

Three Dimensional Digital Modelling of Human Spine Anthropometrics and Kinematics from Meta-Analysis. How Relevant is Existing Anatomical Research?

Justin Magee*, Winder RJ PhD and McClelland B

Ulster University, Research Institute for Art and Design, School of Creative Arts and Technologies, Northland Road, Derry/Londonderry, Northern Ireland, UK

Abstract

Objective: This research aims to provide a complete spine digital model, including vertebral anthropometrics, posture and kinematics to inform biomechanics models.

Background: There is limited integration of published literature on quantitative anatomy, anthropometrics and posture data in current digital models. Most studies Preclude the interconnected nature of the spine.

Method: A literature review from the disciplines of anatomy, manipulative therapy, anthropometrics, occupational ergonomics, biomechanics and forensic science was conducted. The data was unified into a single normative model of the sub-axial spine using a normalisation protocol. A related kinematics meta-analysis was conducted.

Results: 2D orthographic drawings were produced from 590 individual measurements, informing a 3D model. New data relating to vertebral spatial coordinates are published. The kinematics data was applied to the 3D model, interconnecting spine regions. Range of Motion [ROM] ratios of movement were calculated throughout the spine. Inter-vertebral measurements were extrapolated, providing new data. To the best of our knowledge this digital model is the first to quantify skeletal anthropometrics, posture and kinematics.

Conclusion: The model data and the limitations discussed provide a roadmap for other spine model researchers. New basic science anatomical research is needed, revisiting quantitative anatomy and kinematics studies, using interrelated 3D digital technologies, within a standardised protocol framework for researcher to adhere to. From user-centric design, biomechanical engineering to rehabilitation care, quantification of spine anthropometrics at vertebral level and their spatial profile under motion is key. Existing publications in biomechanics, by computer scientists and mathematicians often limits to a few studies or excludes the basic science of human spine anatomy, vertebral anthropometrics, posture and kinematics, choosing to focus on functional mathematics principles. The present research provides a unified model and a potentially powerful tool in quantifying and visualising these attributes. It complements biomechanics research towards better informed and more complex models of the spine.

Keywords: Skeletal anthropometrics; Quantitative anatomy; ROM; Models and measures; Spine; 3D Digital model; Three dimensional; Meta-analysis

Introduction

Pioneering models

Human measurement models were initially developed to assist human factor design in flight simulation, 1959 [1], architecture, 1948 [2], product design, 1955 [3] and Military operations, 1955 [4], later informing gait analysis systems. Since then the anthropometrics, kinematics and biomechanics of the human spine have been extensively researched. Publications have spanned from anatomical proportion models [5] to mathematic models of spine biomechanics [6]. Despite the spine's inherent individuality, consistency of motion patterns exists. Asymptomatic and scoliotic patient groups have similar cervical spine articulation patterns, suggesting predictive hierarchies [7,8] while other have developed theoretical comparisons between human motion and mechanisms [9]. These approaches have significantly developed, through digital modeling, advancing understanding of the spine.

Current models and limitations

3D body scanning produce realistic visual models, while simplified parametric models allow for Finite Element Analysis (FEA). However, the use of anatomical literature to inform vertebrae construction is limited. Radiology has been used to model vertebrae of specific individuals [10,11], however, these models, indicative of others, were based on isolated regions anatomy. One of the more complete full spine models identified used only three studies to inform their

anthropometrics data [12]. Their single spine study reference [13] precedes most 3D spine motion research, omits significant in vivo range of motion [ROM] studies and posture profile models

The most sophisticated digital model is the Human Biodynamics Engine (HBE) and is claimed to be unprecedented in detail and resolution, with validated biomechanics using the VICON motion analysis system [14]. Its biomechanics principles of both hard and soft bodies are well referenced. One of the model deficiencies also relates to the limited skeletal anthropometric and postural data. Recognizing the extent of well conducted anatomy, kinematics and biomechanics research currently published, this research investigates if a unified model of the entire spine is achievable from existing literature data. Subsequently it proposes a new parametric model (Static posture and ROM) of the complete human spine, to inform other biomechanics research. On reflection, it challenges whether new basic science

***Corresponding author:** Justin Magee, Ulster University Research Institute for Art and Design, School of Creative Arts and Technologies, Northland Road, Derry/Londonderry, Northern Ireland, UK, Tel: +44287175355/+44[0]7720073925; E-mail: jdm.magee@ulster.ac.uk

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is required in light of limitations of current spine knowledge, inconsistencies identified in research protocol and advances with imaging technology and technologically enabled access and storage of imaging data.

Methods

A detailed literature review was carried out using the Ulster University library, electronic databases, PubMed, Science Direct and IEEE Explore. Google Scholar was used as a literature scoping tool and a hand search of all article reference lists was conducted. A detailed analysis of the widely published, Hamann-Todd collection, original spread sheet data was conducted. Literature spanned the disciplines of anatomy, manipulative therapy, anthropometrics, occupational ergonomics, biomechanics and forensic science. Search terms for skeletal anthropometrics included anatomy, spine, bone, vertebrae, spinal regions (cervical, lumbar and thoracic) measurement, anthropometrics, morphology, and normal. Search terms for the articulated model included spine, range of motion, ROM, inter-vertebral, movement patterns, articulation, biomechanics, locomotion, kinematics, modelling, named spinal regions and coupling. The inclusion and exclusion criteria were conducted separately, for anthropometrics and articulation, as follows.

Skeletal anthropometrics data

The inclusion criteria involved sub-axial spine data, collected using radiography, Magnetic Resonance Imaging (MRI) or direct measurement of anatomy, for either males or females, from white ethnic origin of any geographic region and aged between 18-65 years. The exclusion criteria precluded studies:

1. Without documented ethnic-geographical source
2. That used one figure type e.g. Endomorphic only
3. That recorded damaged or shrunken cadavers
4. That included spinal degeneration, disease or trauma
5. Without recorded average stature or other scalable references
6. Without historical data [time that the samples existed] making a normalisation process inapplicable.
7. Without measurements enabling an understanding of the anatomy's locational positioning.

Data normalisation

A normalisation rationale was adopted to allow scaling of data so that the results would correspond to a common stature, correcting issues with current practice. A theoretical UK male stature was calculated to the year which initial investigation began (2004); by linear projection between 1998 and 2002 growth patterns [15]. Scaling of anatomy to stature is published in several science disciplines [16-19] including vertebral size [20]. The present research applies these accepted principles to individual vertebrae structures, enabling data from different studies to be comparable. Using normalisation, linear measurements were scaled and then both the normalised linear and originally published angular measurements from the literature (unaffected by scaling) were averaged, increasing the sample number for each parameter. The normal scaling reference was stature; however four studies quantifying the anatomy of the atlas did not define stature [21-24]. They provided the transverse process width (TPW), which has a direct proportional relationship with the absolute size of the vertebrae [20]. These were exceptional cases required to enable an interconnected

spine model. The pelvic anatomy review was conducted with the same rigor as that of the spine but the anthropometrics are not detailed in this paper. ROM relevant to the spine is discussed and its orientation in standing position directly affected the spinal alignment. The cranium which is based on general head anthropometrics interfaces with the C1 vertebrae providing a visual reference.

Articulated spine data

The inclusion criteria involved data captured in vitro or in vivo using invasive or non-invasive methods. Only upright spinal posture was included in seated (cervical spine only) or standing (all regions) position, for male or female subjects (aged 18-65 years), from any ethno-geographic region (as no related variation exists). The exclusion criteria precluded studies:

1. With less than 10 subjects in their research (with the exception of studies with unique quantifiable data)
2. With symptoms of back pain or trauma in vivo
3. With spinal disorders, disease or degeneration in vitro
4. Without recorded documentation of age

For normal spine maximum ROM, preference data was used to ensure the entire spine was represented. These regions were defined as C0-T1, T1-T12 and T12-S1. These were preferred over measurements of C1-C7 for the cervical, and L1-L5 for the lumbar, which eliminated the cervicothoracic (C7-T1), thoracolumbar (T12-L1) and lumbosacral (L1-S1) junctions. From these connected regions the maximum ROM values were identified and average flexion and extension ratios were calculated. A meta-analysis was chosen due to the diversity in measurement methods, protocols and anatomy observed. The maximum ROM data, representing the upper limits of spinal motion, was applied to the skeletal anthropometrics model using 3dsMax animation software [http://www.autodesk.co.uk/]. Average and minimum patterns of full ROM were modelled. Inter-vertebral motion was calculated using average data from the literature, to provide the normal pattern of motion, as less representative patterns are associated with motion extremity. Within the literature, the intervertebral movement of regional junctions (C07-T1 and T12-S1) was omitted from studies which quantified the C0-C7 cervical and the L1-S1 lumbar inter-vertebral motion. Some literature indicated the nature of ROM at C7-T1 [25-27] and T12-L1 lateral bending [28-30] but fell outside the inclusion criteria due to size of study. These principles were applied to the interconnected regions of the C0-T1 cervical and T12-S1 lumbar regions.

Model building methodology

A digital model was constructed using 2D orthographic drawings of each vertebrae (sagittal, coronal and axial views), within Ashlar Vellum, Cobalt software. These were combined together, with spine posture and anatomy data, to create a 2D model (sagittal and coronal view) informing a 3D model of the entire spine using 3dsMax, with linear and angular tolerances of ± 0.1 mm and $\pm 0.1^\circ$. The model was constructed sequentially with the C7 spinous process [standing] height, providing the primary reference. Individual vertebral geometry was constructed as separate 2D drawings with the posterior body height positioned vertically, following recommended techniques [31-33]. The C7-T1 junction has geometric significant for other modelling methods. Specifically Harrison's elliptical modelling of spinal curvature for the cervical [34], thoracic [35] and subsequently lumbar regions [36]. For

each of these spinal regions the length and height was calculated using the normalised vertebral data and disc height integrated. In 3dsMax, the inter-vertebral rotations were mathematically modelled using a software script language (Maxscript) providing their own unique percentage of motion, in all three axis within each region. Numeric motion data was extrapolated for minimum, average and maximum full ROM articulation, at global and vertebral levels.

Skeletal model assumptions

The following assumptions were made during model implementation.

1. The spine was geometrically and kinematically symmetrical.
2. The ratio of stature to any individual bone was uniform and proportionate for the average normal anatomy.
3. The vertebrae bodies were rigid for the purpose of this model, despite elastic behaviour existing in each spinous process.
4. The S1 superior and L5 inferior endplates had similar geometry.
5. C7-T1 had the same ROM as C6-C7
6. T12-L1 had the same ROM as T11-T12:
7. Instantaneous axes of rotation (IAR's) were at the mid-point of the inferior adjacent vertebrae, superior endplate.
8. Distraction or compression of discs was nominal.

Results

A skeletal anthropometric model of the sub-axial spine

Sixty documents were found directly related to the quantitative measurement of human skeletal anatomy of the sub-axial spine [head, spine and pelvic anatomy], with 43 meeting the inclusion/exclusion criteria, following review. Ethno-geographic variation existed especially with the formation of the skull and pelvis. White subjects were most widely investigated and formed the basis of the data selection. The main results for the anthropometric model include:

- Full size 2D orthographic drawings of the entire spine
- A subsequent full scale 3D digital model
- Detailed spread sheets of vertebral anthropometrics and coordinate data

The model is contextualised using general anthropometric geometry representing a white male, with stature of 1758.2 mm as a full scale orthographic drawing (S1, supplementary material). The normalised measurements were calculated for the cervical, thoracic and lumbar spine regions (with 41, 17 and 20 individual measurements totalling at each region respectively). The average age of subject data for each of the spinal regions, quantifying vertebral anatomy was 32.7 years for the cervical spine, 31.6 years for the thoracic spine and 27.9 years for the lumbar spine. In sagittal view, intersecting diagonal lines connecting opposite vertebrae corners were extrapolated to provide vertebral centre locations (Table 1). This new data has particular value in the advancement of digital spine model research, from which a parametric 'S curve' profile can be plotted. Key reference landmarks, identified from the literature, enabled sequential model construction. These included the entire human posture as some reference data was derived from ground level.

- The origin (0,0,0) midway between the feet at ground level,

on the sagittal plane, based on the Z-up, Y-backwards, right-handed coordinate system.

- C7 for the upper regions of the spine geometry, informing the lumbar spine and S1 location.
- S1 informed much of the pelvic geometry, including the Hip Joint Centre (HJC).
- The HJC provided additional pelvic angle data, the acetabulum and the anterior superior iliac spine (ASIS) in sagittal view.
- The ASIS positions concluded angular and linear pelvic measurements in sagittal and coronal views.

An articulated model of the sub-axial spine

From a review of articulation literature, 107 publications contained motion data (ROM and spinal coupling) 59 met the inclusion criteria. Within these there were 123 different motion studies. Included data was reviewed and only data which enabled an interconnected spine was chosen for the ROM model. The age ranges published within the included research are outlined for the cervical (17-62 years), thoracic (18-24 years) and lumbar spine (20-59 years) for the C0-T1, T1-T12 and T12-S1 regions specifically. Average ages were provided for the cervical spine in 60% of studies (35.0 ± 10.2 years) and 25% of studies for the lumbar spine (40.5 years). However inconsistency exists with age data documentation. The main results for the articulated model include:

- A parametric ROM model of the entire interconnected spine, detailing intervertebral motion ratios within each spinal region

3D animations of minimum, average and maximum ROM accumulated across spinal regions as published on the Ulster Institutional Repository [<http://eprints.ulster.ac.uk/26663/>]

Spread sheet data and info-graphic models detailing intervertebral motion patterns for each rotational axis.

Rotations are discussed in terms of Cartesian coordinates for flexion/extension ($\pm Rx$), lateral bending ($\pm Ry$) and axial rotation ($\pm Rz$) respectively. The meta-analysis identified the scope of motion patterns achievable by normal spines. The upper and lower limits published were selected for maximum and minimum ROM, while average ROM was calculated. The flexion and extension ratios were calculated for C0-T1 (+48.4%, -51.6%), T1-T12 (+69%, -31%) and T12-S1 (+28.2%, -71.8%).

The minimum full ROM

From the meta-analysis, the minimum full ROM was published by the same researchers for C0-T1 [37] and T1-T12 [13,37]. The minimum T12-S1 flexion/extension was published by one group of researchers [38] while both lateral bending and axial rotation by another [39]. These existing data were recalculated using the previously identified intervertebral data, the upper (C0-C2) and lower (C3-T1) motion segments of the cervical region and the flexion/extension ratios in each spinal region. The minimum full ROM, accumulated across the entire spine (Figure 1a and 1b) was calculated as Rx [$133.7, -147.9^\circ$], Ry [$\pm 114.7^\circ$] and Rz [$\pm 171.7^\circ$].

Average ROM

The average full ROM (Figure 1c and 1d), accumulated across the entire spine was calculated as Rx [$180.6, -214.8^\circ$], Ry [$\pm 186.9^\circ$] and Rz [$\pm 240.5^\circ$].

Vertebrae	Body centre location [Y,Z]	Vertebrae	Body centre location [Y,Z]
C0	[-4.0, 1602.0]	T6	[32.2, 1365.9]
C1	[-0.9, 1591.2]	T7	[32.4, 1342.6]
C2	[-12.4, 1579.8]	T8	[31.2, 1317.5]
C3	[-18.3, 1561.1]	T9	[27.1, 1291.7]
C4	[-19.7, 1542.3]	T10	[20.7, 1265.9]
C5	[-18.1, 1524.6]	T11	[11.9, 1238.2]
C6	[-15.0, 1507.0]	T12	[0.0, 1208.9]
C7	[-8.5, 1489.1]	L1	[-11.7, 1176.7]
T1	[0.0, 1470.1]	L2	[-22.2, 1142.6]
T2	[10.3, 1451.9]	L3	[-29.6, 1106.8]
T3	[19.0, 1432.0]	L4	[-32.2, 1069.7]
T4	[27.5, 1411.5]	L5	[-23.6, 1031.4]
T5	[29.9, 1389.3]	S1	[-4.6, 1003.1]

Table 1: Skeletal Joe vertebrae centres in millimetres (using Z-up, Y-backwards coordinate system, where X=0 as symmetrical vertical alignment is assumed).

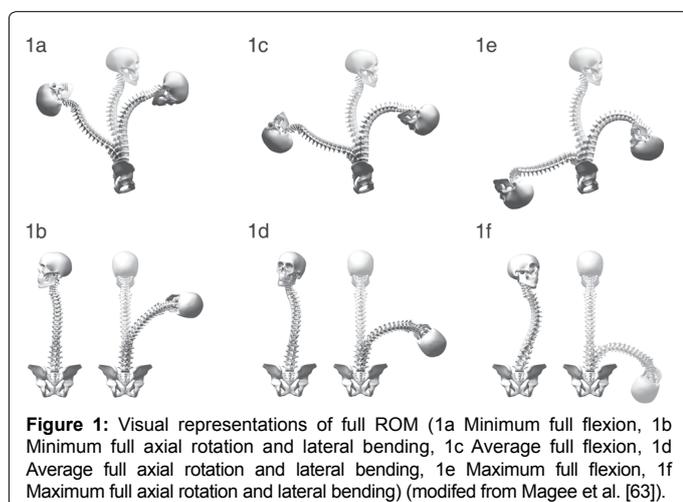


Figure 1: Visual representations of full ROM (1a Minimum full flexion, 1b Minimum full axial rotation and lateral bending, 1c Average full flexion, 1d Average full axial rotation and lateral bending, 1e Maximum full flexion, 1f Maximum full axial rotation and lateral bending) (modified from Magee et al. [63]).

Maximum full ROM

The selected data for maximum full ROM for the C0-T1 cervical spine was provided by different researchers for flexion/extension [40], lateral bending and axial rotation [41]. In the T1-T12 region the relevant data was published by the same researchers [42] and similarly for the T12-S1 region [43]. The maximum full ROM accumulated across the entire interconnected spine was calculated as Rx [+193.7°, -225.6°], Ry [$\pm 208.0^\circ$] and Rz [$\pm 255.7^\circ$]. The regional ROM values are quantified (Table 2). New calculations for each vertebra percentage of ROM within each region was calculated and embedded into a parametric model. The resulting appearance of the model is unusually extreme due to the accumulative maximum values (Figure 1e and 1f). However, it represents the full extent of motion in asymptomatic human spines, reflecting existing publications. Intervertebral rotations across the entire spine are illustrated graphically for all axis of motion (Figure 2).

Discussion and Conclusion

Most spinal research has explored isolated anatomic regions resulting in disconnected models that contradict the integrated nature of the spine. Most models isolate the anthropometrics from the kinematics yet direct relationships exist. The present research begins to identify these issues and proposes a complete spine digital model, including vertebral anthropometrics, posture and kinematics. It is formulated on the principle of asymptomatic spines with theoretically normal posture [44], and theoretically optimal biomechanics [9]. The resulting model and data is intended as an accompaniment for other established and

developing spine model research [all of which have limitations] as the complexity of this topic is vast and requires continued interdisciplinary collaboration. The model provides maximum full ROM, representing the upper extent of articulation inclusive of both the NZ and EZ of motion. The model maps a broad range of normal spine motion and is suitable for vertebral angle measurement applications. This model can extrapolate intervertebral ROM data, making it potentially useful for individual spine evaluation or estimation (orthotics and prosthetics). The average full ROM model provides a useful reference for some clinical assessment. While the skeletal anthropometrics model and all three versions of articulation [minimum, average and maximum] offer benefits within manipulative therapy, ergonomics, biomechanics engineering, spinal software development and design applications, where quantification of intervertebral mobility and geometric profiling, for a range of spines is important. Although the present model is unique being informed by existing anatomy, anthropometrics and posture literature data, it identifies significant limitations and assumptions. These are fundamental contributions to the knowledge base, informing others of the pitfalls associated with digital or mathematic spine model development.

Limitations of the model

The model is affected by several factors including shortcomings or inconsistencies in data, technological limitations, variation in methodology and subsequently, the absence of a measurement and documentation protocol to research, acquire and model spine data consistently, within existing literature. The limitations provide a roadmap for other researchers to consider.

The model is limited by:

- The availability of thoracic spine data in the literature
 - Variations in measurement protocol and documentation within existing anatomical literature.
 - Variations in methods and published limitations of technology used to measure ROM
 - Upright Posture ROM only.
- The model does not include:**
- Intervertebral coupling which had gross variation when reviewed.
 - Global coupling of adjacent spine regions [45,46].
 - ‘S’ shaped configurations under translational movements [46-48].
 - Lateral translations such as the motion between C1 and C2 (± 1.85 mm) during coupled motions [49].
 - Vertebral elevation or translations evident under axial rotation [7,50,51]
 - The elastic quality of intervertebral discs which lag at the start of a motion sequence and then rapidly increase on completion of full motion [52].
 - Sacro-iliac (SI) kinematics has not been included due to conflicting data within the literature.

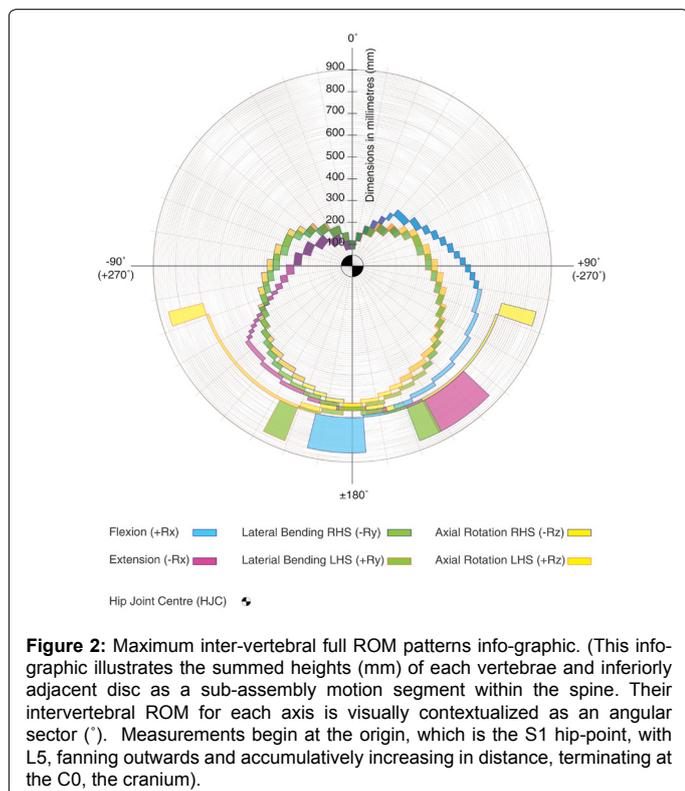
The articular facet joints which did not meet exclusion criteria vii.

Limitations from Existing Literature

Although a great deal of knowledge and data has been published relating to global and intervertebral articulation some of the motions are unknown. Inter-vertebral discs have an elastic quality which lag at

Region	C0-C2	C3-T1	C0-T1	T1-T12	T12-S1
Flexion (Rx)	30.15	63.3	93.45	62.1	38.5
Extension (-Rx)	-32.15	-67.4	-99.55	-29.9	-98.1
Lateral bending (\pm Ry)	\pm 16.1	\pm 46.1	\pm 62.2	\pm 82.0	\pm 63.8
Axial rotation (\pm Rz)	\pm 55.6	\pm 42.6	\pm 98.2	\pm 99.0	\pm 58.35

Table 2: Maximum full ROM angular values of the entire spine (°).



the start of a motion sequence and then rapidly increase on completion of full motion [52]. This elastic quality affects the nature of articulation. These non-linear phases of movement include ‘neutral (NZ) and elastic (EZ) zones of motion’ [33]. Within spine stability, there is a changing relationship from flexibility to stiffness, where the NZ requires ‘no muscular effort’ to maintain its position but the elastic zone experiences motion limitations until it reaches maximum resistance [42]. Entire ROM, which is documented in the present research, is defined as the sum of the NZ and EZ. Much of the current research does not measure the variations between these zones. The most recent reviews have identified that, “The upper cervical spine displays variations” [53]. For thoracic spine coupling; “More rigorous in vivo investigations are needed” [54]. In the lumbar region; “Normal spine motion is not yet precisely defined” [55] and in the sacroiliac joint there was; “Gross incongruity among various reports” [56]. Overall, while similar results were published for the ROM observed in the cervical and lumbar spines, there was little availability of thoracic data and disagreement or large variation reported regarding coupled motion.

The articular facet joints directly affect motion [57]. Surface area [58] or physical dimensions [59] have been published, but their spatial location relative to the vertebrae body is omitted. They too have a direct relationship to their vertebrae body height [60]. Although excluded in the anthropometrics model their function is evident in the results of the included ROM literature, as their anatomy affected mobility patterns. The articulation of the pelvis includes L5-S1 and SI motion. The L5-S1 motions were included within the lumbar spine region. However, it

was difficult to represent the nature of the SI joint movements, with large variation in movements being reported [61]. Nevertheless, their results were inconsistent with others, perhaps due to their methods of surface analysis, rather than measurements from cadavers or radiographs. Most research agreed that the movements were smaller, being “slight and merely of rocking type” [42] quantifying articulation patterns between supine to standing or sitting as 1° to 2° [62]. The most recent review of SI kinematics identified significantly conflicting results regarding “the position of the Instantaneous Axis of Rotation, the extent of movement, and the existence of motion in other dimensional planes” [56].

Articulation measurements by different investigators varied due to methodology and apparatus diversity. There were no ethnographic variations in kinematics reported in the literature, but variations existed due to age. The argument for sex variation was inconclusive within the literature with suggestions that physical length of the spine among individuals may be a more likely reason. Overall, the largest variations were because of the inherent individuality of human spines, which overshadowed other factors [operator error, apparatus and method variation and error]. The overall understanding of the spine was profoundly summarised with the statement; “To date, there are only a few studies that provide enough data to effectively calibrate finite element models for the spine due to its complexity” [53]. The present research has provided some new data but is in agreement with Cook et al.

Relevance of existing anatomical research data

There has been extensive research conducted in the pursuit of spine knowledge. Nevertheless, the present research highlights shortfalls in the literature relating to IAR positions, joint behaviour (vertebrae and SI joint) and coupling data. Within the literature, IAR data was generally descriptive, so assumptions were used based on informed literature for static position only. The IAR positions can be modified in the present parametric model as further knowledge is gained. IAR data remains the primary knowledge gap. When more fully understood, simulation of degenerative discs within individual spines would be feasible, potentially leading to customised posture and estimated ROM modelling based on known patient pathology.

Existing publications are compromised by the many variables in methods and apparatus available at the time of the research, however, provide the only source of data for spinal modelling. Much of this work predates 3D imaging analysis and current imaging data achieving systems such as the picture archiving and communication system (PACS). Subsequently, existing data has several issues in terms of documentation and protocol. To improve on this important body of work, a new approach would be required, using comparable technologies in terms of 3D data acquisition and digital measurement. For static spine anatomy, it would be achievable using 3D laser or CT scanning of cadavers, MRI on internal anatomy and surface scanning of external anatomy. For ROM motion studies, use of either kinematic CT or MRI would be appropriate for cadaver studies, whereas MRI is the only option for in vivo studies considering ethical guidelines (IRMER 2000). These digital technologies have been used occasionally to date

but not systematically under one large and all inclusive study of the spine and pelvis, form and function. The use of these methods would allow for positional data and reference measurements to be applied more reliably and the results of different researchers more effectively shared. While conducting a new study of this nature, best practice protocol established by earlier researchers should be adhered to. The methods used in the development of the present spine model may be useful informing data acquisition study design. Complementary new proposals have been recently published to help address some procedural issues which still exist [63]. The current research provides a consolidated model of existing research data in terms of quantitative anatomy, posture and range of motion data, for the entire interconnected spine. It provides a well-informed foundation model for biomechanical researchers and computer scientists to build upon; introducing their physics based data and more complex parametric control. It fills a gap in the body of knowledge in this regard.

New imaging technology and sophisticated achieving systems, supported by detailed and robust ethical approval and research governance systems (IRAS) are now higher performing, more consistent and result in comparable data, which challenges the relevance of the existing research. Using the experience and methodologies of pioneering research, new basic science studies of anatomy are needed, in keeping with 3D digital technology advancement. These should be conducted within an agreed procedural and production framework so that every new study conducted forms part of an easily integrated jigsaw of knowledge.

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