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Research Article

The Utility of 3-Dimensional Printing for Preoperative Plate Templating in Clavicular Fixation: A Cadaveric Study

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Abstract

Objectives: To investigate the effectiveness and reliability of 3-Dimensional (3D) printed models of the contralateral, unaffected clavicle to serve as templates of the affected side for preoperative planning.

Method: Computed tomography scans of 18 embalmed cadavers (8 male and 10 female) were used to 3D-print mirror images of "unaffected" clavicles which were then used for the selection of a superior midshaft contoured plate. Various morphometric and goodness-of-fit measurements were taken of the 3D-printed clavicle and then the *in-situ* specimen. Statistical analysis was performed using two-tailed, unpaired t-tests with a p value < 0.05.

Results: For 3D-printed models, 7/9 morphometric measurements differed significantly between males and females for both clavicles and in 1 additional measurement for right-sided clavicles. For *in-situ* specimens, 6/9 morphometric measurements differed significantly between male and female clavicles. When comparing the 3D-printed versus the corresponding in-situ clavicle, only 1/9 morphometric measurements differed significantly for both males and females and 1 additional measurement for each sex. The goodness-of-fit of the plate using the 3D-printed template for the *in-situ* specimen differed significantly only for males with a right clavicle mirrored to template for the left clavicle.

Conclusions: Clavicular anatomic complexity and variance supports the need for many contoured plate options for adequate fixation. Preoperatively 3D-printed contralateral, mirrored clavicles for plate selection of midshaft clavicular fractures may reduce intraoperative time.

Keywords: Clavicle; 3D-Printing; Orthopaedic Trauma; Cadaver Model

Level of Evidence: Level V, Therapeutic

Introduction

Clavicular fractures are a common orthopaedic injury, making up 5-10% of all fractures [1-5]. The majority of fractures are midshaft (80%), followed by lateral third (10-18%) and medial third (2-10%) [1,6-8]. Recently, the incidence of operative treatment for clavicular fractures has increased, as it provides strong fixation for early rehabilitation [9,10]. Some indications for operative fixation include related neurovascular compromise, open fractures, skin tenting, severe angulation, 100% displacement, shortening greater than 2 cm and floating shoulder injury [1].

Research has shown a strong correlation between ipsilateral clavicle fractures, especially with shortening and the development of glenohumeral joint arthritis.5 Significant shortening has been associated with worse outcomes, higher incidence of pain, functional deficit and poor cosmesis when treated nonoperatively [11]. There has been investigation into the normal variation in length, cross-sectional morphology, medial and lateral angles and bow in the transverse plane of the clavicle to assist with plate design [8]. Studies have also shed light onto the variation between male and female clavicles as well as between the left and right clavicle in an individual, with the left clavicle tending to be longer and the right thicker; this is hypothesized to be secondary to handedness and clavicular loading [7,11-14]. Variations in mechanical forces, asymmetric vascularization, activity-induced changes and favored loading secondary to handedness are all factors responsible for the asymmetry of various clavicular features [15,16].

The use of 3-Dimensional (3D) printing technology is becoming more common in product design industries, especially in the field of medicine [17-24]. This technology is currently used to create anatomic models for surgical planning and intraoperative navigation, to trial medical device prototypes prior to production and to build patient-specific surgical instruments [24-28]. However, there remains limited data on the accuracy of 3D-printed bony specimens with direct comparison measurements made on cadaveric specimens [11,15,29]. The purpose of this study was to determine not only the effectiveness but the reliability of 3D-printed clavicular models to serve as templates for preoperative planning and contouring of plates with cadaveric verification [30]. It is our vision that the findings of this study can pave the way for more complex bony models for other traumatic orthopaedic injuries.

Material and Methods

Computed Tomography (CT) scans of 18 embalmed cadavers (8 male and 10 female) were used to render the mirror image of the contralateral clavicle for 3D printing with Materialise Mimics Research 19.0 3D medical imaging processing software and Materialise 3-Matic Research 11.0 64-bit 3D modeling software (Materialise, Leuven, Belgium) (Fig. 1). The models were then printed using standard Polylactic Acid (PLA) filament with a MakerBot Replicator+ 3D printer (MakerBot Industries, Brooklyn, NY) to serve as templates for the selection of superior midshaft precontoured Styker VariAx system plates (Stryker, Kalamazoo, MI) (Fig. 2). The precontoured plates were further contoured to fit the 3D-printed model and then applied to the corresponding *in-situ* specimen (Fig. 3). Both left for right and right for left clavicular models were made, but only one iteration per cadaver. The models could be digitally produced within 20 minutes and utilized less than a dollar of material.

Comparisons were made both between male and female clavicles for both types of specimens and between the 3D-printed models and their corresponding *in-situ* clavicles. Various morphometric measurements established by Sehrawat, et al., were recorded (Table 1 and Fig. 4) [15]. Goodness-of-fit of the plate on the clavicular specimens was measured using the Clavicle Congruence Score (CCS) established by Malhas, et al., [7]. A score of 3 (anatomic) signified perfect congruence, with a gap < 1 mm and no plate overhang. A score of 2 (good) signified a gap > 1 mm, every plate hole over bone, either anterior or posterior overhang present and contouring of < 30 degrees being required. A score of 1 (poor) signified complete mismatch with at least 1 plate hole not over bone, either anterior or posterior overhang present and contouring of > 30 degrees being required. Other plating measurements recorded included Sternal Distance (SD), the distance from the sternal end to the medial end of the plate; Acromial Distance (AD), the distance from the acromial end to the lateral end of the plate; Acromial Shaft Height with Plate (ASHP); Sternal Shaft Height with Plate (SSHP) and Midshaft Height with Plate (MSHP). Two-tailed, unpaired t-tests were used to look for statistically significant differences between the measurements.

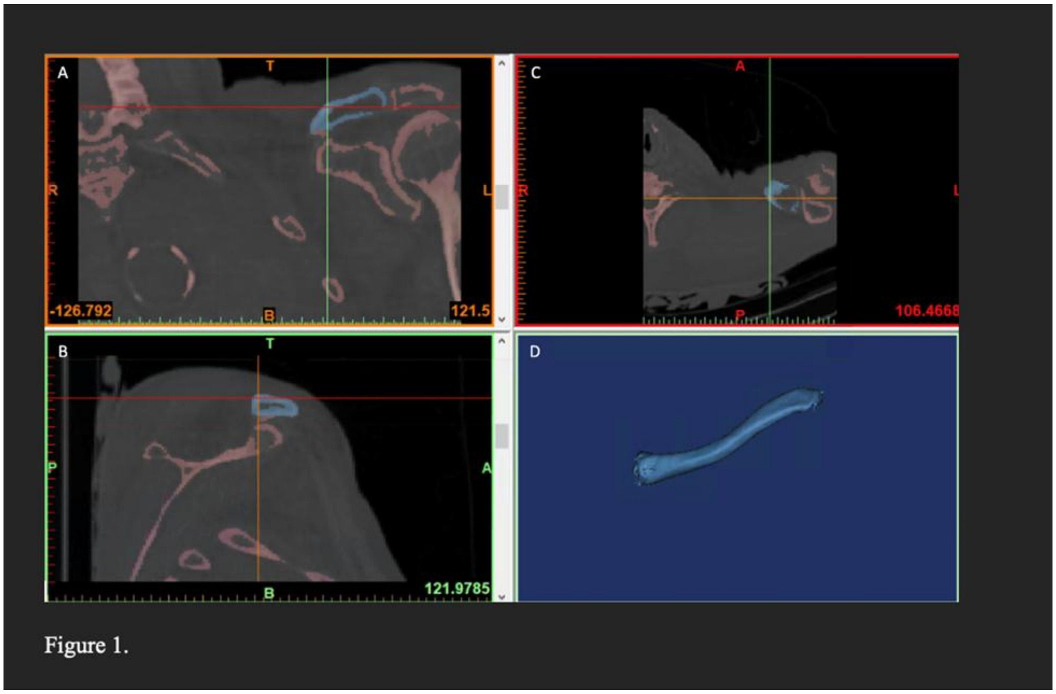

Figure 1: Coronal (A), sagittal (B) and axial (C) views demonstrating the isolation of a left clavicle (D) with Materialise Mimics Research 19.0 3D medical imaging processing software.

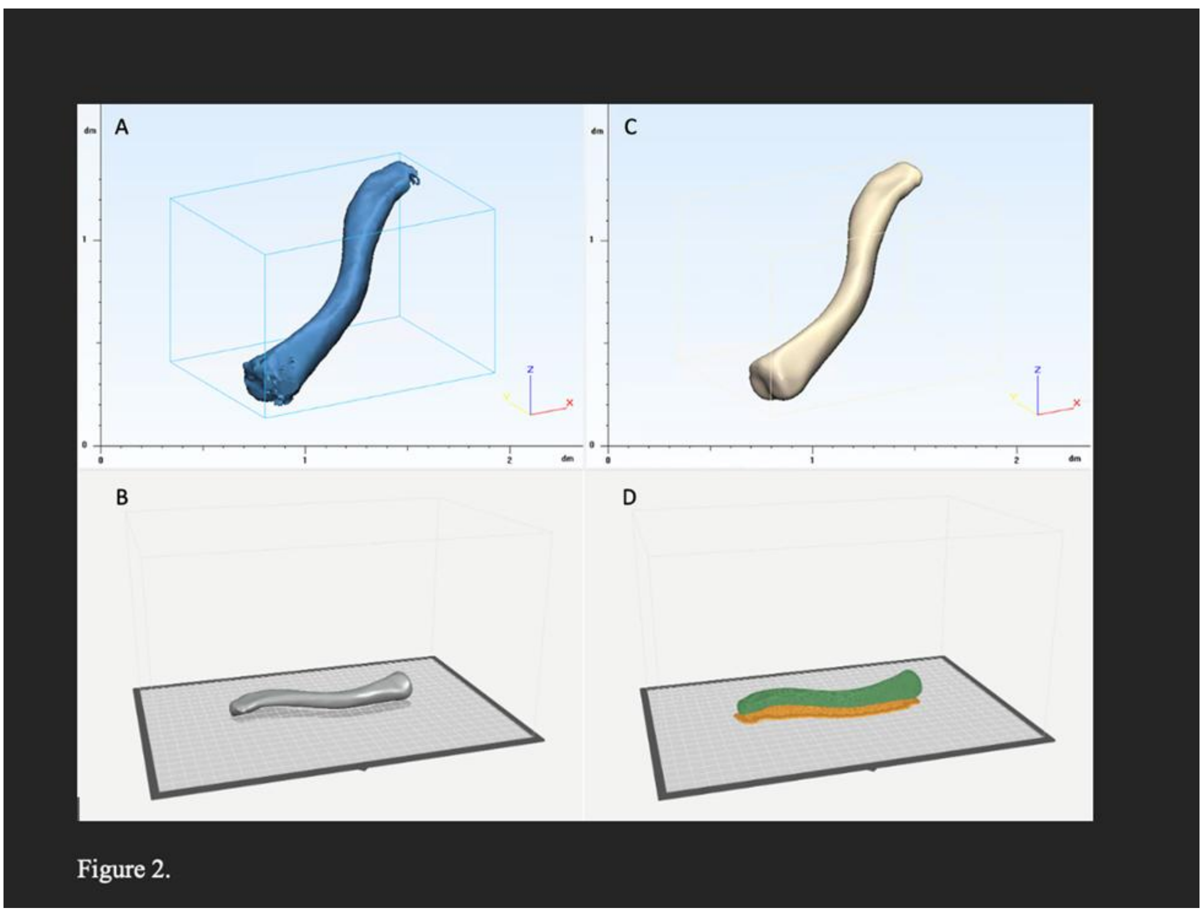

Figure 2: Using exported image file from Materialise Mimics Research 19.0 to Materialise 3-Matic Research 11.0 64-bit 3D modeling software (A) to smooth out rough edges yields a final printable image (B). The image is then exported to MakerBot Print (B), where the software automatically applies support structure (D) easily contrastable from the final printed product. The support structure easily breaks free from the print after printing.

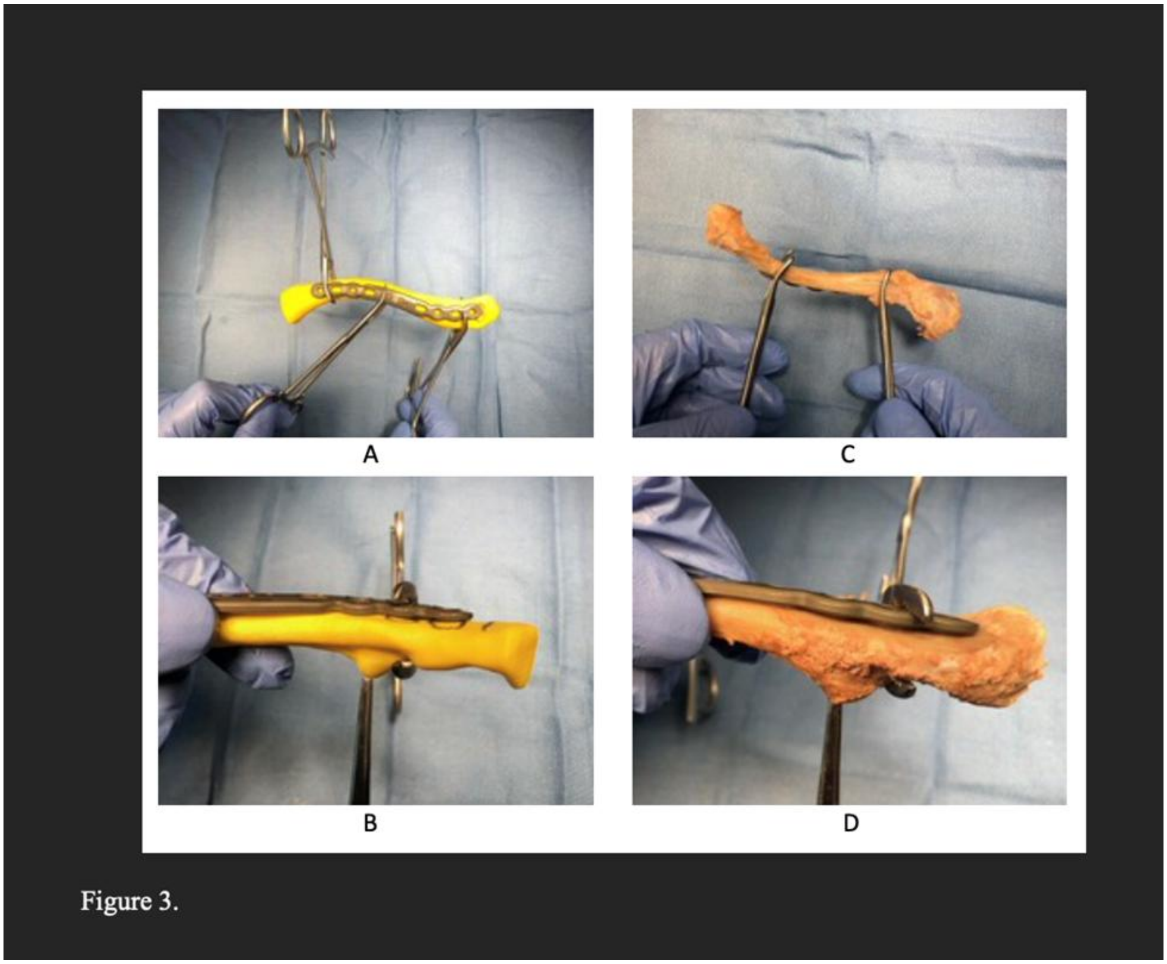

Figure 3: Example of 3D-printed mirror image of the right clavicle (A,B) serving as a template for plate selection for the left-sided cadaveric clavicle (C,D).

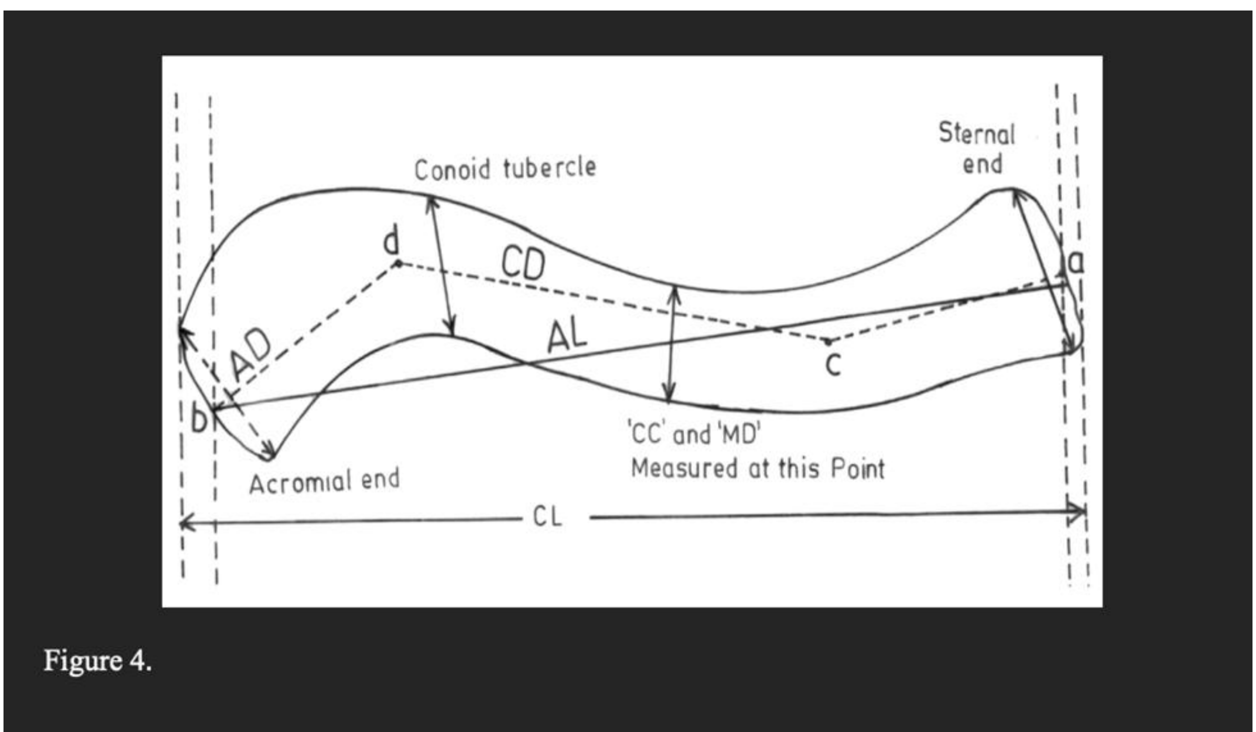

Figure 4: Depiction of morphometric measurements used adopted from Sehrawat, et al., [15].

Results

Morphometric Comparisons

Morphometric comparison results between male and female for 3D-printed versus *in-situ* clavicle specimens are displayed in Table 2. For the 3D-printed specimens, significant differences were found between male and female clavicles for CL, AL, CC, SD, AD, MD, CD and right-sided MA. For *in-situ* clavicles, significant differences were found between male and female clavicles for CL, AL, CC, SD, AD and MD. When directly comparing the 3D-printed and *in-situ* clavicles, there were significant differences between left-sided CC in both male and female clavicles, right-sided AD in female clavicles and left-sided MA in male clavicles.

Plating Comparisons

Clavicular plating comparison results between male and female for 3D-printed versus *in-situ* clavicle specimens are displayed in Table 3. For both the 3D-printed and *in-situ* clavicles, no significant differences in CCS in either male or female clavicles were found. For 3D-printed clavicles, significant differences were found between male and female clavicular right-sided SSHP and both right and left-sided MSHP. For *in-situ* clavicles, significant differences were found between male and female clavicular left-sided SSHP and both right and left-sided MSHP. When directly comparing the 3D-printed and *in-situ* clavicles, the CCS differed significantly only for males with a right clavicle mirrored to template the left clavicle. In addition, significant differences were found for right-sided MSHP in males and females and in left-sided MSHP for females.

Table 1.

Morphometric Measurement	Description
Clavicular Length (CL)	Maximum distance between the outermost tips of the sternal and acromial ends of the clavicle
Articular Length (AL)	Straight distance between the mid-points of the sternal and acromial articular ends of the clavicle
Mid-point Circumference (CC)	Circumference measured around the clavicle at the midpoint of clavicular shaft marked between the acromial and sternal ends
Sternal Diameter (SD)	Straight distance between the highest and lowest point of sternal articular surface in the sagittal plane
Acromial Diameter (AD)	Straight distance between the highest and lowest point of acromial articular surface in the sagittal plane
Middle diameter (MD)	Linear distance between the anterior and posterior surfaces of the clavicular diaphysis measured at the mid-point
Conoid Diameter (CD)	Linear distance between the anterior and posterior surfaces of the clavicular diaphysis measured at the level of the conoid tubercle in the sagittal plane
Lateral Angle (LA)	Angle representing the curvature of the lateral one-third portion of the clavicle
Medial Angle (MA)	Angle representing the curvature of the medial two-third's portion of the clavicle

Table 1: Definitions of morphometric measurements used adopted from Sehrawat, et al., [15].

Table 2.

3D Model Dimension	Side	Male N=8 Mean	SD	Female N=10 Mean	SD	*p* Value	In-situ Specimen Dimension	Side	Male N=8 Mean	SD	Female N=10 Mean	SD	*p* Value	3D vs. In-situ (Male) *p* Value	3D vs. In-situ (Female) *p* Value
CL	R	165.50	3.04	137.20	12.09	0.0061	CL	R	163.46	10.24	132.20	11.01	0.0058	0.8609	0.9624
	L	162.14	12.69	132.55	9.04	0.0058		L	171.90	7.57	141.97	11.86	0.0031	0.2459	0.5063
AL	R	167.03	3.96	138.62	12.33	0.0069	AL	R	163.56	9.89	136.00	7.51	0.0031	0.9240	0.8294
	L	164.22	11.26	134.85	6.93	0.0027		L	174.53	4.98	142.67	11.65	0.0025	0.1108	0.5717
CC	R	49.30	1.35	37.00	2.99	0.0003	CC	R	42.88	2.41	32.08	3.71	0.0002	0.3671	0.0696
	L	44.25	0.70	38.00	3.88	0.0356		L	44.10	1.49	33.45	2.32	0.0093	0.0110	0.0446
SD	R	34.60	3.08	27.08	3.87	0.0229	SD	R	31.97	2.52	26.60	1.82	0.0090	0.5905	0.4349
	L	31.08	2.51	25.25	2.67	0.0119		L	35.07	1.50	28.05	3.14	0.0092	0.8251	0.6450
AD	R	27.60	2.55	19.98	3.27	0.0101	AD	R	25.92	3.18	21.70	1.16	0.0175	0.8011	0.0318
	L	25.48	2.04	19.45	1.12	0.0012		L	30.63	4.53	22.73	3.17	0.0414	0.3693	0.1702
MD	R	16.50	1.35	11.94	1.21	0.0017	MD	R	13.34	1.13	10.50	0.22	0.0012	0.4856	0.0931
	L	13.82	0.93	11.53	1.00	0.0093		L	15.07	1.35	11.20	0.88	0.0018	0.2638	0.1266
CD	R	25.37	3.84	18.08	2.63	0.0114	CD	R	21.32	2.97	17.40	2.15	0.0864	0.5871	0.9356
	L	22.48	3.49	17.53	2.05	0.0413		L	23.17	4.40	18.30	2.99	0.0631	0.5496	0.8967
LA	R	151.67	2.89	154.50	3.39	0.2581	LA	R	151.00	5.48	148.25	11.93	1.0000	0.9066	1.0000
	L	151.60	9.63	148.25	7.89	0.5934		L	155.00	0.00	155.00	5.48	0.6568	0.0918	0.8530
MA	R	153.33	2.89	161.17	4.26	0.0255	MA	R	152.00	4.47	151.25	6.29	0.1395	1.0000	0.7878
	L	152.00	2.74	152.25	3.30	0.9044		L	163.33	2.89	159.17	3.76	0.8398	0.0132	0.4091

Table 2: Morphometric measurement differences between male and female or 3D-printed and *in-situ* clavicle specimens.

Table 3.

3D Model Dimension	Side	Male N=8 Mean	SD	Female N=10 Mean	SD	*p* Value	In-situ Specimen Dimension	Side	Male N=8 Mean	SD	Female N=10 Mean	SD	*p* Value	3D vs. In-situ (Male) *p* Value	3D vs. In-situ (Female) *p* Value
CCS	R	3.00	0.00	2.67	0.52	0.3159	CCS	R	2.80	0.45	2.38	0.48	0.2117	0.3466	0.3202
	L	3.00	0.00	2.75	0.50	0.2924		L	1.83	0.29	2.00	0.55	0.6438	0.0022	0.0552
SDist	R	19.57	6.48	23.15	6.30	0.4512	SDist	R	24.14	2.87	21.95	6.40	0.5113	0.1407	0.7890
	L	28.52	5.26	23.25	6.73	0.2272		L	21.40	4.61	24.77	5.29	0.3821	0.7101	0.6407
ADist	R	28.90	4.85	24.62	3.84	0.1882	ADist	R	24.80	8.55	24.18	3.42	0.8955	0.7227	0.9732
	L	26.94	9.82	24.28	4.58	0.6349		L	28.67	2.67	25.57	6.20	0.4463	0.9454	0.7563
ASHP	R	17.23	3.32	15.05	1.87	0.2343	ASHP	R	15.46	2.12	14.75	2.36	0.6487	0.4156	0.7746
	L	16.36	1.00	15.23	2.12	0.3203		L	13.67	2.48	15.27	3.65	0.5224	0.2103	0.8996
SSHP	R	22.30	3.00	17.22	2.30	0.0246	SSHP	R	16.58	1.44	17.25	3.67	0.7163	0.1649	0.9636
	L	18.40	2.24	17.38	3.77	0.6249		L	20.33	0.31	16.07	2.48	0.0238	0.3218	0.4241
MSHP	R	17.40	1.28	14.00	1.10	0.0042	MSHP	R	14.28	1.53	11.53	1.17	0.0210	0.0150	0.0261
	L	16.86	1.08	13.90	1.12	0.0050		L	16.10	1.01	11.82	1.00	0.0005	0.2395	0.0048

Table 3: Plating measurement differences between male and female or 3D-printed and *in-situ* clavicle specimens.

Discussion

Previous cadaveric study has investigated how appropriately superior midshaft clavicle plate systems contour to the human clavicle [7]. A study by Kim, et al., demonstrated that 3D-printed clavicle model templates were effective for fixation of seven comminuted midshaft clavicle fractures [17]. Our results further expand upon the utility of this technique by demonstrating the variability between male and female clavicles and between left and right clavicles using various measurements. Our goal was to demonstrate that, despite the variable clavicular anatomy between people, the technique of using the contralateral intact clavicle when templating for the clavicle fracture yields a model with very similar dimensions as the *in-situ* clavicle to be fixed. We demonstrated that using this model allows accurate plate fit and placement on the clavicle of interest.

In the present study, there were many significant morphometric measurement differences found between male and female clavicles and between left and right clavicles on average. However, when comparing the 3D-printed clavicles and their corresponding contralateral *in-situ* clavicles, there were no significant differences when it came to morphometric, goodness-of-fit and plate-bone dimension measurements in the majority of cases. In other words, the numerous morphometric measurements that differed significantly had little impact on the actual plate goodness-of-fit, except for men who had a left clavicle template made from the right clavicle. A possible explanation is that longer clavicles typically have broader plating options while maintaining acceptable goodness-of-fit and right sided clavicles tend to be shorter and thicker [7].

For clavicles, picking the appropriate plate can affect the cosmetic acceptability and clinical outcomes, including the need for future hardware removal [31,32]. Today, precontoured implants are manufactured to fit many bones in the body, but they are not always useful or appropriate for bones with as much variable anatomy as the clavicle or bones with large zones of comminution, for which the process described by this study may prove to be more useful [33]. This is important, as plate position and fit, if not close to anatomic in fracture reduction, can malreduce fractures and lead to an array of postsurgical complications. Normally, the complexity and variability in the anatomy of the clavicle necessitates the need for many plating options intraoperatively. In the present study, it was found that 3D-printing a clavicular template before clavicular fracture fixation may be a viable and timely method to both reduce operating room time and reduce the number of surgical trays required intraoperatively by allowing the surgeon to start the procedure with a well-fitting plate already available. A printable digital clavicular model took one of our researchers approximately 20 minutes to produce from CT scans, which can then be printed. Print jobs are done completely by the 3-D printers and take approximately 45 minutes to an hour to complete. It is postulated that a single trained technician can produce similar printable digital imaging from CT scans in less time. Once a surgeon preoperatively uses the model to select and contour a plate, the plate can then be autoclaved for surgery, saving valuable intraoperative time and reducing patient risk profiles from surgery. This method of utilizing a template for fixation purposes could also aid in the preoperative planning of bridge plating comminuted fractures where length, alignment and rotation are more difficult to assess.

Research in the field of 3D-printing to create anatomic models for orthopaedic fixation has been expanding rapidly [34,35]. Though limited, analysis of the utility of 3D virtual surgical planning with 3D-printing has been explored with injuries to the upper extremity and to complicated injuries of the ankle joint [30,36-38]. Future studies should continue to investigate the utility, feasibility and cost effectiveness of 3D-printing. There exists some research analyzing the use of 3D-printing for more complicated fractures of the pelvis and acetabulum [30,39-41]. However, mainstream utility of such methods backed by sufficient evidence remains to be seen. Future studies should also take our results a step further and measure the operative parameters such as cost and operative time to treat clavicle fractures with and without preoperative plate selection.

Our study had limitations intrinsic to most cadaveric studies. Our sample size was small, resulting in the possibility that the clavicles may differ from the general population. Our sample size may also not represent the full spectrum of variations encountered in the clavicle. Another limitation is that the handedness of the specimens was not known and the effect of handedness has been shown to affect the morphology of the clavicle [7,12-16]. Although all measurements were taken and verified by two independent researchers, there remains opportunity for human measurement error during the data collection portions of this study. Although only one plating system was used for this study, the main aim of the study was proof of concept for clavicular fixation, not widespread generalizability among different plating designs. When using different 3D printers, there may be variability encountered regarding print time which affects the generalizability of our results. It is worth mentioning that countries under low-to-middle income categories may find it difficult to hire a technician and use a budget-desktop 3D printer. Lastly, variables such as print temperature and bed temperature which can affect print time and quality, were not recorded in our study [31].

Conclusion

In conclusion, clavicular anatomic complexity, coupled with high variance between males and females, supports the need for many contoured plate options for adequate fixation. Based on experience, we postulate that the low material cost of the 3D-printed clavicle model used for contouring the plate could save anywhere from 3-5 minutes in the operating room. With the utility of a 3D printer, the only other factor to consider is the 20 minutes it takes to render a printable image from a CT scan, which is likely more time than a trained radiology technician would take. The findings of the present study support the accuracy and reliability of preoperatively 3D-printed contralateral, mirrored clavicles for plate selection despite observed variability in clavicular anatomy between right and left sides and between individuals. This method may be a viable way to reduce patient intraoperative time and other surgical costs during clavicular and other fracture fixation.

Conflict of Interests

The authors declare that they have no conflict of interest in this paper.

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None

Authors' Contributions

All authors contributed equally in this paper.

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