Cemented or cementless fixation for primary hip arthroplasty evidence from The International Joint Replacement Registries

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Abstract: The best fixation method (i.e., cemented or cementless) in primary total hip arthroplasty (THA) remains controversial. We reviewed the most updated annual reports from 5 international joint replacement registries with more than 5-year follow up (Sweden, Norway, England-Wales, Australia and New Zealand). We aimed at discovering the fixation method that leads to better long-term survival and less implant-related complications. In addition, we systemically reviewed several randomized controlled trials (RCTs) that were currently available in literature. We concluded that cemented fixation had better overall long-term survivorship than cementless fixation in primary THA. After age stratification, cemented fixation had better survival in older patients while cementless fixation and thus such risk should be informed to patients before surgery.

Keywords: Primary total hip arthroplasty (primary THA); fixation method; joint replacement registry

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Introduction

Total hip arthroplasty (THA) is one of the most successful surgeries during the last century. Due to the aging population, the demand for primary THAs are increasing (1). It was estimated that by the beginning of 2020, more than 500,000 primary THAs would be performed annually in the United States alone (2).

Despite the success, there are still many issues remain controversial, one of which being the best mode of implant fixation. The current fixation in primary THA includes all cemented, all cementless, hybrid (cemented stem, cementless cup) and reverse hybrid (cemented cup, cementless stem). Cemented implants achieve stability from cement-bone mechanical interlock once the polymethylmethacrylate has cured, whereas cementless fixation relies on primary press fit stability with long term stability occurring secondary to endosteal microfractures at the time of preparation and subsequent bone ongrowth or ingrowth (3). Cemented femoral stem was developed in late 1960s and remained the choice in many countries, especially in Scandinavia (4,5). In the late 1980s, cementless stem was introduced and steadily gained its popularity all

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over the world. In the United States, Australia and Canada, it is currently the most common choice (2,6,7).

The optimal fixation method should be determined by clinical outcomes, in particular the implant survivorship (3). Cemented fixation costs less money, yet requires longer surgical time and is associated with complications such as cement aging, microfractures or late loosening, especially when used in young or middle-aged patients (8). In addition, cement implantation syndrome is another big concern that might be potentially life threatening (9). On the contrary, cementless fixation is easier and faster to perform. However, they are costly, and complications such as thigh pain and stress shielding are also not uncommon (10-16).

Excellent long-term survivorship of cemented (17-22) and cementless (23-28) stems have been reported in single or multi-center studies. A hybrid THR, in which the stem is cemented while the cup cementless, has also been shown to provide the benefits of both fixations (29,30). However, these studies were challenged due to their relatively small sample size, short follow-up duration or the retrospective study nature, thus may not represent the regional or national composite data (31). Although several randomized controlled trials (RCTs) have also been conducted previously (11,32-38), various bias or study limitations still existed. Additionally, RCT studies should not be over emphasized. Studies have shown RCTs are more prone to heterogeneity in results than observational studies (39). Therefore, some established national joint replacement registries with large number of THAs registered as well as long-term follow-up may be sufficient in addressing these questions (40).

In this article we reviewed the most updated annual reports from 5 international joint replacement registries with more than 5-year follow up (Sweden, Norway, England-Wales, Australia and New Zealand). The Denmark and Canadian joint replacement registries also meet such criteria. However, the annual report of Denmark registry was not written in English while in the Canadian registry very few data were reported regarding the fixation method, and the request for accessing the data was not responded. Thus these 2 annual reports were not included. Finally, RCTs and meta-analyses currently available in literature were also reviewed. The purpose was to investigate which fixation method provides better long-term implant survivorship and less implant-related complications in primary THA.

Introduction of international joint replacement registries

Sweden is the first country in the world to establish a national joint replacement registry. The launch of the registry has been proven to be successful. Its ability to identify factors important in achieving successful outcomes has resulted in both improved standards and significant cost savings to the healthcare system (6). After Sweden, many countries have established or have started establishing their own national or regional joint replacement registry, including most European countries (Denmark, Norway, Finland, England and Wales, Scotland, Austria, Belgium, Croatia, Czech Republic, Netherlands, France, Germany, Hungary, Portugal, Italy, Romania, Slovakia, Switzerland, Slovenia), and countries in other continents including South Africa, Australia, New Zealand and Canada (31).

In most registries, patients' baseline characteristics as well as some important surgery-related information were recorded, including surgical outcomes, general or implantrelated complications, mortality etc. Some registries even registered patient-reported outcome measurement (PROM), which represents patients' pain relief, satisfaction of surgery or quality of life (4). Thanks to the nation-scale big data and the long follow-up duration in some registries, important indicators such as general implant survivorship or implant-related complications can be summarized. Most registries would regularly analyze the data and release their annual reports.

The Swedish Hip Joint Replacement Register

The Swedish Hip Joint Replacement Register was established in 1979. The register is a combination of two sub-registers: one for surgery with total hip replacement with osteoarthritis as the primary indication, and one for surgery with hemiarthroplasty with femoral neck fracture as the main indication. The latest annual report was released in 2014 (4).

Sweden is currently the only country in the world where cemented stems are regularly used in primary THAs. In the early 1990s, due to the poor results of cementless fixation, the use of cemented stems staggered and reached its peak as 92–93% of all THAs during 1998–2000. Since then the cementless stems regained popularity thanks to the improvement in prosthesis design and surgical skills. The proportion of cemented stems has declined steadily. In 2014, the percentage of cemented stem declined to 64.6%, but still it was higher than any other countries in the world. The percentage of cementless stems was 20.9% in 2014 and most of them were performed in young patients less than 60 years old. The percentage of hybrid stems (cemented stem, cementless cup) was small and didn't change much during a 10-year period.

If stratified by different age groups, cemented stems were used in all age groups, especially in patients 60 years or older (84.8% in patients between 60–75 and 95.9% in patients over 75). Cementless fixation, hybrid or reverse hybrid (cementless stem, cemented cup) fixation, on the contrary, were mostly performed in young patients less than 60 years of age.

All the fixation methods showed satisfactory 10-year implant survivorship. During 1995–2005, the revision rate of cemented fixation (7.2%) was much lower than cementless fixation (9.3%). The difference became smaller (5.7% vs. 5.9%) from 2005–2014. Specifically, it was noted that the general incidence of periprosthetic fracture in 2005–2014 doubled compared with the previous 10 years (1993–2002), from 6.8% to 13.6%. This may largely be due to the increased use of cementless stems. The hybrid and reverse hybrid fixation both showed higher revision rate than either cemented or cementless fixation.

In summary, cemented fixation was still preferred by Swedish joint replacement surgeons. The 10-year implant survivorship analyses showed that the revision rate of cemented fixation was lower than other types fixation. However, the report didn't further stratify the patients by gender or age. It remains unknown if all-cemented fixation would still be superior when treating male/female patients or patients of different ages.

The Norwegian Joint Replacement Register

Following its neighbor Sweden, the Norwegian Joint Replacement Register was established in 1987. The latest annual report was published in 2015, with 190,962 THAs registered as to 2014 (5). In accordance with the global trend, cementless prostheses have been more frequently used than previously, even in elderly patients.

Regarding the implant survivorship, after adjusted for age, sex and diagnosis, cementless fixation has a higher relative risk (RR) of revision compared to cemented fixation either in 1987–2014 (RR=1.35, P<0.001) or 2005–2014 period (RR=1.15, difference not significant). Hybrid fixation has a higher revision rate compared to cemented fixation in 1987–2014 (RR=1.25, P<0.001) but the risk was lower in 2005–2014 (RR=0.88). Reverse hybrid fixation has lower risk of revision to cemented fixation in both periods (RR=0.83, p<0.001 in 1987–2014 and RR=0.91 in 2005–2014, respectively).

After stratifying the data by 4 age groups (<55, 55–64, 65–74 and >75 y), cemented fixation tends to have lowest revision risk when used in people over 75 though the difference was not significant (RR was 0.88, 1.01, and 1.05 for >75, 65–74, and 55–64 y, respectively, with <55 y standardized to 1). Cementless fixation showed no obvious difference when performed in any age groups (RR was 1.03, 0.99, and 1.05 for >75, 65–74, and 55–64 y, respectively, with <55 y standardized to 1). Age did not seem to be a risk factor for revision for these 2 fixation modes. However for hybrid fixation, a much higher revision risk in patients between 55 and 64 was observed (RR=1.61); and for reverse hybrid, the revision rate was significantly higher in patients over 65 (RR=1.71 for >75 y, P<0.001; and RR=1.53 for 65–74 y, P=0.003).

After further stratifying the cases by sex, cementless fixation generally has a higher risk of revision compared to cemented, except in male patients over 75 years and female patients less than 65 years, though the difference was fairly narrow (RR=0.95). It was noted that for female patients over 75, the revision risk of cementless fixation was significantly higher than cemented (RR=1.47, P=0.012). This is understandable as these patients usually suffered from severe osteoporosis, thus leading to unsatisfactory bone ingrowth and early fixation failure (41). The reverse hybrid fixation was noted to have significantly lower revision rate in patients less than 65 regardless of sex, which may suggest its promising advantage in younger patients. The data of hybrid fixation, however, was not available in this annual report.

From the Norwegian registry annual report, one can conclude that although cemented fixation was not as popular as in Sweden, it still showed an overall better longterm survivorship compared to cementless fixation. The latter has significantly higher revision risk than cemented one in female patients over 75 years old.

National Joint Registry (NJR) for England, Wales, Northern Ireland and the Isle of Man

The NJR for England, Wales, Northern Ireland and the Isle of Man was set up in 2002 and is now in its 12th year of annually reporting. Currently over 200,000

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joint replacement surgeries were reported to the registry every year (42).

The 12th annual report of NJR was published in 2015, which summarized the surgeries registered from Sep 2003 to Dec 2014 (42). As of 2015, a total of 711,765 primary THAs were registered, among which 255,926 (36.1%) were cemented, 276,432 (39.0%) were cementless, 121,068 (17.1%) were hybrid and 17,267 (2.4%) were reverse hybrid. The popularity of cemented fixation decreased steadily from around 60% in 2003 to 36% in 2014, while cementless fixation increased from less than 20% to 40%. The average age was 74, 65, 70 and 71 years for cemented, cementless, hybrid and reverse hybrid, respectively. Cementless fixation was performed more in younger patients.

The Kaplan-Meier analyses with 10-year follow-up showed that cementless fixation has higher cumulative revision probability than both cemented fixation and hybrid fixation (stratified by gender and age). Common causes of revision in cementless fixation included aseptic loosening, pain, dislocation, infection, periprosthetic fracture, malalignment, lysis, implant wear, implant fracture, head/socket mismatch or adverse reaction to particulate debris. Hybrid fixation has lower revision rate than cemented in male patients younger than 55 and female patients younger than 65. However, the risk increased with age.

The Australian Orthopaedic Association National Joint Replacement Registry

The Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) was established in 1999 and became fully national in mid 2002. Recently the registry published its annual report in 2015, with 988,667 primary and revision procedures between 1 September, 1999 and 31 December, 2014 analyzed (6).

For partial hip replacement, which was usually indicated in patients with femoral neck fractures, cemented fixation was performed in over 80% cases if unipolar modular prostheses or bipolar prostheses were selected. Whereas 64.8% of cases were performed with cementless stems if unipolar monoblock prostheses were selected. On the contrary, in THAs, cemented fixation accounts for a 7.9% of all fixations, while cementless and hybrid were more popular, with a percentage of 59.1% and 33.0% respectively.

For implant survivorship, in partial hip replacements cemented fixation showed a lower revision rate than cementless regardless of prostheses selection (i.e., unipolar monoblock, unipolar modular or bipolar) and duration of follow-up. For total hip replacements, cemented fixation showed lower revision rate than cementless in the first 7 years after surgery but later surpassed cementless. Hybrid had the lowest revision rate in all fixations.

Revision rates in THAs further stratified by age showed that hybrid fixation generally had the lowest revision rate in all age groups. Additionally, cementless fixation had much higher revision rate than cemented ones in patients older than 75 (3.8% *vs.* 3.0%). While in patients less than 75, the long-term implant survivorship was higher with cementless fixation (<55: cemented 7.6% *vs.* cementless 3.7%; 55–64: cemented 7.0% *vs.* cementless 3.4%; 65–74: cemented 5.4% *vs.* cementless 3.2%).

The New Zealand Joint Registry

The New Zealand Joint Registry was established in 1997. Its 16th annual report from 1999 to 2014 was recently published, with a total of 101, 833 primary hip arthroplasty registered (43). The proportion of overall use of cementless stem decreased to 44.8%, lowest since 2007.

Implant survivorship analysis showed that the 15-year survival for cemented fixation was 88.4%, with cementless and hybrid 87.0%, respectively. Cemented fixation continued to show a better long-term survivorship than cementless and hybrid fixation (43).

After stratifying by age, cementless and hybrid fixation had a significantly lower revision rate than cemented ones in patients younger than 55 (yearly revision rate: cementless 0.97 and hybrid 1.14 *vs.* cemented 1.81). But there was no significant difference between the first two. In patients between 55 and 64, hybrid fixation had a significantly lower revision rate than cemented and cementless ones (yearly revision rate: hybrid 0.75 *vs.* cemented 1.06 and cementless 0.90). For the 65–74 and >74 age groups, hybrid hips had significantly lower revision rates than cementless hips. For the >74 age band, cemented hips had a significantly lower revision rate than hybrid and cementless hips (yearly revision rate: cemented 0.37 *vs.* cementless 0.74 and hybrid 0.50).

To make a summary of the New Zealand registry, cemented fixation had a higher overall implant survivorship than cementless and hybrid fixation. After stratifying patients by age, in younger patients who are less than 55, cementless stems had the lowest revision rate. For patients between 55–74, hybrid had the lowest revision rate. For patients over 75, cemented stems had the lowest revision rate.

International collaboration

International collaborations among different national registries have been established to increase the study power and facilitate communication. The most famous ones are the Nordic Arthroplasty Registry Association (NARA) and International Society of Arthroplasty Registries (ISAR).

The NARA was established in 2007, consisted of Denmark, Norway and Sweden registries. Finland subsequently joined in 2010. A recently published report based on the NARA database included 347,899 THAs in patients aged over 55 from 1995 to 2011 (40). Analysis showed that 232,603 cases of them were fully cemented (66.9%), 71,454 were fully cementless (20.5%), 28,215 were hybrid (8.1%) and 15,627 were reverse hybrid (4.5%). Using Kaplan-Meier survival analysis with at least one component removal or exchange as end-point, and after adjusted for age, sex and diagnosis, the results showed that the survival of cemented implants were higher than that of cementless in patients over 65. It was also noted that periprosthetic fracture was a more common reason for revision in cementless implants (27% of all revisions) than 4% in cemented stems.

Pedersen *et al.* in another study based on the NARA data included 29,558 primary THAs in young patients under 55 for osteoarthritis, and found no overall difference between cemented and cementless prostheses. Young patients with cementless prostheses had fewer revisions due to aseptic loosening, and more early revisions due to dislocation, periprosthetic fracture and infection than cemented prostheses (44).

Besides the studies from NARA, another study published in 2014 analyzed primary THAs for osteoarthritis from 2001 to 2010 from 6 national and regional registries (Australian, Catalan Arthroplasty Register from Spain, Emilia-Romagna Joint Registry R.I.P.O. from Italy, the HealthEast Joint Replacement Registry from the United States, the Kaiser Permanente Total Joint Replacement Registry from the United States and the Norwegian Arthroplasty Register). The multivariate meta-analysis showed that for patients over 75, cementless fixation had a significantly higher risk of revision than hybrid fixation, with a hazard ratio of 1.575 (P<0.001). They also found a similar but lesser effect in the intermediate age group of 65 to 74 years (hazard ratio, 1.16, P=0.021) and in the younger age group of 45 to 64 years (hazard ratio, 1.205, P=0.041). There were no significant differences between hybrid and cemented bearings across age groups. The study

suggested that cementless stems should be avoided in older patients (8). Similarly, another research based on 7 national hip registries (Australia, Canada, Denmark, New Zealand, Norway, England-Wales and Sweden, with last follow-up in 2010) also concluded that cemented fixation in patients over 75 had lower risk of revision (31).

RCTs

RCTs were still considered to be the 'gold standard' in evaluating the effectiveness of interventions. Several single or multi-center RCTs have been reported in literature in comparing cemented or cementless fixation for primary hip arthroplasty while variable results were observed (11,32-38) (*Table 1*).

Several meta-analyses based on some of these RCTs have been done but with different conclusions drawn (45-47). One meta-analysis included 7 RCTs showed that cemented hemiarthroplasty achieved better hip function, lower residual pain and less implant-related complications compared to cementless hemiarthroplasty in elderly patients with femoral neck fractures. Moreover, they were associated with no increased risk of mortality, cardiovascular and cerebrovascular complications, general complications, local complications or reoperation rate (45). However, another meta-analysis which included several old RCTs concluded that cemented THA is similar if not superior to cementless THA, but provided better short term clinical outcomes (46).

A 2010 Cochrane systematic review (47) demonstrated that these RCTs should be criticized for their sample size, inclusion criteria, poor randomization, limited reporting of outcomes, inadequate follow-up, and exclusion of patients. Nevertheless, the study concluded that patients with cemented prostheses experienced less pain at one year or later and had improved postoperative mobility. No differences in mortality or complications between the groups were found at any time point. Furthermore, the authors of this review also acknowledged that the majority of the included studies evaluated traditional prostheses such as the cemented Thompson and cementless Austin Moore prostheses. Thus, despite its conclusion in favor of cementing, the review raised the need for further studies in comparing cemented prostheses with modern cementless prostheses (34,47).

The 2014 American Association of Orthopaedics Surgeons (AAOS) evidence-based clinical practice guidelines for the management of hip fractures in the elderly claimed that there was moderate evidence in

Study	Disease	Surgery	Place	Randomization	Allocation concealment	Blinding	Follow-up Implant	Implant	Z	Age I	Results
Figved <i>et al.</i> , 2009 (32)	Femoral neck fracture	Bipolar hemiarthroplasty	2 hospital, 36 surgeons	Computer random number generator	Sealed, numbered, opaque envelopes	Evaluator blinded	Evaluator 12 months blinded	Cernented: Spectron Cernentless: Corail	112 8 108 8	83.4 83.0 83.0 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Cementless: shorter surgical time, less blood loss; no difference: Harris Hip score, Barthel index and EQ-5D (3 and 12 m), complications/ mortality; conclusions: both arthroplasties had good results
Corten <i>et al.</i> , 2011 (11)	Hip osteoarthritis	Total hip replacement	Single center, 2 surgeons	Computer- generated number, stratified by surgeon	A	A N	17 years	Cernented: Mallory- head total hip system Cernentless: Mallory- head total hip system	124 N 126 N	A A Z	Cementless: better 10-year survivorship
Parker <i>et al.</i> , 2010 (33)	Intracapsular fracture of hip	Hemiarthroplasty	Performed or supervised by 1 surgeon	Å	Sealed opaque numbered envelope	Evaluator 3.7 years blinded	3.7 years	Cemented: Thompson Cementless: Austin-Moore	200 5	8 8 8 8	Cemented: less hospital stay, less pain (first 3 m), better regaining mobility (first 6 m); cementless: shorter surgery time; no difference: blood transfusion, mortality, implant-related complications, re- operations, post-op medical complications
Taylor <i>et al.</i> , 2012 (34)	Subcapital femoral neck fracture	Hemiarthroplasty	Single center, different surgeons	Computer- generated number	Sealed and opaque envelope	Assessor blinded	2 years	Cemented: Exeter Cementless: Zweymuller alloclassic	80 80	85.3 e	Cemented: lower implant-related complications; trends towards better function and better mobility; no difference: pain

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Table 1 (continued)	need)										
Study	Disease	Surgery	Place	Randomization	Allocation concealment	Blinding	Follow-up	Implant	z	Age I	Results
DeAngelis <i>et al.</i> , 2012 (35)	Femoral neck fracture	Femoral neck Hemiarthroplasty fracture	Single center, surgeons surgeons	Blinded block design	۲	۲ Z	1 year	Cemented: VerSys LD/Fx Cementless: VerSys Beaded Fullcoat	64 66	81.8 82.8 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 8 2 8 2	No difference: operative time, postoperative hemoglobin level, transfusion rate, discharge disposition, acute complication rate, mortality, disposition, need for assistance with ambulation, Older Americans Resources and Services Activities of Daily Living subscales, the Energy/ Fatigue Scale
Sonne-Holm <i>et al.</i> , 1982 (36)	Femoral neck fracture	Femoral neck Hemiarthroplasty fracture	Single hospital	A	A	A	1 year	Cemented: Austin Moore Cementless: Austin Moore	55 57	Y Y Z	Cemented: better walking at 6 weeks, 3 m and 6 m; cementless: significantly more patients have residual pain at 6 m; no difference: hip mobility and mortality
Santini et al., 2005 (37)	Femoral neck fracture	Bipolar hemiarthroplasty	Single institution	NA	A	AN	12 months	Cemented: NA Cementless: NA	53	82.1 0 79.7 %	Cemented: longer surgery duration, higher postoperative haemoglobin value, cheaper; no difference: 1 year mortality, total functional score
Emery <i>et al.</i> , 1991 (38)	Displaced subcapital fractures of the femoral neck	Bipolar hemiarthroplasty	Single institution, same group of surgeons	Randomized card	Sealed envelope	۲	17 months	17 months Cemented: Thompson Cementless: Moore	26	79.6	Cemented: significantly less pain at 17 m; significantly fewer people dependent on walking aids; no difference: the incidence of postoperative complications, early mortality rate, operative time, blood loss

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supporting the use of cemented fixation. More long term studies designed specifically to elucidate potential differences in postoperative fracture risk between cemented or press fit stems are required (48).

Conclusions

Despite the success of international joint replacement registries, their limitations have to be acknowledged. First, most registries used revision as endpoint, but the definition is not standardized (6,8). Some registries used component year to indicate the revision risk, which was not recommended by some researchers (40). Second, most registries only documented implant-related issues such as survivorship and complication; but patient reported outcome measurement (PROM) including pain, mobility, quality of life or patients' state of health were not registered (40). These are also important factors when appraising the best fixation mode for primary hip arthroplasty. Third, the completeness/validity of data varies, which may result in strong bias when directly comparing among registries. Finally, the current national registries represent only the regional data. More registries from other parts of the world or more collaborations between registries are needed in future.

In spite of these limitations, we concluded from these annual reports of 5 international joint replacement registers as well as systematic reviews of RCTs that cemented fixation showed an overall good long-term survivorship than cementless fixation in primary hip arthroplasty. Specifically, cemented fixation survived better in older patients while cementless fixation survived better in younger patients. Periprosthetic fractures were more common in cementless fixation, thus such risk should be informed to patients before surgery.

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Footnote

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