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Outcomes of primary total hip arthroplasty using 3D image-based custom stems in unselected patients: a systematic review

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- To report clinical and radiographic outcomes of primary THA using three-dimensional (3D) image-based custom stems.
- This systematic review was performed according to PRISMA guidelines and registered with PROSPERO (CRD42020216079). A search was conducted using MEDLINE, Embase and Cochrane. Clinical studies were included if they reported clinical or radiographic outcomes of primary THA using 3D image-based custom stems. Studies were excluded if specific to patients with major hip anatomical deformities, or if not written in English.
- Fourteen studies were eligible for inclusion (n = 1936 hips). There was considerable heterogeneity in terms of manufacturer, proximal geometry, coating and length of custom stems. Revision rates ranged from 0% to 1% in the short-term, 0% to 20% in the mid-term, and 4% to 10% in the long-term, while complication rates ranged from 3% in the short-term, 0% to 11% in the mid-term and 0% to 4% in the long-term. Post-operative Harris hip scores ranged from 95 to 96 in the short-term, 80 to 99 in the mid-term, and 87 to 94 in the long-term. Radiographic outcomes were reported in eleven studies, although none reported 3D implant sizing or positioning, nor compared planned and postoperative hip architecture.
- Primary THA using 3D image-based custom stems in unselected patients provides limited but promising clinical and radiographic outcomes. Despite excellent survival, the evidence available in the literature remains insufficient to recommend their routine use. Future studies should specify proximal geometry, length, fixation, material and coating, as well as management of femoral offset and anteversion. The authors propose a classification system to help distinguish between custom stem designs based primarily on their proximal geometry and length.

Keywords: clinical outcomes; custom stems; primary total hip arthroplasty; radiographic outcomes; unselected patients

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Introduction

Primary total hip arthroplasty (THA) is a successful procedure and has demonstrated excellent mid- to long-term survival rates.[1] Off-the-shelf femoral stems have been the default choice due to considerations of cost and versatility, as most designs are available in a range of sizes, neck lengths and offsets. Custom femoral stems were introduced for selected THA patients, notably those with major anatomical deformities,[2,3] for which off-the-shelf implants would not be suitable. Despite their higher unit cost,[4–6] custom stems are sometimes used for unselected THA patients, including standard/general cases that have no anatomical deformities. The rationale for custom stems is maximization of metaphyseal fit and fill,[7] which could increase both rotational and axial stability, though their clinical benefits for unselected THA patients are yet to be confirmed.

Custom stems have been manufactured in various ways over the past three decades.[8,9] Intraoperatively-made custom stems were machined based on silicone elastomer moulds of the femoral canal after reaming and broaching, which increased operation time by at least one hour.[8,10] Preoperatively-made custom stems are based on conventional radiographs[11,12] or more accurate 3D images, such as computed-tomography (CT) or magnetic resonance imaging (MRI).[4,13] The stem size and shape, as well as the stem and coating materials vary across implant manufacturers; while some custom stems are short and metaphyseal-engaging, others are straight and long to surpass any existing femoral defects.[14–17]

A number of studies have reported the clinical and radiographic outcomes of THA using custom stems; however, there is not yet a systematic review which synthesizes their results in the literature. Therefore, the aim of this systematic review was to report the clinical and radiographic outcomes of primary THA in unselected patients using custom stems that have been designed from preoperative 3D imaging.

Materials and methods

This systematic review was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines and registered with PROSPERO prior to commencement of the study (CRD42020216079).

Search strategy

An electronic literature search was conducted on 19 November 2020 using MEDLINE, Embase and the Cochrane Database of Systematic Reviews. The search strategy was based on the following key terms: "total hip arthroplasty", "custom", and "stem" (see full search strategy in appendix). No date or publication restrictions were applied in the search. Subject matter experts (AN, IT, CC) were consulted to identify additional relevant studies that were not found in the electronic search, and review registries were consulted for ongoing reviews on the subject. Additionally, reference lists of selected articles, internet resources and grey literature were searched to identify further relevant studies that were not found during the electronic search.

Selection criteria

Duplicate articles were removed, and then titles and abstracts were screened independently by two authors (SRP, JHM) to determine their relevance in accordance with the following inclusion and exclusion criteria. The inclusion criteria were studies that reported clinical or radiographic outcomes of primary THA in unselected patients using custom stems designed from preoperative 3D imaging; whether comparative or non-comparative, retrospective or prospective, or even case reports. The exclusion criteria were: studies specifically on patients with major hip anatomical deformities (such as developmental dysplasia of the hip (DDH)), studies specifically on revision THA, studies on animals, and studies on computer simulations. Narrative reviews, systematic reviews, meta-analyses, editorials, and expert opinions were also excluded, as well as papers published in languages other than English to avoid translation errors. While studies specifically on patients with major hip anatomical deformities (such as DDH) were excluded, they were included if only a portion of the patients had anatomical deformities.

Full text versions of the articles were retrieved if they were found to be relevant, or if the title and abstract did not provide sufficient information to establish final eligibility, and these were screened independently by two authors (SRP, JHM). Any disagreement between authors was solved by review and consensus.

Data extraction and quality assessment

The following characteristics were extracted from the included studies independently by two authors (SRP, JHM): title, lead author, year of publication, journal, time frame, population, indication for surgery, type of stem, surgical approach, intervention and comparator, number of patients included per intervention and comparator, age, body mass index (BMI), gender distribution, follow-up period, revision rate, reoperation rate, complication rate, survival rate, clinical outcomes and radiographic outcomes. Extracted data was compared between the two authors and if discrepancies were found, consensus was achieved through review and discussion. Where two or more studies were based on the same patient population, the longest follow-up and/or most complete data were presented, and shorter follow-up and/or incomplete data were disregarded.

The methodological quality of the studies was assessed according to the Joanna Briggs Institute (JBI) Checklist.[18] Any discrepancies in appraisal were resolved through discussion and consensus between the two authors.

Data analysis

When available in the original articles, outcomes were tabulated: continuous outcomes were reported as means, standard deviations and ranges, while categorical outcomes were reported as proportions. Harris hip score (HHS), revision rates and complication rates were the only outcomes consistently reported across studies. Meta-analyses could not be performed because there were only two comparative studies (custom *versus* off-the-shelf stems) reporting sufficient data. Instead, HHS, complication rates and revision rates were tabulated and presented graphically. Since outcome measures can depend on follow-up, the authors presented short- ($\leq$ 2 years), medium- (> 2 to 10 years) and long- (> 10 years) term findings separately.

Results

Literature search

The electronic literature search identified 415 references, of which 117 were duplicates (Fig. 1). The title and abstract of the remaining 298 references were screened, and 257

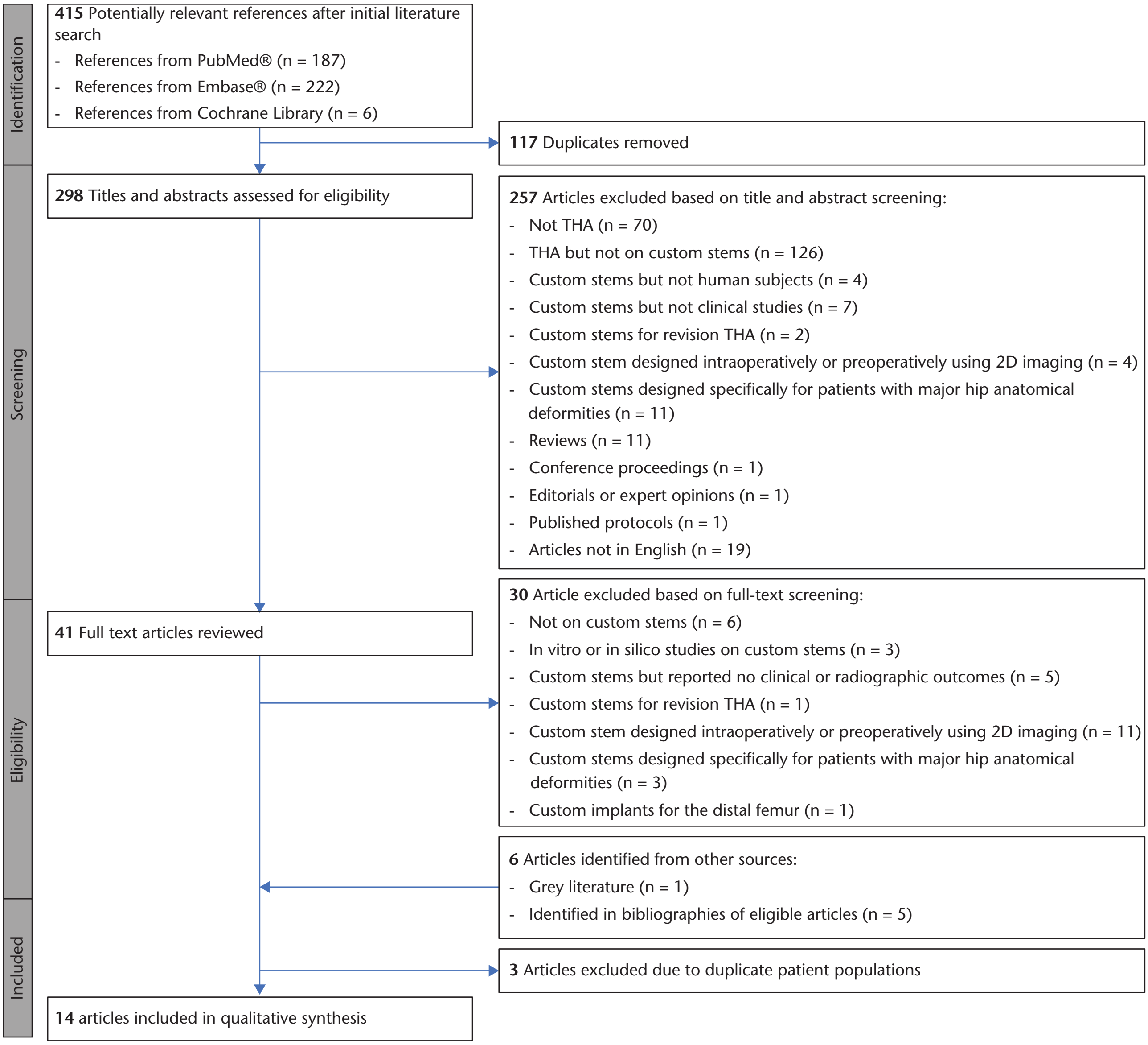

Fig. 1 Flowchart of the study selection procedure.

were excluded because they did not meet the inclusion criteria. The remaining 41 articles underwent full-text screening, of which a further 30 articles were excluded because: 11 were on custom stems designed intraoperatively or preoperatively using two-dimensional (2D) imaging,[8,10–12,19–25] six were not on custom stems,[26–31] five were on custom stems but reported no clinical or radiographic outcomes,[32–36], three were on custom stems designed specifically for patients with major hip anatomical deformities,[2,3,37] three were *in vitro* or *in silico* studies on custom stems,[38–40] one was on custom stems for revision THA,[41] and one was on custom implants for the distal femur.[42] A search in the grey literature identified one more eligible article,[13] and searching the reference lists of the included articles identified five more eligible articles.[6,9,15,43,44] Thus, a total of 17 articles were eligible for data extraction,[4–6,9,13,15–17,43–51] all of which reported on clinical or radiographic outcomes of primary THA using custom stems designed from 3D imaging. Finally, the outcomes of three articles were disregarded[16,17,45] because their patient populations were presented in other articles at longer follow-up and/or with more complete data, leaving 14 studies with unique patient populations.[4,6,9,13,15,17,43,44,46–51]

Characteristics of included studies

The 14 included studies were published between 1989 and 2020, reporting on a total of 1936 hips (15 to 259 per study) (Tables 1 and 2). The patient population was

Table 1. Characteristics of the studies included in the systematic review

Author, year	Journal	Study design	Control/comparator	Type of stem	Approach	Time frame	Population
Short-term follow-up (≤ 2 years)							
Sandiford, 2010[47]	J Orthop Surg & Res	Case control	Custom stem vs	Custom uncemented (not specified)	Min. invasive P	2000-2002	Young active pts (< 65 years)
			Hip resurfacing	Off-the-shelf resurfacing implant (not specified)	P	2000-2002	Young active pts (< 65 years)
Grant, 2005[50]	J Orthop Res	Case control	Custom uncemented vs	Custom uncemented (Scandinavian Customized Prostheses)	Modified Hardinge	Not specified	General
			off-the-shelf cemented	Off-the-shelf modular cemented (DePuy)	Modified Hardinge	Not specified	General
Bargar, 1989[9]	CORR	Case control	Custom primary vs	Custom uncemented (not specified)	Not specified	Not specified	General
			custom revision vs	Custom uncemented (not specified)	Not specified	Not specified	General
			off-the-shelf primary & revision[a]	Off-the-shelf uncemented (Zimmer)	Not specified	Not specified	General
Mid-term follow-up (3–10 years)							
Chow, 2015[46]	JOA	Case control	Custom vs	Custom short uncemented (Biomet)	Less-invasive PL	2004-2006	Pts < 70 years
			off-the-shelf	Off-the-shelf short uncemented (Stryker)	Less-invasive PL	2004-2006	General
Al-Khateeb, 2014[43]	JOA	Case series	None	Custom uncemented (Stanmore Implants Worldwide)	AL or P	1996-2003	Pts w/ Legg-Calve-Perthes disease
Benum, 2010[13]	Acta Orthop	Prosp. case series	None	Custom uncemented (Scandinavian Customized Prostheses)[b]	DL	1995-2009	General
Götze, 2009[48]	AOTS	Case control	Custom vs	Custom uncemented (Endopro)	Not specified	Not specified	General
			off-the-shelf	Off-the-shelf uncemented (Zimmer)	Not specified	Not specified	General
Albanese, 2009[49]	Acta Orthop	Case control	Short custom vs	Custom short uncemented (Stanmore Orthopaedics)	Not specified	Not specified	General
			ultra-short custom	Custom ultra-short uncemented (DePuy)	Not specified	Not specified	General
Reize, 2007[15]	Int Orthop	Case series	None	Custom uncemented, (Endopro)	Bauer's lateral	Not specified	Pts < 60 years
Wettstein, 2005[6]	CORR	Case series	None	Custom uncemented (Symbios)	AL	1990-1995	Pts < 65 years
Aubaniac, 1995[51]	Surg Technol Int	Case control	Custom from CT (Symbios) vs	Custom uncemented (Symbios)	Not specified	Not specified	General
			custom from radiograph (Egoform)	Custom uncemented HA-coated (Egoform)	Not specified	Not specified	General
Long-term follow-up (>10 years)							
Jacquet, 2020[4]	Orthopäde	Case series	Young patients (< 50 years) vs	Custom uncemented (Symbios)	AL (Watson-Jones)	1990–2002	Young pts (17–50 years)
			Severe DDH (Crowe III or IV)	Custom uncemented (Symbios)	AL (Watson-Jones)	1990–2013	Pts w/ DDH (Crowe grade III or IV)
Flecher, 2018[5]	Int Orthop	Case series	None	Custom uncemented (Symbios)	AL (Watson-Jones)	1992-2005	Conversion from fused hip to THA
Akbar, 2009[44]	Acta Orthop	Case series	None	Custom uncemented (Orthopedic Services)	AL	1992-1994	Young pts < 40 years

Abbreviations: AL, anterolateral; PL, posterolateral; DL, direct lateral; P, posterior; pts, patients; DDH, developmental dysplasia of the hip; THA, total hip arthroplasty; CT, computer tomography

[a]A maxmimum of 16% of the THAs included were revision surgeries.

[b]Two different stem generations were used, the first generation before January 2001 (n=50), and the second generation after January 2001 (n=8).

mostly unselected including standard/general cases that have no major anatomical deformities, although one study had a comparator group consisting of patients with severe DDH (Crowe III or IV).[4]

None of the studies found were randomized controlled trials; there was only one prospective non-comparative study (case series),[13] while seven were retrospective comparative studies (case controls)[9,46–51] and six were retrospective non-comparative studies (case series).[4–6,15,43,44] Four studies compared custom *versus* off-the-shelf stems,[9,46,48,50] one of which also compared primary *versus* revision custom stems.[9] Additionally, one study compared short *versus* ultra-short custom stems,[49] one study compared CT-based *versus* radiograph-based custom stems,[51] one study compared outcomes in patients with severe DDH (Crowe III or IV) *versus* young patients (< 50 years),[4] and one study compared THA using custom stems *versus* hip resurfacing.[47]

Quality assessment using the JBI 10-point checklist indicated that four studies[43,44,49,50] scored seven or more points, six studies[4–6,46–48] scored between four and six points, while four studies[9,13,15,51] scored three points or less (Fig. 2).

Brands and designs of custom stems

The 14 included studies reported on THA using custom stems designed by seven different manufacturers: Symbios (four studies), Scandinavian Customized Prosthesis (two studies), Endopro (two studies), Orthopedic Services (one study), Biomet (one study), Stanmore (two studies) and DePuy (one study) (Table S1 in the supplemental material). It is worth noting that one of the

Table 2. Patient demographics of the studies included in the systematic review

Author, year	Control/ comparator	Indications: Primary OA	AVN	DDH (Crowe I–IV)	DDH (Crowe I & II)	DDH (Crowe III & IV)	Posttraumatic	Other	Initial cohort: Hips	Patients	Age (yrs): Mean	±SD	(Range)	BMI (kg/m²): Mean	±SD	(Range)	Male: n	(%)
Short-term follow-up (≤ 2 years)																		
Sandiford, 2010[47]	Custom stem vs	141 (100%)							141	134	54		(25 –65)	26		(17 –38)	75	(56%)
	hip resurfacing	141 (100%)							141	137	55		(28 –65)	26		(18 –36)	93	(68%)
Grant, 2005[50]	Custom uncemented vs				Non-inflammatory arthritis				19	37	52		(31 –65)				16	(43%)
	off-the-shelf cemented				Non-inflammatory arthritis				19									
Bargar, 1989[9]	Custom primary vs				Pain and disability				81		54							
	custom revision vs				Pain and disability				75									
	off-the-shelf primary & revision[b]				Pain and disability				25		54							
Mid-term follow-up (3–10 years)																		
Chow, 2015[46]	Custom vs				OA, AVN, post-traumatic, inflammatory arthritis				69	61[a]	56	±9	(16 –69)	29	±6[a]	(26 –55)[a]	35	(57%)
	off-the-shelf				Not specified				148	139[a]	65	±12	(30 –86)	29	±7[a]	(20 –67)[a]	79	(57%)
Al-Khateeb, 2014[43]	None				Secondary OA to Legg-Calve-Perthes disease				15	14	33		(23 –55)				6	(43%)
Benum, 2010[13]	None	58 (30%)	7 (4%)	88 (46%)				38 (20%)	191		48		(20 –65)				76	(39%)
Götze, 2009[48]	Custom vs	11 (46%)	2 (8%)	9 (38%)			2 (8%)		24	20	54		(32 –65)					
	off-the-shelf	13[c] (57%)		6[c] (26%)				3[c] (13%)	23	20	59		(45 –75)					
Albanese, 2009[49]	Short custom vs				Primary and secondary OA					11[a]	63	±10		25	±4		9	(82%)
	ultra-short custom				Primary and secondary OA					26[a]	50	±9		26	±4		22	(85%)
Reize, 2007[15]	None	100 (57%)	11 (6%)	35 (20%)			5 (3%)	60[b] (34%)	175		54		(26 –68[b])					
Wettstein, 2005[6]	None	62 (100%)							62	57	57		(35 –64)				33	(58%)
Aubaniac, 1995[51]	Custom from CT (Symbios) vs	81 (24%)		94 (28%)			37 (11%)	128[b] (38%)	215		56							
	custom from radiograph (Egoform)								122		49							
Long-term follow-up (> 10 years)																		
Jacquet, 2020[4]	Young patients (< 50 years) vs	41 (18%)	77 (33%)		88 (38%)		27 (12%)		233[a]	212	40	±7	(20 –50)	25	±5	(16 –48)	106	(50%)
	Severe DDH (Crowe III or IV)					26 (100%)			26	23[a]	45	±12	(17 –73)	27	±6	(16 –52)	13	(62%)
Flecher, 2018[5]	None			3 (13%)			6 (26%)	14 (61%)	23	23	49	±9	(28 –69)	25		(19 –33)	13	(57%)
Akbar, 2009[44]	None	2 (3%)	16 (22%)	25 (35%)			12 (17%)	17 (24%)	72	61	35		(22 –40)	26	±5	(18 –41)	33[a]	(54%)

Abbreviations: DDH, developmental dysplasia of the hip; OA, osteoarthritis; AVN, avascular necrosis; BMI, body mass index; yrs, years; CT, computer tomography

[a]Discrepancy in data between tables and text

[b]A maxmimum of 16% of the THAs included were revision surgeries. For the paper by Reize & Wülker[15] some of the revision patients were > 60 years.

[c]Missing data for 1 hip

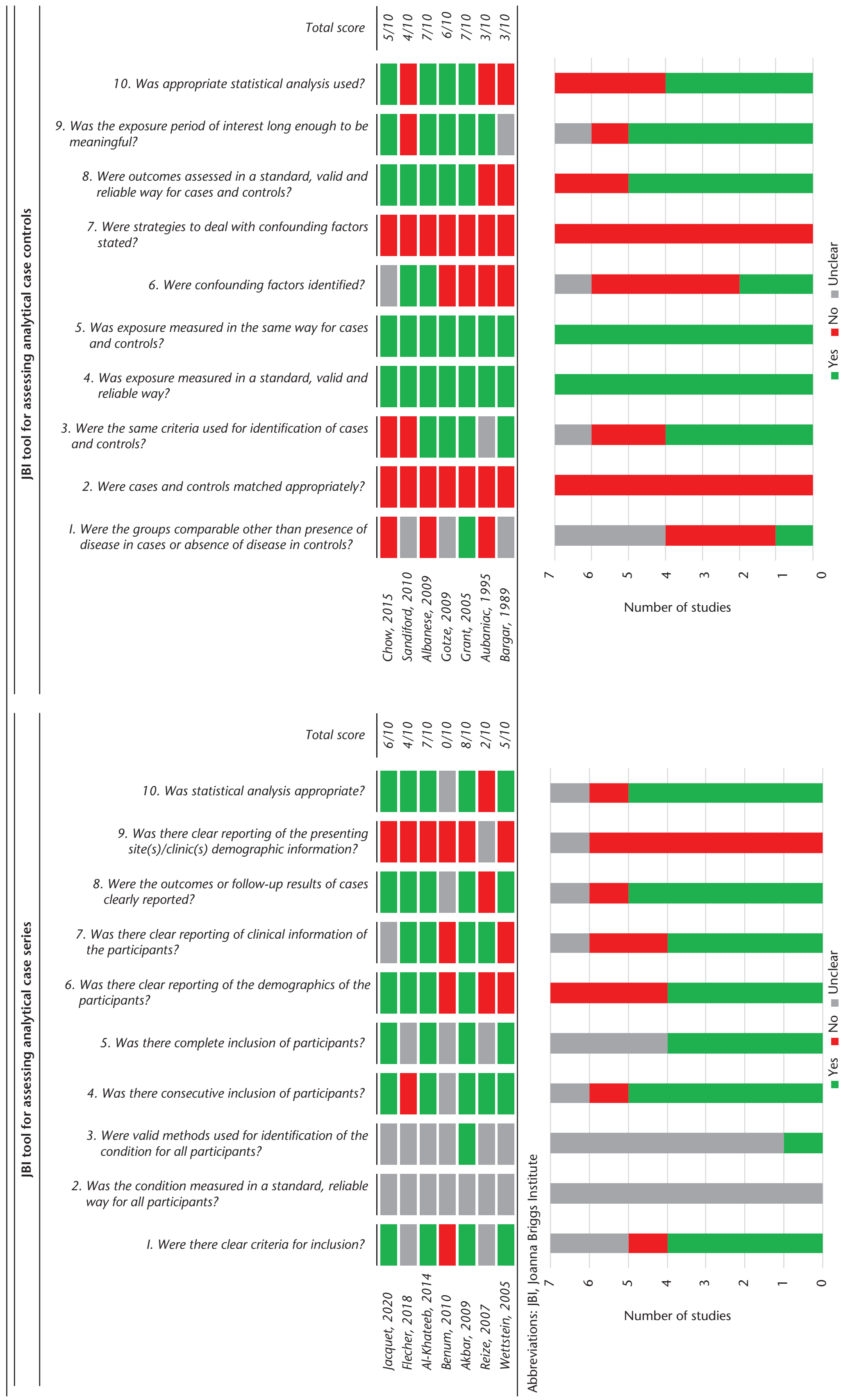

Fig. 2 The methodological quality of the studies was assessed according to the Joanna Briggs Institute Checklist.

Table 3. Rates of revisions, reoperations and survival for the studies included in the systematic review

Author, year	Control/comparator	FU (yrs)	Revision rate		Reoperation rate		KM survival (revision of any component for any reason)			KM survival (stem revision for any reason)			KM survival (stem revision for aseptic reasons)		
			n	(%)	n	(%)	FU (yrs)	(%)	(95% CI)	FU (yrs)	(%)	(95% CI)	FU (yrs)	(%)	(95% CI)
Short-term follow-up (≤ 2 years)															
Sandiford, 2010[47]	Custom stem vs	2	0	(0%)											
	hip resurfacing	1	0	(0%)											
Bargar, 1989[9]	Custom primary vs	2	1	(1%)											
	custom revision		1	(1%)											
Mid-term follow-up (3–10 years)															
Chow, 2015[46]	Custom vs	6	2	(3%)											
	off-the-shelf	6	2	(1%)											
Al-Khateeb, 2014[43]	None	10	3	(20%)	2	(13%)				10	100%				
Benum, 2010[13]	None	7	2	(1%)	0	(0%)									
Götze, 2009[48]	Custom vs	4	2	(8%)											
	off-the-shelf	5	0	(0%)											
Reize, 2007[15]	None	6	0	(0%)											
Wettstein, 2005[6]	None	8			0	(0%)									
Long-term follow-up (> 10 years)															
Jacquet, 2020[4]	Young patients (< 50 years) vs	20	23	(10%)	12	(5%)	20	77%	(72–83)				25	95%	(92–97)
	Severe DDH (Crowe III or IV)	16	6	(23%)	1	(4%)	15	73%	(45–100)				15	88%	(77–99)
Flecher, 2018[5]	None	15	1	(4%)	2	(8%)	15	96%	(92–99)						
Akbar, 2009[44]	None	14	5	(7%)						14	100%				

Abbreviations: CI, confidence interval; FU, follow-up; KM, Kaplan-Meier; yrs, years

aforementioned studies compared outcomes of custom stems by Stanmore *versus* DePuy, while two studies did not specify the stem manufacturer. All 14 studies specified that the custom stems used were uncemented, of which 11 specified that they were coated with hydroxyapatite (HA), either fully (n = 3) or partially (n = 6). Only nine studies specified that custom stems were made of titanium, while the other five studies did not specify stem material. The custom stems were described as “straight” in three studies, “metaphyseal”-engaging/-filling in four studies and “intramedullary proximal femoral fit” in two studies, while stem morphology was not specified in five studies. The stems were ultra-short, short or medium-short in three studies, long in five studies, and the length was not specified in six studies. Detailed information regarding stem design and stem positioning are presented in the appendix if available in the original articles.

Survival, revisions and reoperations

Kaplan-Meier survival for custom stems was reported in three studies (Table 3): 100% at ten years considering stem revision for any reason,[43] 100% at 14 years considering stem revision for any reason[44] and 95% at 25 years considering stem revision for aseptic reasons.[4] None of the four studies that compared custom to off-the-shelf implants reported stem survival.

Revisions were reported in ten studies, with rates ranging from 0% to 1% in the short-term (≤ 2 years),[9,47] 0% to 20% in the mid-term (> 2 to 10 years)[6,13,15,43,46,48,51] and 4% to 10% in the long-term (> 10 years)[4,5,44] (Table 3, Fig. 3). Of the four studies that compared custom to off-the-shelf stems, only two reported revision rates[46,48] and found them to be higher in the mid-term for custom stems (3% to 8% *versus* 0% to 1%), but neither mentioned statistical significance, likely because their cohort sizes were insufficient.

Reoperations that did not require implant removal were reported in five studies, with rates ranging from 0% to 13% in the mid-term (> 2 to10 years)[6,13,43] and 5% to 8% in the long-term (> 10 years)[4, 5] (Table 3). None of the four studies that compared custom to off-the-shelf stems reported on reoperation rates.

Complications

Complications including intra- and post-operative events were reported in 13 studies, with rates ranging from 3% in the short-term (≤ 2 years),[47], 0% to 11% in the mid-term (> 2 to 10 years)[6,13,15,43,46,48,51] and 0% to 4% in the long-term (> 10 years)[4,5,44] (Table 4). Of the four studies that compared custom to off-the-shelf stems, only two reported complication rates[46,48] with conflicting results; one reporting fewer complications using off-the-shelf stems (8% *versus* 0% at 5 years),[48] while the other reported fewer complications using custom stems (0% *versus* 3% at 6 years),[46] but neither study mentioned statistical significance, likely because their cohort sizes were insufficient. Of the 13 studies that reported complications, six specified that there were no intraoperative complications, while seven specifically reported them. The most common intraoperative complication was femoral fracture. Reize & Wülker[15], who reported on one of the largest series of 175 hips, used a straight, rectangular, Ti-alloy

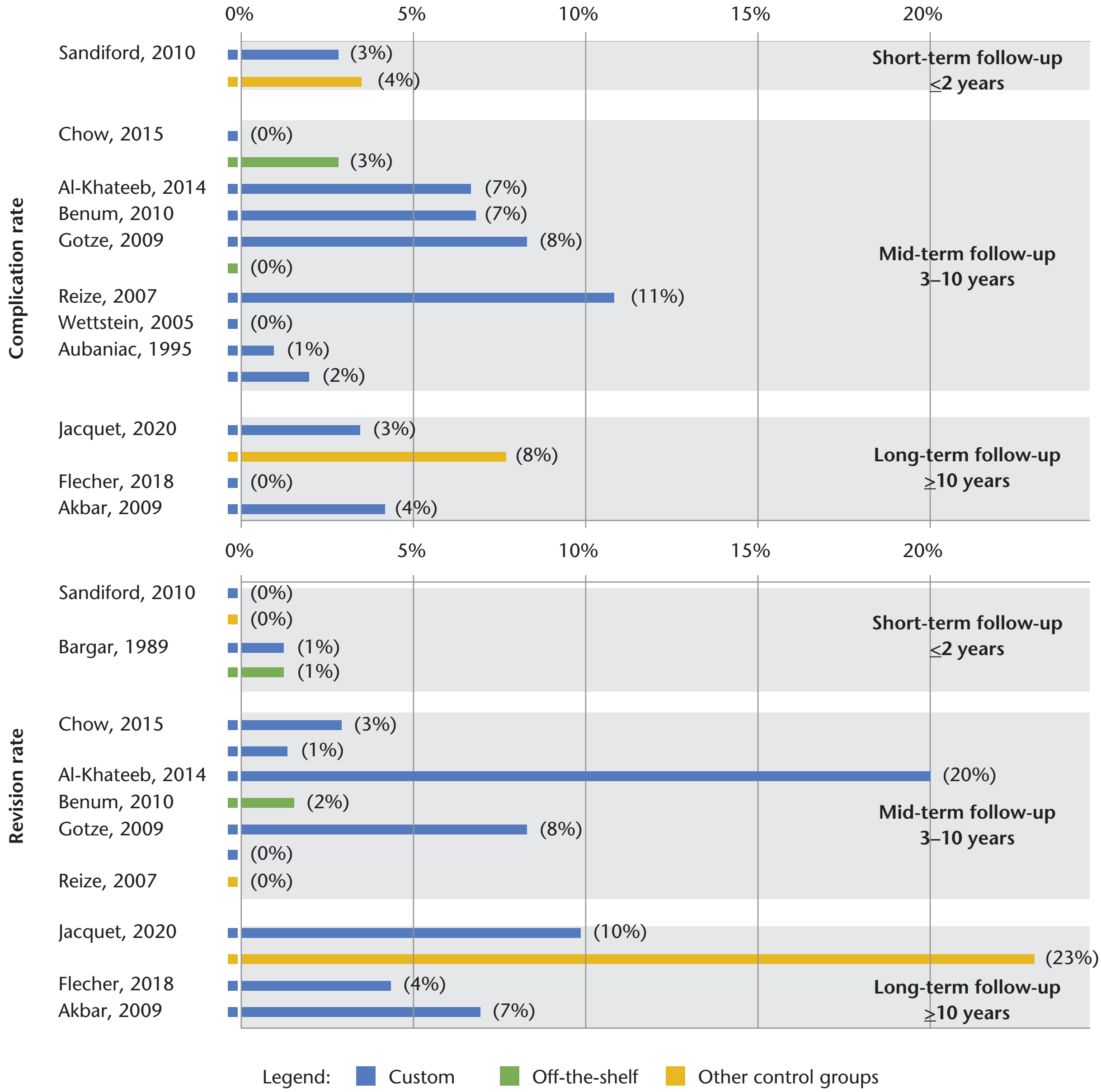

Fig. 3 Complications rate and revisions rate reported across the included studies.

implant (Adaptiva, Endopro), and observed 12 greater trochanter fractures and eight shaft fissures requiring wire cerclage, notably "in patients who received large-volume stems with prominent ventral ribs," and that excessive limb-length was a common problem "because surgeons could not reach the correct implantation depth". Of the four studies that compared custom to off-the-shelf stems, only two reported intraoperative complication rates with conflicting results; one reporting fewer complications using off-the-shelf stems (4% *versus* 0% at 5 years),[48] while the other reported fewer complications using custom stems (0% *versus* 1% at 6 years),[46] but neither mentioned statistical significance, likely because their cohort sizes were insufficient. Only one of the 14 studies reported an instance where the custom prosthesis failed to fit adequately; however, this was not in the primary THA group, but in the first revision THA case. Bargar[9] reported that during revision surgery "an unrecognized open-section defect was present laterally from a guttering of the femur at an earlier revision", which made it impossible to implant the stem. In this case, the patient had a second surgery with another custom prosthesis two weeks later. The authors report that, following that instance, they requested the manufacturer to change the way in which custom stems are designed thereafter: "(1) increased anterior flare, (2) use of collars if the canal-calcar ratio was greater than

Table 4. Information on complications for the studies included in the systematic review

Author, year	Control/comparator	FU (yrs)	Complications rate*		Intraoperative complications rate*		Detailed intraoperative complications	LLD PREOP (mm)			LLD POSTOP (mm)			Notes
			n	(%)	n	(%)		Mean	±SD	(Range)	Mean	±SD	(Range)	
Short-term follow-up (≤ 2 years)														
Sandiford, 2010[47]	Custom stem vs	2	4	(3%)	0	(0%)								
	hip resurfacing	1	5	(4%)	0	(0%)								
Grant, 2005[50]	Custom uncemented vs	2	2	(5%)	0	(0%)								
	off-the-shelf cemented	2												
Bargar, 1989[9]	Custom primary vs	2	11	(7%)	11	(7%)	Femoral cracks treated by CW							
	custom revision													
Mid-term follow-up (3–10 years)														
Chow, 2015[46]	Custom vs	6	0	(0%)	0	(0%)								
	off-the-shelf	6	4	(3%)	1	(1%)	Femoral fracture treated by CW							
Al-Khateeb, 2014[43]	None	10	1	(7%)	0	(0%)								
Benum, 2010[13]	None	7	13	(7%)	2	(1%)	Femoral fissures treated by CW							
Götze, 2009[48]	Custom vs	4	2	(8%)	1	(4%)	Femoral fracture treated by CW							
	off-the-shelf	5	0	(0%)	0	(0%)								
Reize, 2007[15]	None	6	20	(11%)	20	(11%)	Femoral fractures/ fissures treated by CW							LLD in 24%
Wettstein, 2005[6]	None	8	0	(0%)	0	(0%)								
Aubaniac, 1995[51]	Custom from CT (Symbios) vs	4	15	(4%)	2	(1%)	Femoral fractures treated by CW							
	custom from radiograph (Egoform)	5			2	(2%)	"Errors in anteversion"							
Long-term follow-up (> 10 years)														
Jacquet, 2020[4]	Young patients (<50 years) vs	20	8	(3%)	0	(0%)					2		(0 –13)	LLD >5 mm in 6%
	Severe DDH (Crowe III or IV)	16	2	(8%)	0	(0%)					7		(0 –17)	
Flecher, 2018[5]	None	15	0	(0%)	0	(0%)		21	±12	(-5 –50)	8	±2	(0 –12)	LLD >5mm in 22%
Akbar, 2009[44]	None	14	3	(4%)	1	(1%)	Femoral fissure left untreated							

Abbreviations: FU, follow-up; yrs, years; LLD, limb length discrepancy; CW, cerclage wires; CT, computer tomography

*None of these complications required revision or reoperation

0.7, (3) bevelling of AP surfaces, and (4) increased stem diameters to provide better fill in the AP dimension distally".

Clinical scores

Post-operative HHSs were reported in 13 of the 14 studies, with scores ranging from 95 to 96 in the short-term (≤ 2 years),[47,50] 80 to 99 in the mid-term (> 2 to 10 years)[6,9,15–17,43,46,48,49,51] and 87 to 94 in the long-term (≥ 10 years)[4,5,44,45] (Table 5, Fig. 4). All four studies that compared custom to off-the-shelf stems reported post-operative HHS; three favoured custom stems (96 *versus* 94, 95 *versus* 94 and 94 *versus* 86),[9,46,50] while one favoured off-the-shelf stems (91 *versus* 95),[48] but none found a statistically significant difference between groups.

One study also reported the Oxford hip score (OHS) and the hip disability and osteoarthritis outcome score (HOOS), while two studies reported the University of California Los Angeles (UCLA) activity score and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and three studies reported the Postel Merle d'Aubigne (PMA) score (Table 5 and Table S2 in the supplemental material). Of the four studies that compared custom to off-the-shelf stems, only one reported on clinical scores other than the HHS, with a lower (better) postoperative WOMAC for off-the-shelf stems (four *versus* three), although the difference was not statistically significant.[46]

Radiographic outcomes

Radiographic outcomes of the custom stems were reported in 11 of the 14 studies, with three studies reporting on bony ingrowth and pedestal formation, four studies reporting on stem migration and femoral cortical hypertrophy, six studies reporting on femoral radiolucent lines and seven studies reporting on stem subsidence, femoral osteolysis and heterotopic ossification (Table 6). None of the studies reported on 3D sizing or positioning of implants, nor compared the planned and postoperative hip architecture.

Of the four studies that compared custom to off-the-shelf stems, only two reported radiographic outcomes[46,48]

Table 5. Clinical outcomes of the studies included in the systematic review

Author, year	Control/comparator	Final cohort		FU (yrs)		HHS preop			HHS postop			Pain free postop	
		Hips	Patients	Mean	(Range)	Mean	±SD	(Range)	Mean	±SD	(Range)	n	(%)
Short-term follow-up (≤ 2 years)													
Sandiford, 2010[47]	Custom stem vs		134	2	(0–3)	46		(7–87)	96		(65–100)		
	hip resurfacing		137	1	(0–3)	54		(7–97)	97		(59–100)		
Grant, 2005[50]	Custom uncemented vs			2					95[b]				
	off-the-shelf cemented			2					94[b]				
Mid-term follow-up (3–10 years)													
Chow, 2015[46]	Custom vs	69	61[a]	6	(5–7)	55		(20–90)	96		(55–100)		
	off-the-shelf	148	139[a]	6	(4–8)	52		(10–100)	94		(55–100)		
Al-Khateeb, 2014[43]	None	15	14	10	(5–15)	41		(27–57)	80		(51–94)		
Benum, 2010[13]	None	152		7									
Götze, 2009[48]	Custom vs			4	(3–5)	43	±9	(29–61)	91	±11	(56–100)		
	off-the-shelf			5	(3–5)	46	±16	(14–72)	95	±6	(76–100)		
Albanese, 2009[49]	Short custom vs			3		43			95				
	ultra-short custom			3		47			96				
Reize, 2007[15]	None	175		6	(4–7)	47			96			148	(84%)
Wettstein, 2005[6]	None	62	57	8	(6–11)	61	±8	(28–78)	99	±2	(84–100)		
Aubaniac, 1995[51]	Custom from CT (Symbios) vs			4		44			93				
	custom from radiograph (Egoform)			5					91				
Bargar, 1989[9]	Custom primary vs			3[c]					94				(89%)
	custom revision vs			3[c]					82				
	off-the-shelf primary & revision			3[c]					86				(36%)
Long-term follow-up (> 10 years)													
Jacquet, 2020[4]	Young patients (< 50 years) vs		200	20	(14–27)	54		(26–87)	94		(48–100)		
	Severe DDH (Crowe III or IV)	26	23[a]	16	(10–22)	42		(21–70)	82		(48–96)		
Flecher, 2018[5]	None			15	(9–22)	59		(40–84)	89		(75–100)	21	(91%)
Akbar, 2009[44]	None	70	59	14	(10–16)	41		(17–58)	87		(42–100)	44	(63%)

Abbreviations: FU, follow-up; yrs, years; HHS, Harris hip score; CT, computer tomography; preop, preoperatively; postop, postoperatively

[a]Discrepancy in data between tables and text

[b]Values reported are median, not mean

[c]Number of hips at this follow-up not specified

and found 100% bony ingrowth and no radiolucent lines for both custom and off-the-shelf stems. Additionally, custom stems had lower rates of stem subsidence (0% *versus* 1%)[46] and femoral osteolysis (29% *versus* 35%),[48] but higher rates of stem migration (17% *versus* 9%),[48] femoral cortical hypertrophy (13% *versus* 0%)[48] and pedestal formation (3% to 17% *versus* 0% to 1%).[46,48] Neither study mentioned statistical significance, likely because their cohort sizes were insufficient. The difference between stem subsidence and stem migration was not clearly specified in any of the studies; however, the thresholds were different across studies, ranging from > 2mm to > 5mm.

Discussion

The most important finding of this systematic review is that primary THA using 3D image-based custom stems in unselected patients provides limited but promising clinical and radiographic outcomes in the short-, mid-, and long-term. Despite excellent survival of custom stems, ranging from 100% at 14 years to 95% at 25 years, the evidence available in the literature remains insufficient to recommend routine use of custom stems in unselected patients. Nonetheless, the present systematic review is the first to synthesize the literature to date on the under-investigated topic of custom stems for THA. While the four comparative studies found no statistically significant differences between outcomes of custom stems and off-the-shelf stems, they reported contradictory findings regarding complication rates and clinical scores, which were better for custom stems in three studies,[9,46,50] but better for off-the-shelf stems in one study.[48] These contradictory findings could be explained by the heterogeneity in custom stem designs by the seven different manufacturers, which varied in terms of proximal geometry (straight or metaphyseal-engaging), HA coating (full or partial), and length (ultra-short, short, medium-short or long).

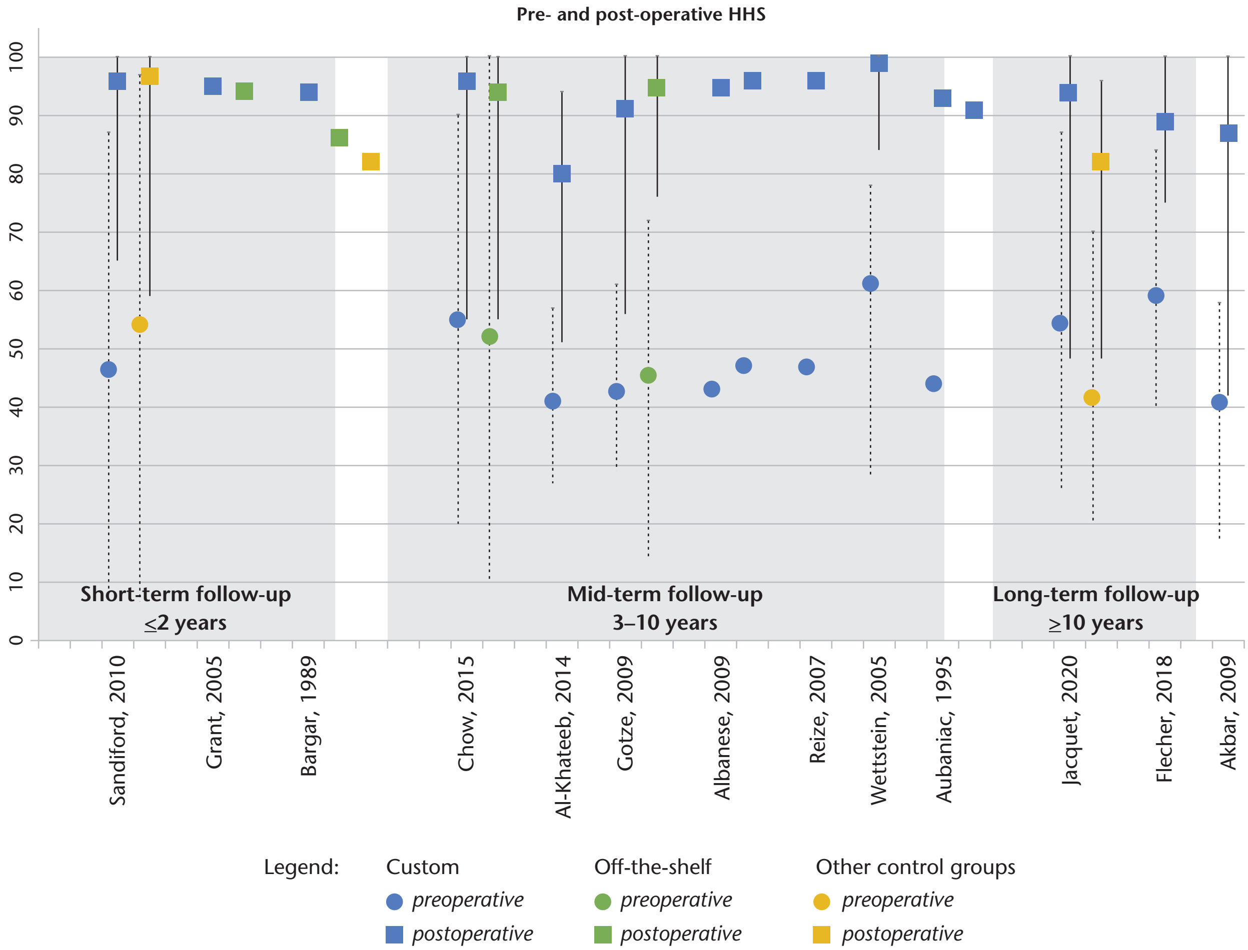

Fig. 4 Pre- and post-operative Harris hip score reported across the included studies.

Across the 14 studies included in this systematic review, reporting on stem design and manufacturing techniques was both insufficient and inconsistent, which made it difficult to classify stems according to these parameters. Only two studies[6,46] provided sufficient information on the six design parameters of manufacturer, proximal geometry, length, fixation, material and coating (seven studies reported on five parameters, three reported on four, one reported on three, and one reported only on one). The findings of the present systematic review therefore suggest that it would be inappropriate to consider all custom stems as a single entity or family of implants, but rather they should be considered as a concept that includes several designs and philosophies. Future studies on custom stems should provide specific details regarding proximal geometry, length, fixation, material and coating, as well as management of femoral offset and anteversion. The authors also propose a classification system to help patients and surgeons distinguish between custom stem designs based primarily on their proximal geometry and length (long or short metaphyseal-engaging stems, or long or short straight stems).

Custom stem manufacturers can either base their design on an off-the-shelf stem, which they modify to match patient anatomy in one plane[15,48] or base their design on 3D patient anatomy, by fully optimizing femoral fit and fill in 3D.[4–6] When creating custom stems, it is important that surgeons have an active role in stem design, instead of blindly trusting the manufacturer, because stem design must be fine-tuned to ensure it matches patient anatomy and corrects patient pathology. Thus, customization should be considered a continuous process of matching intramedullary anatomy, correction or restoration of extramedullary hip architecture, as well as optimizing surgical techniques.

Even though custom stems are designed preoperatively from 3D images of the femur, it is possible that during surgery they fail to fit adequately in the femoral canal or cause femoral fractures or cracks as the surgeon tries to implant them. Across the 14 studies reviewed, none of the 3D

Table 6. Radiographic outcomes of the studies included in the systematic review

Author, year	Control/ comparator	Final cohort		FU (yrs)		Bony ingrowth		Stem subsidence		Stem migration		Femoral osteolysis		Femoral radiolucent lines		Femoral cortical hypertrophy		Heterotopic ossification		Pedestal formation	
		Hips	Patients	Mean	(Range)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
Short-term follow-up (≤ 2 years)																					
Bargar, 1989[9]	Custom primary vs	81		2				12[c]	(8%)												
	custom revision	75																			
Mid-term follow-up (3–10 years)																					
Chow, 2015[46]	Custom vs					69	(100%)	0[b]	(0%)					0	(0%)					2	(3%)
	off-the-shelf					148	(100%)	1[b]	(1%)					0	(0%)					1	(1%)
Al-Khateeb, 2014[43]	None	15	14	10	(5 –15)									2	(13%)			1	(7%)		
Götze, 2009[48]	Custom vs	24	20							4[d]	(17%)	7	(29%)	0	(0%)	3	(13%)			4	(17%)
	off-the-shelf	23	20							2[d]	(9%)	8	(35%)	0	(0%)	0	(0%)			0	(0%)
Albanese, 2009[49]	Short custom vs							0	(0%)					0	(0%)			0	(0%)		
	ultra-short custom							0	(0%)					0	(0%)			0	(0%)		
Reize, 2007[15]	None	175		6	(4 –7)			0[b]	(0%)	0	(0%)	0	(0%)			101	(58%)	19	(11%)		
Wettstein, 2005[6]	None	62	57	8	(6 –11)			0[b]	(0%)			0	(0%)	0	(0%)			2	(3%)		
Aubaniac, 1995[51]	Custom from CT (Symbios) vs						(68%)			2[b]											
	custom from radiograph (Egoform)						(64%)														
Long-term follow-up (> 10 years)																					
Jacquet, 2020[4]	Young patients (<50 years) vs	125[a]	112	20	(15 –27)			0	(0%)			7	(6%)			6	(5%)	0	(0%)		
	Severe DDH (Crowe III or IV)	26	23[a]					0	(0%)			2	(8%)			0	(0%)	1	(4%)		
Flecher, 2018[5]	None			15	(9 –22)							1	(4%)	0	(0%)			3	(13%)		
Akbar, 2009[44]	None	70	59	14	(10 –16)			0[b]	(0%)	0[e]	(0%)	0	(0%)	3	(4%)	46	(66%)	22	(31%)		

Abbreviations: FU, follow-up; yrs, years; CT, computer tomography

[a]Discrepancy in numbers between tables and text

[b]Defined as >2mm

[c]Defined as >3mm in the first six weeks

[d]Defined as vertical migration >3mm

[e]Defined as >5mm compared with baseline AP radiographs

image-based custom stems for primary THA (1357 hips) failed to fit adequately; in fact, there was only one instance where the custom prosthesis failed to fit, and it occurred during a revision surgery, when an unrecognized open-section defect made it impossible to implant the stem.[9] Across the 14 studies reviewed, seven reported femoral fractures or cracks; with Reize & Wülker[15] who used long straight stems, reporting the highest incidence (11%), particularly in patients who received large-volume stems with prominent ventral ribs. Furthermore, the authors reported limb-length discrepancy (LLD) in 24% of patients because the surgeon could not reach the correct implantation depth. Femoral fractures or cracks ranged between 4% to 11% for long stems,[9,15,48] compared to 0% to 1% for short stems,[13,46] suggesting that longer custom stems may result in higher rates of intraoperative complications.

A drawback of using custom stems for unselected THA patients is their extra cost compared to off-the-shelf stems. In the early 1990s, custom stems were 2 to 3 times more expensive than off-the-shelf stems,[6,15] though the unit cost of custom stems is decreasing[4] with more efficient production processes as manufacturers achieve 'economies of scale'. In fact, a study from 2010[17] stated that the cost of custom stems was approximately 40% greater than that of off-the-shelf stems. It remains unclear, however, whether custom stems enable short-term savings on hospital inventory, logistics and sterilisation of instruments, and whether they have the potential to reduce long-term expenditure on reoperations and revisions. The extra cost of custom stems could be justified for unselected patients if they provide better functional outcomes or implant survival, since the cost of revision THA is significantly greater than that of primary THA.[52,53]

Performing efficient, painless and long lasting THA for young adults is probably a major challenge for the coming decade, as recent publications demonstrate relatively poor results in this physically demanding population.[54–56] From this point of view, custom implants should be considered as an opportunity to increase our understanding of THA through independent management of the intramedullary shape of the implant and extramedullary design (neck length, offset and anteversion). However, this systematic review identified an important gap in the literature, as none of the studies reported on 3D sizing or positioning of implants, nor compared the planned and postoperative hip architecture.[57–59] Future studies should provide a rigorous evaluation of custom implants, including a 3D postoperative evaluation of anatomic parameters.

This systematic review has a number of limitations. First, there were only four studies which compared custom stems to off-the-shelf stems, and only two which reported clinical and radiographic outcomes in sufficient detail, therefore a meta-analysis could not be performed. Second, HHS was the only clinical score to be widely reported across studies. However, this score is known to have a 'ceiling-effect'[60] and is therefore unable to accurately distinguish small differences in high scores across groups. Third, in terms of the quality of the included studies, four of the 14 studies had a quality score of three points or less, out of ten. Moreover, although risk of bias was assessed using the JBI checklist, the influence of detected bias on the reported outcomes and interpretation thereof cannot be determined. Fourth, there was considerable heterogeneity across the included studies in terms of stem design, patient demographics, surgical procedures, follow-up times, etc. and these were not always the same across groups in comparative studies. Nonetheless, this can also be considered a benefit of custom stems because they provided satisfactory clinical and radiographic outcomes regardless of stem design, patient demographics, surgical procedures, follow-up times, etc.

Conclusions

This systematic review demonstrated that primary THA using 3D image-based custom stems in unselected patients provides limited but promising clinical and radiographic outcomes in the short-, mid-, and long-term. Despite excellent survival, the evidence available in the literature remains insufficient to recommend routine use of custom stems in unselected patients. Reporting on stem design and manufacturing techniques was insufficient and inconsistent across studies, and future studies should specify proximal geometry, length, fixation, material and coating, as well as management of femoral offset and anteversion. The authors propose a classification system to help distinguish between custom stem designs based primarily on their proximal geometry and length.

Take home messages

- The rationale for custom stems is maximization of metaphyseal fit and fill, which could increase both rotational and axial stability.
- Primary THA in unselected patients (including standard/general cases that have no anatomical deformities) using 3D image-based custom stems provides limited but promising clinical and radiographic outcomes in the short-, mid-, and long-term. There is not sufficient evidence to demonstrate that outcomes of custom stems are better than off-the-shelf stems.
- Reporting on stem design and manufacturing techniques is insufficient and inconsistent across studies.
- A classification system could be used to help patients and surgeons distinguish between custom stem designs based primarily on their proximal geometry and length (long or short metaphyseal-engaging stems, or long or short straight stems).

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