kim et al. 2002). Further, it has been shown that proper femoral canal lavage and vacuum suction reduce embolic events with cement implantation (Christie et al. 1995, Pitto et al. 1998). Modern cement techniques may therefore account for lower incidence of peri-operative mortality with cement use compared with earlier studies.

In conclusion, this study shows a small but statistically significantly increased risk of mortality at 1 day when cement is used for monoblock hemiarthroplasty procedures. By 1 week, there is no longer a mortality advantage by avoiding cement, and by 1 year, mortality is less when cement is used. This may be due to a higher overall revision rate with uncemented monoblock components. When modular components are compared, there is no mortality difference at any time analyzed, although there is a higher implant revision rate when uncemented components are used. These data support the use of cemented hemiarthroplasty components in patients with hip fracture.

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# Figures & Tables:



Figure 1: All cause mortality in cemented and uncemented hemiarthroplasty patients.



*Figure 2:* All cause mortality for cemented and uncemented monoblock hemiarthroplasty.



*Figure 2a:* All cause mortality in cemented and uncemented monoblock hemiarthroplasty patients stratified by age.

*Figure 3:* All-cause mortality between cemented and uncemented modular components.



Component type		Total		Age		% Female
			<70	71-80	>80	
Monoblock	Cemented	3634	169 (4.7%)	946 (26.0%)	2519 (69.3%)	74
	Uncemented	10362	420 (4.1%)	2550 (24.6%)	7392 (71.3%)	74
	Subtotal	13996	589	3496	9911	
Modular	Cemented	9301	1518 (16.3%)	3233 (34.8%)	4550 (49.6%)	74
	Uncemented	2442	446 (18.3%)	750 (30.7%)	1246 (51.0%)	72
	Subtotal	11	743 1964	3983	5796	
Total		25739	2553	7479	15707	

Table 1: Patient demographics of hemiarthroplasty procedures

	HR (95% CI) (cementless v cemented)	p-value	Cemented no of deaths (n=12,935)	Cementless no of deaths (n=12,804)
1 day	0.59 (0.43-0.79)	0.0005	109	70
1 week	1.36 (1.05-1.74)	0.02	345	384
1 month	1.27 (1.03-1.58)	0.03	860	1170
1 year	1.37 (1.29-1.49)	<0.0001	2680	3794

Table 2: Hazard ratios (HR) for risk of death by fixation for all hemiarthroplasty.

	Cemented			Cementless			
	No at risk at start of period	Deaths	Cumulative Survival	No at risk at start of period	Deaths	Cumulative Survival	HR (cementless compared to cemented monoblock hemiarthroplasty)
0	3634	0	100.0	10362	0	100.0	
1	3582	46	99.3 (99.0, 99.6)	10299	62	99.9 (99.8, 99.9)	0.47 (0.32-0.68)
2	3557	70	98.7 (98.3, 99.0)	10258	102	99.4 (99.2, 99.5)	0.57 (0.35-0.95)
3	3540	85	98.1 (97.6, 98.5)	10196	161	99.0 (98.8, 99.2)	1.35 (0.76-2.37)
4	3524	100	97.7 (97.1, 98.1)	10143	212	98.4 (98.2, 98.7)	1.17 (0.66-2.07)
5	3508	113	97.2 (96.7, 97.7)	10092	259	98.0 (97.7, 98.2)	1.24 (0.67-2.29)
6	3497	123	96.9 (96.3, 97.4)	10055	295	97.5 (97.2, 97.8)	1.24 (0.61-2.49)

**Table 3:** Hazard ratios (HR) for day of operation to day 6 for risk of death by fixation for monoblock hemiarthroplasty.

	HR (95% CI) (cementless v cemented)	p-value	Cemented no of deaths (n=3634)	Cementless no of deaths (n=10,362)
1 day	0.47 (0.32-0.68)	<0.001	46	62
1 week	1.16 (0.81-1.66)	0.43	138	340
1 month	0.95 (0.71-1.26)	0.71	359	1051
1 year	1.23 (1.13-1.34)	<0.0001	1015	3413

*Table 4:* Hazard ratios (HR) for risk of death by fixation for monoblock hemiarthroplasty.

	HR (95% CI) (cementless v cemented)	p-value	Cemented no of deaths (n=9301)	Cementless no of deaths (n=2442)
1 day	0.48 (0.23-1.01)	0.052	63	8
1 week	1.18 (0.70-7.97)	0.53	207	44
1 month	0.91 (0.55-1.49)	0.7	501	119
1 year	0.89 (0.78-1.02)	0.09	1665	381

Table 5: Hazard ratios (HR) for risk of death by fixation for modular hemiarthroplasty.

# **Contributions of Authors**

Costain DJ	prepared and edited the manuscript
Whitehouse SL	conceived the study, prepared and edited the manuscript
Pratt NL	performed the statistical analysis, edited the manuscript
Graves SE	edited the manuscript
Ryan P	supervised the statistical analysis, edited the manuscript
Crawford RW	conceived the study, edited the manuscript

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