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# Wear of highly crosslinked polyethylene acetabular components

## A review of RSA studies

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**Background and purpose** — Wear rates of highly crosslinked polyethylene (XLPE) acetabular components have varied considerably between different published studies. This variation is in part due to the different techniques used to measure wear and to the errors inherent in measuring the relatively low amounts of wear in XLPE bearings. We undertook a scoping review of studies that have examined the *in vivo* wear of XLPE acetabular components using the most sensitive method available, radiostereometric analysis (RSA).

**Methods** — A systematic search of the PubMed, Scopus, and Cochrane databases was performed to identify published studies in which RSA was used to measure wear of XLPE components in primary total hip arthroplasty (THA).

**Results** — 18 publications examined 12 primary THA cohorts, comprising only 260 THAs at 2–10 years of follow-up. The mean or median proximal wear rate reported ranged from 0.00 to 0.06 mm/year. However, differences in the manner in which wear was determined made it difficult to compare some studies. Furthermore, differences in RSA methodology between studies, such as the use of supine or standing radiographs and the use of beaded or unbeaded reference segments, may limit future meta-analyses examining the effect of patient and implant variables on wear rates.

**Interpretation** — This scoping review confirmed the low wear rates of XLPE in THA, as measured by RSA. We make recommendations to enhance the standardization of reporting of RSA wear results, which will facilitate early identification of poorly performing implants and enable a better understanding of the effects of surgical and patient factors on wear.

### *The clinical problem*

Implant loosening and periprosthetic bone loss remain the most common reasons for revision of primary total hip arthroplasty (THA) in the medium to long term (AOANJRR 2013). The tissue response to polyethylene wear particles is an important cause of periprosthetic bone loss – osteolysis – behind acetabular components (Dumbleton et al. 2002). Review articles on THAs with conventional polyethylene have confirmed that the greater the amount of polyethylene wear, the higher the incidence of osteolysis (Oparaugo et al. 2001, Dumbleton et al. 2002) and that osteolysis is rare below a linear wear rate of 0.1 mm/year (Dumbleton et al. 2002). Research has therefore been focussed on improving the wear properties of polyethylene and on monitoring the *in vivo* wear of polyethylene liners of acetabular components of THAs by using various radiographic methods.

### *The introduction of XLPE*

The first ultra-high-molecular-weight polyethylene (UHMWPE) that was intentionally gamma irradiated at a high level (100mRad) was first used clinically in 1971 (Oonishi et al. 2001). However, further research into the optimal dose of gamma radiation and its effect on the wear properties of conventional UHMWPE was not performed until the 1990s. Manufacturing methods were developed to crosslink polyethylene by exposing it to gamma or electron beam irradiation and then annealing or remelting the material by thermal treatments (Oonishi et al. 1997, Sun et al. 1997). *In vitro* hip simulator studies were able to show that highly crosslinked polyethylene (XLPE) components show significantly reduced wear compared to UHMWPE components (Kurtz et al. 1999,

Muratoglu et al. 2001). Thus, XLPE components were introduced for use in THA surgery in 1998 (Kurtz et al. 2011), and by 2003 XLPE was used in two-thirds of hip arthroplasties in the USA (Kurtz 2004). More recently in Australia, the 2013 annual report of the joint replacement registry reported that XLPE was used in 94% of all primary THAs incorporating a PE bearing (AOANJRR 2013). When used in primary THA, XLPE has a lower rate of revision for any reason than conventional PE (AOANJRR 2013). Different companies continue to use different manufacturing methods for each XLPE product, aiming to balance resistance to wear, oxidation, and fatigue fracture (Pruitt et al. 2013). Ideally, as with all new prosthetic components, new XLPEs should be rigorously tested in clinical trials before being released for general use because of potential variation in manufacturing methods, which may lead to possible failure (Rohrl et al. 2005, Malchau et al. 2011).

The *in vivo* wear rate of XLPE acetabular components has been shown to be less than that of conventional UHMWPE components (Mu et al. 2009, Kurtz et al. 2011, Kuzyk et al. 2011). However, the wear rates reported for XLPE components have varied considerably between different published studies (Kurtz et al. 2011). For example, the mean 2D wear rate of one type of XLPE liner, using different measurement techniques after 5 years or more, has varied between 0.01 and 0.05 mm/year (Engh et al. 2006, Bitsch et al. 2008, Mutimer et al. 2010, Engh et al. 2012, Callary et al. 2013a).

### Methods of wear measurement

Clinical studies of bearing surfaces use serial radiographs to measure the amount of femoral head penetration within the acetabular component as a representation of wear of the bearing surface. Traditionally, plain anteroposterior and/or lateral radiographs have been taken at regular time points postoperatively and the measurements have been made either manually (Livermore method (Livermore et al. 1990); Dorr and Wan method (Dorr and Wan 1995)) or using a software program that analyzes digitized radiographs (Martell's "Hip Analysis Suite" (Martell and Berdia 1997); Devane's "PolyWare" (Devane et al. 1995a, Devane et al. 1995b)). Measurements made from plain radiographs were sensitive enough to measure wear of conventional UHMWPE. However, due to the improved wear properties of XLPE, measurement of the lower amounts of *in vivo* wear associated with XLPE is more challenging, ideally requiring a more sensitive measurement method—namely radiostereometric analysis (RSA) (Bragdon et al. 2006a, Stilling et al. 2012).

### Radiostereometric analysis

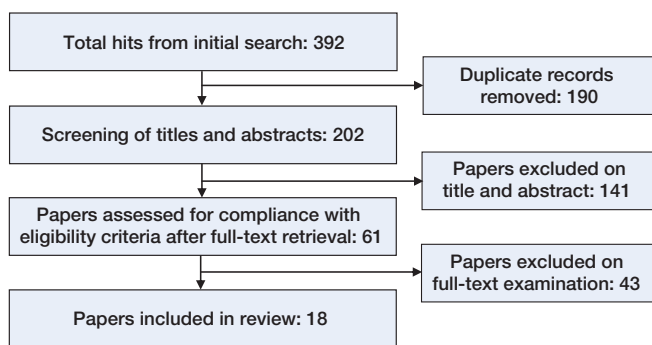
RSA uses dual simultaneous radiographs taken over a calibration cage to calculate the 3D movement of one skeletal body segment relative to another (Karrholm et al. 2006). The traditional RSA method relies on the implantation of small spherical tantalum markers (0.8 and 1.0 mm diameter) to represent each skeletal body of interest (Karrholm et al. 1997). RSA was

first used to measure polyethylene wear in 1976 (Baldursson et al. 1979). To measure polyethylene wear, tantalum markers are usually implanted in the peripheral rim of the polyethylene liner or on the back side of the cemented polyethylene components at the time of surgery, or (for a small number of studies) at the time of manufacture. The patient then undergoes consecutive radiographic examinations at set time points to measure the penetration of the femoral head within the polyethylene component. Accuracy of RSA under optimal conditions has been reported to 33, 22, 86, and 55  $\mu\text{m}$  for measurement of medial, proximal, anterior, and 3D wear, respectively (Bragdon et al. 2002).

If the influences of patient and implant factors on wear rates of XLPE are to be investigated in detail, ideally it should be through meta-analysis of RSA studies. Before a meta-analysis, the published literature must be surveyed to determine whether the data reported in primary studies are sufficient to enable comparison of such factors. Scoping review is a method of inquiry similar to a systematic review but with the distinct aim of assessing the quantity and scope of the research studies conducted on a certain topic (Grant and Booth 2009, The Joanna Briggs Institute 2011). We therefore undertook a scoping review of studies on wear of XLPE acetabular components measured by RSA, using a systematic search to identify these studies.

## Methods

A systematic search of the published literature in PubMed, Scopus, and Cochrane databases was performed on December 19, 2013. Title, abstract, and keyword fields were queried using the following keywords and index terms in the databases where applicable: "radiostereometric" AND "wear"; "radiostereometric" AND "polyethylene"; "radiostereometry" AND "wear"; "radiostereometry" AND "polyethylene"; "rsa" AND "wear"; "rsa" AND "polyethylene"; "stereophotogrammetric" AND "wear"; "stereophotogrammetric" AND "polyethylene" (Figure 1). These search terms were chosen based on the different names used to describe RSA studies. Publications in English were included if they reported the wear of XLPE, as measured by RSA, in either cemented or uncemented acetabular components in primary THAs. All such studies were included in this review, as the aim of scoping reviews is to determine the extent of the literature on a certain topic and therefore, unlike meta-analyses or systematic reviews, exclusion based on critical appraisal of methodological quality is not required. Polyethylene components were defined as highly crosslinked when intentionally treated using a total radiation dose ranging from 50 to 105 kGy (Kurtz et al. 2002). Duplicate publications, theses, case reports, conference proceedings, and abstracts were all excluded. Data extracted from the studies included details of the patient cohort, the RSA methodology used, precision, total femoral head penetration, bedding-in/creep, and wear.



Flow chart of the systematic search performed of the PubMed, Scopus, and Cochrane databases.

## Results

We found 18 publications (Table 1) that fitted the criteria (Figure), representing 12 independent cohorts of patients. 9 of the 18 publications (Digas et al. 2004, Digas et al. 2007, Rohrl et al. 2007, Glyn-Jones et al. 2008b, Thomas et al. 2011, Johanson et al. 2012, Rohrl et al. 2012, Callary et al. 2013a,b) were longer-term follow-up reports of these cohorts. The wear of 7 different XLPE components was measured, incorporating 3 designs of cemented XLPE acetabular components and 4 designs of XLPE liners of uncemented acetabular compo-

nents, as detailed in Table 1. 10 of the 12 cohorts received 28-mm articulations, and 2 cohorts involved larger articulations (32-mm and 36-mm). The material of the femoral head was cobalt chromium in 8 cohorts and oxidized zirconium in one. The material was not reported for 3 cohorts.

Collectively, RSA results have been reported for a maximum of 260 THAs (Table 2). The initial report of each cohort was published at either 2 or 3 years, and the longest follow-up was 10 years. The age of each cohort at THA varied between a mean or median of 48 and 72 years.

The specific RSA methodology used varied between cohorts (Table 2). For example, supine radiographs were used for RSA examinations in 6 cohorts, standing in 4, and a combination of both supine and standing in 2. All but 1 of the RSA studies used the UmRSA software package (RSA Biomedical, Umea, Sweden), but with different versions over time. The remaining study used software described by Gill et al. (1998). Tantalum beads were implanted within the XLPE component in 11 of 12 cohorts, to represent the acetabular segment. In most cases, RSA radiographs within the first postoperative week were used as the reference examination.

The precision of proximal wear measurements was reported for 6 cohorts and varied from 0.02 to 0.11 mm (Table 3). Both proximal and 3D head penetrations were reported for almost all cohorts, but the time over which the wear rate was calculated varied due to the time period allowed for bedding-

Table 1. Implants used in each patient cohort

Cohort	Publication	XLPE component	Head size, mm	Head material	Femoral component
1	Digas et al. 2003; Digas et al. 2004; Digas et al. 2007; Johanson et al. 2012	Durasul (Zimmer)	28	CoCr	Spectron (Smith & Nephew)
2	Digas et al. 2004; Digas et al. 2007	Longevity liner within Trilogy shell (Zimmer)	28	CoCr	Spectron (Smith & Nephew)
3	Rohrl et al. 2005; Rohrl et al. 2007; Rohrl et al. 2012	Osteonics Cup made of Crossfire PE (Stryker Orthopaedics)	28	CoCr	Exeter Femoral Stem (Stryker Orthopaedics)
4	Zhou, et al. 2006	XLPE 10 within Reflection Shell (Smith and Nephew)	28	CoCr	Spectron (Smith & Nephew)
5	Bragdon et al. 2007	Longevity liner within Trilogy Shell (Zimmer)	28	NR	NR
6	Bragdon et al. 2007	Longevity liner within Trilogy Shell (Zimmer)	36	NR	NR
7	Glyn-Jones et al. 2008a; Glyn-Jones et al. 2008b; Thomas et al. 2011	Longevity liner within Trilogy Shell (Zimmer)	28	CoCr	CPT (Zimmer)
8	Ayers et al. 2009	Longevity liner within Trilogy Shell (Zimmer)	28	NR	ML Taper (Zimmer)
9	Campbell et al. 2010a; Callary et al. 2013a	Marathon liner within Pinnacle Shell (Depuy Orthopaedics)	28	CoCr	Corail (Depuy Orthopaedics)
10	Campbell et al. 2010b; Callary et al. 2013b	X3 liner within Trident Shell (Stryker Orthopaedics)	32	CoCr	Accolade (Stryker Orthopaedics)
11	Kadar et al. 2011	Reflection All-Poly XLPE (Smith & Nephew)	28	CoCr	Spectron EF (Smith & Nephew)
12	Kadar et al. 2011	Reflection All-Poly XLPE (Smith & Nephew)	28	Oxinium	Spectron EF (Smith & Nephew)

NR: not reported.

Table 2. Details of RSA studies

Cohort	Age (range)	Number of patients	Follow-up, months	Report	Years of follow-up	Number of patients included in RSA results	Software	Acetabular reference	Standing/Supine
1	Median 54 (35–68)	31	within 7 days, 3, 6, 12, 24, 36, 60, 84, 120	1st 2nd 3rd 4th	2 3 5 10	(Digas et al. 2003); 23 supine, 21 standing (Digas et al. 2004); 20 supine, 18 standing (Digas et al. 2007); 28 supine, 22 standing (Johanson et al. 2012); 23 supine	UmRSA	B	Supine <sup>a</sup>
2	Median 48 (29–70)	32	within 7 days, 3, 6, 12, 24, 36, 60	1st 2nd	2 5	(Digas et al. 2004); 22 supine, 20 standing (Digas et al. 2007); 19 supine, 12 standing	UmRSA	B	Supine <sup>a</sup>
3	Mean 58 (49–79)	10	within 7 days, 2, 12, 24, 36, 60, 72, 120	1st 2nd 3rd	3 6 10	(Rohrl et al. 2005); 10 (Rohrl et al. 2007); 9 (Rohrl et al. 2012); 8	UmRSA	B	Supine
4	Mean 68 (53–83)	30	3 to 7 days, 2, 12, 24	1st	2	(Zhou et al. 2006); 28	UmRSA 6.0	B+E	Supine
5	Mean 56 (36–77)	16	6 weeks, 6, 12, 24, 36	1st	3	(Bragdon et al. 2007); 16(25/30 <sup>b</sup> )	UmRSA 6.0	B; B+ E; E	Standing
6	Mean 56 (36–77)	14	6 weeks, 6, 12, 24, 36	1st	3	(Bragdon et al. 2007); 14 (25/30 <sup>b</sup> )	UmRSA 6.0	B; B+ E; E	Standing
7	Mean 68 (52–76)	27	PO, 3, 6, 12, 24, 36, 60, 84	1st 2nd 3rd	2 3 7	(Glyn-Jones et al. 2008a); 26 (Glyn-Jones et al. 2008b); 26 (Thomas et al. 2011); 22	Gill et al. 1998	Un- bedead	Standing
8	Mean 58 (SD 8)	24	6 weeks, 6, 12, 24	1st	2	(Ayers et al. 2009); 24	UmRSA	B	Standing
9	Median 72 (55–80)	30	4–6 days, 6, 12, 24, 72	1st 2nd	2 6	(Campbell et al. 2010a); 25 (Callary et al. 2013a); 24	UmRSA 6.0	B+E	Supine
10	Median 63 (47–76)	21	Within 7 days, 6, 12, 24, 60	1st 2nd	2 5	(Campbell et al. 2010b); 19 (Callary et al. 2013b); 18	UmRSA 6.0	B+E	Supine
11	Mean 70 (SD 5)	30	9–15 days, 3, 6, 12, 24	1st	2	(Kadar et al. 2011); 29	UmRSA 5.0	B	Supine
12	Mean 70 (SD 5)	30	9–15 days, 3, 6, 12, 24	1st	2	(Kadar et al. 2011); 24	UmRSA 5.0	B	Supine

<sup>a</sup> Supine and standing from 3 months.

<sup>b</sup> Combined number of patients included in wear results for cohorts 5 and 6.

B: beaded; B+E: beaded plus ellipse; E: ellipse

in, which ranged from 2 to 24 months (Table 4). The proximal wear rate calculated after this period of assumed bedding-in ranged from a mean or median of 0.00 to 0.06 mm/year.

## Discussion

New materials, such as XLPE components used in THA, need to be closely monitored as part of their stepwise introduction into clinical use (Malchau 1995, Malchau et al. 2011). The wear rates reported for XLPE components varied between studies. Some of this variation is likely to be due to the different measurement methods used (Kurtz et al. 2011). However, some variation could also be due to variables that include patient factors such as BMI and activity;

Table 3. Precision of RSA from double examinations in each cohort

Cohort	Publication in which precision was reported	Original calculation method	Number of double examinations	Adjusted precision (95% CI = 1.96 × SD)			
				x	y	z	3D
1	Digas et al. 2003	99% CI	45	0.10	0.08	0.15	0.17
2	Digas et al. 2004	99% CI	45	<sup>a</sup>	<sup>a</sup>	<sup>a</sup>	<sup>a</sup>
3	Rohrl et al. 2007	95% CI	99	<sup>b</sup>	0.08	<sup>b</sup>	0.16
4	Rohrl et al. 2012	1.96 × SD	<sup>b</sup>	<sup>b</sup>	0.09	<sup>b</sup>	0.31
	Zhou et al. 2006	Beaded	28	<sup>b</sup>	0.08	<sup>b</sup>	0.22
5 and 6	<sup>b</sup>	1.96 × SD	<sup>b</sup>	<sup>b</sup>	0.10	<sup>b</sup>	0.28
		Ellipse	28	<sup>b</sup>			
7	<sup>b</sup>	<sup>b</sup>	<sup>b</sup>	<sup>b</sup>	<sup>b</sup>	<sup>b</sup>	<sup>b</sup>
8	<sup>b</sup>	<sup>b</sup>	<sup>b</sup>	<sup>b</sup>	<sup>b</sup>	<sup>b</sup>	<sup>b</sup>
9	Campbell et al. 2010a	95% CI	22	0.03	0.02	0.07	<sup>b</sup>
10	<sup>b</sup>	<sup>b</sup>	<sup>b</sup>	<sup>b</sup>	<sup>b</sup>	<sup>b</sup>	<sup>b</sup>
11 and 12	Kadar et al. 2011	2.009 × SD	50	0.11	0.11	0.33	0.21

<sup>a</sup> Precision not specified for each axis, "between 0.07 and 0.32 mm".

<sup>b</sup> Not reported.



Table 4. Proximal and 3D femoral head penetration, bedding-in, and wear rate reported for each cohort in each follow-up report

Cohort	Follow-up years		Femoral head penetration <sup>a</sup> (mm)	Bedding-in <sup>b</sup> mm	Wear rate <sup>c</sup> mm/year
<b>Proximal</b>					
1	2	(Digas et al. 2003)	0.13 (0.03 to 0.31) <sup>d</sup>	0.1 <sup>d</sup>	0.03 <sup>f</sup> (3–24 m) <sup>e</sup>
	3	(Digas et al. 2004)	0.13 (-0.02 to 0.30) <sup>d</sup>	0.1 <sup>d, g</sup>	0.03 <sup>f</sup> (3–36 m) <sup>e</sup>
5	5	(Digas et al. 2007)	0.15 (-0.10 to 0.86) <sup>d</sup>	0.1 <sup>d, g</sup>	0.02 <sup>f</sup> (3–60 m) <sup>e</sup>
	10	(Johanson et al. 2012)	0.15 <sup>g</sup>	0.1 <sup>d, g</sup>	0.01 (SE 0.00) (2–10 yr) <sup>d</sup>
2	2	(Digas et al. 2004)	0.08 (-0.03 to 0.28) <sup>d</sup>	0.08 <sup>d</sup>	0.03 <sup>f</sup> (3–24 m) <sup>e</sup>
	5	(Digas et al. 2007)	0.08 (-0.02 to 0.24) <sup>d</sup>	0.08 <sup>d, g</sup>	0.02 <sup>f</sup> (3–60 m) <sup>e</sup>
3	3	(Rohrl et al. 2005)	NR	0.05 (0–2 months)	0.01 (2–24 m)
	6	(Rohrl et al. 2007)	0.08 (CI 0.02 to 0.13)	0.06 <sup>g</sup>	0.01 (2–72 m)
	10	(Rohrl et al. 2012)	0.07 (CI -0.02 to 0.15)	0.06 <sup>g</sup>	0.00 (2–120 m)
4	2	(Zhou et al. 2006)	0.07 <sup>g</sup>	0.06 <sup>g</sup>	0.01 (2–24 m)
5	3	(Bragdon et al. 2007)	0.06 <sup>h</sup> (SE 0.03)	0.06 <sup>h</sup> (SE 0.04)	0.03 <sup>h</sup> (SE 0.02)
6	3	(Bragdon et al. 2007)	0.06 <sup>h</sup> (SE 0.06)	0.07 <sup>h</sup> (SE 0.02)	0.00 <sup>h</sup> (SE 0.06)
7	2	(Glyn-Jones et al. 2008a)	NR	NR	0.06 (SD 0.07) (3–24 m)
	3	(Glyn-Jones et al. 2008b)	NR	0.17 <sup>g</sup>	0.02 <sup>g</sup>
	7	(Thomas et al. 2011)	NR	NR	0.01 (CI ±0.03)
8	2	(Ayers et al. 2009)	0.07 <sup>h</sup> (-0.04 to 0.19)	0.07 <sup>h</sup> (-0.14 to 0.16)	0.02 <sup>g</sup>
9	2	(Campbell et al. 2010a)	0.12 (-0.10 to 0.38)	0.11 (-0.01 to 0.39)	0.01
	6	(Callary et al. 2013a)	0.19 (0.00 to 0.51)	0.11 (-0.01 to 0.39)	0.01 (-0.02 to 0.06)
10	2	(Campbell et al. 2010b)	0.02 <sup>h</sup> (-0.07 to 0.16)	0.01 <sup>h</sup> (-0.09 to 0.12)	0.02 <sup>h</sup>
	5	(Callary et al. 2013b)	0.02 (-0.11 to 0.13)	0.01 (-0.09 to 0.12)	0.00 (-0.03 to 0.03)
11	2	(Kadar et al. 2011)	0.09 (CI 0.06–0.12)	0.06 <sup>g</sup>	0.03
12	2	(Kadar et al. 2011)	0.08 (CI 0.04–0.12)	0.06 <sup>g</sup>	0.02
<b>3D</b>					
1	2	(Digas et al. 2003)	0.18 (0.07–0.35) <sup>d</sup>	0.15 <sup>d</sup>	0.11 <sup>f</sup> (3–24 m) <sup>e</sup>
	3	(Digas et al. 2004)	0.23 (0.04–0.41) <sup>d</sup>	0.18 <sup>d, g</sup>	0.09 <sup>f</sup> (3–36 m) <sup>e</sup>
	5	(Digas et al. 2007)	0.23 (0.02–0.91) <sup>d</sup>	NR	0.04 <sup>f</sup> (3–60 m) <sup>e</sup>
	10	(Johanson et al. 2012)	0.22 <sup>d, g</sup>	0.18 <sup>d, g</sup>	0.01 <sup>f</sup> (SE 0.00) (2–10 yr) <sup>d</sup>
2	2	(Digas et al. 2004)	0.22 (0.05–0.40) <sup>d</sup>	0.25 (supine)	0.19 <sup>f</sup> (3–24 m) <sup>e</sup>
	5	(Digas et al. 2007)	0.20 (0.10–0.61) <sup>d</sup>	0.24 (supine)	0.07 <sup>f</sup> (3–60 m) <sup>e</sup>
3	3	(Rohrl et al. 2005)	0.17 (CI 0.06–0.28)	NR	NR
	6	(Rohrl et al. 2007)	0.23 (CI 0.10–0.35)	NR	0.03 (2–72 m)
	10	(Rohrl et al. 2012)	0.20 (CI 0.03–0.36)	0.19 <sup>g</sup>	0.00 <sup>f</sup> (2–120 m)
4	2	(Zhou et al. 2006)	0.19 <sup>g</sup>	0.15 <sup>g</sup>	0.03 <sup>f</sup> (2–24 m)
5	3	(Bragdon et al. 2007)	NR	NR	NR
6	3	(Bragdon et al. 2007)	NR	NR	NR
7	2	(Glyn-Jones et al. 2008a)	0.31 (SD 0.18)	0.30 <sup>g</sup>	0.06 (SD 0.06) (3–24 m)
	3	(Glyn-Jones et al. 2008b)	0.35 (SD 0.14)	0.26 (SD 0.17)	0.03 (SD 0.06)
	7	(Thomas et al. 2011)	0.33 (CI ± 0.10)	0.29 (95% CI ±0.07)	0.01 (CI ± 0.02)
8	2	(Ayers et al. 2009)	NR	NR	NR
9	2	(Campbell et al. 2010a)	0.23 (0.02–0.84)	0.23 (0.06 to 0.93)	0.00 <sup>f</sup>
	6	(Callary et al. 2013a)	0.32 (0.05–0.60)	0.23 (0.06 to 0.93)	0.018 (-0.11 to 0.08)
10	2	(Campbell et al. 2010b)	0.16 <sup>h</sup> (0.07–0.26)	0.16 <sup>h</sup> (0.02 to 0.32)	-0.04 <sup>h</sup>
	5	(Callary et al. 2013b)	0.15 (0.04–0.32)	0.19 (0.02 to 0.32)	-0.01 (-0.06 to 0.04)
11	2	(Kadar et al. 2011)	0.19 (CI 0.15–0.23)	NR	NR
12	2	(Kadar et al. 2011)	0.18 (CI 0.13–0.22)	NR	NR

CI: 95% confidence interval

NR: not reported.

<sup>a</sup> Initial to final follow-up unless otherwise noted; mean (range).<sup>b</sup> Initial examination to 1-year follow-up unless otherwise noted; mean (range).<sup>c</sup> Annual rate from 1-year follow-up to final follow-up unless otherwise noted; mean (range).<sup>d</sup> Supine<sup>e</sup> Standing<sup>f</sup> Manually calculated to be rate/year from a reported value given after bedding-in.<sup>g</sup> Visualized from graph<sup>h</sup> Median

implant factors such as femoral head material, liner thickness, and manufacturing methods for XLPE; and surgical factors such as inclination angle of the acetabular component. Thus, while the wear rate of XLPE acetabular components has been shown to be substantially less than that of conventional UHMWPE components (Kurtz et al. 2011, Kuzyk et al. 2011, Mu et al. 2009), the possible influence of the above variables remains unclear. Although a meta-analysis would be required to investigate the influence of these variables on wear rates of XLPE, the number of patients required for a meta-analysis would greatly exceed that included in the current literature, due to the low wear of XLPE and the relatively weak effect of such variables on wear. Our scoping review identified a relatively small number of studies that had measured the wear of XLPE components using the most sensitive measure available, namely RSA. Overall, the studies examined 12 cohorts involving only 260 THAs. By recommending further guidelines to standardize the reporting of RSA wear studies, we hope that this will assist retrospective analysis of the influence of these factors in the future.

## Methodology of RSA studies

### Cohort size

All of the cohorts had a sample size of between 10 and 32 at recruitment. As RSA has been demonstrated to have high sensitivity (Bragdon et al. 2002), statistical power can be achieved with fewer observations and therefore a small sample size is not, in itself, necessarily a methodological limitation. However, most studies had decreasing sample sizes over time. Missing or poor-quality RSA examinations further reduced the size of the originally recruited cohort, after exclusions for death and other reasons for loss to follow-up. This common problem of decreasing availability of RSA data over time must be considered when designing RSA-based clinical trials, especially if longer-term follow-up is required.

### Follow-up time points

Follow-up time points within the first year varied between the RSA studies, thereby potentially influencing the amount of femoral head penetration recorded. The first reference RSA examination was usually performed within the first week postoperatively. However, some studies used 11–15 days, 2 weeks, or 6 weeks as their baseline examination. This may influence both bedding-in and femoral head penetration measurements. How bedding-in and wear varies between different types of XLPE components remains unknown. The amount of initial plastic (permanent) deformation of the polyethylene liner may differ due to design, manufacturing error, fit of the liner within the shell, elasticity of the metal shell, and surface of the inner shell. Bedding-in may also differ between cemented XLPE components and XLPE liners within uncemented metal shells.

### RSA software and acetabular reference segment

The specific manner in which RSA was undertaken also varied between the studies, and may therefore also affect the outcome of meta-analyses. Early versions of the UmRSA software required the implantation of tantalum markers in the polyethylene, and subsequently measured the movement of the center of the femoral head within the rigid body defined by the markers in the polyethylene. A recent modification to the UmRSA software allows metal-backed hemispherical acetabular components to be measured using an ellipse algorithm (Borlin et al. 2006). Therefore, the movement of the femoral head can be measured within the ellipse of the metal acetabular components or by using beads in the liner, or by using a combination of both methods (beaded plus ellipse) (Borlin et al. 2006). The study that used Gill's software (Gill et al. 1998) used the known dimensions of the prostheses and measured the femoral head penetration relative to the center of the metal acetabular component, this approach being similar to the ellipse-only method. Studies that do not use beads have the potential to save time and money, and also eliminate safety concerns relating to the implantation of beads. Furthermore, there is no exclusion of patients due to insufficiently marked components, which is a common reason for exclusion of hips in beaded analysis (Borlin et al. 2006). RSA wear measurements in the proximal direction using the ellipse algorithm alone are less precise than those using a beaded reference segment: 0.10 mm and 0.08 mm, respectively (Zhou et al. 2006). A combination of beads and the ellipse algorithm was found to have the smallest error (Borlin et al. 2006) and the least amount of variance (Bragdon et al. 2007). To date, only 1 study has presented the results of all 3 different reference segments (beaded, beaded plus ellipse, and ellipse only), and showed only slight variation in the results (Bragdon et al. 2007). However, these different representations of the acetabular reference segment may influence the measurement of early creep and bedding-in if there is early movement between the liner and the metal-backed shell.

### Patient positioning

Another methodological difference between studies was the use of standing and/or supine positioning during RSA examinations (Table 2). Standing radiographs are thought to position the femoral head in the deepest part of its wear track within the polyethylene liner. However, standing radiographs may have poorer image quality due to different soft tissue exposure (stomach overhang) and different pelvic positioning. Patients have also reported that standing examinations caused discomfort at the initial postoperative examination (Digas et al. 2003). 3 RSA studies have investigated the differences in measurements made using standing and supine radiographs. Specifically, von Schewelov et al. (2006) reported that 3D wear measurements made from supine and standing (i.e. weight-bearing) examinations taken on the same day had a high correlation and there was no difference in the magnitude

of penetration. Digas et al. (2004) also found no difference in the proximal head penetration recorded, while Bragdon et al. (2006b) found small differences in some wear measurements between standing and supine examinations, but the occurrence was low and did not affect the average results.

### **Precision reported in RSA studies**

Given the typically low amounts of XLPE wear reported in RSA clinical studies, determination of the precision of the RSA method is important. Despite the RSA-reporting guidelines recommending the inclusion of precision measurements in clinical studies (Valstar et al. 2005), double examinations to determine precision were undertaken for only 6 of the 12 cohorts. While double examinations give a slight increase in radiation exposure of patients, the precision of RSA measurements cannot be determined using a phantom model (Borlin et al. 2006). Proximal wear measurements were more precise (range: 0.02–0.11 mm) than 3D wear measurements (range: 0.16–0.28 mm). The RSA method is more precise in the x- and y-axes relative to the z-axis because the latter measurements are made “out of plane” in the uniplanar setup (Karrholm et al. 1997). This will in turn affect the precision of the 3D measurement, namely the vectorial sum of all 3 axes.

### **Reporting of RSA wear results**

To summarize the wear rate derived from studies identified in this review, the reported results were described using 3 terms: (1) “femoral head penetration” (initial examination to latest follow-up), (2) “bedding-in” (initial examination to the 1-year examination), and (3) “wear rate” (the annual wear rate between the 1-year examination and latest follow-up). RSA provides measurements in 3 axes: proximal-distal, medial-lateral, and anterior-superior. Proximal and 3D (vectorial sum) femoral head penetration and wear rates were most commonly reported, although the axis of measurement was not defined in some publications. Interpretation of the results was further complicated by the use of a number of different terms to denote the same concept. For example, proximal measurements were variously referred to as superior, longitudinal, or linear—and 3D measurements as total, linear, or maximum total point motion (MTPM). Interestingly, the 2D wear rates, which allow comparison of results to those of studies using less sophisticated techniques and plain radiographs, were only reported in 2 cohorts (Callary et al. 2013a, Callary et al. 2013b).

Mean and median values were commonly reported, but for some publications these figures had to be estimated from graphs or calculated using other data provided in the publication (Table 4). Within any one cohort, varying numbers of patients were often included at different follow-up time points, possibly affecting the reported mean wear rate, particularly if patients with wear rates at either end of the range were differentially represented over time. The mean annual proximal wear rate did not exceed 0.06 mm/year for any cohort. Only 2 publications reported mean 3D wear rates above 0.06 mm/

year (Digas et al. 2003, Digas et al. 2004). However, because the wear rate in both of these cohorts was calculated between 3 months and the latest follow-up, some of the penetration attributed to wear may in fact have been due to bedding-in. This is supported by the finding that a much lower mean 3D wear rate of 0.005 mm/year was reported for the same cohort between 2 and 10 years (Rohrl et al. 2012). It is therefore important to emphasize that if wear rate is calculated using a reference time point within the bedding-in phase, the reported rate may be an overestimation of the true wear rate. Although the majority of studies used 1 year as the baseline reference for wear rate calculations, the assumed end of bedding-in/creep and the beginning of wear has varied in the literature, ranging from 2 months to 2 years (McCalden et al. 2005).

Studies of UHMWPE identified that an annual wear rate exceeding 0.1 mm/year was associated with an increased risk of developing osteolysis (Dumbleton et al. 2002), and an increased risk of revision surgery due to loosening or lysis. This suggests that the percentage of THAs with wear exceeding certain thresholds is, in fact, of more clinical importance than a mean or median wear rate. It is important to emphasize that the threshold of XLPE wear possibly associated with osteolysis is unknown. Therefore, presentation of scatter plots of individual wear rates, coupled with long-term clinical follow-up of patients, will facilitate a better understanding of the relationship between XLPE wear and subsequent development of osteolysis. Only 4 publications in the current review have reported percentages of patients exceeding specified thresholds (Digas et al. 2007, Thomas et al. 2011, Callary et al. 2013a, Callary et al. 2013b). Specifically, 3 reported no patients with a wear rate greater than 0.1 mm/year (Thomas et al. 2011, Callary et al. 2013a, Callary et al. 2013b) and 1 reported that 24 of 28 patients in cohort 1 had a wear rate of less than 0.05 mm/year and that all patients in cohort 2 had a wear rate below 0.05 mm/year (Digas et al. 2007).

### **Recommendations to improve reporting of RSA wear results**

13 guidelines were described by Valstar et al (2005) for standardization of RSA of implants. These guidelines have recently been incorporated within the ISO for measuring migration with RSA (ISO 16087:2013 (E)). The findings of the present scoping review have led to further recommendations of important items that should be included when reporting RSA wear results (Table 5). Standardization of the manner in which RSA wear results are presented will enable a better understanding of the effects of surgical and patient factors on wear. Most importantly, such standardization is also likely to facilitate early identification of poorly performing implants.

### **Future studies on wear using RSA**

Our review has identified that the wear rates reported for XLPE components are low, which is encouraging for continued clinical use. With 1 exception, the mean proximal and 3D annual



Table 5. Recommendations to enhance reporting of RSA wear results

Recommendations to enhance reporting of RSA wear results	
Methodology	
1	Components used (femoral head size and material; description of XLPE component)
2	Patient positioning (supine or standing)
3	Software and acetabular reference segment used
Results	
4	Allow one year for bedding-in and creep, and report results using the terms: <ul style="list-style-type: none"> <li>– femoral head penetration (initial examination to latest follow-up)</li> <li>– bedding-in (initial examination to the one-year examination)</li> <li>– wear rate (the annual wear rate between the one-year examination and latest follow-up)</li> </ul>
5	Report axis of measurement (x, y, z, 2D or 3D)
6	Use scatter plots of wear results to allow identification of outliers

wear rates decreased when the length of follow-up increased. In the cohort in which this was not the case (Campbell et al. 2010a, Callary et al. 2013a), the liner was manufactured using an irradiation dose at the lower end of the range included as XLPE (50 kGy). Thus, new designs of XLPE components need to be monitored prospectively. Second-generation XLPEs are being introduced rapidly internationally and differ from first-generation XLPEs by being either sequentially irradiated and annealed, mechanically deformed or compressed, or diffused with vitamin E (Dumbleton et al. 2006). However, we identified only 1 cohort in which the bedding-in and wear of a second-generation XLPE liner had been investigated (Campbell et al. 2010b, Callary et al. 2013b). In this cohort, the mean proximal bedding-in was lower than that of all first-generation XLPE components (0.007 mm vs. 0.06–0.17 mm).

The low wear rates reported for XLPE have also encouraged the use of larger articulations, which have been shown to reduce the incidence of dislocation within the first year after THA (Howie et al. 2012). In Australia, head sizes of 32 mm or more have been increasingly used over the last 5 years in primary THAs with XLPE components (AOANJRR 2013). However, the effect of articulation size on XLPE wear rates is poorly understood. To date, only 1 RSA study has compared the wear rates of 28- and 36-mm articulations. Although that study reported no difference at 3 years (Bragdon et al. 2007), it is important to note that this non-randomized comparison included only 25 hips.

Identification of any potential association between patient-related factors such as age, sex, weight, or activity on the one hand and wear of XLPE on the other is desirable. However, such studies require relatively large samples, given the variability in these factors between patients. Individual RSA studies are limited in this regard due to the costly specialized equipment and analysis required, and to the need for prospective radiographs above a calibration cage. Conversely, although other measurement techniques, such as Martell's Hip Analysis Suite (Martell and Berdia 1997) and PolyWare (Devane et al. 1995a,b), are able to measure the wear rates of larger cohorts retrospectively using plain radiographs, they

are limited by their lack of sensitivity. In future, meta-analyses of data pooled from existing RSA studies may provide a means of examining not only the effect of patient-related factors on XLPE wear, but also the relationship between XLPE wear and osteolysis.

### Conclusion

Despite the almost universal acceptance of the use of XLPE in acetabular components, to date the publications reporting in vivo wear of XLPE measured using RSA have

been based on 12 small cohorts covering only 260 hips. The present scoping review has identified variation in both the methodology and the manner of reporting results of RSA studies. We have made a number of recommendations to enhance the reporting of RSA-based wear results. Longer-term studies are required to determine whether the low wear of XLPE identified in the short term does indeed translate to a low incidence of osteolysis in the medium to long term and, importantly, to a reduction in the need for revision surgery.

SC: performed scoping review, collected data from publications included, and wrote the manuscript. LS: assisted with collection of data and proofread the manuscript. OH: analyzed the review data and contributed to the manuscript. DC: planned the study and proofread the manuscript. ZM: planned systematic search criteria and assisted with the scoping review. DH: planned the study and contributed to the manuscript.

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