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Comparison of revision rates and radiographic observations of long and short, uncoated and coated humeral stem designs in total shoulder arthroplasty

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- There is no consensus on outcomes of long *versus* short and uncoated *versus* coated uncemented stems in total shoulder arthroplasty (TSA).
- We reviewed the literature to compare revision rates and adverse radiographic observations at ⩾ 2 years of various uncemented humeral stem designs.
- We performed an electronic PubMed search for studies on uncemented primary TSA that reported one or more of the following observations at ⩾ 2 years for distinct stem designs: stem revision; subsidence; stress shielding; radiolucent lines; and humeral loosening.
- The search returned 258 records, from which 20 articles (22 cohorts) met the inclusion criteria.
- The most frequently reported designs were short uncoated stems (7/13 cohorts) at < 3 years and long uncoated stems (8/9 cohorts) at > 3 years.
- The incidences of revisions and adverse radiographic observations were lower for short coated designs, compared with short and long uncoated designs, but these findings should be confirmed by prospective studies with a longer follow-up.

Keywords: total shoulder arthroplasty; humerus; stem designs

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Introduction

Total shoulder arthroplasty (TSA) with uncemented humeral stems – also known as press-fit stems – has become the standard treatment for glenohumeral osteoarthritis with intact rotator cuffs.[1,2] While TSA grants satisfactory functional improvements and pain relief,[3,4] it is frequently associated with failures of the glenoid component. Aseptic loosening of the humeral implant is less commonly described, although it is a potential long-term problem,[5] with a reported rate of 9% of humeral loosening at 20 years.[6]

Multiple humeral uncemented stems were designed to improve osteointegration with various metaphyseal configurations and surface treatments, including combinations of grit-blasting, porous titanium and hydroxyapatite coatings. Third and fourth generations of TSA stems reduced rates of loosening, though stress shielding – characterized by bone resorption due to the altered stress distribution – remains common.[7] Efforts to reduce stress shielding have led to novel implant designs with shorter stems or stemless implants.[8]

To date, there is no consensus on the outcome of long *versus* short and uncoated *versus* coated uncemented stems in primary TSA. The authors therefore aimed to review the relevant literature and compare revision rates and radiographic observations at ⩾ 2 years of different uncemented humeral stem designs of various lengths and surface treatments.

Material and methods

Search strategy

The authors conducted an electronic literature search using MEDLINE (PubMed) on 22 March 2018 for articles on radiographic observations of humeral stems in TSA using the following keywords: ('total shoulder arthroplasty' OR 'TSA' OR

Table 1. Keyword search terms

	Database search	Results
1	'total shoulder arthroplasty' OR 'TSA' OR 'total shoulder replacement' OR 'anatomic shoulder arthroplasty' OR 'anatomic shoulder replacement'	8,595
2	'humeral' OR 'humeri' OR 'humerus'	27,806
3	'implant' OR 'component' OR 'stem'	1,028,208
4	'revision' OR 'stress shielding' OR 'stress-shielding' OR 'loosening' OR 'radiolucent line' OR 'lucent line' OR 'lucency'	75,455
5	1 AND 2 AND 3 AND 4	258

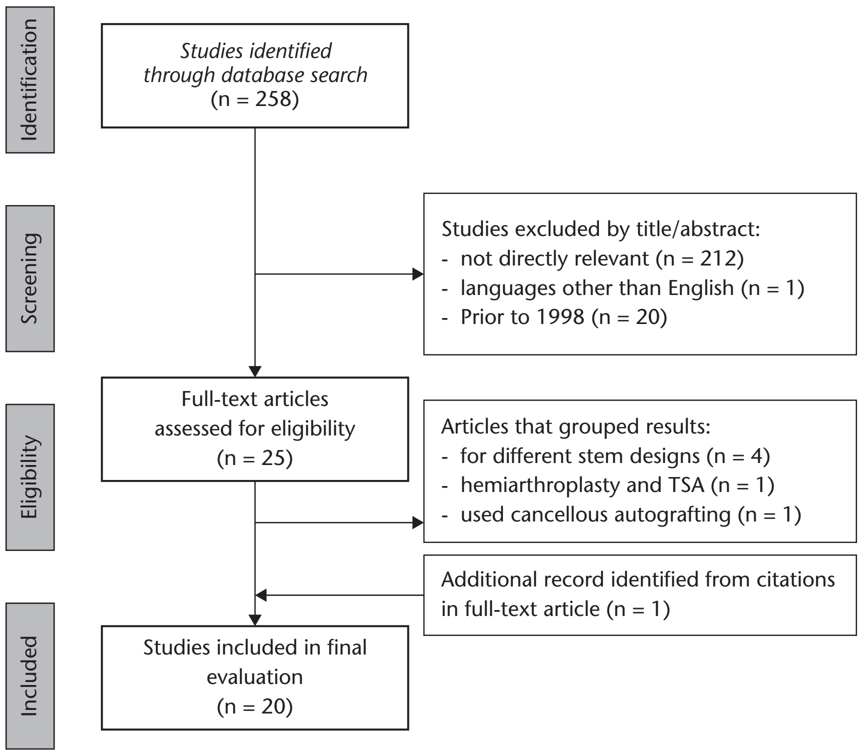

Fig. 1 PRISMA flow diagram.

'total shoulder replacement' OR 'TSR' OR 'anatomic shoulder arthroplasty' OR 'anatomic shoulder replacement') AND ('humeral' OR 'humeri' OR 'humerus') AND ('implant' OR 'component' OR 'stem') AND ('revision' OR 'revised' OR 'stress shielding' OR 'stress-shielding' OR 'loosening' OR 'radiolucent line' OR 'lucent line' OR 'lucency') (Table 1). The electronic literature search returned 258 records which were screened to determine relevance in accordance with the established guidelines from Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA).[9]

Inclusion criteria consisted of:

- articles on uncemented primary TSA that report one or more of the following observations: stem revision; subsidence; stress shielding; radiolucent lines; and humeral loosening for distinct stem designs;
- follow-up ⩾ 2 years.

Exclusion criteria were:

- guidelines, recommendations and expert opinions;
- articles written in languages other than English;
- articles published before 1998;
- studies that used impaction cancellous autografting of the humeral stem.

A total of 233 articles were excluded by reading their titles and/or abstracts, while a further six articles were excluded by reading their full text, because they grouped the radiographic observations of different surgeries (TSA and hemiarthroplasty, n = 1) or stem designs (n = 4) or used cancellous autografts (n = 1). An additional relevant article was identified from citations when reading full text articles. This left a total of 20 articles from which data were extracted for this review (Fig. 1).[5,7,8,10-26]

Data extraction

Two investigators (LN and AM) independently tabulated and verified the following data from each article: first author; study design; aetiology; treatment; cohort size; age at surgery; follow-up; clinical and radiographic outcomes; reported complications; and revision rate. In cases of discrepancies between abstract and full text, data were extracted from the most comprehensive source. Disagreements were discussed until consensus was reached.

Results

Of the 20 selected articles that reported radiographic observations of uncemented humeral stems at ⩾ 2 years, published between 2000 and 2017, three studies presented outcomes for short coated stems,[13,16,22] seven studies presented outcomes for short uncoated stems,[8,11,12,16,17,21,24] one study presented outcomes for long coated stems[5] and 11 studies presented outcomes for long uncoated stems (Table 2).[10,12,14,15,18-20,23,25,26] The cohort sizes were in the range of 20 to 131 shoulders with mean follow-up in the range of 24 to 238 months. There were ten cohorts with short-term follow-up (24 to 36 months), none of which reported outcomes for long coated stems, and 12 cohorts with long-term follow-ups (43 to 238 months), none of which reported outcomes for short coated or uncoated stems (Table 3). Level of evidence was heterogeneous with four Level-II prospective studies, ten Level-III cohort studies and eight Level-IV case series.

The articles included a total of 15 different stem designs, of which:

- four short titanium-coated stems: BioModular / Comprehensive (Zimmer Biomet) evaluated in a single cohort,[13] Aequalis Ascend Flex (Wright Medical)[22] and Aequalis Ascend PTC (Wright Medical);[16]
- two short uncoated stems: Aequalis Ascend (Wright Medical)[8,11,16,21] and Apex (Arthrex);[12,17]
- one long cobalt-chromium and titanium-coated stem: Cofield 2 (Smith and Nephew);[5]
- eight long uncoated stems: Aequalis (Wright Medical),[7,27] Bigliani/Flatow total shoulder (Zimmer Biomet),[14] Global (Depuy Synthes),[15,20] Neer II (Depuy Synthes),[2,10,19] Trabecular Metal (Zimmer Biomet),[26] Cofield 1 (Smith and Nephew)[23,25] and Nottingham TSR (Zimmer Biomet).[24]

Of the 20 selected articles, 13 reported stem revision rates.[5,8,10,11,13,14,16,17,22-25,27] Of these, 11 specified stem revision rates for humeral loosening.[5,8,10-13,16,17,22-25] Furthermore, two reported stress shielding,[7,8,11] ten reported subsidence rates[8,10,12,15,16,19,21,22,24,26] and six reported numbers of radiolucent lines (RLL) ⩾ 2 mm.[5,11,17,19,23,25] Finally, six reported number of stems at risks of loosening[5,11,16,17,19,23] according to the definition established by Sanchez-Sotelo,[19] ten specified humeral loosening rates[5,7,8,11,16,18,21,22,24,27] and three reported metaphyseal and diaphyseal canal filling ratios, defined as the quotient of the bone external diameter and the stem diameter.[21,22,24]

Revision rates and radiographic observations at short-term follow-up

The overall incidence of revision was 0.0% for short coated stems[13,16,22] and 0.0% to 12.0% for short uncoated stems (Tables 2 and 4).[8,16,17,24] Similarly, the incidence of revision due to humeral loosening was 0.0% for short coated stems[13,22] and 0.0% to 8.2% for short uncoated stems.[8,12,16,17]

The incidence of stress shielding was 13.6% for short uncoated stems.[11] Subsidence rates were 0.0% to 2.9% for short coated stems,[16,22] 0.0% to 8.8% for short uncoated stems[8,12,16,21,24] and 0.0% to 1.7% for long uncoated stems.[15] The incidence of humeral RLL was 0.0% for short coated stems[13] and 7.1% to 11.6% for short uncoated stems.[11,17]

The incidence of risks of loosening was 2.9% for short coated stems,[16] and 8.7% to 20.6% for short uncoated stems.[16,17] Incidence of humeral loosening was 0.0% for short coated stems,[16,22] 0.0% to 16.0% for short uncoated stems[8,12,16,21,24] and 0.0% to1.7% for long uncoated stems.[12,15]

Metaphyseal canal filling ratio was 59.6% for short coated stems[22] and 58.3% to 61.6% for short uncoated stems.[8,24] Diaphyseal canal filling ratio was 58.0% for short coated stems[22] and 56.1% to 63.0% for short uncoated stems.[21,24]

Revision rates and radiographic observations at long-term follow-up

The incidence of stem revision was 0.0% for long coated stems[5] and 9.0% to 14.0% for long uncoated stems (Tables 2 and 5).[10,23,25] The incidence of revision due to humeral loosening was 0% for long coated stems[5] and 2.0% to 6.0% for long uncoated stems.[10,23,25]

The incidence of subsidence rates was in the range of 0.0% to 43.0% for long uncoated stems.[10,12,19,26] The incidence of stress shielding was 62.7% for long uncoated stems.[7] The incidence of humeral RLL ⩾ 2 mm was 0% for long coated stems[5] and 8% to 25% for long uncoated stems.[19,23,25]

The incidence of risk of loosening was 0.0% for long coated stems[5] and 0.0% to 55.6% for long uncoated stems.[7,19,23] The incidence of humeral loosening was 0.0% for long coated stems[5] and 0.0% to 3.0% for long uncoated stems.[7,18]

Table 2. Review table of radiographic outcomes of TSA stem designs

Design	Manufacturer	Authors	Year	Level of evidence	Cohort size	Mean age (years)	Mean follow-up (months)	Stem revision (SR) (%)	SR for humeral loosening (%)	Stress shielding (%)	Sub-sidence	Radio-lucent line > 2 mm (%)	Risk of loosening (%)	Humeral loosening (%)	Meta-physeal canal filling ratio (%)	Dia-physeal canal filling ratio (%)
Short stems																
Coated																
Aequalis Ascend Flex/PTC	Wright Medical	Morwood et al	2016	III	34	70	24	0.0	0.0		2.9		2.9	0.0		
Aequalis Ascend Flex	Wright Medical	Schnetzke et al	2017	II*	32	63	25	0.0	0.0		0.0			0.0	59.6	58
BioModular/ Comprehensive	Zimmer Biomet	Jost et al	2011	IV	49	67	29	0.0	0.0			0.0				
Uncoated																
Apex	Arthrex	Denard et al	2017	III	35	67	25	0.0	0.0		8.6			16.0	61.6	56.1
Apex	Arthrex	Denard et al	2018	III	56	65	25				5.4			1.8		
Apex	Arthrex	Romeo et al	2018	IV	64	64	25	0.0	0.0			7.1	9.0			
Aequalis Ascend	Wright Medical	Morwood et al	2016	III	34	69	30	2.9	2.9		8.8		26.0	0.0		
Aequalis Ascend	Wright Medical	Schnetzke et al	2015	IV*	82	71	31	1.2	0.0	13.6	0.0			0.0		
Aequalis Ascend	Wright Medical	Schnetzke et al	2016	IV	52	72	32				0.0			0.0	58.3	63
Aequalis Ascend	Wright Medical	Casagrande et al	2016	IV	73	63	33	12.0	8.2			11.6	8.7	11.0		
Long stems																
Coated																
Cofield 2	Smith and Nephew	Throckmorton et al	2010	IV	76	68	55	0.0	0.0			0.0	0.0	0.0		
Uncoated																
Bigliani/Flatow	Zimmer Biomet	Lichtfield et al	2011	IV	74	68	24	1.4								
Univers II	Arthrex	Denard et al	2018	III	58	65	31				1.7			1.7		
Global	DePuy Synthes	Matsen et al	2003	IV	131	64	36				0.0					
Trabecular Metal	Zimmer Biomet	Panti et al	2016	III	76	70	43				0.0					
Neer II	DePuy Synthes	Sanchez-Sotelo et al	2001	III	81	62	48				43.0	25.0	55.6			
Cofield I	Smith and Nephew	Sperling et al	2000	IV*	62	63	55		2			8	10			
Aequalis	Wright Medical	Raiss et al	2014	IV	67		66			62.7			0.0	3.0		
Nottingham TSR	Zimmer Biomet	Rosenberg et al	2007	II*	103	58	77							0.0		
Global	DePuy Synthes	Sandow et al	2013	II	20	68	120†	10	0.0							
Neer II	Smith and Nephew	Sperling et al	2004	III*	36	41	168	14	6							
Neer II	DePuy Synthes	Betts et al	2009	II*	14	48	238	9	2		7.1					

*level of evidence inferred
†minimum follow-up

Table 3. Number of cohorts by time of median follow-up

	Short-term follow-up (24 to 36 months)	Long-term follow-up (43 to 238 months)
Short stems		
Coated	3	0
Uncoated	7	0
Long stems		
Coated	0	1
Uncoated	3	8

Table 4. Short-term revision rates and radiographic outcomes

Treatment	Cohorts (n)	Total cohort	Stem revision (%)	Stem revision for humeral loosening (%)	Stress shielding (%)	Subsidence (%)	Radiolucent line > 2 mm (%)	Risk of loosening (%)	Humeral loosening (%)	Metaphyseal canal filling ratio (%)	Diaphyseal canal filling ratio (%)
Short stems											
Coated	3	115	0	0		0-2.9	0	2.9	0	59.6	58.0
Uncoated	7	396	0-12	0-8.2	13.6	0-8.8	7.1-11.6	8.7-20.6	0-16	58.3-61.6	56.1-63
Long stems											
Coated	0	0	-	-	-	-	-	-	-	-	-
Uncoated	3	263	1.4	-	-	0-1.7	-	-	1.7	-	-

Table 5. Long-term revision rates and radiographic outcomes

Treatment	Cohorts (n)	Total cohort	Stem revision (%)	Stem revision for humeral loosening (%)	Stress shielding (%)	Subsidence (%)	Radiolucent line > 2 mm (%)	Risk of loosening (%)	Humeral loosening (%)	Metaphyseal canal filling ratio (%)	Diaphyseal canal filling ratio (%)
Short stems											
Coated	0	0	-	-	-	-	-	-	-	-	-
Uncoated	0	0	-	-	-	-	-	-	-	-	-
Long stems											
Coated	1	76	0.0	0.0	-	-	0.0	0.0	0.0	-	-
Uncoated	8	459	9-14	0-6	63	0-43	8-25	0-56	0-3	-	-

Discussion

There are only 20 published clinical studies on revision rates and radiographic observations of uncemented humeral stems after primary TSA, of which only four are on coated stems. Moreover, only four studies were prospective (Level II), which made it difficult to draw firm conclusions about the performance of long *versus* short and uncoated *versus* coated humeral stems.

Long stem designs

Humeral stems have gone through many design adaptations, from first-generation cemented Neer stems with a unique geometry in five sizes of increasing diameters, to fourth-generation uncemented humeral stems, featuring short and stemless designs.[28] Cemented long stems, which were the norm from the late 1970s to the early 2000s, largely improved in function and pain,[4,29] but their revision rate is around 10% at ten years and 20% to 30% at 20 years.[7,30] Our review revealed overall stem revision rates of 9% to 14% at 10 to 20 years for uncemented uncoated long designs. Notably, rates of stem revision for humeral loosening were only 0% to 6%. Most humeral revisions reported were therefore likely due to worn glenoid components, whose revision often require removal of well-fixed monobloc humeral stems.

Long uncemented stem designs rely on diaphyseal fixation, which can result in stress shielding, radiolucency and risks of loosening.[7] Stress shielding is the consequence of change in load distribution which, according to Wolff's law, causes bone remodelling in response to stimulus. Its radiographic manifestations include tuberosity resorption, cortical thinning and medial calcar osteolysis. Stress shielding rarely occurs with cemented stems, which distributes load uniformly, but is reported in varying extents and locations when using uncemented stems.[31] The studies reviewed calculated the incidence of humeral RLL with various criteria of length and size. In order to report RLL in a systematic manner, Sperling et al[23] first divided the humeral stem-bone interface into eight zones and defined risk of loosening as the presence of RLL > 2 mm in three or more zones and/or occurrence of tilt or subsidence.

Various combinations of surface treatments and coatings were developed to promote osteointegration and thus reduce risks of loosening. At ⩾ 3 years follow-up, studies of uncemented uncoated long stems reported subsidence in 0% to 43%, radiolucent lines ⩾ 2 mm in 8% to 25%, and risks of loosening in up to 56%, while the single series of long coated stems reported excellent results with no RLL ⩾ 2 mm or risks of humeral loosening. The addition of coating to uncemented press-fit stems therefore seems to promote osteointegration, as with short stem designs.

Short stem designs

Shorter humeral stems were developed to improve bone preservation, vascularity and osteointegration as well as to facilitate revision.[31] Bone remodelling is the hypothetical weakness of short stem designs. It depends mainly on humeral stem geometry, size and filling ratio.[33] Although we found no comparative data about the influence of stem geometry on radiographic observations, two studies reported canal filling ratio for the Aequalis Ascend short stem either uncoated[8] or coated,[22] and one study reported the canal filling ratio for the Apex uncoated stem.[24] While these three studies reported diaphyseal and metaphyseal filling ratios, these ratios were calculated as stem width over external bone diameter, thus ignoring the thickness of cortical bone. Nevertheless, the Apex uncoated stems had a higher metaphyseal filling ratio (61.6%) than both coated (59.6%) and uncoated Aequalis stems (58.3%), while the Aequalis uncoated stem had a higher diaphyseal filling ratio (63%) than both the Aequalis coated stem (58%) and Apex (56.1%). The clinical significance of these differences is uncertain, especially that these studies did not adjust for stem size. Schnetzke et al[21,22] found that a higher diaphyseal filling was associated with greater risks of bone remodelling. Setting aside the influence of stem geometry and coating, greater diaphyseal filling could shield the proximal humerus from normal loading and thereby increase risks of loosening. Therefore, the optimal humeral stem should grant stability by metaphyseal fixation and minimize diaphyseal width.

By shifting the location of humeral fixation from the diaphysis to the metaphysis, short stem designs could prevent stress shielding, subsidence and loosening. While these theoretical advantages are supported by Razfar et al's[31] finite element analysis, only few clinical studies reported radiographic observations around short stems designs. Loosening of uncemented short stems remains a concern, mostly for uncoated designs, although this problem is often due to failure of glenoid components. Morwood et al[16] compared two-year observations of the same short stem designs either coated (Aequalis Ascend Flex) or uncoated (Aequalis Ascend) and found that the latter had a significantly higher risk of loosening (3% *vs* 21%; $p = 0.03$). Our review corroborates that humeral loosening and risks of humeral loosening are lowest for short coated stems (0% and 2.9%) compared with short uncoated stems (0% to 16% and 8.7% to 20.6%). Furthermore, short coated stems had less subsidence (0% to 2.9% *vs* 0% to 8.8%) and RLL > 2 mm (0% *vs* 7% to 12%) than short uncoated stems, which confirms that coating promotes stability and osteointegration.

Limitations

This review, which aimed to compare the revision rates and radiographic observations of different humeral uncemented stem designs, demonstrates the scarcity of publications on humeral components in total shoulder arthroplasty. The limitations of this review include: small number of studies reporting radiographic observations for specific stem design, which did not permit consideration of the influence of stem geometry; variability in radiographic measurement techniques; a majority of Level-III and Level-IV retrospective studies; and the lack of study on short stem designs with > 3-year follow-up, so that their promising results are yet to be confirmed. Moreover, it is possible that the studies by Denard et al[12,34] and Schnetzke et al[8,21] had overlapping cohorts, but their respective studies mostly reported outcomes for different observations. The strengths of this review include: a documented systematic process for searching relevant literature and a rigorous comparison of radiographic observations according to stem size and surface treatment.

Conclusions

Over the last 20 years, only 20 studies reported revision rates and radiographic observations for specific humeral stem designs. Of the ten studies that focused on short stems, none had a follow-up > 3 years. The lowest incidence of revision and stress shielding, subsidence, radiolucency, risks of loosening and loosening were obtained by short coated designs compared with short and long uncoated designs. These promising results need to be confirmed by further prospective studies with a longer follow-up.

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