Why off-the-shelf clavicle plates rarely fit: Anatomical analysis of the clavicle through statistical shape modeling

S. Vancleef^{a,*,1}, M. Herteleer^{b,c,1}, Y. Carette^{d,2}, P. Herijgers^e, J. R. Duflou^{d,2}, S. Nijs^{c,f}, J. Vander Sloten^a

^a Biomechanics Section, KU Leuven, Leuven, Belgium

^b Organ Systems, KU Leuven, Leuven, Belgium

^c Department of Traumatology, Universitaire Ziekenhuizen (UZ) Leuven, Leuven, Belgium

^d Department of Mechanical Engineering, KU Leuven, Leuven, Belgium

^e Anatomy Skills Center, KU Leuven, Leuven, Belgium

^f Department of Development and Regeneration, KU Leuven, Leuven, Belgium

¹ These authors contributed equally to the performed research.

² Member Flanders Make

* Corresponding author: sanne.vancleef@kuleuven.be

ABSTRACT

Background

The clavicle presents a large variability in its characterizing sigmoid shape. Prominent and non-properly fitting fixation plates (FP) cause soft tissue irritation and lead to hardware removal. It is therefore key in FP design to account for shape variations. Statistical shape models (SSMs) have been built to analyze a cluster of complex shapes. The goal of this study was to describe the anatomical variation of the clavicle using SSMs.

Methods

Two different SSMs of the clavicle were created and their modes of variation were described. One model contained 120 left male and female clavicles. The other model consisted of 76 left and corresponding right clavicles, 41 originating from men and 35 from women.

Results

The model of 120 left clavicles showed that 10 modes of variation are necessary to explain 95% of the variation. The most important modes of variation are the clavicle length, inferior-superior bow, and medial and lateral curvature. Statistically significant differences between male and female clavicles were seen in length, sigmoid shape, and medial curvature. Comparison in men between left and right revealed significant differences in length and medial curvature. For women, a statistically significant difference between left and right was only seen in the length.

Conclusion

Although the operative treatment of displaced midshaft clavicular fractures has clear benefits, the variable anatomy of the clavicle often makes it challenging for the surgeon to make the plate fit adequately. Based on the identified variability in the clavicle's anatomy, it seems unlikely that a clavicle plating system can fit the entire population.

Level of Evidence: Basic Science, Computer Modeling

Keywords: Clavicle anatomy, Statistical Shape Modeling, Principal Component Analysis, Anatomic Parameters, Fixation Plate Design

41 ARTICLE

42 **Introduction**

43 Clavicular fractures are common injuries with an incidence of up to 71 per 100,000 persons per
44 year.¹⁴ The middle third of the clavicle is where 65% to 71% of these fractures occur.^{15,20} In the
45 past, these midshaft fractures were mostly treated conservatively.²⁵ However, recent high-quality
46 evidence supports the practice of operative treatment for displaced midshaft clavicle fractures.³⁴
47 Fixation plates or intramedullary nails can be used for the operative treatment of midshaft
48 clavicular fractures.^{4,13}

49 Both techniques have their advantages and disadvantages, but the most common complication of
50 plate osteosynthesis is soft tissue irritation, typically resulting in implant removal. Large
51 retrospective studies show that these removal rates are between 15% and 18.8%, and some
52 authors even report removal rates up to 53%.^{22,26,33} Naimark et al. also demonstrated that this
53 hardware removal is associated with worse long-term clinical outcomes.²⁶ Several authors have
54 suggested positioning the clavicle plate anteroinferior in order to reduce implant related
55 complications.^{7,12,17,27} Although the scientific evidence suggests that an anteroinferior position
56 could be associated with a decreasing incidence of symptomatic hardware, it is associated with a
57 more extensive muscle dissection and most available plates are designed for a superior
58 position.¹⁷

59 The renewed interest in midshaft clavicular fracture fixation has led to several anatomical studies
60 that have focused on how current plates fit the clavicle.^{6,16,24} All of these studies investigated the
61 fitting of superiorly positioned plates and showed that the current plates poorly fit the clavicle,
62 which might be a contributing factor to the high hardware removal rates.

Several authors used advanced 3-dimensional analysis methods to study the clavicle's anatomy in order to improve implant design and reduce hardware related complications.^{5,16,24} These studies demonstrate that the shape of the clavicle is highly variable and that current plates only have an optimal fit for a limited part of the population. However, the currently available studies do not systematically describe the statistical variations of the anatomical shape or identify relationships that exist between features of the anatomical shapes.

A statistical shape model (SSM) is a model that represents the mean shape of a population and its modes of variation. These SSMs have been used to describe shape variations in the population.^{31,29,10 28} Principal Component (PC) Analysis (PCA) is used to create these models. This mathematical technique separates interrelated variables into a set of linearly independent variables or modes of variation and therefore allows to show related geometries within one component to be shown.¹⁹ Few studies have used SSMs to describe the shape variations of the clavicle and in these studies used only a limited set of samples.^{10,23}

Therefore, the primary goal of this study was to describe the variability in the shape of the clavicle through SSM. The secondary goal was to describe differences between men and women, and left and right clavicles.

79 **Materials and Methods**

80 *Data*

81 A database with clavicles was set up, and 100 anonymized forensic CT scans were obtained and
82 screened by a medical doctor (MH) for abnormalities in the clavicle. No pathologic signs were
83 seen on the CT scans for 82 left and 81 right clavicles. From the University Hospital Leuven, we
84 obtained 13 additional anonymized CT scans from the thorax and shoulder containing left
85 clavicles and in which no clavicle pathologies were present.

86 The CT scans were segmented in Mimics 19 software (Mimics Innovation Suite, Materialise,
87 Leuven, Belgium) and exported as STL files. Twenty-five left historically available dry clavicles
88 were obtained from the Anatomy Skills Center (KU Leuven, Leuven, Belgium) and laser
89 scanned (LC60Dx, Nikon Metrology, Leuven, Belgium). The resulting point clouds were then
90 meshed to the STL format using 3-Matic 12 (Mimics Innovation Suite) and added to the group of
91 95, resulting in 120 left clavicles. These were first manually aligned and then automatically
92 aligned using a best fit algorithm in 3-Matic.

93 *SSM technique*

94 An SSM describes the geometrical variations or modes of variation of a set of shapes, such as a
95 set of clavicles. To create such an SSM, a 1-on-1 mesh correspondence between all bones was
96 first obtained by a non-rigid surface registration algorithm. During this process, a selected source
97 clavicle mesh was registered to all other clavicle meshes in the data set. The registration
98 algorithm was based on Danckaers et al⁹ and was implemented in Matlab (Mathworks, USA).
99 Secondly, a Procrustes analysis⁸ was performed to align the registered clavicles with the source.
100 Finally, an SSM was generated using PCA. In PCA, the mean clavicle shape and its modes of

variation or PCs were calculated. An important property of these PCs is that they are independent from each other. Each clavicle can then be described by the SSM using formula (1), in which y is a random clavicle mesh, $\bar{x}$ is the mean clavicle mesh, w corresponds to a weighting factor and p denotes the mode of variation or PC.

$$y = \bar{x} + \sum_{i=1}^n w_i p_i \quad (1)$$

Two SSMs were built: a model consisting of all left clavicles ($n=120$), and a model consisting of 152 clavicles. The latter consisted of 76 left and their corresponding right clavicles of which 41 clavicles came from men and 35 from women.

Description of the Principal Components

The anatomical description was done for the first 5 PCs. Firstly, the standard deviation (SD) of the weighting factors was calculated for each component. Secondly, to visualize the influence of one particular PC on the mean clavicle, point clouds were generated from the SSM for which only that particular PC was given a weighting factor of -3 SDs and +3 SDs. To describe the PCs, several anatomic parameters were measured using Matlab. These parameters are length, medial, lateral, and superior radius from a specific region of interest, as shown in Figure 1. The measurements were performed in a semiautomated way to improve the reliability and repeatability. The length was measured by first calculating the inertia axis of each clavicle.³⁰ Then, the clavicle and its inertia axes were aligned with the world coordinate system, and the difference between the maximal and minimal value along the longitudinal axis was used as the length of the clavicle. The medial, lateral, and superior curvature regions were first marked on the average clavicle of each SSM. Since all meshes built with the SSM are 1-on-1 corresponding,

coordinate indices of the regions of interest of the mean clavicles correspond to the same region in any other mesh resulting from that SSM. Therefore, a Matlab script was used to automatically select the regions of interest in each point cloud of the first 5 modes of variation (-3SD to +3SD) and to fit a sphere in each region.¹⁸ This sphere was then used to describe the radius of each region (Figure 2).

Evaluation of the SSMs

Evaluation of the SSMs was performed by assessing the model compactness and generalization. The model compactness is a measure of the model's efficiency and corresponds to the number of PCs required to describe a fixed preset percentage of variation.³⁵ Generalization is a measure of how well a random clavicle can be described by the model.²³ The latter was performed by a leave-one-out reconstruction and measuring the average distance between the reconstructed and original clavicle. Reconstruction was performed using an increasing number of PCs.

Evaluation of the variation in anatomy

To evaluate the variation in anatomy, the model consisting of 152 clavicles was used. In addition to the measurements to describe the principal components, 2 generalization graphs were plotted: the first containing the mean geometric error of female left, female right, male left, and male right reconstructed clavicles, and the second containing the mean geometric error of male, female, left, and right reconstructed clavicles. Paired and unpaired *t* tests were performed in Matlab to test for significant differences ($p < 0.05$) in weighting factors of the PCs between side and sex, respectively.

Results

Variation of the clavicle anatomy (120 left clavicles)

Evaluation of the statistical shape model

Figure 3 shows the compactness and generalization graphs of the SSM that included 120 left clavicles. The compactness graph shows that 10 PCs are required to explain 95% of the variation. The first 5 PCs explain, respectively, 78.5%, 6%, 3.6%, 2.6%, and 1.5% of the total variation. Adding these numbers gives 92.2% of the total variation being described. The generalization graph shows that a random clavicle can be reconstructed with an average accuracy of 0.33mm.

Description of the PCs

The mean length was 150.8 mm, the mean radius of the medial curvature was 79.5 mm, and the mean radius of the lateral curvature was 42.9 mm. The effect of the PCs on the mean clavicle can be seen in Figure 4. In the first PC, the length variation of the clavicle is most prominent and varied between 184.1 mm (- 3 SD) and 117.9 mm (+3 SD). Within the first PC, the medial and lateral curvature changed in function of the length. Larger clavicles had larger medial and lateral curvatures, and smaller clavicles had smaller medial and lateral curvatures (Table I).

In the second PC, the anatomic parameter that mainly varied was the inferior-superior bending of the clavicle. It varied between a strongly superiorly bowed clavicle (red clavicle in Figure 4), where the fitted sphere was positioned on the inferior side of the clavicle and had a radius of 193mm (-3 SD), and a lesser inferiorly bowed clavicle (blue clavicle in Figure 4), where the sphere was fitted on the superior side of the clavicle and had a radius of 324 mm (+3 SD; Figure 2).

In the third PC, the variation is seen in the volume of the clavicle. This is related to the medial and lateral curvature in which clavicles with a smaller volume have a lesser bowed medial (94.2mm [+3SD] vs. 68.5 mm[-3 SD]) and lateral curvature (46.8 mm [+3 SD] vs. 34.8 mm [-3 SD]). In the fourth PC, the largest variation is present in the medial curvature of the clavicle (114.0 mm [-3 SD] vs. 62.0 mm [+3 SD]). The radius of the lateral curvature also changes, but less prominently (49.7 mm [+3 SD] vs. 35.8 mm [+3 SD]). In the fifth PC, the main variation is found in the lateral curvature (55.2mm [-3SD] vs. 31.4mm [+3SD]). In this component, a larger volume of the sternal part of the clavicle is related to a straight shaped acromial side of the clavicle. The detailed measurements of the described principal components are provided in Table I.

Variation between men and women, left and right (152 clavicles)

Evaluation of the SSMs

In the SSM consisting of 152 clavicles, 9 components explain 95% of the variation. The first 5 components explain, respectively, 78.7%, 6.3%, 3.1%, 2.7% and 1.5% of the variation. The generalization graphs in Figure 5 show that the variation between male left and right is similar, whereas there is more variation in female right than in female left. In addition, Figure 5 shows that there is more variation in male than female clavicles and that the variation between left and right clavicles is similar. Overall, a random clavicle can be reconstructed with an average geometric error of 0.24 mm.

Description of the PCs

As can be seen in Figure 6, PC 1 corresponds to a scaling factor in length and thickness of the clavicle, and PC 2 corresponds to the inferior-superior bow. The overall sigmoid shape and

diameter of the clavicle is visible in PC 3. In PC 4, variation in the medial curvature is present, while in PC 5, variation in the lateral curvature is present. Absolute values can be found in Table II.

Evaluation of sex and side differences

Looking at the weighting factors of each clavicle for the first 5 PCs reveals a statistically significant difference between male left and right for PC 1 ($p=0.0322$) and PC 4 ($p=0.00071$). Between women left and right, only a statistically significant difference is seen in the weighting factor of PC 1 ($p=0.0072$). Comparison between the left clavicle of men and women revealed statistically significant differences in the weighting factor of the PC 1 ($p=6.00 \times 10^{-9}$), and PC 4 ($p=0.0065$). The same weighting factors differed significantly between men right ($p=1.35 \times 10^{-8}$) and women right ($p=3.95 \times 10^{-4}$). An unpaired t test between male and female showed statistically significant differences in weighting factors of PC 1 ($p=2.91 \times 10^{-16}$), PC 3 ($p=0.0292$) and PC 4 ($p=9.59 \times 10^{-6}$). The mean clavicle length was 157.3 mm in men and 144.4 mm in women. A paired t test between left and right showed statistically significant differences in weighting factors of PC 1 ($p=0.0011$), PC 2 ($p=0.0152$) and PC 4 ($p=3.48 \times 10^{-4}$). The mean left clavicle has a longitudinal length of 152 mm, and the mean right clavicle measures 150.7 mm.

Discussion

In this study, we created 2 SSMs of the clavicle, the first to describe the variation in the clavicle, the second to compare male and female, left and right clavicles. The created SSMs had excellent performances regarding their compactness and generalization. The most important finding was that the medial and lateral curvature varied largely in 4 of the first 5 PCs. This means that a clavicle's sigmoid shape is not only related to its length but that it is also an independent variable. Analysis of the side- and sex-specific models showed significant differences in the weighting factors for the modes of variation between male and female, and left and right clavicles.

Our models contained 120 left clavicles and 152 left and corresponding right clavicles, which is a larger number than other studies that used PCA to evaluate the shape of the clavicle (Daruwalla et al. – 21 clavicles, Lu et al. – 20 clavicles).^{10,23} When looking at the quality of our SSMs by evaluating the generalization and compactness graphs (Figure 3), we see that Lu et al. had a geometric error of 2mm, compared to only 0.33 mm in our study. This indicates that a random clavicle can be more accurately described by our SSM than by earlier described models. Lambert et al.²¹ did not report any data about the generalization of their model. When looking at the compactness graph of our 120 left clavicle model (Figure 3), the first PC accounted for 78.5% of variation. The SSMs of Daruwalla et al. and Lu et al. showed that the first PC explained 70.5% and only 31.9%, respectively. We believe that these differences are mainly explained by the small number of clavicles they included.

In the first PC the largest shape variation is seen in the clavicle's length, which is in accordance with the results of previous studies.^{10,21,23} The second PC of our analysis shows a large variation in the inferior and superior bending of the clavicle. Although this bending is briefly mentioned in

the articles by Daruwalla et al. and Lambert et al., its variation is not described. Aira et al. also described a large variation in the inferior bending of the clavicle.²

PCs 3, 4, and 5 of our study show varying medial and lateral curvatures independent of the clavicle's length. This is the most important finding of our study because it implies that the curved shape of the clavicle is not only determined by its length but is also highly variable. These findings are reported visually in the studies by Lu et al. and Daruwalla et al., but are not quantified. However, as mentioned before, these 2 studies only included a small number of clavicles (20 and 21 clavicles respectively)^{10,23}. The only study, to our knowledge, that used PCA to describe the variation in clavicle anatomy and that included a large number of clavicles (174 clavicles from 95 individuals) is the study by Lambert et al.²¹. However, their SSM was based on a region of interest on the anterosuperior aspect of the clavicle and not on the entire clavicle. They state in their conclusion that the largest variation in clavicle anatomy is explained by the length of the bone which is in accordance to our and other authors' results.^{10,21,23} However, they also state that because the second and third PCs contribute less to the compactness of the model, the shape variations in these components are less important for implant design. This assumption is however contradicted by our results.

The SSM containing 152 clavicles consisting of 76 left and corresponding 76 right clavicles, was created with the purpose to detect sex and side differences. From the comparison between male and female clavicles it can be concluded that the average female clavicle is smaller than the male clavicle, which other authors have also reported.^{1,3,11} In addition, significant differences were found between male and female clavicles in PC 1, PC 3, and PC 4. These differences might be explained by differences in the muscle strength compared of men compared with women, as hypothesized by Fatah et al¹. The comparison between left and right revealed statistically

significant differences in length, inferior/superior bow, and medial curvature. This is in contradiction with the study of Daruwalla et al, in which no significant differences were observed.¹⁰ This can, however, be explained by the small subject group. Andermahr et al³ also reported on significant side differences in medial curvature, which is in accordance with our results. In addition, there is a larger variation is observed between men and women than between left and right. We therefore advise that it is more important to include male and female clavicles than to include left and right clavicles in the SSM to describe the anatomical variation.

Furthermore, the percentage of explained variation is similar in both models. The average geometric error from the generalization graph was 0.24 mm in case of the second model (Figure 5). At first sight this model performs better than the model of 120 left clavicles, but we should pay attention while interpreting these results. Figure 5 was obtained by a leave-one-out experiment. Because the model contained a left and right clavicle from the same patient, information about the right side of the patient is still present in the model when describing the left side of this patient. Although significant side differences were identified, the presence of the corresponding side in the model might induce a certain bias.

The identified variation in the clavicle raises the question how implants should be designed to assure a better fit and thus to make sure less intraoperative contouring is necessary. First, most clavicle fixation plates only possess the sigmoid shape, but as indicated by the second PC, the bow in the coronal plane also has an important contribution to the variation. Plating systems should therefore also at least take this variation into account. In addition, because the medial and lateral radius vary independently from each other, the sigmoid shape will not fit each clavicle. Moreover, no sex-specific plates currently exist, although there is a difference of 13mm between the average left male and female clavicle. In a plating system designed to take into account 3

sizes of each component, 3 to the power of 5 combinations are possible, resulting in 243 plates.

Therefore, the use of patient-specific implants to reduce hardware irritation could be the solution to avoid this complication.³²

Our study has some limitations that need to be addressed. We chose to focus on the surface morphology because this will determine the fit of a plate and did not provide any information about the intramedullary canal or the cortical thickness. Due to the anonymized patient data, we could not relate any of the information regarding the shape to other patient's characteristics such as length, ethnicity, age, or hand dominance. One of the strengths of our study was the new methodology that was used to describe the morphologic parameters of the different PCs. Several authors have used different methods to describe the morphologic characteristics of the clavicle.² We believe that because of the clavicle's complex individual geometry, aligning and orientating a group of clavicles in a repeatable and methodologically correct way would be very difficult. Computer-assisted measurement methods allow researchers to make reliable and repeatable measurements.

289 **Conclusion**

290 Although there are clear benefits for the operative treatment of displaced midshaft clavicle
291 fractures, the variable anatomy of the clavicle often makes it challenging for the surgeon to make
292 the plate fit adequately. Based on the identified variability in the clavicle's anatomy it seems
293 unlikely that a clavicle plating system can fit the entire population. Our results encourage
294 research to focus on the improvement of implant design that could lead to less hardware related
295 removal. Although patient specific solutions could be beneficial from an anatomical point of
296 view, its clinical impact remains unknown terrain.

297

298

References

1. Abdel Fatah EE, Shirley NR, Mahfouz MR, Auerbach BM. A three-dimensional analysis of bilateral directional asymmetry in the human clavicle. *Am. J. Phys. Anthropol.* 2012;149(4):547–559. doi:10.1002/ajpa.22156
2. Aira JR, Simon P, Gutierrez S, Santoni BG, Frankle MA. Morphometry of the human clavicle and intramedullary canal: A 3D, geometry-based quantification. *J. Orthop. Res.* 2017 Feb;doi:10.1002/jor.23533
3. Andermahr J, Jubel A, Elsner A, Johann J, Prokop A, Rehm KE, et al. Anatomy of the clavicle and the intramedullary nailing of midclavicular fractures. *Clin. Anat.* 2007;20:48–56. doi:10.1002/ca.20269
4. Andrade-Silva FB, Kojima KE, Joeris A, Santos Silva J, Mattar R. Single, superiorly placed reconstruction plate compared with flexible intramedullary nailing for midshaft clavicular fracture. *J. Bone Joint Surg. Am.* 2015;97:620–626. doi:10.2106/JBJS.O.00118
5. Bachoura A, Deane AS, Kamineni S. Clavicle anatomy and the applicability of intramedullary midshaft fracture fixation. *J. Shoulder Elb. Surg.* 2012;21:1384–1390. doi:10.1016/j.jse.2011.10.032
6. Bachoura A, Deane AS, Wise JN, Kamineni S. Clavicle morphometry revisited: a 3-dimensional study with relevance to operative fixation. *J. Shoulder Elb. Surg.* 2013 Jan;22(1):e15-21. doi:10.1016/j.jse.2012.01.019
7. Baltes TPA, Donders JCE, Kloen P. What is the hardware removal rate after anteroinferior plating of the clavicle? A retrospective cohort study. *J. Shoulder Elb. Surg.* 2017

- 320 Oct;26:1838–1843. doi:10.1016/j.jse.2017.03.011
- 321 8. Bookstein FL. Morphometric Tools for Landmark Data. Cambridge: Cambridge
322 University Press; 1991.
- 323 9. Danckaers F, Huysmans T, Lacko D, Ledda A, Verwulgen S, Van Dongen S, et al.
324 Correspondence Preserving Elastic Surface Registration with Shape Model Prior. Pattern
325 Recognit. (ICPR), 22nd Int. Conf. 2014;2143–2148.
- 326 10. Daruwalla ZJ, Courtis P, Fitzpatrick C, Fitzpatrick D, Mullett H. An application of
327 principal component analysis to the clavicle and clavicle fixation devices. J. Orthop. Surg.
328 Res. 2010;5:21. doi:10.1186/1749-799X-5-21
- 329 11. Daruwalla ZJ, Courtis P, Fitzpatrick C, Fitzpatrick D, Mullett H. Anatomic variation of
330 the clavicle: A novel three-dimensional study. Clin. Anat. 2010;23:199–209.
331 doi:10.1002/ca.20924
- 332 12. Galdi B, Yoon RS, Choung EW, Reilly MC, Sirkin M, Smith WR, et al. Anteroinferior
333 2.7-mm versus 3.5-mm plating for AO/OTA type B clavicle fractures: a comparative
334 cohort clinical outcomes study. J. Orthop. Trauma. 2013;27(3):121–5.
335 doi:10.1097/BOT.0b013e3182693f32
- 336 13. Groh GI. Clavicle Fractures: Pins, Plates, and Drilling Down. J. Bone Jt. Surgery-
337 American Vol. 2015;97(8):e38-1–2. doi:10.2106/JBJS.O.00118
- 338 14. Herteleer M, Hoekstra H, Nijs S. Diagnosis and treatment of clavicular fractures in
339 Belgium between 2006 and 2015. J. Shoulder Elb. Surg. 2018;27:1512–1518.
340 doi:10.1016/j.jse.2018.01.016

- 341 15. Herteleer M, Winckelmans T, Hoekstra H, Nijs S. Epidemiology of clavicle fractures in a
342 level 1 trauma center in Belgium. *Eur. J. Trauma Emerg. Surg.* 2017;1–10.
343 doi:10.1007/s00068-017-0858-7
- 344 16. Huang JI, Toogood P, Chen MR, Wilber JH, Cooperman DR. Clavicular anatomy and the
345 applicability of precontoured plates. *J. Bone Joint Surg. Am.* 2007;89:2260–2265.
346 doi:10.2106/JBJS.G.00111
- 347 17. Hulsmans MHJ, van Heijl M, Houwert RM, Timmers TK, van Olden G, Verleisdonk
348 EJMM. Anteroinferior versus superior plating of clavicular fractures. *J. Shoulder Elb.*
349 *Surg.* 2016;25(3):448–454. doi:10.1016/j.jse.2015.09.005
- 350 18. Jennings A. Sphere fit [Internet]. 2011 [cited 2017 Aug 25];Available from: Matlab
351 Central File Exchange
- 352 19. Jolliffe IT, Cadima J. Principal component analysis: a review and recent developments.
353 *Philos. Trans. R. Soc. A Math. Phys. Eng. Sci.* 2016 Apr;374(2065):20150202.
354 doi:10.1098/rsta.2015.0202
- 355 20. Kihlström C, Möller M, Lönn K, Wolf O. Clavicle fractures: epidemiology, classification
356 and treatment of 2 422 fractures in the Swedish Fracture Register; an observational study.
357 *BMC Musculoskelet. Disord.* 2017;18(1):82. doi:10.1186/s12891-017-1444-1
- 358 21. Lambert S, Al-Hadithy N, Sewell MD, Hertel R, Sudkamp N, Noser H, et al.
359 Computerized tomography based 3D modeling of the clavicle. *J. Orthop. Res.*
360 2016;34(7):1216–1223. doi:10.1002/jor.23145
- 361 22. Leroux T, Wasserstein D, Henry P, Khoshbin A, Dwyer T, Ogilvie-Harris D, et al. Rate of

and Risk Factors for Reoperations After Open Reduction and Internal Fixation of
Midshaft Clavicle Fractures: A Population-Based Study in Ontario, Canada. *J. Bone Joint
Surg. Am.* 2014;96:1119–1125. doi:10.2106/JBJS.M.00607

23. Lu Y-C, Untaroiu CD. Statistical shape analysis of clavicular cortical bone with
applications to the development of mean and boundary shape models. *Comput. Methods
Programs Biomed.* 2013;111(3):613–628. doi:10.1016/j.cmpb.2013.05.017

24. Malhas AM, Skarparis YG, Sripada S, Soames RW, Jariwala AC. How well do contoured
superior midshaft clavicle plates fit the clavicle? A cadaveric study. *J. Shoulder Elb. Surg.*
2016;25:954–959. doi:10.1016/j.jse.2015.10.020

25. Micev AJ, Hsu D, Edwards SL, Marra G, Saltzman MD. The Rising Incidence of
Operative Fixation of Acute Mid-Shaft Clavicle Fractures. *J. Shoulder Elb. Surg.*
2014;23(9):e237. doi:10.1016/j.jse.2014.06.018

26. Naimark M, Dufka FL, Han R, Sing DC, Toogood P, Ma CB, et al. Plate fixation of
midshaft clavicular fractures: Patient-reported outcomes and hardware-related
complications. *J. Shoulder Elb. Surg.* 2016;25:739–746. doi:10.1016/j.jse.2015.09.029

27. Nourian A, Dhaliwal S, Vangala S, Vezeridis PS. Midshaft Fractures Of The Clavicle. *J.
Orthop. Trauma.* 2017 Sep;31(9):461–467. doi:10.1097/BOT.0000000000000936

28. Plessers K, Vanden Berghe P, Van Dijck C, Wirix-Speetjens R, Debeer P, Jonkers I, et al.
Virtual reconstruction of glenoid bone defects using a statistical shape model. *J. Shoulder
Elb. Surg.* 2017;27(1):160–166. doi:10.1016/j.jse.2017.07.026

29. Poltaretskyi S, Chaoui J, Mayya M, Hamitouche C, Bercik MJ, Boileau P, et al. Prediction

- 383 of the pre-morbid 3D anatomy of the proximal humerus based on statistical shape
384 modelling. Bone Jt. J. 2017;99B:927–933. doi:10.1302/0301-620X.99B7.BJJ-2017-0014
- 385 30. Small Satellites. Moments of inertia, center of mass [Internet]. 2012 [cited 2018 Mar
386 19];Available from: [https://nl.mathworks.com/matlabcentral/fileexchange/39371-](https://nl.mathworks.com/matlabcentral/fileexchange/39371-moments-of-inertia-center-of-mass?focused=3776583&tab=function)
387 [moments-of-inertia-center-of-mass?focused=3776583&tab=function](https://nl.mathworks.com/matlabcentral/fileexchange/39371-moments-of-inertia-center-of-mass?focused=3776583&tab=function)
- 388 31. Vanden-Berghe P, Demol J, Gelaude F, Vander Sloten J. Virtual anatomical
389 reconstruction of large acetabular bone defects using a statistical shape model. Comput.
390 Methods Biomech. Biomed. Engin. 2017 Apr;20(6):577–586.
391 doi:10.1080/10255842.2016.1265110
- 392 32. Vanhove H, Carette Y, Vancleef S, Duflou JR. Production of thin Shell Clavicle Implants
393 through Single Point Incremental Forming. In: Procedia Engineering. Elsevier; 2017. p.
394 174–179.doi:10.1016/j.proeng.2017.04.058
- 395 33. Wijdicks FJG, Van Der Meijden O a J, Millett PJ, Verleisdonk EJMM, Houwert RM.
396 Systematic review of the complications of plate fixation of clavicle fractures. Arch.
397 Orthop. Trauma Surg. 2012;132(5):617–625. doi:10.1007/s00402-011-1456-5
- 398 34. Woltz S, Krijnen P, Schipper IB. Plate Fixation Versus Nonoperative Treatment for
399 Displaced Midshaft Clavicular Fractures. J. Bone Jt. Surg. 2017;99:1051–1057.
400 doi:10.2106/JBJS.16.01068
- 401 35. Zhang J, Malcolm D, Hislop-Jambrich J, Thomas CDL, Nielsen PMF. An anatomical
402 region-based statistical shape model of the human femur. Comput. Methods Biomech.
403 Biomed. Eng. Imaging Vis. 2014;2(3):176–185. doi:10.1080/21681163.2013.878668

Figures

Figure 1: Superior and Anterior view on the mean clavicle of the statistical shape model with the marked medial, lateral and superior region of interest.

Figure 2: Fitted sphere in second principal component -3 standard deviations (left) and +3 standard deviations (right)

414

415 Figure 3: Evaluation of the statistical shape model containing 120 left clavicles. A) Compactness
 416 of the statistical shape model showing that 10 Principal Components explain 95% of the total
 417 variation. B) Generalization graph. Our model allows a random clavicle to be reconstructed with
 418 an average accuracy of 0.33mm.

419

420

421 Figure 4: Shape variations of the statistical shape model consisting of 120 left clavicles. The
 422 green clavicle is the mean clavicle and is the same in all images. The red clavicles correspond
 423 with -3 standard deviations, and the blue clavicles correspond with $+3$ standard deviations of the
 424 respective principal component.

Figure 5: Generalization graph of A) Men left, Men right, Women left and Women right. B) Left, Right, Men and Women

Figure 6: Shape variations of the statistical shape model consisting of 152 clavicles. The green clavicle is the mean clavicle and is the same in all images. The red clavicles correspond with -3 standard deviations, and the blue clavicles correspond with $+3$ standard deviations of the respective principal component.

Tables

Table I Description of the regions of interest of the statistical shape model that consists of 120 left clavicles. The superior curvature is only given for PC2 as the inferior/superior bow of the clavicle only changed in this component. Note that the 193 mm radius corresponds with the superior bowed (Red) clavicle in Figure 4 and the 324 mm radius corresponds with the inferior bowed (blue) clavicle in Figure 4.

		Medial radius (mm)	Lateral radius (mm)	Superior radius (mm)	Length (mm)
Mean		79.5	42.9	/	150.8
PC1	-3SD	94.3	52.1	/	184.1
	+3SD	65.9	33.6	/	117.9
PC2	-3SD	81.0	44.2	193	151.7
	+3SD	77.6	42.7	324	151.4
PC3	-3SD	68.5	34.8	/	147.8
	+3SD	94.2	46.8	/	155.2
PC4	-3SD	114.0	49.7	/	152.4
	+3SD	62.0	35.8	/	150.6
PC5	-3SD	90.6	55.2	/	150.5
	+3SD	71.0	31.4	/	151.7

Table II Description of the regions of interest of the statistical shape model containing 152 clavicles. The superior curvature is only given for PC2 as the inferior /superior bow of the clavicle only changed in this component.

		Medial radius (mm)	Lateral radius (mm)	Superior radius (mm)	Length (mm)
Mean		74.7	47.5	/	150
PC1	-3SD	90.7	53.8	/	182.4
	+3SD	58.6	40.4	/	117.7
PC2	-3SD	78.9	56.5	136.4	150.4
	+3SD	70.8	40.4	393.5	150
PC3	-3SD	74.4	39	/	147.9
	+3SD	74.1	56.5	/	153.7
PC4	-3SD	109.6	59	/	151.7
	+3SD	57.7	34.4	/	148.3
PC5	-3SD	65.3	33.3	/	151.5
	+3SD	87.6	50.9	/	149