



The accuracy of statistical shape models in predicting bone shape: A systematic review

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Abstract

Background: This systematic review aims to ascertain how accurately 3D models can be predicted from two-dimensional (2D) imaging utilising statistical shape modelling.

Methods: A systematic search of published literature was conducted in September 2022. All papers which assessed the accuracy of 3D models predicted from 2D imaging utilising statistical shape models and which validated the models against the ground truth were eligible.

Results: 2127 papers were screened and a total of 34 studies were included for final data extraction. The best overall achievable accuracy was 0.45 mm (root mean square error) and 0.16 mm (average error).

Conclusion: Statistical shape modelling can predict detailed 3D anatomical models from minimal 2D imaging. Future studies should report the intended application domain of the model, the level of accuracy required, the underlying demographics of subjects, and the method in which accuracy was calculated, with root mean square error recommended if appropriate.

KEYWORDS

3D imaging, bone, joints, modelling, orthopaedic, statistical shape modelling

1 | INTRODUCTION

Medical imaging plays a vital role in orthopaedic surgery and a more recent development is the use of three-dimensional (3D) imaging to better appreciate anatomy, assist with surgical planning, guide assistive technology such as robotics, and even to develop patient specific implants.^{1,2}

The current gold-standard for producing 3D bone models is through segmentation of images derived from Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) scans.^{3,4} CT is generally preferred when focussing on bone shape as it displays a lower margin

of error when compared to MRI derived models, which tend to be more accurate when focussing on soft tissue.⁴⁻⁶ Currently, CT-based models have been shown to have an average error of 0.15 mm and MRI-based models 0.23 mm, with both modalities displaying extremely high 3D geometric accuracy.⁴ When applied to surgery, Livyatan et al. suggest a model which displays reconstruction accuracy of 1–1.5 mm is 'desirable' whereas 2–3 mm is considered 'acceptable'.⁷

The widespread adoption of these imaging techniques has been restricted due to cost and time implications, and for CT imaging there is the issue of additional radiation exposure for the patient.^{8,9} Statistical Shape Models (SSMs) offer a potential solution to this

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problem—they can utilise common 2D imaging modalities such as radiographs to predict 3D models of a patient, thus eliminating the need for CT or MRI scans.¹⁰ The required accuracy of these SSMs will depend on their clinical application, and for their potential use in surgical planning or patient-specific implants, the accuracy will need to be within degrees (for surgical planning cuts/angles) and millimetres (in implant design, for example) of the currently accepted gold-standard. It follows that before the widespread adoption of SSMs in clinical practice, their accuracy in reconstructing bone shape must be evaluated.

Accuracy is assessed by comparing the SSM predicted bone shape with a ground truth model. Two commonly employed numerical methods exist to calculate these differences: root-mean-square-error (RMSE) and average error. RMSE is a quadratic scoring rule, with the difference between each forecast and corresponding value squared and then averaged between samples. The outcome is scale dependent.¹¹ Average error is a broad term describing the average magnitude of errors between forecast and corresponding values. Larger errors are given a higher weight in RMSE as the errors are squared before they are averaged. In average error, the forecast and its corresponding values can be found between points or between points to the surface. As these differences are small, the methods in which correspondence is calculated will not be considered in this review.

This systematic review set-out to assess whether SSMs designed to predict 3D bone shape can deliver a level of accuracy suitable for clinical application.

2 | MATERIAL AND METHODS

2.1 | Search strategy

An electronic Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) compliant search was conducted in May 2021 and then repeated in September 2022.¹² The search utilised a combination of medical subject heading terms (MeSH) and key words (Table 1). The databases searched included MEDLINE/PubMed, EMBASE and The Cochrane Library—terms were modified to meet each respective database criteria. Reference lists of included studies were also reviewed for eligibility. Any duplicate manuscripts were removed. For information which was replicated by authors in the form of a paper alongside conference proceedings, the publication with the most complete data set was retrieved.

2.2 | Selection criteria

Eligibility was confirmed where authors predicted a 3D bone model through application of 2D radiological images using an SSM and compared the predicted model to a ground truth model. Exclusion criteria included studies which did not assess accuracy, paediatric datasets, and non-English language papers—full inclusion and exclusion criteria are listed in Table 2. There were no date limits applied. In titles where inclusion or exclusion was not obvious, the full text was retrieved and reviewed.

TABLE 1 Search strategy terms for literature search on MEDLINE (via OVID).

Population AND→	Intervention AND →	Intervention/Comparison
Bone*	SSM*	Exp imaging, three-dimensional
Joint exp. Joints	Statistic* shape* model*	Exp diagnostic imaging
Hip* OR acetabulum OR femur* or pelvi*	Statistic* adj4 shape*	Exp image processing, computer-assisted
Knee* OR tibia OR fibula OR patella		Exp tomography, X-ray computed
Ankle* OR foot		CT
Lower limb		Computed tomography
Exp lower extremity		Exp magnetic resonance imaging
Hand* OR wrist* or radius OR ulna		Magnetic resonance imag*
Elbow* OR olecranon		MRI
Shoulder* OR glenohumeral OR acromioclavicular		Exp fluoroscopy
Clavicle OR humerus		Exp X-rays
Upper limb		Radiograph*
Exp upper extremity		X-ray*
Spine OR spinal OR back OR vertebra*		Exp absorptiometry, photon
Cervical OR thoracic OR lumbar		Dual energy X-ray absorptiometry
		DEXA
		DXA

TABLE 2 Inclusion and exclusion criteria.

	Inclusion	Exclusion
Population	Human, adult (≥ 18 years) Bone/group of bones	Paediatric population (< 18 years) Model unrelated to orthopaedics (e.g., chest wall, maxillofacial) Isolated soft tissue models
Intervention	3D statistical shape model Use of 2D imaging to derive predicted 3D model	Segmentation technique (e.g., manual vs. automatic segmentation)
Comparison	3D ground truth model	Experiment dataset same as training dataset
Outcome	Accuracy assessed through comparison of 3D predicted model to 3D ground-truth model using RMSE or average error	
Other	English language	Review articles, letters to the editor, supplementary articles, technique papers

Abbreviations: 2D, two dimensional; 3D, three dimensional; RMSE, root mean square error.

2.3 | Data extraction and critical appraisal

Search results were exported to a reference manager, Covidence (Veritas Health Innovation Ltd.). Two independent reviewers (AP and KK) analysed the titles and abstracts to identify studies meeting the inclusion criteria. Any conflicts between author decisions were discussed at a consensus meeting. A third reviewer (GJ) was available if an agreement could not be reached, however, there were no papers to which this applied.

The same reviewers utilised a two-part standardised form to extract data based on the Critical Appraisal and Data Extraction for Systematic Reviews of Prediction Modelling Studies (CHARMS) tool.¹³ The first form identified general study characteristics such as the publication year, study authors and anatomical area of interest. Details of the SSM were also collected, including population type (cadaver, human, plastic model), number of specimens, general demographics of specimens and the type of 3D imaging. The second form focussed on the validation experiment designed to assess accuracy—population type, number of subjects the model was tested on, method of 2D imaging, derivation of ground truth model.

Finally, the numerical value of accuracy alongside the method in which it was calculated was recorded. These were then classified as either 'RMSE' or 'average error', as described by the two equations below (Figure 1). In studies where both methods were tested, the best value was taken. Any conflicts were discussed at a consensus meeting and a third reviewer (GJ) was available if an agreement was not reached, however, there were no papers to which this applied.

2.4 | Risk of bias

Risk of Bias of included studies was assessed by two independent reviewers (AP and KK), utilising the Prediction model Risk of Bias Assessment Tool (PROBAST) tool.¹⁴ PROBAST contains a total of 20

$$RMSE = \sqrt{\frac{1}{n} \sum_{i=1}^n (\text{predicted}_i - \text{ground truth}_i)^2}$$

$$\text{Average error} = \frac{1}{n} \sum_{i=1}^n \text{abs}(\text{predicted}_i - \text{ground truth}_i)$$

FIGURE 1 Predicted_i = 3D model predicted from SSM, Ground truth_i = 3D model derived from CT/MRI imaging. CT, computed tomography; MRI, magnetic resonance imaging; SSM, statistical shape model.

signalling questions, divided into four key domains relevant to prediction models: Participants, Predictors, Outcomes, Analysis. Each domain is rated for risk of bias (low, high or unclear) based on the signalling questions. The applicability of these domains from each model is also assessed in relation to the review question.

3 | RESULTS

3.1 | Search results, study and subject characteristics

A total of 2127 citations were retrieved. After the initial screening of abstracts, the full text of 75 records were analysed (Figure 2). Following full-text review, 34 studies were included for final data extraction.¹⁵⁻⁴⁸

The 34 studies originated from several countries, with the majority of authors based in Europe. A total of 2233 images were utilised to develop 31 different SSMs—three study groups applied the same model in two separate published papers; this work is included as one model. 26 of these models (83.9%) used one scan per subject whereas three models (9.7%) utilised contralateral scans taken from the same subject. In two models it was unclear if each scan was from separate subjects. Almost all models were developed

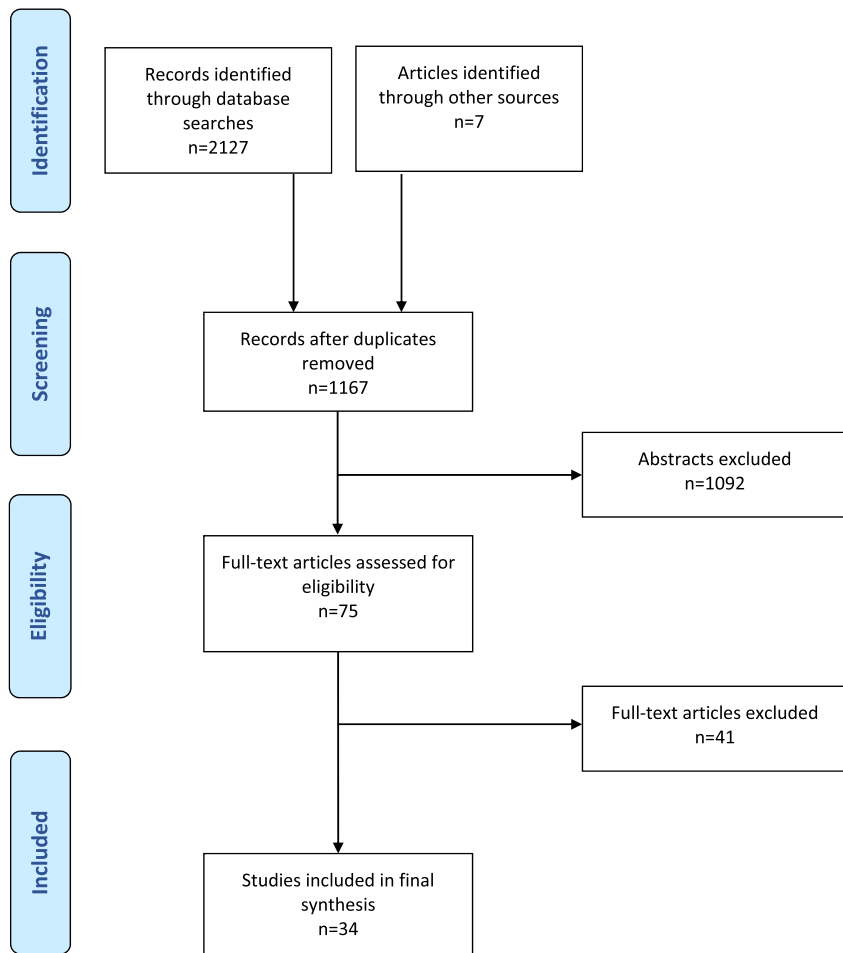


FIGURE 2 PRISMA diagram of articles selected for review.

using patients (58.1%) or cadaveric specimens (16.1%) or a combination of both (16.1%). A single study (3.2%) made use of dry bones as well as patient images to develop their SSM (Table 3). In two models (6.5%) it was unclear where images were obtained to develop their model.

Fourteen models (45.1%) specified details the gender of subjects included, with 573 males and 465 females. 14 models (45.1%) provided details of the underlying age and only one study (3.2%) commented on ethnic background of the subjects used to develop the SSM. The models described six different bone shapes: Scapula, Lumbar Vertebra, Pelvis, Femur, Patella, Tibia (Table 3).

3.2 | Assessment of accuracy

Sample sizes for validation experiments varied between 1 and 180 subjects. In total, the models were validated on 740 subjects—these consisted of patients, cadavers and artificial saw bones (Table 2). The choice of 2D imaging applied to the models varied between plain radiographs, fluoroscopy, DXA or digitally reconstructed radiographs (DRRs). The ground-truth models were derived solely from CT scans in 30 (88.2%) studies. Two papers (5.9%) used a combination of CT scan and laser-scan reconstruction. The remaining two papers (5.9%) utilised MRI scans (Table 4).

Based on Livyatan et al.'s criteria, 24 (77.4%) of the included models demonstrated desirable accuracy and five (16.1%) demonstrated acceptable accuracy.⁷ One study utilised an SSM which displayed desirable accuracy in femur reconstruction but acceptable accuracy in the tibia.²⁷ One study reported an unacceptable error of 3.2 mm.¹⁷ The three study groups which applied the same model in different papers showed desirable accuracy in both publications.^{15,16,25,36,37,48} Overall, accuracy in studies using RMSE ranged between 0.45 and 1.95 mm. Studies utilising mean errors ranged between 0.16 and 3.2 mm (Table 5).

3.3 | Risk of bias (Table 6)

Risk of bias was generally low with regards to Participants and Outcomes. Certain studies provided limited data on methods of participant selection and therefore the risk of bias was unclear. There was a high risk of bias in the Predictors and Analysis domains due to minimal information being provided with regards to the demographics of the training dataset, which is known to have a substantial effect on the accuracy of the SSM, as well as the use of small sample sizes.⁴⁹ Applicability of the models, due to the strict inclusion and exclusion criteria, was generally marked as high where datasets were complete.



TABLE 3 Details of statistical shape model development.

Study n	Model n	Statistical shape model									
		Lead author, year	Country	Anatomical location	Imaging	Anatomical specimens (n)	Use of contralateral anatomy	Population type	Males/females (n)	Age (mean ± SD or range)	
1	1	Mutsvanga, 2017 ¹⁷	South Africa	Scapula	CT	27	No	Cadaver	-	-	
2	2	Picazo, 2018 ¹⁸	Spain	Lumbar spine	qCT	90	No	Adult-alive	66/24	55.2 ± 11.3	
3	3	Whitmarsh, 2013 ³⁰	Spain	Lumbar spine	CT	66	No	Adult-Alive	0/66	54 ± 11	
4	4	Zheng, 2010 (C) ³⁵	Switzerland	Lumbar spine	CT	39 (L1 = 3, L2 = 5, L3 = 9, L4 = 14, L5 = 8)	No	Adult-Alive	-	-	
5	5	Zheng, 2011 ³⁴	Switzerland	Lumbar spine	CT	50	No	Adult-Alive	-	-	
6	6	Sadowsky, 2007 ¹⁹	United States	Pelvis	CT	110	No	Adult-Alive	110/0	-	
7	7	Zheng, 2010 (B) ³²	Switzerland	Pelvis	CT	24	No	Dry bones Adult-Alive	-	-	
8	8	Schumann, 2013 ²¹	Switzerland	Femoral head Acetabulum	CT	30	Yes	Adult-Alive	-	-	
9	9	Klima, 2016 ⁴⁶	Czech republic	Femoral shaft	CT	22	No	Unclear	-	-	
10	10	Whitmarsh, 2010 ²⁹	Spain	Proximal femur	CT	60	No	Cadaver	28/32	79 ± 11	
11	11	Hurvitz, 2008 ⁴⁵	Israel	Proximal femur	CT	17	No	Cadaver	-	-	
12	12	Vaanenen, 2015 ²⁶	Finland	Proximal femur	CT	69	Yes	Cadaver Adult-Alive	57/12	54	
13	13	Kurazume, 2009 ⁴⁷	Japan	Proximal femur	CT	56	No	Adult-Alive	-	-	
14	14	Dong, 2009 ⁴³	Switzerland	Proximal femur	CT	13	No	Unclear	-	-	
15	15	Spinelli, 2012 ²³	Spain	Proximal femur	CT	115	No	Adult-Alive	42/73	55 ± 12	
16	16	Humbert, 2017 ⁴⁴	Spain	Proximal femur	qCT	111	No	Adult-Alive	30/81	56.2 ± 12.1	
17	17	Whitmarsh, 2011 ²⁸	Spain	Proximal femur	qCT	85	No	Adult-Alive	27/58	55 ± 12	
18	18	Zheng, 2009 (B) ³⁶	Switzerland	Proximal femur	CT	30	No	Adult-Alive	-	-	
19	19	Zheng, 2009 (A) ³³	Switzerland	Proximal femur	CT	30	No	Adult-Alive	-	-	
20	20	Zheng, 2010 (A) ³⁷	Switzerland	Proximal femur	CT	30	No	Adult-Alive	-	-	
21	21	Grassi, 2021 ⁴⁰	Sweden	Proximal femur	CT	59	No	Adult-alive	40/19	58 (18–188)	
22	22	Tang, 2005 ²⁴	Canada	Distal femur	CT	40	Yes	Cadaver	-	-	

(Continues)



TABLE 3 (Continued)

Study n	Model n	Lead author, year	Country	Anatomical location	Imaging	Statistical shape model			Age (mean ± SD or range)	
						Anatomical specimens (n)	Use of contralateral anatomy	Population type		
23	22	Zhu, 2011 ³⁹	United States	Distal femur	MRI	40	No	Adult-Alive	24/16	29.9
24	23	Cerveri, 2018 ³⁸	Italy	Distal femur	CT	80	No	Adult-Alive	-	67 ± 10
25	24	Baka, 2011 ¹⁶	Netherlands	Distal femur	CT angiogram/ CT	43	No	Cadaver	30/13	23-92
26	24	Baka, 2012 ¹⁵	Netherlands	Distal femur	CT angiogram/ CT	43	No	Cadaver	30/13	23-92
27	25	Wu, 2021 ³¹	United States	Distal femur	CT	300	Unclear	Adult-Alive	-	-
28	26	Schumann, 2016 ²⁰	Switzerland	Femur Tibia	CT	129-Femur 17-Tibia	No	Adult-Alive	-	-
29	27	Gajny, 2022 ⁴¹	France	Femur Tibia	CT	158	Unclear	Cadaver	-	-
30	28	Baka, 2014 ²⁷	Netherlands	Distal femur Proximal tibia Proximal fibula	CT	61	No	Cadaver	-	21-66
31	29	Li, 2014 ⁴⁸	United States	Distal femur Proximal tibia	CT	152	Yes	Adult-Alive	34/46	M 51.1 ± 6.6 F 43.5 ± 6.2
32	29	Tsai, 2015 ²⁵	United States	Distal femur Proximal tibia Patella	CT	152	Yes	Adult-Alive	34/46	M 51.1 ± 6.6 F 43.5 ± 6.2
33	30	Lu, 2021 ⁴²	Taiwan	Distal femur, proximal tibia	CT	60	No	Adult-alive	60/0	22.89 ± 2
34	31	Smoger, 2017 ²²	United States	Patella	MRI	50	No	Cadaver	35/25	64 (44-87)

Abbreviations: CT, computerised tomography; F, female; M, male; MRI, magnetic resonance imaging.



TABLE 4 Validation experiments of included studies.

Lead author, year	Anatomical location	Validation experiment			
		Anatomical specimens (n)	Population type	2D imaging	Ground truth imaging
Mutsvanga, 2017 ¹⁷	Scapula	1	Cadaver	XR	CT
Picazo, 2018 ¹⁸	Lumbar spine	180	Adult (alive)	DXA	qCT
Whitmarsh, 2013 ³⁰	Lumbar spine	30	Adult (alive)	DXA	qCT
Zheng, 2010 (C) ³⁰	Lumbar spine	12	Cadaver	Fluoroscopy	CT
Zheng, 2011 ³⁴	Lumbar spine	4	Cadaver	Fluoroscopy	CT
Sadowsky, 2007 ¹⁹	Pelvis	11	Adult (alive)	DRR	CT
Zheng, 2010 (B) ³²	Pelvis	14	Plastic Cadaver Adult (alive)	Radiograph	CT
Schumann, 2013 ²¹	Femoral head Acetabulum	7	Cadaver	Radiograph	CT
Klima, 2016 ⁴⁶	Femoral shaft	96	Adult (alive)	DRR	CT
Whitmarsh, 2010 ²⁹	Proximal femur	30	Cadaver	DRR	qCT
Hurvitz, 2008 ⁴⁵	Proximal femur	1	Cadaver	DRR	qCT
Vaanenen, 2015 ²⁶	Proximal femur	12	Adult (alive)	DXA	CT
Kurazume, 2009 ⁴⁷	Proximal femur	4	Adult (alive)	Fluoroscopy	CT
Dong, 2009 ⁴³	Proximal femur	5	Cadaver	Radiograph	CT
Spinelli, 2012 ²³	Proximal femur	2	Cadaver	DXA	qCT
Humbert, 2017 ⁴⁴	Proximal femur	157	Adult (alive)	DXA	qCT
Whitmarsh, 2011 ²⁸	Proximal femur	30	Adult (alive)	DXA	qCT
Zheng, 2009 (B) ³⁶	Proximal femur	23	Plastic Cadaver	Radiograph	CT T-scan (laser reconstruction)
Zheng, 2009 (A) ³³	Proximal femur	1	Plastic bone	Radiograph	CT
Zheng, 2010 (A) ³⁷	Proximal femur	11	Cadaver	Fluoroscopy	CT T-scan (laser reconstruction)
Grassi, 2021 ⁴⁰	Proximal femur	11	Cadaver	DXA	CT
Tang, 2005 ²⁴	Distal femur	2	Cadaver	DRR	CT
Zhu, 2011 ³⁹	Distal femur	10	Adult (alive)	Fluoroscopy	MRI
Cerveri, 2018 ³⁸	Distal femur	20	Adult (alive)	DRR	CT
Baka, 2011 ¹⁶	Distal femur	2	Cadaver	Radiograph	CT
Baka, 2012 ¹⁵	Distal femur	10	Adult (alive)	Fluoroscopy	CT
Wu, 2021 ³¹	Distal femur	5	Adult (alive)	Fluoroscopy	CT
Schumann, 2016 ²⁰	Femur Tibia	36	Cadaver	Radiograph	CT
Gajny, 2022 ⁴¹	Femur Tibia	29	Cadaver	DRR	CT
Baka, 2014 ²⁷	Distal femur Proximal tibia Proximal fibula	16	Cadaver adult (alive)	Fluoroscopy	CT

(Continues)

TABLE 4 (Continued)

Lead author, year	Anatomical location	Validation experiment			
		Anatomical specimens (n)	Population type	2D imaging	Ground truth imaging
Li, 2014 ⁴⁸	Distal femur	3	Adult (alive)	Fluoroscopy	CT
	Proximal tibia				
Tsai, 2015 ²⁵	Distal femur	2	Adult (alive)	Fluoroscopy	CT
	Proximal tibia				
	Patella				
Lu, 2021 ⁴²	Distal femur	10	Adult (alive)	Fluoroscopy	CT
	Proximal tibia				
Smoger, 2017 ²²	Patella	49	Cadaver	Radiograph	MRI

Abbreviations: CT, computerised tomography; DRR, digitally reconstructed radiograph; DXA, dual-energy x-ray absorptiometry; MRI, magnetic resonance imaging.

TABLE 5 Best achievable accuracies categorised as root mean square error (RMSE) or average error.

Study	Anatomical location	Best accuracy (mm ± SD or range)
		RMSE
Wu, 2021 ³¹	Distal femur	1.04 ± 0.33
	Proximal tibia	1.03 ± 0.19
Klima, 2016 ⁴⁶	Femoral shaft	1.74
Li, 2014 ⁴⁸	Distal femur	1.16
	Proximal tibia	1.4
Baka, 2014 ²⁷	Distal femur	1.18
	Proximal tibia and fibula	1.56
Baka, 2012 ¹⁵	Distal femur	1.48 ± 0.41
Cerveri, 2018 ³⁸	Distal femur	0.75
Smoger, 2017 ²²	Patella	0.45 ± 0.007
Baka, 2011 ¹⁶	Distal femur	0.68
Zheng, 2009 (A) ³³	Proximal femur	1.3
Tang, 2005 ²⁴	Distal femur	1.71
Lu, 2021 ⁴²	Distal femur	0.64 ± 0.084
	Proximal tibia	0.69 ± 0.069
Average error		
Tsai, 2015 ²⁵	Distal femur	0.30 ± 0.81
	Proximal tibia	0.34 ± 0.79
	Patella	0.36 ± 0.59
Gajny, 2022 ⁴¹	Femur	1
	Tibia	1.1
Schumann, 2013 ²¹	Acetabulum	1.06 ± 0.14
	Femoral head	1.01 ± 0.16

TABLE 5 (Continued)

Study	Anatomical location	Best accuracy (mm ± SD or range)
Picazo, 2018 ¹⁸	Lumbar vertebrae (L1–L4)	1.51
Humbert, 2017 ⁴⁴	Proximal femur	0.93
Mutsvanga, 2017 ¹⁷	Scapula	3.2
Schumann, 2016 ²⁰	Proximal femur	1.12 ± 0.89
	Distal femur	1.13 ± 0.84
	Proximal tibia	0.88 ± 0.63
	Distal tibia	0.78 ± 0.56
Zheng, 2011 ³⁴	Lumbar vertebrae	0.77
Zhu, 2011 ³⁹	Distal femur	0.16 ± 1.16
Zheng, 2010 (B) ³⁷	Pelvis	1.6
Zheng, 2009 (B) ³⁶	Proximal femur	0.95 ± 0.22
Zheng, 2010 (A) ³⁷	Proximal femur	1
Zheng, 2010 (C) ³⁵	Lumbar vertebrae	1
Sadowsky, 2007 ¹⁹	Pelvis	1.42
Whitmarsh, 2013 ³⁰	Lumbar vertebrae–L2	1
	Lumbar vertebrae–L3	0.93
	Lumbar vertebrae–L4	1.34
Whitmarsh, 2010 ²⁹	Proximal femur	1.2
Hurvitz, 2008 ⁴⁵	Proximal femur	1.44
Vaanenen, 2015 ²⁶	Proximal femur	1.41
Kurazume, 2009 ⁴⁷	Proximal femur	0.8–1.1
Dong, 2009 ⁴³	Proximal femur	1.6
Spinelli, 2012 ²³	Proximal femur	1.2
Whitmarsh, 2011 ³⁰	Proximal femur	1.1
Grassi, 2021 ⁴⁰	Proximal femur	1.02



TABLE 6 Risk of bias (RoB) assessment using the PROBAST tool in order from low RoB to high RoB.

Lead Author, Year	Domain 1—Participants				Domain 2—Predictors				Domain 3—Outcome				Domain 4—Analysis		Overall Assessment	
	RoB		App		RoB		App		RoB		App		RoB		RoB	App
	DEV	VAL	DEV	VAL	DEV	VAL	DEV	VAL	DEV	VAL	DEV	VAL	DEV	VAL		
Picazo, 2018	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Whitmarsh, 2010	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Vaanenen, 2015	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Spinelli, 2012	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Humbert, 2017	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Whitmarsh, 2011	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Grassi, 2021	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Zhu, 2011	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Cerveri, 2017	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Baka, 2011	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Baka, 2012	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Baka, 2013	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Li, 2014	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Tsai, 2015	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Smoger, 2017	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Lu, 2021	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Whitmarsh, 2013	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Sadowsky, 2007	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Klima, 2016	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Zheng, 2009A	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Hurvitz, 2008	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Zheng, 2008	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Zheng, 2009B	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Mutsvanga, 2017	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Zheng, 2010B	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Kurazume, 2009	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Tang, 2005	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Zheng, 2010A	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Zheng, 2011	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Schumann, 2013	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Dong, 2009	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Schumann, 2016	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Jing, 2021	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
Gajny, 2022	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●

Note: ●, high RoB/high concern of applicability; ●, unclear; ●, low RoB/low concern of applicability. Abbreviations: App, applicability; DEV, development; VAL, validation.

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4 | DISCUSSION

The results of this review provide evidence that accurate and validated 3D anatomical models suitable for clinical use have been predicted from 2D imaging through statistical shape modelling techniques. To our knowledge, this is the first piece of work to systematically review the accuracy of SSMs.

All measurements of accuracy were calculated by comparing a reconstructed model to a ground-truth model derived from CT or MRI, which is the current gold-standard in clinical practice. Furthermore, all test subjects were independent to the training dataset. The best achievable accuracies ranged between 0.45–1.74 mm (RMSE) and 0.16–3.2 mm (Average Error). Based on Livyatan et al.'s description of acceptable clinical accuracy, only one model failed to meet the level required to be 'desirable' or acceptable.⁷ Currently, the gold standard methods of CT and MRI demonstrate accuracy within 0.5 mm when predicting 3D bone shape.⁴ The majority of SSMs included in our review do not exceed this error margin.

The calculation of accuracy in this review was understood to be the difference between the predicted 3D model and the ground-truth model, calculated as RMSE or Average Error. However, it must be noted the target accuracy of a model will depend on its intended use, and surface reconstruction error might not be the only valid measure of prediction accuracy. For example, Zheng's research group assessed the accuracy of their SSMs (based on a single AP radiograph to reconstruct the 3D anatomy of the pelvis following total hip replacement) by measuring the angular anteversion of the acetabular cup. They concluded that their SSM method was more accurate than a plain radiograph but inferior to CT-based measurements.^{50–52} Whereas Nolte et al. evaluated the accuracy of their SSM femoral bone model using a number of different metrics such as femoral head radius, neck angle, bow angle, and angle between femoral mechanical and anatomical axis, and then combined this with grey scale values to compare the mechanical properties (stress and strain) of the bone with the ground truth.⁵³ Other examples of different outcome measurements include kinematic studies where accuracy is measured in terms of rotation or translation of a particular bone and implant design where surface point accuracy is key.^{15,48,54} This highlights the importance of acknowledging different measurements of accuracy depending on the intended use of the prediction model, as well as the need for standardisation of reporting measures wherever possible. For example, a large bone (femur) or joint (hip) is likely to have a larger acceptable margin of error than a smaller bone (carpal) or joint (facet). A range of measurements which would define acceptable accuracy depending on anatomical location and intended clinical use could be derived from expert opinions and would be of significant benefit to those developing these models.

It is noteworthy that the distal femur was a commonly modelled bone, with 12 separate publications.^{15,16,20,24,25,27,31,38,39,41,42,48} A likely reason for this is the role of patient specific instrumentation (PSI) in knee replacement (TKR) surgery. PSI is a technique designed to improve overall surgical accuracy during prosthesis insertion.⁵⁵

This innovation involves designing patient-specific cutting blocks from pre-operative CT or MRI imaging alongside a full-length standing AP radiograph.⁵⁵ Intra-operatively these guides are designed to fit the patient's own bones like a glove, and once secured, guide the surgeon, via slots, to perform the bony cuts according to a previously agreed 3D plan.^{38,55} If this could be achieved without the need for CT or MRI, then this approach would become more efficient and cost-effective. Five of the studies describe sub-millimetre accuracy of the distal femur SSI model, with one study (Tsai et al.) reporting sub-millimetre accuracy for the entire knee joint.²⁵ These results are promising and suggest SSMs may play a significant role in future PSI work. Indeed, it is interesting to note that Zimmer Biomet has recently introduced the world's first CE marked, x-ray based PSI for TKR surgery.⁵⁶

4.1 | Limitations

Morphology of joints and bones are known to vary according to ethnicity and gender.^{57,58} The underlying ethnicity of the study participants was only mentioned in one of the included studies and gender was only provided in 16 papers. This key information may affect the model's accuracy depending on the patient cohort it is being applied to and resulted in several papers being categorised as 'at risk of bias'. It should be noted that one possible reason for not providing demographics may be related to anonymous cadaveric specimens being donated by medical facilities.^{17,36} However, it will be important for future studies, particularly those using patients or images from joint registries, to include this essential information to ensure that applicability for all patient populations can be assessed.

Although all included measurements were a comparison between the predicted 3D model and the ground-truth model, a meta-analysis of model accuracy was not possible due to the inconsistent use of RMSE and average error. Moreover, the average error was calculated using varying methods across the studies, with some using medians and others using means. This variation in reporting the overall accuracy meant that direct statistical comparison between values is not possible. Again, for future studies, it would be useful to standardise the method of reporting to facilitate model comparisons, and a recommended set of reporting guidelines is proposed (Figure 3). All papers aiming to validate a statistical shape model would ideally have a standardised method of calculating accuracy, such as the RMSE of average error, allowing for direct comparison. We recommend this be reported alongside other commonly used clinical bone metrics, such as neck/shaft angle, femoral mechanical and anatomical axis angle or acetabular anteversion depending on the intended use.

Also of note were the number of studies which validated their SSM using a small number of bone samples (<50) and had a prediction error above 1 mm ($n = 21$), which makes interpretation difficult. Another limitation to be aware of is that this review focussed on a highly specific area of research which meant that several of the included papers were from the same research groups, with a resultant risk of publication bias.



FIGURE 3 Proposed set of reporting guidelines for future studies.

<u>Statistical Shape Model</u>	Anatomical Location Imaging Modality (<i>including slice thickness, resolution</i>) Number of Subjects Number of Anatomical Specimens (<i>ie were contralateral images used</i>) Population Type (<i>Cadaver, Patient, Dry Bone</i>) Gender Distribution Age (<i>Range</i>) Ethnicity (<i>and stated if not known</i>) Underlying Pathology Method of Segmentation Review of Imaging (<i>Clinician/Scientist as well as level of expertise</i>)
<u>Validation Experiment</u>	2D Imaging Modality (<i>including different types and number of views</i>) Ground-Truth Imaging Modality Number of Subjects Number of Anatomical Specimens (<i>ie were contralateral images used</i>) Population Type (<i>Cadaver, Patient, Dry Bone</i>) Gender Distribution Age (<i>Range</i>) Underlying Pathology SSM application domain (<i>ie surgical planning, custom implant design</i>) Measure of accuracy (<i>RMSE alongside the relevant application variables – ie. neck/shaft angle, acetabular cup placement</i>)

5 | CONCLUSION

This systematic review provides evidence that statistical shape modelling has the potential to accurately reconstruct detailed 3D anatomical models from standard 2D imaging. Prior to acceptance in healthcare, clinical validation studies are required with sufficient sample sizes and varying populations. A standard set of reporting guidelines has been proposed, to facilitate the analysis and comparison of SSMs in future studies, particularly with regards to the detailed demographics of the training and validation sets, the required variables necessary for the application, and the method of reporting model accuracy.

AUTHOR CONTRIBUTIONS

Gareth G. Jones, Amogh Patil and Shuqiao Xie contributed to study conception and design. Data collection was performed by Amogh Patil and Krishan Kulkarni. Data analysis was performed by Amogh Patil, Krishan Kulkarni, Shuqiao Xie, Anthony M. J. Bull and Gareth G. Jones. Original manuscript was prepared by Amogh Patil. The final manuscript was reviewed and edited by Krishan Kulkarni, Shuqiao Xie, Anthony M. J. Bull and Gareth G. Jones.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interests.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the published references provided within the text. Any other data that is required may be requested from the corresponding author upon reasonable request.

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