

Computed Tomography–Based Assessment of the Congruency of Precontoured Anatomical Clavicle Plates in the Indian Population: A Hospital-Based Observational Study

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Abstract

Purpose

Precontoured anatomical clavicle plates are designed predominantly from Western morphometric data, and ethnic variation in clavicular anatomy may compromise plate-to-bone congruency in Indian patients. This study evaluated the congruency of a precontoured anatomical clavicle plate in an Indian population using computed tomography (CT)-based mathematical modelling and the Clavicle Congruence Score (CCS).

Methods

In this hospital-based observational study conducted at a tertiary care hospital in South India between May 2024 and October 2025, adult patients undergoing CT of the thorax or neck were included after applying predefined eligibility criteria. Three-dimensional reconstructions were used to derive clavicular morphometric parameters, and a commercially available anatomical clavicle plate was virtually superimposed on each reconstruction to measure vertical plate-to-bone gap and anterior and posterior overhang. Plate fit was graded by the CCS as anatomical, good or poor.

Results

Twenty-two clavicles from 22 participants (mean age 44.6 ± 16.3 years; 63.6% male) were analysed. Mean clavicular length was 143.6 ± 10.8 mm. Mean vertical plate-to-bone gap was 2.4 ± 1.6 mm, with mean anterior and posterior overhang of 1.8 ± 1.4 mm and 2.0 ± 1.5 mm, respectively. CCS grading showed anatomical fit in 27.3%, good fit in 45.4% and poor fit in 27.3% of clavicles.

Conclusion

Considerable morphological variability was observed, and the evaluated plate did not achieve anatomical fit in a substantial proportion of Indian clavicles, supporting preoperative anatomical assessment and population-specific implant design.

Level of Evidence:

Level IV, observational study.

Introduction

Clavicle fractures account for approximately 2.6–5% of all fractures and 35–45% of injuries involving the shoulder girdle, with nearly 80% occurring in the middle third of the clavicle because of its unique anatomical and biomechanical characteristics [1–3]. While minimally displaced fractures are generally managed non-operatively, displaced midshaft fractures are associated with higher rates of nonunion, malunion and functional impairment following conservative treatment, favouring an increasing preference for operative fixation [4, 5].

Open reduction and internal fixation using precontoured anatomical locking plates is widely used for displaced midshaft clavicle fractures, restoring clavicular length and alignment while providing stable fixation and allowing early mobilisation [4, 5]. Despite these advantages, implant-related complications such as hardware prominence, soft-tissue irritation and secondary implant removal continue to be reported frequently [6–8].

The clavicle exhibits a complex three-dimensional S-shaped morphology, with considerable inter-individual variation in length, curvature, bowing and cross-sectional anatomy [9–11]. Commercially available precontoured plates, designed largely from Western morphometric data, may therefore fail to reproduce native clavicular anatomy in every patient, resulting in imperfect plate-to-bone congruency [6, 12, 13]. Several morphometric studies have demonstrated significant differences in clavicular anatomy according to sex, ethnicity and geographic population [11, 14–17], and Indian clavicles have been shown to differ from Western populations with respect to length, curvature and angular parameters, raising uncertainty about the applicability of implants designed predominantly from Caucasian morphometric databases [10, 16–19].

Poor plate congruency has important clinical implications, including increased implant prominence, soft-tissue irritation, difficulty during fracture reduction, excessive intraoperative contouring and altered screw trajectories [7, 8, 13, 20], and excessive contouring may also prolong operative time [7]. Malhas et al. introduced the Clavicle Congruence Score (CCS) as an objective method of classifying implant fit into anatomical, good and poor categories based on plate-to-bone gap and implant overhang [21]. Subsequent cadaveric and CT-based studies have reported anatomical congruency in only approximately 30–50% of clavicles, with substantial variation between different implant systems [6, 7, 20].

Despite these advances, CT-based mathematical assessment of clavicle plate congruency in the South Indian population remains limited, and population-specific evidence is needed to guide implant selection and to inform the development of anatomically optimised implants. The present study was therefore undertaken to evaluate the congruency of a commercially available precontoured anatomical clavicle plate in the Indian population using CT-based three-dimensional mathematical modelling, and to objectively classify plate fit using the CCS.

Materials and Methods

Study Design and Setting

This hospital-based observational study was conducted in the Department of Orthopaedics at a tertiary care teaching hospital in South India between 1 May 2024 and 31 October 2025, following approval from the Institutional Ethics Committee. The study is reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement.

Study Population

Adult patients undergoing computed tomography (CT) of the thorax or neck for routine clinical indications during the study period were considered eligible. CT examinations were not performed specifically for the study; only existing diagnostic imaging data were analysed, so no participant underwent additional imaging or radiation exposure. Written informed consent was obtained from all participants.

Sample Size

The sample size was calculated from the mean and standard deviation reported in a previous mathematical plate-prominence study [22]. Assuming an absolute precision of 2.5 mm at a 95% confidence interval, the minimum required sample size was 22 clavicles, calculated using nMaster software. Consecutive sampling was used until this target was achieved. One clavicle was analysed per participant, so the 22 clavicles were obtained from 22 different individuals.

Eligibility Criteria

Inclusion criteria were age ≥ 18 years and CT examination of the thorax or neck with complete visualisation of the clavicle. Exclusion criteria were previous clavicular surgery, malunited clavicle fracture and congenital clavicular deformity.

CT Acquisition and Three-Dimensional Reconstruction

CT datasets were retrieved from the institutional radiology database after obtaining the necessary permissions. Images were acquired on a multidetector CT scanner according to the routine departmental imaging protocol, and three-dimensional reconstructions were generated on the CT workstation to enable accurate visualisation and morphometric assessment of the entire clavicle.

Clavicular Morphometric Assessment

Three-dimensional reconstructions were analysed to obtain total clavicular length, distance to the apex of the superior bow, and medial and lateral clavicular angles, using digital measurement tools. Clavicular length was measured from the sternal to the acromial end along the longitudinal axis of the bone; the apex of the superior bow was defined as the point of maximum superior curvature measured from the

lateral end. Medial and lateral angles represented the curvature of the medial and lateral clavicular segments, respectively.

Anatomical Clavicle Plates and CT-Based Mathematical Modelling

A commercially available precontoured anatomical clavicle locking plate was evaluated in three lengths, comprising six-hole, seven-hole and eight-hole plates. Plate length, width, curvature and inter-screw-hole distance were recorded and incorporated into CT-derived mathematical models. Each plate was virtually positioned over the three-dimensional clavicular reconstruction to enable objective, non-invasive assessment of plate-to-bone congruency without physical implantation, by quantifying the relationship between the undersurface of the plate and the superior clavicular cortex along the entire implant.

Plate Congruency Assessment

Congruency was evaluated using three objective parameters. The vertical plate-to-bone gap was the perpendicular distance between the plate undersurface and the superior clavicular cortex, measured at predefined locations including screw-hole positions. Anterior overhang was the distance by which the plate projected beyond the anterior cortical margin, and posterior overhang was the distance between the posterior plate edge and the posterior cortex.

Clavicle Congruence Score

Plate fit was classified according to the Clavicle Congruence Score (CCS) described by Malhas et al. [21] as anatomical, good or poor, using the criteria summarised in Table 1.

Table 1
Clavicle Congruence Score grading criteria, applied as described by Malhas et al. [21]

Grade	Definition
Anatomical (score 3)	Plate-to-bone gap < 1 mm with no plate overhang
Good (score 2)	Plate deviation > 1 mm; all screw holes positioned over bone; anterior or posterior overhang present; contouring < 30°
Poor (score 1)	Complete mismatch; one or more screw holes not positioned over bone; anterior and posterior overhang; contouring > 30°

Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics version 20.0 (IBM Corp., Armonk, NY, USA). Continuous variables were tested for normality using the Shapiro–Wilk test; all were normally distributed and are expressed as mean ± standard deviation, with median, range and 95% confidence interval reported where relevant. Categorical variables were summarised as frequencies and percentages.

Continuous variables were compared between groups using the independent-samples t-test, and associations between categorical variables were analysed using the chi-square test. A p value < 0.05 was considered statistically significant.

Results

A total of 22 clavicles, one from each of 22 adult participants satisfying the eligibility criteria, were included in the final analysis. The mean age of the study population was 44.6 ± 16.3 years, with a median age of 43 years (range 18–75 years); the largest proportion of participants belonged to the 31–45-year age group (31.8%). Male participants constituted 63.6% (n = 14) of the cohort and females 36.4% (n = 8) (Table 2).

Table 2
Demographic and clavicular morphometric characteristics of the study population (n = 22)

Variable	Value
Participants, n	22
Clavicles analysed, n	22 (one per participant)
Mean age, years	44.6 ± 16.3
Median age, years (range)	43.0 (18–75)
Male, n (%)	14 (63.6)
Female, n (%)	8 (36.4)
Clavicular length, mm – mean $\pm$ SD (median; range; 95% CI)	143.6 ± 10.8 (144.0; 120–168; 138.8–148.4)
Apex of superior bow, mm – mean $\pm$ SD (median; range; 95% CI)	38.2 ± 8.6 (38.5; 24–55; 34.4–42.0)
Medial angle, ° – mean $\pm$ SD (median; range; 95% CI)	145.8 ± 7.0 (146.0; 132–159; 142.7–148.9)
Lateral angle, ° – mean $\pm$ SD (median; range; 95% CI)	142.5 ± 7.5 (143.0; 126.0–155.0; 139.2–145.8)

Three-dimensional CT reconstruction showed a mean clavicular length of 143.6 ± 10.8 mm (range 120–168 mm), a mean apex-of-superior-bow distance of 38.2 ± 8.6 mm, and mean medial and lateral clavicular angles of $145.8 \pm 7.0^\circ$ and $142.5 \pm 7.5^\circ$, respectively (Table 2). Males demonstrated significantly longer clavicles than females (148.2 ± 9.4 mm vs 135.6 ± 8.2 mm; p = 0.004); no statistically significant differences were identified between right- and left-sided clavicles for any morphometric parameter (p = 0.751).

The mean vertical plate-to-bone gap was 2.4 ± 1.6 mm; only 27.3% of clavicles demonstrated an anatomical fit with a gap < 1 mm, while the remainder exhibited varying degrees of plate elevation

requiring additional contouring. The mean anterior overhang was 1.8 ± 1.4 mm and the mean posterior overhang was 2.0 ± 1.5 mm (range 0–5.5 mm), with 40.9% of clavicles showing 1–2 mm of posterior overhang and 27.3% showing minimal (< 1 mm) posterior overhang (Table 3).

Overall assessment using the CCS demonstrated anatomical fit in 27.3% ($n = 6$) of clavicles, good fit in 45.4% ($n = 10$) and poor fit in 27.3% ($n = 6$) (Table 3). Thus, 72.7% of clavicles achieved either anatomical or good congruency, while approximately one-quarter required substantial intraoperative contouring because of poor congruency.

Table 3
Plate congruency measurements and Clavicle Congruence Score (CCS) distribution ($n = 22$)

Parameter	Value
Vertical plate-to-bone gap, mm – mean $\pm$ SD	2.4 ± 1.6
Anterior overhang, mm – mean $\pm$ SD	1.8 ± 1.4
Posterior overhang, mm – mean $\pm$ SD (range)	2.0 ± 1.5 (0–5.5)
Anatomical fit (CCS score 3), n (%)	6 (27.3)
Good fit (CCS score 2), n (%)	10 (45.4)
Poor fit (CCS score 1), n (%)	6 (27.3)

Male clavicles demonstrated a higher proportion of anatomical fit than female clavicles (35.7% vs 12.5%), although this difference did not reach statistical significance ($p = 0.418$), and no significant difference in CCS distribution was observed between right- and left-sided clavicles ($p = 1.00$). Anatomical fit declined with increasing plate length, observed in 50.0% of clavicles fitted with six-hole plates, 25.0% with seven-hole plates, and 0% with eight-hole plates, although this difference did not reach statistical significance ($p = 0.214$). Of the 22 clavicles assessed, six-hole plates were evaluated in 8, seven-hole plates in 8, and eight-hole plates in 6.

Discussion

The present study evaluated the congruency of a commercially available precontoured anatomical clavicle plate in an adult Indian population using CT-based three-dimensional mathematical modelling and the Clavicle Congruence Score. Clavicular morphology demonstrated considerable inter-individual variation, and the evaluated implant did not achieve an anatomical fit in all clavicles, with a substantial proportion requiring contouring or demonstrating implant mismatch.

The mean clavicular length of 143.6 ± 10.8 mm observed in this study was comparable with previously reported Indian morphometric data, reinforcing that clavicular dimensions vary by ethnicity and sex and that implants designed predominantly from Western anatomical databases may not adequately represent Indian patients [10, 16–19]. A key strength of this study is the use of CT-based three-

dimensional reconstruction, which avoids the limitations of specimen availability and preservation-related artefact inherent to cadaveric studies, while enabling reproducible, non-invasive virtual implant simulation without additional radiation exposure, since only clinically indicated CT scans were analysed.

Anatomical congruency was achieved in only 27.3% of clavicles, broadly consistent with previous reports of 30–50% anatomical fit using the CCS in other populations [6, 7, 20], and confirming that precontoured designs frequently require intraoperative contouring despite being marketed as anatomically shaped [7, 8, 13]. Excessive contouring may prolong operative time [7]. The CCS proved to be a practical and objective tool that incorporates measurable parameters – vertical gap and anterior and posterior overhang – thereby enhancing reproducibility and enabling meaningful comparison across implant systems and study populations, and its wider adoption may facilitate future multicentre implant-evaluation studies.

Sex-based variation in clavicular morphology was also evident, with male clavicles significantly longer than female clavicles, consistent with normal skeletal dimorphism reported elsewhere [11, 14, 15]. This has direct implications for implant manufacturers, since a single plate design may not adequately accommodate both male and female clavicular anatomy, and sex- or population-specific implant options may improve anatomical fit and reduce implant-related complications. Similarly, anatomical fit declined as plate length increased in this cohort (50.0%, 25.0% and 0% for six-, seven- and eight-hole plates, respectively), although this trend did not reach statistical significance ($p = 0.214$) and involved small subgroups; it nonetheless suggests that plate-length selection may influence anatomical fit and warrants further evaluation with larger samples across different implant systems.

From a clinical perspective, improved congruency may reduce soft-tissue irritation and implant prominence, facilitate fracture reduction and optimise screw trajectory, particularly in fractures involving small lateral or medial fragments, potentially lowering rates of secondary implant removal. Preoperative CT assessment of clavicular anatomy may help guide implant selection in anatomically atypical patients, and the morphometric data generated in this study may assist manufacturers in developing implants tailored to the Indian population.

This study has several limitations. It was a single-centre study with a relatively small sample size (22 clavicles), although this met the calculated requirement; larger multicentre studies across different Indian regions are needed to confirm generalisability. Virtual CT-based modelling, while providing accurate quantitative measurement, cannot fully replicate intraoperative conditions such as fracture reduction, soft-tissue tension and surgeon-dependent contouring. Only one commercially available plate system was evaluated, and assessment of multiple systems would allow a more comprehensive comparison of currently available implants. Measurements were not formally assessed for inter- and intra-observer reliability. Finally, this study assessed implant congruency rather than clinical outcomes, so correlations with fracture union, functional scores or implant removal rates could not be established and should be addressed by future outcome-based studies.

Conclusion

CT-based three-dimensional mathematical modelling is an effective and reproducible method for evaluating the congruency of precontoured anatomical clavicle plates. Considerable variability in clavicular morphology was observed within the study population, highlighting the limitations of a universal implant design. Although the evaluated implant achieved satisfactory congruency in most clavicles, anatomical fit was not consistently obtained, and a substantial proportion of clavicles demonstrated a measurable plate-to-bone gap or overhang, indicating that current implant designs do not fully accommodate the anatomical variability of the Indian population. These findings support incorporation of population-specific anatomical data into future clavicle plate design to improve congruency, reduce implant-related complications and minimise the need for intraoperative contouring. Larger multicentre studies evaluating multiple implant systems and correlating congruency with clinical outcomes are required to validate these findings.

Declarations

Author Contribution

All authors had full access to the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Conceptualization, V.P. and N.B.; Methodology, V.P. and K.H.; Investigation, V.P.; Formal Analysis, V.P., K.H. and A.D.; Resources, N.B. and K.H.; Data Curation, V.P.; Writing – Original Draft, V.P. and K.H.; Writing – Review & Editing, N.B., K.H., H.S. and A.D.; Visualization, V.P. and A.D.; Supervision, N.B., H.S. ; Project Administration, N.B.

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Data Availability

The datasets generated and analysed during the current study are available from the authors on reasonable request.

Ethical Compliance

All experiments in this study comply with the current laws of the country in which they were performed.

References

1. Postacchini F, Gumina S, De Santis P, Albo F (2002) Epidemiology of clavicle fractures. *J Shoulder Elbow Surg* 11(5):452–456
2. Robinson CM (1998) Fractures of the clavicle in the adult. Epidemiology and classification. *J Bone Joint Surg Br* 80(3):476–484
3. Nordqvist A, Petersson C (1994) The incidence of fractures of the clavicle. *Clin Orthop Relat Res* (300):127–132
4. Post M (1989) Current concepts in the treatment of fractures of the clavicle. *Clin Orthop Relat Res* (245):89–101
5. Prillwitz M, Martetschläger F, Tauber M (2025) Clavicular fractures: diagnostics, treatment and management. *Orthopädie (Heidelb)* 54(2):157–165
6. Bauer DE, Hingsammer A, Schenk P, Vlachopoulos L, Imam MA, Fürnstahl P, Meyer DC (2018) Are commercially available precontoured anatomical clavicle plating systems offering the purported superior optimum fitting to the clavicle? A cadaveric analysis and review of literature. *Orthop Traumatol Surg Res* 104(6):755–758
7. Mendes Junior AF, Tavares AK, Oppe IG, Pires RE, Belangero WD, Labronici PJ (2022) Pre-contoured superior locking plates offer poor bone fit for midshaft clavicle fracture fixation: cadaveric analysis of four commercially available systems. *Rev Col Bras Cir* 49:e20223177
8. Patel M, Ahmad M, Agrawal N, Patil ST, Santoshi JA, Rathinam B et al (2023) The use of precontoured plates for midshaft clavicle fractures is not always the best course of treatment. *Anat Cell Biol* 56(4):456–462
9. Daruwalla ZJ, Courtis P, Fitzpatrick C, Fitzpatrick D, Mullett H (2010) Anatomic variation of the clavicle: a novel three-dimensional study. *Clin Anat* 23(2):199–209
10. Sudha R (2014) Study of clavicle: length and curvatures in South Indian population. *Natl J Clin Anat* 3:198–202
11. Sehrawat JS, Pathak RK (2016) Variability in anatomical features of human clavicle: its forensic anthropological and clinical significance. *Transl Res Anat* 3–4:5–14
12. Huang JI, Toogood P, Chen MR, Wilber JH, Cooperman DR (2007) Clavicular anatomy and the applicability of precontoured plates. *J Bone Joint Surg Am* 89(10):2260–2265
13. Vancleef S, Herteleer M, Carette Y, Herijgers P, Duflou JR, Nijs S, Vander Sloten J (2019) Why off-the-shelf clavicle plates rarely fit: anatomic analysis of the clavicle through statistical shape modeling. *J Shoulder Elbow Surg* 28(4):631–638
14. Qiu XS, Wang YN, Xu T et al (2016) Anatomical study of the clavicles in a Chinese population. *Biomed Res Int* 2016:6219761
15. Wang H, Zhang Y, Liu Y et al (2017) Morphometric analysis of the clavicles in Chinese population. *Biomed Res Int* 2017:8149109
16. Kundu B, Saha PK, Mukherjee P (2021) Study of morphometry of clavicle in East Indian population. *Int J Anat Radiol Surg* 10(2):AO09–AO12

17. Singh J, Choudhary AK, Kaur R et al (2017) Morphometric analysis of clavicle in North Indian population. *J Anat Soc India* 66(2):120–124
18. Kotekar MF, Pai S, Yogesh K, Kumar MA, Shetty MS (2020) Anatomy of clavicle in the Indian population and its applicability in pre-contoured plating. *Int Orthop* 44(4):699–704
19. Barde MA, Sharma DA, Yadav S (2024) Employing computed tomography to assess clavicle symmetry in healthy adults in the Indian population of Dakshina Karnataka. *J Hand Microsurg* 16(3):100054
20. Van Tongel A, Huysmans T, Amit B, Sijbers J, Vanglabbeek F, De Wilde L (2014) Evaluation of prominence of straight plates and precontoured clavicle plates using automated plate-to-bone alignment. *Acta Orthop Belg* 80(3):301–308
21. Malhas AM, Skarparis YG, Sripada S, Soames RW, Jariwala AC (2016) How well do contoured superior midshaft clavicle plates fit the clavicle? A cadaveric study. *J Shoulder Elbow Surg* 25(6):954–959
22. Zenker M, Theodorou E, Andermatt D, Winkler R, Hoyer HA, Jaeger M, Jiang C, Lambert S, Nijs S, Fontana AD (2023) Quantifying osteosynthesis plate prominence – mathematical definitions and case study on a clavicle plate. *Comput Methods Biomech Biomed Engin* 26(8):917–926