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A comprehensive, integrated study of the clavicle: Its topographical anatomy, biomechanical architecture and function; pathological anatomy of mid-shaft fractures and the decision-making process for a surgical approach when planning an intramedullary implant:

Part 8 Ideal Approaches for the Insertion of an Intramedullary Implant for Fixation of Diaphyseal Fractures

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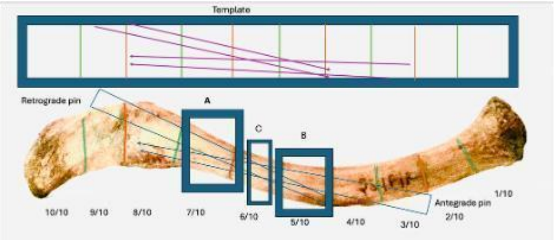
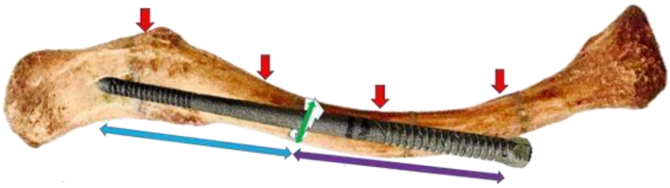
Highlights: The shape and form of the clavicle is neither S, ζ nor like the ƒ-musical key, but rather resembles a swan's neck. Therefore, fractures in its 3/5th and 4/5th sections lend well to an intramedullary implant. The primary function of an intramedullary device is to reduce and realign displaced fragments and hold them in place until there is sufficient stabilizing woven callus.

Stability depends on the length, diameter and interference fit of an intramedullary implant bridging the fracture. The antegrade approach to insert an IM implant is suitable for fractures in the 5/10th and 6/10th sections, and the retrograde approach for the 6/10th and 7/10th sections from the sternal end of the clavicle. There is less than 30 degrees of clavicle rotation under 90 degrees of arm elevation, which is less than 45 degrees of the screw turn or quarter of its pitch, so it can hardly cause a significant loosening of a threaded implant.

Graphic abstract:





Keywords: Clavicle, Mid-diaphyseal fractures, Intramedullary fixation, Antegrade approach, Retrograde approach, Supraclavicular nerves, Biomechanics

1.0 Claviform clavicle resembles Swan neck:

Figure 1. There is a greater resemblance of the clavicle to the swan's neck than to the sigmoid S or sigma ζcurves, and less so to the ƒ-musical key. The right image shows the swan's neck overlapping the clavicle.

The clavicle is a geometrical wonder that performs extraordinary functions in complex movements of the pectoral girdle. Its anatomical form is unique among all the long bones. Topographically, it is almost perpendicular to the body's sagittal median plane and connects the appendicular and axial skeleton, articulating at both its ends, within a limited space, makes it more challenging to insert an intramedullary implant than any other long bone.

Figure 2. A. Clavicles held together with the manubrium sterni, as mirror images of each other and **B.** A hanslee, yoke, to hitch a pair of oxen (created in PowerPoint by the author).

The hyperbolic paraboloid architecture of the clavicle resembles the swan's neck and one-half beam of the yoke. In Punjabi, the clavicle and yoke are both called *Hanslee*, derived from the Sanskrit word *Hansa.H, itself derived from Hasa.h,* meaning swan (**Fig. 1**). Describing the shape and form of the clavicle as S-shaped, sigmoid, sigma or resembling clef *ƒ,* one of the basic music notations *"forte"* to play loud, are all inappropriate descriptions. The acute S-shaped curves deter the idea of applying a straight, rigid or flexible intramedullary device to fix mid-diaphyseal fractures of the clavicle. The English name clavicle is appropriate from the Latin *Clevis* > cleave to mean hold fast, such as hold on to a wagon or tractor; *Clavis* means key, referring to the *clef ƒ*; and *Clavicula* means bolt. A yoke is any device or force that links two objects together in a team. The right and left clavicles, joined across the manubrium, resemble a yoke or hanslee (**Fig. 2**).

The bilateral arrangement of the two clavicles across the midline, analogous to a yoke, distributes applied forces evenly across manubrium sterni when the interclavicular ligament resists the weight carried in both the hands. As a paired structure, it works in tandem with the rest of the musculoskeletal system of the pectoral girdle. The team of the two clavicles must fit evenly on either side of the sternum *(median plane)* for the pectoral girdle to function effectively. Hence, restoration of the anatomy and the biomechanical architecture of the clavicle following its fracture is crucial, including its length, axial alignment, reconstruction of the medial and lateral curvatures, inferior and other secondary curvatures, proximal to distal diaphyseal torsional angle spiralling around the screw axis, version, inclination angle at the acromial third, and offset between medial and the lateral curvatures, to normalize excursion of the scapulothoracic synsarcosis. The ipsilateral scapula, via scapulothoracic synsarcosis, redirects the clavicle's cranking force for generating power at the glenohumeral articulation. Therefore, restoring a fractured clavicle is vital for delivering an overhead projectile and underhand daily tasks without persistent post-injury discomfort, pain, paresthesia, loss of strength or early fatigue.

2.0 Appropriateness of an intramedullary implant for fractures of the clavicle:

Biomechanically, the anatomy of the clavicle is integral to the upper extremities for a normal range of motion at the glenohumeral articulation. Therefore, the loss of clavicle's integrity disrupts its power-generating cranking system, necessitating reconstruction as best as possible surgically to support future remodelling in all three planes. Displaced fractured fragments should be immobilized in corrected alignment in all three planes and maintained with an external or internal device until sufficient self-stabilizing provisional callus has formed. Analogous in appearance to the '*Hass'* (yoke) or *'Hans greevaa'* (swan neck), the curves of the clavicle have relatively large radius of curvature or an obtuse angle of curvature when measured at the centreline. The medial curvature has a much greater angle than the lateral curvature (**Fig. 3**). The third-fifth and fourth-fifth sections from the sternal end are the commonest sites of diaphyseal fractures.

The commonest fracture site and architectural design of obtuse angles lend well to rigid (Stainless steel) and semirigid (Titanium alloy) intramedullary fracture fixation devices for managing central third diaphyseal fractures. A canal-filling threaded or an interference-fit implant with high contact at the bone-implant interface would generate sufficient torsional shear stress to constrain the fracture fragments during the early healing phase, supported in a shoulder immobilizer. Postoperatively, with the limb appropriately immobilized, patient education will prevent excessive torsional forces until the provisional callus becomes visible on plain radiographic imaging and confirmed clinically.

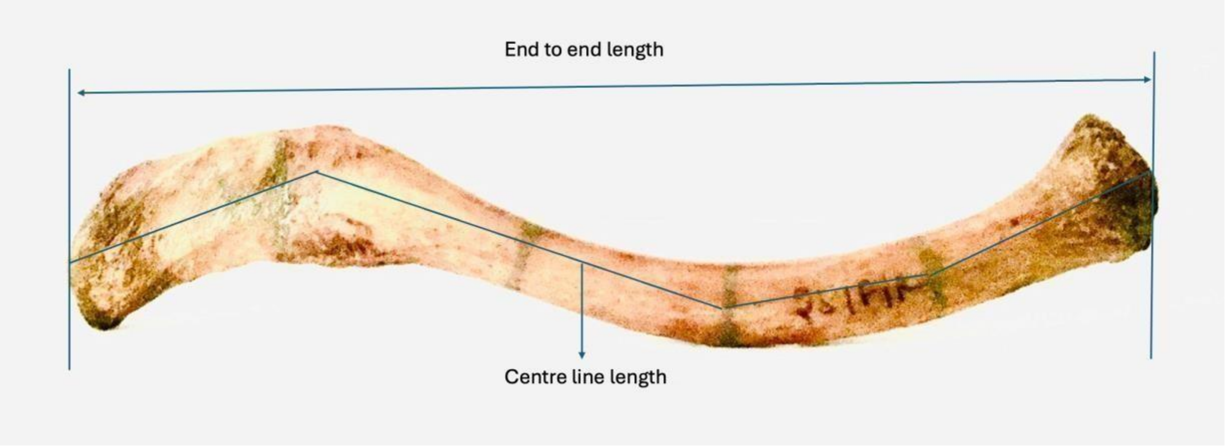


Figure 3. Obtuse angles formed by the medial and the lateral curvatures (created in PowerPoint by the author).

Do not view immobilization in a broad arm sling as a disadvantage in the early healing phase, following intramedullary implant-assisted fracture reduction and fixation. The soft immobilizer helps control pain, and early, gentle motion promotes the rapid formation of a healthy provisional callus, which is consistent with biological principles of bone healing. By contrast, rigid "absolute" fixation with plate and screws is contrary to the "strain theory" of fracture healing. Absolute rigidity for rapid early mobilization of the adjacent joints in extra-articular fractures is a biased opinion of the school of primary bone healing techniques. Begin graded range of motion once the stable provisional callus appears. The movements will modify and remodel the callus in relation to individual activities, developing individual-specific torsional and version angles around the screw axis. The subtle anatomical modifications based on loading conditions would ultimately help restore the kinematics of the clavicle and the glenohumeral articulation. At the same time, this will prevent excessive shear forces at the sternoclavicular and acromioclavicular joints.

Although not always possible, envision the subtleties in developing age-related patient-specific implant designs by understanding the clavicle geometry and increasing awareness of its effective role as a cranking system. In addition, preventing geometrical malunion *(any degree of measurable three-dimensional deformity of a healed fractured bone)* will restore strength and power by achieving the final few degrees of abduction and forward elevation with adjunct external rotation. The failure to gain the last few degrees of abduction and forward flexion is often reported as statistically insignificant and clinically irrelevant. Nonetheless, the setting and terminal phases of glenohumeral movements are vital to an individual's performance and should not be ignored.

3.0 Current modalities for fixation of the clavicle fractures:

Management of acute undisplaced, displaced, and comminuted fractures of the clavicle has been well-researched over the past twenty-five years. The range of modalities used by the school of conservative treatment yields fair to good results in minimally displaced fractures of mid-diaphysis. Similarly, several implant designs are available to achieve rigid fixation with pre-contoured plates and screws, and flexible intramedullary devices for biological fixation. Each has advantages and disadvantages, as extensively described by the favoured schools of fracture management. The key surgical precaution common to both implant techniques is the protection of the subclavian vessels and brachial plexus passing posterior and inferior to the medial three-fifths of the clavicle.

The plating technique of open reduction and internal fixation demands a much longer incision overlying the middle two-thirds of the clavicle. It is prone to injury of the Supraclavicular nerves despite careful dissection, compared with the intramedullary device implantation, whether via an antegrade or retrograde approach to open the medulla of a fractured clavicle. Other much-discussed factors include blood loss, operative time, a second surgery for implant removal, superficial wound infection, and refracture after implant removal, which is more common after plating than after intramedullary devices, due to differences in fracture-healing biology. Unlike plating, the intramedullary technique is a semi-rigid biological fixation that leads to secondary fracture healing. Currently, both implant systems have well-recognized pros and cons, dividing the trauma surgical communities and creating relative indications for choosing one implant over the other. A better understanding of the clavicle's anatomy and biomechanical architecture dynamics will encourage further innovation.

As with the shortening of the clavicle, it is unclear whether lengthening affects the kinematics of the scapulothoracic synsarcosis and glenohumeral articulation. Precise reduction of the fracture fragments can be challenging.

Nevertheless, when an intramedullary implant is applied, the longer the radius of the medial curvature (*longer moment arm*), the greater the mechanical advantage of its cranking system (**for details see Part 7 of the series**).

Several meta-analyses and systematic reviews favour surgical intervention for displaced and fragmented clavicle fractures at the earliest. Only 1.4% of operated cases develop non-union, compared with 16.5% managed conservatively. The reported functional outcomes (DASH and Constant scores) are better in the former group(Guerra et al., 2019). Even though pain and shoulder function are similar or modestly better in the operated cases than in the non-operated group at one year review, early surgical intervention can help prevent malunion and non-union(Lenza et al., 2019; Yan et al., 2022). Nearly one-third of patients treated conservatively for displaced fractures are dissatisfied when the displacement is greater than 20 mm(Hill et al., 1997).

4.0 Epidemiology and mode of injury:

The pattern and mode of injury of mid-diaphyseal fractures of the clavicle have changed over the last few decades due to increased physical activity and road traffic accidents. However, more than 90% of the fractures result from a direct fall onto the lateral aspect of the shoulder, some fall onto an outstretched hand, and a few are due to a direct blow to the clavicle(Robinson, 1998; Robinson et al., 2004; Stanley et al., 1988).

5.0 Clinical presentation:

At the time of presentation, the typical local signs and symptoms at the fracture site include pain, tenderness, and reported crepitus by the patient. Visible subcutaneous deformity of the displaced fracture fragments pointing frequently in a posterior-superior direction, occasionally with tenting that can jeopardize the skin integrity at its apex, is alarming. It is uncommon to note neurovascular signs and symptoms early on. The thoracic aperture compression syndrome often presents late, in cases of displaced fractures with shortening and angular deformity, which heals with frustum formation and a large callus after conservative treatment. Depending on the mode of injury leading to a displaced fracture, there may be superficial skin grazing, bruising, soft tissue contusion or even a laceration at the site where the shoulder or palm impacts the landing surface. In high-velocity accidents, carefully search for associated soft tissue and bony injuries to adjacent structures, particularly the first rib and first costovertebral articulation, and at remote sites, because in polytrauma the discovery of one more pathology leads to the discovery of another (**Fig. 4**).

Figure 4. Subluxation of the first costovertebral articulation **(for anatomical details, see Part 6 of the series)** accompanying a displaced clavicle fracture directed posteriorly. Note the forward-facing tip of the mispositioned coracoid process, with the Coracoid cortical Ring Light up Sign-G is on **(for details see Part 4 of the series)**.

6.0 Imaging of a fractured clavicle:

The normal anatomy of the clavicle is highly variable. It has variable angles to the median, coronal and transverse planes, as well as a plane relative to the scapula. These relationships are significantly disturbed in a displaced clavicle fracture. To elucidate the exact pathological anatomy and orientation of the clavicle fragments, obtaining anterior-posterior, posterior-anterior and oblique cephalic and caudal axial views at 30-45 degrees can be challenging. None of the currently available views of fractured clavicle follows the basic radiology principle that the X-ray beam should be perpendicular to the clavicle under examination and the recipient bucky.

Oblique false axial views do not provide exact qualitative or quantitative measurements of axial and angular displacement of the fracture fragments because it is difficult to acquire the correct orientation of the beam directed at the fracture fragments and the bucky. The same applies when taking a posterior-anterior chest view for diagnostic and morphometric purposes to measure the length of the uninjured clavicle to replicate during operative reduction and fixation of the fractured clavicle, while recognizing that there is directional asymmetry in 30% of the population. Indeed, it is inappropriate to accept any amount of shortening measured using the anterior-posterior view of a fractured clavicle relative to the uninjured clavicle(Jones et al., 2014). Therefore, base the decision to operate on a displaced clavicle fracture with an angular deformity for shortening on alternative radiographic modalities, such as computed tomography.

Considering the directional asymmetry, the right clavicle is frequently shorter than the left, and a direct percutaneous measurement of the uninjured clavicle pre-operatively with a measuring tape with a little error, may still be a preferable technique to excessive radiation exposure during a computed tomographic examination. Alternatively, knowing the directional asymmetry, using a radio-opaque ruler, and adding up the lengths of each fracture fragment and the intact clavicle are reasonable options when reconstructing a diaphyseal fracture of the clavicle. A Staedtler's engineering flexible curve ruler with double-sided graduations in both metric and imperial measurement, encasing a radio-opaque lead core, that hold the shape for measuring is an excellent tool for this purpose. It can measure end-to-end and centreline length of the intact and individual fracture fragments of the clavicle percutaneously.

A shortening of 12-15 mm (>10%) is associated with poor functional outcomes in displaced clavicle fractures. Therefore, carefully consider length restoration when deciding upon operative treatment(Nordqvist et al., 1998).

7.0 Technical factors for restoring anatomy and biomechanical architecture of clavicle fractures:

Anatomical restoration for achieving the original biomechanical functions of a fractured hyperbolic paraboloid clavicle, with patient-specific torsion and version angles, transverse and coronal plane offsets, is far more intricate than any other long bone fracture. There are three basic components for restoring the biomechanical architecture of a bone: anatomical, mechanical and kinematic alignments. These have been well studied and applied to correct long-bone deformities at other sites(Butcher & Atkins, 2003; Paley, 2003; Thomas & Round, 2023). Correcting the alignment of a long bone centres on the anatomical axis, the mechanical axis, and the kinematic axii at adjacent joints to achieve successful fracture reduction and prevent malunions.

An axis is an imaginary line, a point of reference, through the centre of an object that tends to rotate in space around it. The structure does not experience stresses along its length under load. The normal or neutral axis of an object within a system plays a critical role in determining how the moments are distributed across its cross-sections and along its entire length. The mechanical axis of a bone is the straight line that connects the centroids of the proximal and distal joints, bearing static mechanical load. Following a malunited fracture, there is a lack of collinearity between the joints, deviating from the normal mechanical axis. The mechanical axis can be best assessed on twodimensional plain radiographs taken in two planes. However, this is not a simple measurement in the case of the clavicle because neither of the joints is perpendicular to its mechanical axis, and lateral curvature offsets from the medial curvature with a curved screw axis due to axial torsion running throughout its length. The anatomical axis of a long bone follows an end-to-end centreline passing through the medulla of the diaphysis(Luo, 2004). The clavicle has medial and lateral curvatures and a mixture of individual variations in craniocaudal curves in the coronal plane; therefore, the anatomical axis follows these curvatures, which differ slightly in all planes.

The kinematic alignment of the clavicle is three-dimensional, and the dynamic kinematic axii pass through the centroids or lie outside the joint space owing to the design and orientation of the articular surfaces at either end of the clavicle(Kapandji, 2005). The kinematic alignment is established in space around the three axii, x, y and z, in relation to both sternoclavicular and acromioclavicular joints. These axii change in conjunction with the three axii of the glenohumeral articulation during a particular upper extremity motion.

The ideal realignment of a fractured bone is the restoration of collinearity among the involved joints. Any loss of collinearity between joints indicates malalignment, whether due to malreduction or malunion of a fracture. Any degree of frustum formation will alter the biomechanical architecture of the clavicle, disrupting the anatomical and mechanical axii and kinematic alignment on various axii passing through the diaphysis of the clavicle and its articulations. Consequently, the three-dimensional deformity within the substance of the clavicle and the conjunct articulations will alter the force vectors across the entire power transmission crank system and the length-tension relationship of the acting musculature, thus affecting the function of the bilaterally represented pectoral girdle and ipsilateral shoulder complex.

The shortening and reversal of medial curvature, due to varying degrees of posterior-superior angulation and fracture site, also alter the offset to the lateral curvature(Edelson, 2003). The dorsoventral and craniocaudal curvatures, and other elements of the clavicle's architecture, are optimized for an individual during development, with the formation of progressively changing moment arms and the length-tension relationship of all involved muscles acting on the bone and joints. The altered muscle length-tension relationship following a fracture malunion is a well-recognized cause of loss of strength and power at the key joints. The limitation of the strength and normal range of motion reduce the force required to complete the task at hand. These limitations are partially overcome naturally through remodelling of the fracture callus and, during rehabilitation, by adapting to less-than-optimum newly modified crank system afforded by the 'healed' clavicle fracture. In addition, increased shear stresses at the articular surfaces lead to post-traumatic arthrosis, which becomes a long-term cause of pain and limited range of motion.

Therefore, realignment of the biomechanical architecture of the clavicle is key to balancing the forces transmitted through the bone, muscles, ligaments and capsules enclosing the joints. In this regard, restoring the mechanical alignment through anatomical realignment is fundamental to reducing adverse forces on the joints by achieving near-normal kinematic realignment, thereby minimizing compensatory changes. The restoration of anatomy realigns the mispositioned neurovascular bundle enclosed in the cervical fasciae intimately related to the posterior and inferior surfaces of the clavicle, thereby preventing thoracic aperture compression syndrome.

8.0 Surgical anatomy of the clavicle, subclavian vessels and the brachial plexus, and safety of intramedullary devices:

Compared to the intramedullary implants, the plate and screws technique for the resynthesis of the middle thirdfifth and fourth-fifth sections of the clavicle fracture demands dissection that spans far more than the extension of the fracture lines. Several screw holes are mandatory in the bone, with variable trajectories depending on whether the chosen plate design is placed superiorly or anteriorly, to hold the fragments rigidly for primary fracture healing. In the case of an intramedullary implant, there is a single-entry hole perforating the cortex, generally in the anterior cortex for a medial to lateral antegrade and posterior cortex for a lateral to medial direction retrograde approach. Occasionally, limited exposure of the fracture site is required.

Creating several screw insertion sites at varying trajectories requires a thorough knowledge and understanding of the pathological anatomy of the neurovascular structure following displacement of fracture fragments. At the medial one-fifth section of the clavicle, the subclavian vessels, particularly the vein, are vulnerable to surgical injury, lying posterior and inferior, separated by the tendon of the Subclavius muscle **(for details see Part 1 of the series)**. At the second-fifth and third-fifth sections of the diaphysis, the vessels descend steeply from the posterior aspect, intimately relating to the inferior surface of the clavicle (**Fig. 5**), and at the fourth-fifth section lie directly inferior to it, separated by the Subclavius muscle(Sinha et al., 2011).

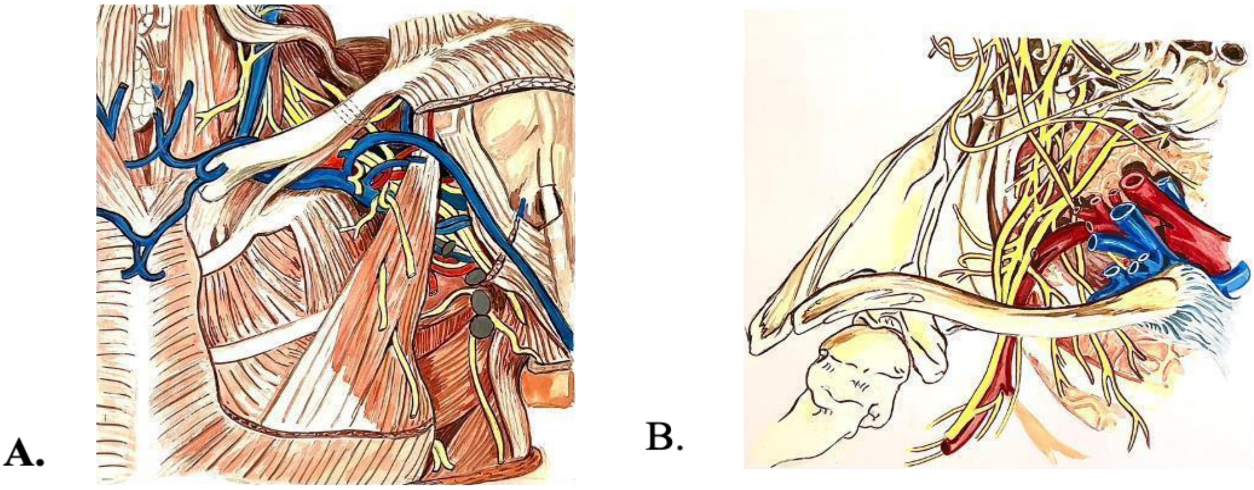


Figure 5. Artwork - Illustrations **A** and **B** show the relationship of the subclavian vessels and the brachial plexus trunks and cords to the clavicle. (**A.** Modified illustration of specimen S 350 in the museum of the Royal College of Surgeons, England. **B.** Modified illustration from Illustrated Handbook in Local Anaesthesia, Second edition, page 79).

The neurovascular structures in the infraclavicular region, past the lateral border of the first rib, diverge widely from the lateral one fifth of the clavicle due to the offset between medial and lateral curvatures, dorsocranial orientation of the clavicle and forward-facing concavity of the lateral curvature. The anatomical relationship of the neurovascular bundle to the clavicle described in cadaveric studies is generally fixed due to the posture of the neck and arm, unlike dynamic positions met during surgery. Therefore, observe greater care when drilling in the anterior to posterior, posterior to inferior, and craniocaudal directions at the medial one-fifth, second-fifth and third-fifth sections of the clavicle diaphysis, respectively, with proper protection of the structures by applying blunt retractors subperiosteally. Compared to the intramedullary technique during plating, every additional screw insertion with prior drilling and tapping increases the risk of injury by manifold to the vessels, brachial plexus and apical pleura.

9.0 Pertinence of intramedullary fixation devices for the hyperbolic paraboloid shape of the clavicle:

Several biomechanical and clinical computed tomography morphometric studies support use of the intramedullary implants despite the clavicle's three-dimensional curvatures and eccentric medullary shape. (**Fig. 6).** The clavicle lends itself well to flexible and rigid intramedullary devices for reconstruction(Aira et al., 2017; Andermahr et al., 2007; Bachoura et al., 2012, 2013; Bernat et al., 2014; King et al., 2014, 2019). Patient- specific end-to-end and centreline lengths of the clavicles vary due to differences in the length of the medial curvature(Lambert et al., 2016). Given the large radius of the medial curvature, an intramedullary implant can comfortably negotiate the medullary canal of a fractured clavicle, with a varying degree of difficulty depending on the type of fracture, with or without fragmentation.

Figure 6. Note changing cross-sectional profile of the segments and eccentric holes left after the removal of an intramedullary implant inserted retrograde in a Sawbone©

The type and site of a fracture determine technical feasibility, the ease with which a rigid implant can bridge the fracture to achieve mechanical stability and realign the fragments. Of course, it cannot match the exact threedimensional static rigidity achieved with a pre-contoured plate and screws, but none are patient-specific and often need intra-operative modifications. Ask whether "absolute" rigid fixation and early mobilization is essential and whether the operating surgeons favour early fracture healing and future remodelling. Is the operating surgeon seeking primary fracture healing with a prolonged remodelling process, or healing with a self-stabilizing cuff of an early provisional callus and faster remodelling, based on the individual's biomechanical forces to reshape the bone with a gradually increasing range of motion by applying an intramedullary implant offering semi-rigid fixation?

10.0 Intramedullary implant feasibility: morphometry and virtual segmentation of the clavicle in fifths:

The surgical importance of a topographic anatomical classification system for pre-operative workup lies in its adherence to the surface anatomy of bones, muscles and ligament attachments, and their relationship with neurovascular and other vital structures. Several classifications segment the clavicle into thirds and fifths to describe the commonly observed fracture site, degree of fragmentation and displacement, and whether the fracture is closed or open with associated neurovascular injury(Allman, 1967; Nordqvist & Petersson, 1994; Robinson, 1998; Walters et al., 2010). None of the anatomical classifications pay attention to the footprints of the ligament attachments, origins and insertion of the muscles, and sites of the nutrient arteries. From the perspective of fracture prognosis, the clavicle has been divided into the lateral and medial fifth and the middle three-fifths, technically dividing the clavicle into three portions(Robinson, 1998). Most fractures occur in the middle three-fifths, and type 2B (69.2%), characterized by complete displacement with significant fragmentation, is the most studied(Robinson, 1998). The study did not indicate which of the middle three-fifths fractures are most commonly present. However, an older study on a review of 690 cases of clavicle fractures reported that 44% of the middle third fractures occurred at the transition between the middle and the lateral thirds *(fourth-fifth section)* and 38% directly at the middle third *(third fifth section)* sections of the clavicles(Rowe, 1968).

In a study considering gender, race and other differences, for an average clavicle length of 152 mm, the narrowest region of the clavicle measured 13.29 mm, and the intramedullary canal was 3.82 mm(Aira et al., 2017). In the same study, the mean medial curvature radius was 91.20 mm, and the average radius of the inferior curvature was 256.70 mm. The measured medial curve had a significantly larger radius of curvature in males than in females, and the left clavicles had a larger radius than the right clavicles. There was no significant correlation between medial and lateral radii of curvatures of the clavicles. The left clavicles are flatter and longer than the right. In a bilateral computed tomography study, 71% of the clavicles were symmetrical, 21% were asymmetrical by 5 mm, and the remainder had asymmetry of more than 10 mm(Cunningham et al., 2013).

In this study, the clavicle has been sectioned into five segments from the sternal to the acromial end to facilitate the placement of intramedullary devices, considering the most common fracture sites **(Fig. 7)**. The most common sites of the fractures are in the third-fifth and fourth-fifth sections of the bone. This assumption has been used to select an antegrade or retrograde approach for realignment and stable fracture fixation in these diaphyseal zones.

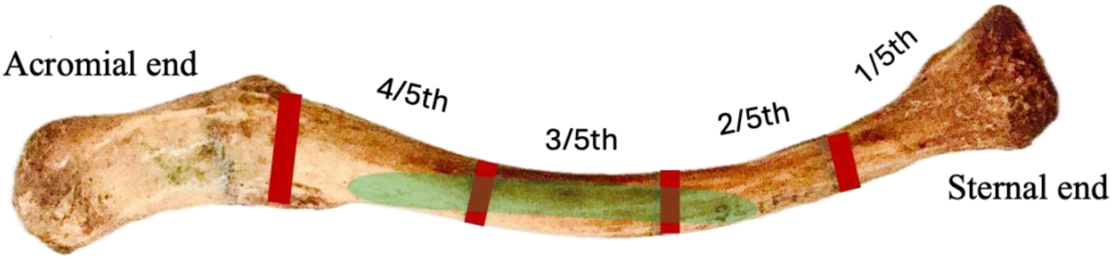


Figure 7. Division of a cadaveric clavicle into fifths from the sternal to the acromial end, showing a straight corridor in the three central segments, represented by the green transparency (created in PowerPoint by the author).

Experimentally, given the presence of a relatively straight, cylindrical medullary corridor in the second-, third- and four-fifth sections from medial to lateral, an intramedullary implant can engage a length of two cortical diameters in most fractures **(Fig. 7)**. In a study, 15 out of 22 clavicle specimens, with a mean length of 136 mm, a cortical diameter of 11.4 mm, and a cortical thickness of 3.6 mm on either side of the midline fractures; on an average, 43.8 mm (65%) of the corridor was lateral and 23 mm (35%) was medial to the midpoint fracture line(Bachoura et al., 2012).

11.0 Adaptability of intramedullary devices:

Operative treatment of displaced clavicle fractures in athletes with intramedullary flexible nails is safe, providing a stable construct when inserted using a minimally invasive technique, with or without the need for fracture site exposure. It is a favourable technique both functionally and aesthetically(Jubel et al., 2003). A smooth, flexible 3.5 mm Titanium implant takes 70 Newton of force to bend and, when pushed through the medullary canal, rebounds to undo the normal medial curvature of the clavicle(Andermahr et al., 2007). The increased radius of curvature due to rebound would result in a gain in length, which could be an advantage where tiny fracture fragments are lost, provided the interfragmentary gap does not exceed 2mm. Technically, an increase in length provides an additional cranking effect at the acromial end because the greater the radius of curvature, the greater the moment arm, and the greater the cranking force (**for details see Part 7 of the series**) The increased cranking effect is advantageous when choosing a smooth, flexible Titanium nail or a rigid threaded intramedullary device.

The cortical shell is thin and less dense at the medial ventral surface and dorsal acromial end cortex(Andermahr et al., 2007). Therefore, the ease with which cortical perforation occurs at these sites allows for selection of antegrade and retrograde insertion for various intramedullary implant designs. However, controlled force is required when making a pilot hole with a drill or an awl, lest it plunge deeper, particularly at the medial end, where the neurovascular structures are intimately related to the posterior and inferior surfaces of the clavicle. Generally, the shorter inferior curvature, concentrated at the junction of medial and lateral curvatures, has a very large radius of curvature(Aira et al., 2017; Qiu et al., 2016). Therefore, it does not cause any technical difficulty However, if variations in the existing inferior curvature in the coronal plane laterally and in superior curvatures more medially are ignored during a closed technique, there is always a likelihood of breaching the inferior or superior cortices with a misdirected trajectory, particularly as the medullary canal traverses an eccentric path(Aira et al., 2017).

The medullary canal of the clavicle is large enough to accommodate commonly available intramedullary implants in most cases(King et al., 2014). The medullary canal has sufficient length on either side of the midpoint of the diaphysis to receive an intramedullary device to adequately bridge fractures at the middle two-fifths of the clavicle(Bachoura et al., 2012, 2013). Like an aeroplane propeller, the cross-section of the clavicle can vary from the medial to the lateral ends, taking different shapes at different segments in various planes. It can be prismoid, oval, circular, triangular, or rectangular (**Fig. 6**). So does the cross-sectional shape of the medulla vary along its length, within the same clavicle, and between individuals across populations(Harrington et al., 1993; Walters et al., 2010).

On the anterior-posterior X-ray view, the shape of the medulla from sternal to the acromial end appears as a slender hourglass, narrowest at the fourth-fifth section, the transition zone between medial and lateral curvatures.

From the biomechanical perspective, a well-selected intramedullary device during surgical planning is likely to offer greater stability of fractures in the third and fourth-fifth sections of the clavicle, depending on whether an antegrade or retrograde approach is chosen based on pathological anatomy and exact site of the fracture. The medulla is patent in a small number of cases. The width of the medulla in both planes and cortical thickness is critical for developing a safe trajectory for inserting an intramedullary device. Computed tomography would help when planning a closed technique. Reaming of the medullary corridor with an appropriately sized flexible reamer may be necessary when the medullary canal is trabecular or rudimentary, or when the medial curvature is short and unusually curved, and the implant must be negotiated through the cortico-cancellous canal.

12.0 Biological and mechanical principles of stable fixation and fracture healing:

Major muscles attach to the clavicle, covering most of its superior and anterior surfaces, and the posterior-superior border at medial and lateral ends, leaving only the central third-fifth section with clear surfaces for the placement of a plate and screws(Imazato et al., 2023). These muscles attach directly to the periosteum, which forms the primary source of blood supply to the cortex of the clavicle. Therefore, careful subperiosteal dissection to expose the fracture site and adjacent bone is critical for preserving the fracture site's vascularity and allowing placement of a surface implant. Despite the biomechanical advantages of offering a stronger three-dimensional construct, plating has limitations, including subperiosteal dissection and unavoidable neurotmesis of the Supraclavicular nerves with long skin incisions. In addition, plates have a higher incidence of subcutaneous implant-related irritation and superficial infection and refracture rate after implant removal compared to intramedullary implants, despite similar functional outcomes(King et al., 2019; Li et al., 2020). Nearly 50% of cases of clavicle fractures treated with plate and screws experience altered infraclavicular cutaneous sensory changes(Houwert et al., 2012). Rigid fixation of a plate is well known to affect periosteal vascularity beneath it, which may lead to bone necrosis(Perren, 2002).

12.1 Interfragmentary 2 mm gap and strain theory:

For accelerated fracture healing, an optimal interfragmentary gap, micro-motion and stable fixation have been known for a long time. In simple fractures, a gap of less than 2 mm is optimal, whereas in a fragmented fracture, a gap of a little more than 2 mm between the substantial fragments is acceptable(Ito & Perren, 2007). In a characteristic corticocancellous structure without a true medullary canal, fracture healing occurs without a significant external callus. After the inflammatory stage, it enters the intramembranous ossification phase, driven by the tremendous angiogenic potential of the trabecular bone. With stable fixation, the fibrous tissue in the fracture gap rapidly converts into bone(Ito & Perren, 2007). Displaced clavicle fractures tend to develop a stabilizing callus quickly with the simplest of devices such as collar and cuff sling. With intracortical trabecular healing and the formation of a little to moderate circumferential cuff of soft callus, there is adequate stability to prevent shortening, which is one of the major parameters in clavicle fracture outcome. However, the unsupported early callus may not be strong enough to resist torsional and bending stresses. The process of remodelling, depending on the immobilization method and the time since fracture stabilization, can span from a few months for the secondary callus to several years in the case of primary cortical bone healing, before the fracture site returns to its original morphology and physiological function.

Under load, all materials deform, the softer granulation tissue much more than the provisional woven callus. The presence of an optimal gap decides the amount of deformation, which forms the basis of strain theory. Intact bone tolerates 2% strain, and granulation tissue tolerates 100% strain(Halvachizadeh & Pape, 2020; Perren, 1991). The amount of strain depends on the interfragmentary motion, which in turn depends on the interfragmentary gap. Interfragmentary motion stimulates callus formation, accelerating fracture healing(Claes et al., 1998). A fragmented fracture can tolerate greater strain because the deformation is shared and averaged across multiple small and large fragments. A flexible fixation, such as an intramedullary implant, can stimulate early callus formation, which is self-stabilizing, attains proportionate strain, and further optimizes healing and remodelling.

On the other hand, in a simple fracture with a fracture gap of less than 2 mm and relative stability, persistent shear stresses result in bone resorption and delayed healing, and a risk of non-union. Whereas in a multi-fragmentary fracture with > 2mm gap provides relative stability, secondary bone healing results in substantial circumferential callus, providing early torsional resistance with a well-designed intramedullary device. Any attempt to attain absolute rigidity and stability, and less than a 2 mm gap results in bone resorption at the fractured ends, delayed healing, and slow osteonal remodelling, with a likelihood of non-union. In cases of refracture after plate removal, consider an intramedullary device rather than repeat plating for a rigid fixation and absolute stability. It is reasonable to treat an undisplaced clavicle fracture conservatively if it does not displace into a frustum deformity during the formation of a soft circumferential callus, and soon after starting an advanced passive and gentle exercise program.

13.0 Smooth, flexible or a threaded intramedullary device:

Classically, a straight, rigid, non-locking nail, or a pair of elastic canal-filling nails with uniplanar curvature, intramedullary implants in curved femur and radius have achieved stable fracture fixation through a three-point contact loading mechanism, high shear forces and resistance to bending. A smooth implant does not resist torsional and axial shear forces without an interference fit with the endosteal walls. The hyperbolic paraboloid architecture and variable centring of the cross-sections of the clavicle tend to defy the three-point fixation principle. Fitting a rigid, threaded intramedullary implant in its eccentric medullary canal can be challenging.

Various intramedullary fixation devices, despite being technically known to yield less than stable constructs under torsional loads, have shown excellent clinical outcomes(Fuglesang et al., 2017; Proubasta et al., 2004; Richardson et al., 2013). Most recently, in a biomechanical study evaluating a threaded intramedullary clavicle implant, cadaveric clavicles with several fracture patterns (simple oblique, butterfly fragment and wedge fracture) were compared to an intact clavicle. Each fracture type, with controlled right- and left-sidedness, bone density, length, and diameter, was fixed through a retrograde approach using a 90 mm long and 3 mm diameter solid titanium alloy device. Under torsional and cantilever bending loads, there was no significant difference in their gross biomechanical bone-implant performance(Kunkle et al., 2021). The constructs were weaker in torsion during clockwise rotation on the left and counterclockwise rotation on the right. The loosening of the implant was less on the left side than on the right.

Obviously, the right-handed screw thread unwinds on the right and tightens on the left side with rotation of the clavicle. However, such right-hand and left-hand screw thread issues have long been resolved in the case of bicycle pedals attached to the crank, so they don't loosen and come undone during pedalling action, which turns one pedal clockwise and the other counterclockwise. A left-hand screw thread device is selected to counteract the forces that cause the right-hand screw to loosen.

The results of biomechanical experiments conducted under varying conditions cannot be compared to outcomes in surgical cases. With the sternal end fixed, and the free acromial end subjected to a moving load, the repeatedly observed torsional failure in cadaveric biomechanical experiments under cantilever bending loads is driven by difficult-to-control instantaneous rotation arising from inherent torsion and version angles, the inclination angle, the laterally concentrated inferior curvature in the coronal plane, and the offset between the medial and lateral curvatures in the transverse plane. As the Formula racing cars have a single wheel nut, right-hand and left-hand screw threads are tapped at each end of the axle so that when the wheels spin, the nuts don't come loose. Likewise, reconstruction of the clavicle fracture with right- and left-handed threaded intramedullary implants of appropriate length and diameter, stabilized between sternoclavicular and acromioclavicular articulations, will resist rotation and prevent loss of fracture stability.

It is crucial to understand the differences between left- and right-hand threaded implants, to determine which direction a threaded intramedullary implant will loosen during arm elevation. Under 90 degrees of abduction and less than 45 degrees of dorsal axial rotation of the clavicle, unwinding is limited to a quarter of the screw pitch, with negligible equivalent translation between the implant and the bone. Immobilization of the arm in a shoulder immobilizer and underarm movements during the early healing phase will restrict abduction and rotation. Unless the patient is advised to make frequent underarm flexion and extension shoulder movements, which may serve no useful purpose, the implant is likely to unscrew, with repeated short arc turning movements. Early graded movements, and safe rehabilitation programme will encourage self-stabilizing provisional callus formation, which can be assessed and correlated radiographically over the following 3-4 weeks.

For displaced clavicle fractures with limited fragmentation, load-sharing intramedullary devices combined with closed reduction technique can effectively achieve the goals of biological fixation. An intramedullary device with a differential screw thread, first engaging the shorter of the two major fragments and then driving them closer within a 2mm interfragmentary gap through controlled movements under x-ray imaging, can be successfully stabilized, depending on the degree of fragmentation.

14.0 Surgical access and bone-implant fit for quality fixation of an intramedullary implant:

Fracture classifications based on bone and joint anatomy, fracture pattern, and fracture energy generally offer limited guidance on the choice of surgical access and the selection of plate and intramedullary implant design for stability and prognosis of a given fracture type. There is a well-recognized system of surgical approaches in Orthopaedic based on the course of major nerves and vessels. The topographic anatomy of the clavicle does not lend itself to such a system because major neurovascular structures instead running along the axis of the clavicle, they run almost perpendicular in an oblique path and intimately related to its posterior and inferior surfaces. The principle of the inter-nervous surgical approach to avoid injury to the Supraclavicular nerves applies to making short vertical incisions for limited exposure to the fracture site and minimally invasive fixation techniques. The branches of the Supraclavicular nerves have variable anatomy and distribution, so they can be still get easily cut during vertical or a full-scale transverse exposure for plating (**Fig. 8**).

Figure 8. The author's dissection showing multiple cutaneous branches of the Supraclavicular nerves crossing the clavicle obliquely rather than vertically.

The most common sites of clavicle's diaphyseal fractures are in their fourth-fifth section (44%) and third-fifth section (39%), from the sternal to the acromial end. There are two popular surgical approaches for inserting intramedullary implants: antegrade and retrograde. However, there is no scientific basis determining when to use one or the other, depending on the site and pattern of fracture, to attain optimal biomechanical stability, strength and stiffness of the construct when applying an intramedullary implant.

The primary function of an intramedullary device is to help reduce and realign displaced fragments and hold them in place until sufficient stabilizing woven callus is formed. The stability of the fragments in a reduced position depends on the length of the intramedullary implant bridging the fracture site and its diameter to provide an interference fit against the endosteum. Apart from the implant material, additional stability, strength, and stiffness can be achieved by developing greater intimate fixation, with a threaded implant engaging into the endosteum to increase shear resistance and reduce translation at the bone-implant interface. To avoid loosening under torsional loads, have a specific right- and left-handed screw threaded implant design for the left- and right-sided clavicles, respectively. It will limit implant loosening when arm movements for feeding, and hygiene activities are under 90 degrees during the early postoperative period. The posterior axial rotation of the clavicle from its resting position is less than 10 degrees for under 60 degrees of arm elevation(Inman et al., 1944; Ludewig et al., 2009).

Theoretically, with less than 45 degrees of axial rotation of the clavicle, a threaded implant is unlikely to rotate exceeding 45 degrees, a quarter of thread pitch, during active arm elevation of up to 90 degrees. This partial unthreading is equivalent to a quarter-pitch translation of the fragments with each abduction movement may introduce beneficial longitudinal micromovements without shear of fractured ends, owing to the bridging implant segment. However, intentional, uncontrolled, frequent arm elevation would cause endosteal erosion, implant loosening, and increase endosteal shear forces at the fracture site, thereby widening the interfragmentary gap. A well-seeded, stable threaded implant with a differential thread may advance to close the gap between the fractured ends rather than being extruded subcutaneously.

A lack of bone implant interference is detrimental to fixation. A smooth pin produces a low interfacial shear stress, leading to linear sliding, early loosening, and pin extrusion. In a comparative study, the engagement length for 3.2 mm diameter pins was 91.2 mm, equivalent to an eight-hole plate and for 4.0 mm pins, the engagement length was 71.7mm, equivalent to a six-hole plate when inserted from the acromial end of the clavicle (*retrograde approach*)(Harnroongroj & Jeerathanyasakun, 2000). The pin engagement length in the lateral fragments was 48.7 mm for 3.2 mm and 42.6 mm for the 4.0 mm, whereas pin engagement in the medial fragments was 42.4 mm for 3.2 mm and only 29.1 mm for 4.0 mm pins. The long axis of the 3.2 mm pin was found to be more aligned with the long axis of the clavicle than the 4.0 mm. The greater the pin diameter, the shorter the engagement in the far fragment for a given radius of the medial curvature.

The medial curvature with a large radius of curvature is straighter and has a relatively circular medullary canal. In the retrograde approach, shorter engagement and less-than-required bone-implant interference (*transition fit*) result in moderate-quality implant engagement in the far-end medial fragment with larger-diameter pins. On the other hand, a smaller-diameter pin providing more extended engagement in both the fragments with a poor interference fit (*clearance fit*), would lead to implant extrusion. The angle of the implant across the fracture site is determined by the angle to the entry cortex at the time of its insertion, depending on the radius of curvature of the medial and lateral curves and the length and diameter of the implant. Once in the medullary canal of the near fragment, it decidedly continues to hold the same angle into the far end fragment(Harnroongroj & Jeerathanyasakun, 2000). Undoubtedly, a smaller-diameter pin will have greater engagement lengths, but doing so would compromise the strength and stiffness of the entire bone-implant construct for a given fracture pattern and stability, failing to restore the biomechanical architecture of the clavicle. The clearance fit is associated with vibration at the bone-implant interface and fatigue failure of the implant.

15.0 Biomechanical principles for secure fixation of an intramedullary implant:

The biomechanical principles for secure fixation of an intramedullary implant demand optimal length engagement and canal-filling *interference fit* for patient-specific morphometry of the clavicle. Consider the secure fixation of an intramedullary device analogous to a latch, where a crossbar or a draw bolt design secures a door closure, ensuring a strong, safe, and reliable connection between all its elements. In a double-panelled door, a latch with a draw bolt engaged in two or more cleats or eyes, with a hasp and corresponding staple for a lock, provides a secure mechanism often termed “bolting a door” (**Fig. 9**).

Figure 9. A double-panel door draw-bolt is analogous to the stable fixation of a two-piece fracture with or without fragmentation of the clavicle with an intramedullary implant (the photographs by the author) .

The length of the draw bolt on either side of the door opening and spacing of the cleats between the panels are manually adjusted by trial and error for each door, such that even without the hasp in the staple, it remains secure when pushed from the opposite side by an entrant.

Similarly, for a secure and stable fixation with sufficient strength *(the ability of a composite construct to resist 3 times the expected load to satisfy the safety requirements)* and stiffness *(the ability of a composite construct to resist deformation under load and return to its original state upon unloading),* an unyielding intramedullary boneimplant relationship should follow the same mechanical principle as that of the classic modular draw-bolt door latch. A key principle of such a fastening system to keep the door securely closed is the ratio of the draw bolt length on either side of the opening and diameter of the cleats by adjusting the space between them for a custom latching solution.

Similarly, the stability, strength, and stiffness are critical for a secure intramedullary bone-implant construct. Theoretically, considering the ratio of the length to the diameters of an intramedullary implant relative to the measured average external cortical diameters at the fractured ends in both anterior-posterior and superior-inferior directions, the working lengths on either side of the fracture must be 3-5 times to prevent disengagement under physiological loads. The medullary canal should be prepared to safely accommodate the maximum major diameter of the implant for an interference fit. The length-to-diameter ratio of a draw bolt and the spacing of the cleats is a good guide to achieving secure fixation after the fracture has been reduced within 2 mm of the interfragmentary gap *(the available measuring tool is the thickness at the tip of a traditional Bard-parker scalpel handle)* depending on the fracture pattern. It does not have to be a rigid axial fixation in compression for absolute rigid stability.

Fracture stabilization with an intramedullary implant depends on the bone-implant interface of an elastic implant and the stiffness of healthy adjacent bone. Reaming the medullary canal allows the use of an implant with a greater radius, increasing strength and endosteal contact surface area, expanding the indications for more complex fracture patterns. The gentle reaming with a flexible hand reamer would limit excessive trabecular bone removal, allowing better implant threading into the denser endosteal surface. For small and medium-sized clavicles, proportionate reaming or no reaming is preferable to preserve the cortical thickness and bone strength. In the closed reduction and fixation technique, the reamed bone debris delivers autogenous osteoinductive bone cells in the fracture gap(Kretek, 2007).

In a biomechanical study, the clavicles modelled after simple mid-point short oblique fractures were fixed with 2.5 mm and 3.5 mm diameter smooth Titanium elastic nails, inserted from the medial to lateral direction (*antegrade*)(Chung et al., 2015). Specimens were tested in a jig, applying a three-point bending load (*akin to pushing the door panels against the drawbar of the bolting latch*) to measure stiffness and failure load, to study the influence of implant length and diameter relative to the external diameter of the clavicle specimens. For each of the two major fracture fragments, for a 2.5 mm diameter nail, the length must be more than three outer diameters of the clavicle. For a 3.5 mm diameter nail, the minimum length should be three diameters to provide adequate stiffness for firm fixation. However, in higher-risk cases, such as elderly patients with osteoporosis having a voluminous medulla and displaced, fragmented fractures, the fixation length must be 5 times the diameter for an extended fixation, which would provide clearance or transition interference, reducing stiffness and strength, with the likelihood of extrusion. A larger-diameter intramedullary implant increases the surface area of bone-implant interface, thereby increasing interference, contact shear stresses and, hence, greater resistance to torsion.

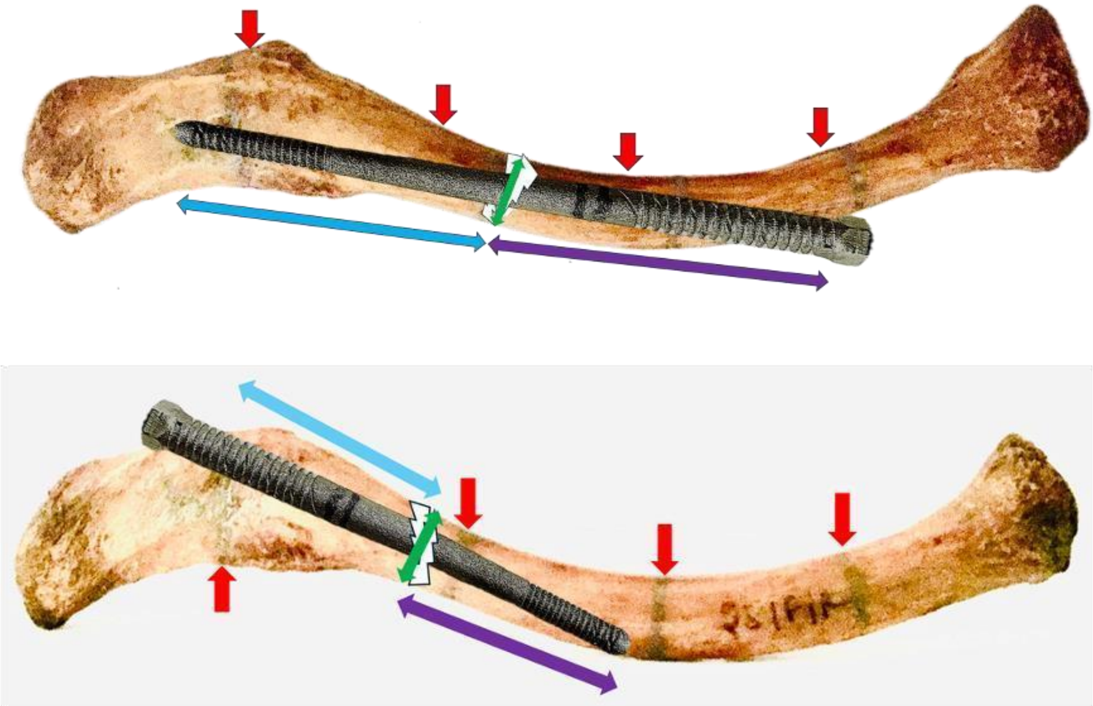


Figure 10. Cadaveric clavicles with an overlapping intramedullary CRISP-G© prototype implant. Antegrade and retrograde approaches: the minimum length of engagement on either side of the fracture should be three to five times the maximum cross-sectional diameter, equivalent to the length of the green arrow. The red arrows indicate one-fifth sections (created in PowerPoint by the author).

In summary, for an intramedullary implant, whether smooth or threaded the minimum engagement length on either side of a fracture should exceed 3 times the average external diameter in two planes at the fracture site (**Fig. 10**). This ensures the implant does not disengage easily under cantilever bending loads during the rehabilitation period, before circumferential callus seals the fracture gap. Always choose an implant with the largest possible diameter for an interference fit. The bending rigidity (*modulus of elasticity, i.e. how far it will deflect*) of a rod increases with (radius)^4 and the weight goes up with (radius)^2. A 10% increase in diameter increases its strength by 50% and its polar moment of inertia.

16.0 Considerations for preoperative planning:

The minimal requirements for managing diaphyseal fractures of the clavicle are restoration of centreline length, linear alignment with offset, and axial rotation. The clavicle is not a straightforward bone, so achieving these targets is not easy. After restoring length, restore transverse plane curvatures, medial-lateral curvature offset, version and torsional angle around the screw axis, and kinematic alignment to establish the spatial intercalary relationship to the sternoclavicular and the acromioclavicular joints, thereby normalizing the range of motion, strength and power of the glenohumeral joint. Any shortening will affect the relationship between muscle length and tension. An angular deformity will cause frustum formation, impairing axial rotation of the clavicle during arm elevation. No golden implant design is yet available to fulfil these requirements for restoring of clavicle's anatomy and biomechanical architecture back to its original state. Therefore, plates and screws cannot be considered a "gold standard." After the primary polytrauma assessment, following the advanced trauma life support (ATLS) criteria, identify and manage the primary and associated injuries. Patient-specific and patient-appropriate management of clavicle fractures includes site and pathological anatomy of the fracture, regional soft tissue injury, age, gender, comorbidities, risk factors, essential daily functions, patient expectations and surgeon experience(Gandhi, 2022b, 2022a). The displacement of the fracture fragments seen on radiological images is static and current. Consider the dynamic state of fracture and soft-tissue distortions, as well as injury severity, based on the patient's described mode of injury. The expectations and process of rehabilitation begin soon after the injury, centred on the personality and attitude of the patient to the injury for mental and physical well-being.

Take bilateral plain X-rays of the clavicle in the anterior to the posterior direction at a right angle to the plane of the clavicle, including sternoclavicular, acromioclavicular and the glenohumeral joints. For additional information, obtain oblique cephalic and caudal views between 20-45 degrees, and repeat at the chosen angle throughout the follow-up. Follow the clavicle fracture trauma series discussed in Part 4 of the study. Alternatively, undertake computed tomography before deciding upon surgical intervention. Consider measuring the surface length of the uninjured clavicle, noting that there is a directional asymmetry in 30% of the cases. Timing for surgery, apart from the life-threatening polytrauma and open fractures, is arbitrary and varies between hospital practices and surgeon experience. The philosophy should be 'earlier the better' for pain control and restoration of the topographic anatomy to avoid sustained deformity of the bone and soft tissues, particularly of the vessels and nerves, thereby improving the quality of patient care.

When selecting an implant type and size, consider gender and maturity, geographical and racial differences in body stature, handedness, occupation and overhead activities, which affect the anatomical and morphometric variations due to the biomechanical forces acting on the clavicle. In adults, significant correlations exist in clavicle length and supine length, weight and surface area of the body(Kaur H & Sahni H, 2002). The length of the clavicle increases by 7.11 mm on the right side and 6.49 on the left side between the ages of 18 and 30 years, and a decrease in length over 61 years! In the lateral to medial axial view on computed tomography, maximal torsional angle *(twist)* measured at the transition zone, 30 to 70 mm from the acromial end is 35 degrees(Lambert et al., 2016). However, the torsion angle varies significantly along the diaphysis of the clavicle in everyone, and so does the version angle between the articular surfaces of the sternal and the acromial ends. The author measured the variable distribution of torsional angles along the diaphysis and version angles of ten dry clavicles, from the medial to the lateral end, using digital inclinometers at five stations **(for details see Part 2 of the series).**

Morphometric difference across numerous studies varies not by geographical origin but varying techniques and selected parameters that deter making comparisons. Secondly, there is a significant variability depending upon the versatility and manual activity of the members included in each cohort examined, influencing the length, depth of the curvatures and two planar diameters affected by biomechanical forces during growth and development. Therefore, the reported morphometric data collected from computed tomography and cadaveric dry clavicles, based on age, gender, height and weight in the literature may not be the best guide. It certainly informs a trauma surgeon to be cognizant of such variabilities when practicing in regions with diverse population. For comparison, the patient-specific surface and radiographic measurements obtained on the uninjured side, accounting for 3 to 8 mm of directional asymmetry following post-reduction and provisional fixation of the fractured clavicle are more realistic before concluding the surgery rather than seeking an alternative technique.

A limited post-reduction lengthening is preferable to shortening. The secondary guide to reduction and approximation to pre-fracture length is to assess malposition and winging of the scapula by safely re-posturing the patient on the operating table and moving the glenohumeral joint through a full range of motion. Further guided by reinstating the position and orientation of the coracoid process radiographically to confirm that the 'Coracoid Light up sign' is turned off **(for details see Part 4 of the series).**

17.0 Surgical planning and selecting an antegrade or retrograde approach for stable fixation of mid-diaphyseal fractures:

Pre-operative planning is the primary step to managing even a simple displaced fracture of the clavicle. "Failing to plan is planning to fall"(Porteus et al., 2007).

The pathological anatomy and site of the fracture are key to selecting an implant and choosing an approach to insert an intramedullary implant. The third-fifth and fourth-fifth sections of clavicle are the proclaimed central third and the most common site of the diaphyseal fractures. Obtain adequate quality X-rays perpendicular to the plane of the clavicle fragments and the intact clavicle, including pectoral girdle joints on both sides, at the same magnification. Despite the knowledge of directional asymmetry, with the left clavicle being generally longer, the mirror image of the uninjured side can be flipped over on the injured clavicle as a template for approximate length and quality of reduction of the clavicle, at least in two dimensions, pre-, intra- and post-surgery. Although there are studies on computer-assisted surgical techniques for treating non-union and malunion of the clavicle fractures, but no commercial surface templates accompany individual implant designs for sizing implants to fit fractured clavicles.

An analogue surface template may prove cost-effective and practical during surgery when selecting the length and diameter of an implant.

Direct clinical measurement of the contralateral clavicle during surgery under an image intensifier, with a radio-opaque sterile ruler fixed on the surface is worthwhile. Radiographic accuracy of the clavicle length for selecting an implant length will depend on managing the parallax and magnification to minimize the error. Correlate the radiographic length by measuring the direct end-to-end length of the uninjured clavicle using skin markings between palpable sternal and acromial ends. However, this may prove less accurate in obese patients with a thick subcutaneous coat. In obese patients, metallic markers such as ECG tabs can be placed at the ends of the clavicle and adjusted radiographically as required. The distance between the markers can be measured with a sterile ruler intra-operatively, a Staedtler's flexible radio-opaque tool or a 250 mm digital vernier calipers pre-operatively for greater accuracy.

When using a closed technique, compare the injured clavicle to the uninjured after the fracture reduction, with the reduction tool in place. From the perspective of anatomy and biomechanical architecture, and stable reconstruction, subdivide the one-fifth segmentation scheme of the clavicle into ten smaller stations (**Fig. 11**). For fractures falling in the third-fifth section's subdivisions (5/10, fifth-tenth and 6/10, sixth-tenth stations), select the antegrade approach. For the fourth-fifth section's subdivisions (6/10, sixth-tenth and 7/10, seventh-tenth stations), select the retrograde approach, following the mechanical principles of the classic modular draw bolt latch for secure fixation as explained above. The length of the intramedullary implant, on either side of the fracture site should be 3 to 5 times the measured external diameters of the fractured ends in two planes, depending on its major diameter. Measure the estimated length and major diameter of a threaded intramedullary implant against the plain radiographic A-P view taken perpendicular to the uninjured clavicle. All measurements can be adjusted directly during surgery after fracture reduction, which is held provisionally with the canulated reduction instrument in the intramedullary implant fixation.

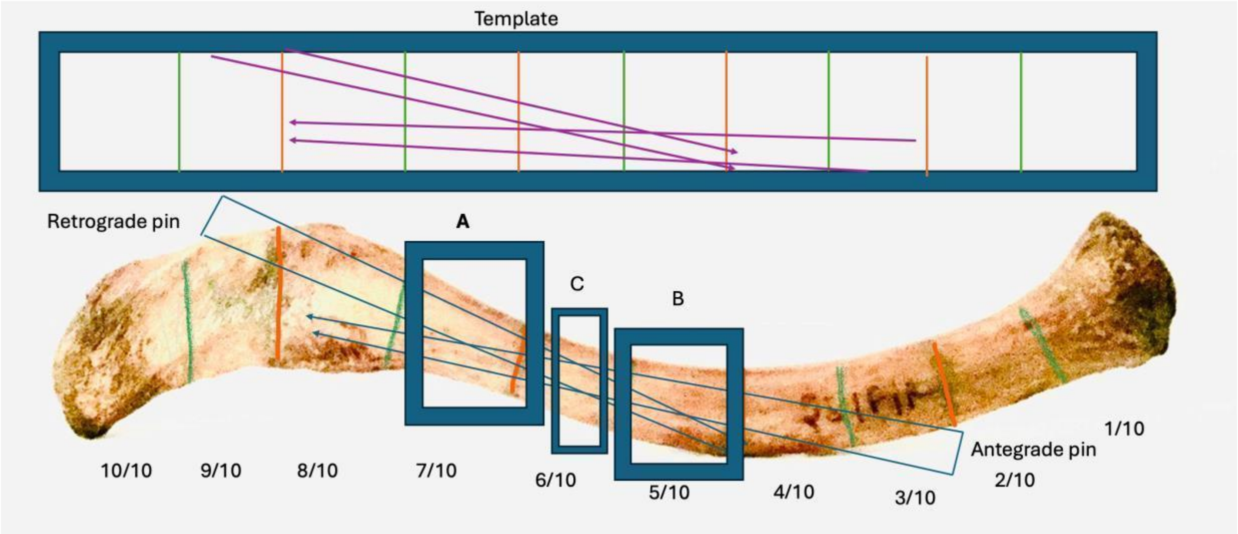


Figure 11. The top image shows a suggested one-tenth scale template and the likely direction and length of an intramedullary implant. At the bottom, the illustration shows three fracture windows in the 7/10th, 6/10th and 5/10th stations of a cadaveric clavicle, along with corridors for an antegrade and retrograde medulla before reaming, to accommodate the maximum-diameter implant for an interference fit (created in PowerPoint by the author) **(for details, see Part 9 of the series).**

The blood supply to each layer of soft tissue covering the bone is through a widespread network of interconnected small vessels and an arteriolar system, invisible to the unaided eye(Volgas DA & Harder, 2007). Therefore, meticulous dissection is key to exposing of surgical entry points. The minimal access antegrade and retrograde approaches require layer-by-layer dissection without heavy-handedness to protect the subcutaneous sternal and acromial branches of the Supraclavicular nerves. A minimally invasive approach does not mean buttonhole "stab" incisions to insert in an intramedullary implant, wrenching the soft tissues while inserting a smooth pin or a threaded implant, which can leave an ugly little raised scar.

18.0 Antegrade technique (Fig. 12):

Antegrade access to insert an intramedullary implant is indicated for fractures in the 5/10th and 6/10th diaphyseal stations of the clavicle. Before beginning the access, verify the surgical side. The operation is performed under general anaesthesia with the patient in a beach chair position at approximately 45 degrees. Place a sandbag between the scapulae to let the shoulders fall freely apart, reducing telescoping with retraction of the lateral fragment, and dorsolateral repositioning of the scapula. Turn the head and neck away from the fractured clavicle to maximize the space between the mandible and nipple for access and positioning of the surgical team and unobstructed imaging. Keep the ipsilateral arm outside the drapes for free glenohumeral joint movements. Follow the institutional pre-operative wound infection prophylactic protocol.

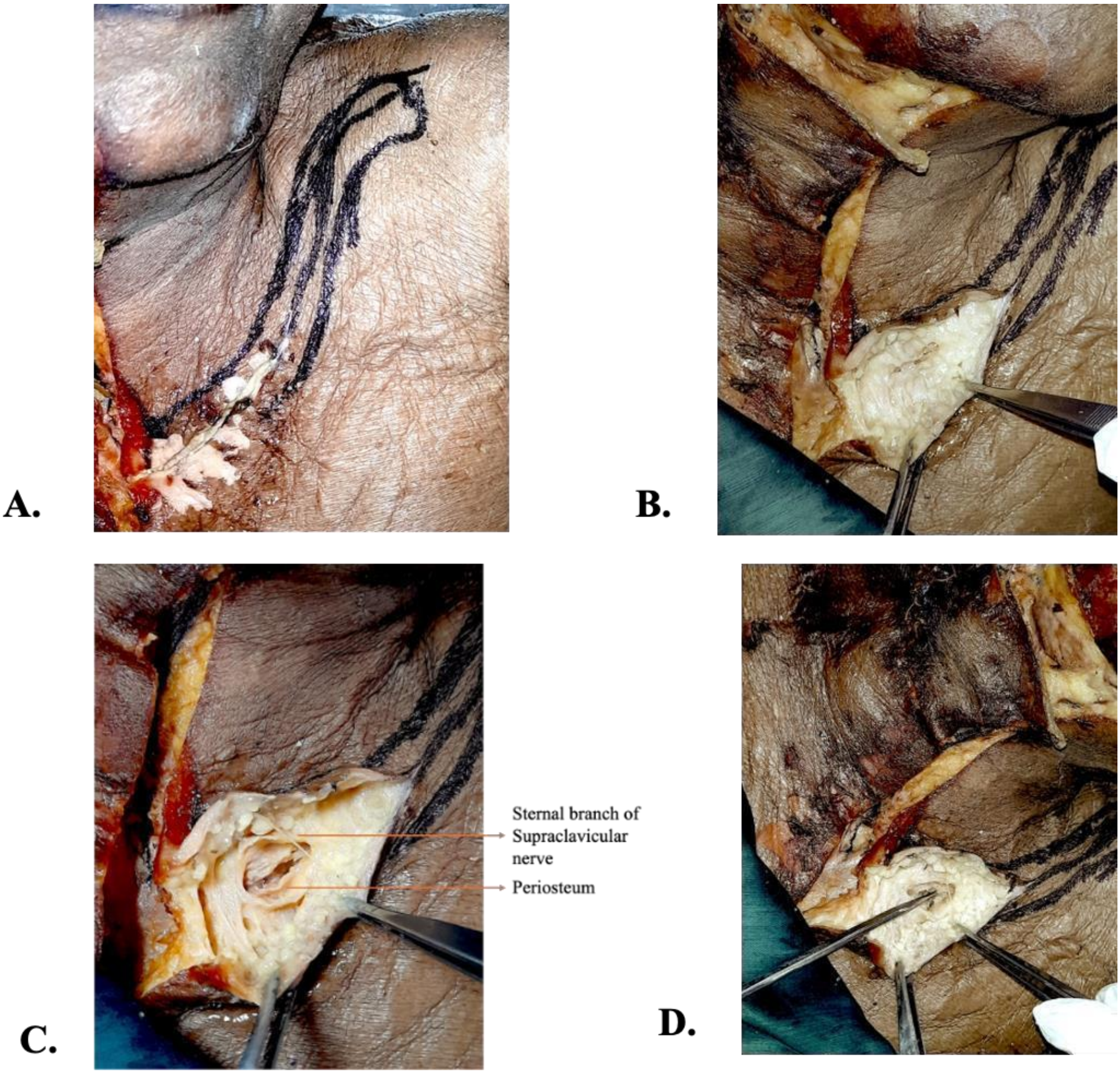


Figure 12. The author's dissection shows an antegrade approach. **A.** Incision; **B.** Subcutaneous dissection revealing one of the sternal branches of the Supraclavicular nerves; **C.** Subperiosteal dissection of the anterior surface of the clavicle, preserving the nerve at the lateral angle of the wound; **D.** Perforation of the anterior cortex with a sharp awl (or a 2.5 mm drill bit).

Before skin preparation, measure the length of the uninjured clavicle using the direct clinical and radiographic methods mentioned above. Leave the ECG monitoring tabs, if applied, under the sterile drapes to repeat the measurement for comparison. Apply ECG tabs at the tip of the coracoid process and at the inferior and medial angles of the scapulae to assess recovery of the scapula on the operated side, at the end of surgery, comparing it to the uninjured side, by constructing similar triangles on both sides on an A-P chest X-ray. Relate the coracoid process to the clavicles and vertebral column to the medial borders of scapulae. For a higher-quality image reproduction and observer reliability, keep the arms in a neutral position beside the body. To centralise the chest, keep the mandible well above the sternum, and the sternoclavicular joints equidistant from the mid-sagittal line, ensuring that the clavicles are in the same transverse plane and the upper eight ribs with costovertebral articulations clearly visible in the frame. Position the beam perpendicular to the clavicles with full inspiration to achieve even bilateral exposure and descent of the diaphragm, thereby improving image quality of the scapulae and clavicles for comparison. Join the tips of the ECG tabs to obtain mirror images of the drawn triangles and superimpose the clavicle by flipping one over the other by applying segmentation and registration techniques.

The patient's position should allow easy palpation of the scapula to assess scapulothoracic translation for signs of winging at rest and during abduction and forward flexion of the arm after fracture fixation. At the same time, take the opportunity to check stability, strength, and stiffness of the bone-implant construct under control, to judge whether early post-operative passive movements permissible in a shoulder immobilizer.

Select an incision site 2-3 cm from the sternal end of the clavicle, at the junction of 2/10th and 3/10th stations on the superior aspect of the clavicle. Make a 3-5 cm long incision, depending on the thickness of the subcutaneous layer. After dividing the skin and the platysma, where present, perform blunt dissection with artery forceps to preserve the sternal branches of the Supraclavicular nerves, exposing the periosteum in between the attachments of the Cleidomastoid and the Cleidobrachialis pectoralis muscles at the pectoralis ridge (**Fig. 12**). Apply gentle retraction to the skin and the subcutaneous layer to incise the periosteum sharply with a scalpel blade. Do not use a cautery to cut it. Lay open the superior and anterior surfaces by retracting the flaps with small sets of blunt bone levers or self-retaining retractors subperiosteally to protect the underlying subclavian vessels below and behind the clavicle. This allows safe access to both superior and anterior surfaces.

With assistance, hold the arm away from the torso and apply in-line traction along the long axis of the clavicle in the cephalic and dorsal directions to reduce the fracture. Avoid excessive traction to prevent overstretching of the axillary vessels and the brachial plexus. When approaching 90-degree abduction, flex the elbow and, with external rotation of the humerus, eliminate ptosis and medial rotation of the shoulder under the image intensifier. Hold the arm in a shoulder arthroscopy holder, if available, to maintain reduction, or have the assistant keep it in place. While holding the reduced major fragments, lay the selected cannulated threaded intramedullary implant (CRISP-G) across the clavicle to mark the direction and ends of the implant and the width of the clavicle, using a skin marker. Mark the medial curvature and the point of entry on the anterior (ventral) surface. With a 2.5 mm drill, open the anterior/ventral cortex at the pectoralis ridge under control; because the cortex is thin and easy to plunge, follow the medullary track carefully under the image intensifier. Once within the medullary canal, introduce the blunt trocar and cannula to reduce and realign the major fragments (**Fig. 13**). Develop the canal by breaking the trabeculae while advancing with oscillating movements to reach the fracture site. Under the image intensifier, use it as a reduction tool, like a joystick, to enter the lateral fragment.

Figure 13. A 2 mm prototype of a blunt trocar and canula for the opening of the medullary canal.

After three failed attempts to realign the fragments, it is wise to make a 15-20 mm vertical skin incision to open the fracture site. Introduce blunt bone-holding forceps to realign and hold the fragments. When successful, advance the reduction trocar and cannula with oscillating movements to reach the desired distance of 3 to 5 times the clavicle diameter from the fracture ends. Check the reduction and position of the reduction tool on the A-P and oblique cephalic and caudal views under the image intensifier. Check the end-to-end clavicle length using clinical and radiographic methods against the measured contralateral side. Correct the rotation to reorient the coracoid process and hold the arm in place. Remove the trocar and replace it with a guide wire, then extract of the cannula, leaving the guide wire in place. In young patients, use the provided appropriately sized handheld flexible reamer to break the trabeculae, controlling the rotation of the fragments enlarge the medullary canal, and compress the bone debris against the endosteum. Ream partially because of the variable cross-sectional diameter of the eccentric medulla and the non-uniform thickness of the cortex of the clavicle. The single most important objective of reaming is to prepare it to accept a largest possible major diameter of a CRISP-G for better purchase in the endosteum.

Although the CRISP-G has a differential screw thread, the leading threads may not fully engage the far fragment circumferentially because of its tapered design, bone curvature, variable internal diameter of the bone, and oblique placement of the implant within the curved shape of the medullary canal. The CRISP-G's differential screw thread offers limited interfragmentary compression. The device reduces and realigns the fracture fragments, allowing required interfragmentary strain and micromotion. The distal threaded surface provides a transition fit, and the proximal threads an interference fit adding strength and stiffness to the construct and reducing implant vibration. Choose the correct length, major diameter, and right- or left-handed threaded implant as required. The implant and technique are based on the draw bolt principle to achieve high interfacial shear stress, bending, and torsional stability, in contrast to smooth, flexible devices.

The screw threads at both the trailing and the leading ends of the CRISP-G are self-cutting. The major fracture fragments must be reduced and held firmly in all the three planes to prevent rotation while driving the implant forward over the guidewire into the lateral fragment. Once the length, offset, and angular deformity are corrected, the patient-specific torsional and version angles can be achieved and checked on anterior-posterior imaging, profiling the thickness of the cortices and the shape of the medullary canal against the intact contralateral clavicle on the same view. Check that the tip of the coracoid process has repositioned relative to the edge of the glenoid fossa, re-establishing the slender hourglass profile of the medullary canal on the anterior-posterior view. Close the interfragmentary gap without applying excessive compression, as the design of the CRISP-G doesn't behave like a true compression screw for absolute rigidity. Correct any residual deformity by registering it against the intact clavicle.

If confident in the fixation quality, remove the arm from the arm holder while the guide wire is still in place. Sit the patient forward with the help of the anaesthetist and an assistant to assess the orientation of the scapula for any residual winging. Take the chest X-ray as suggested above. Elevate the arm to 120 degrees of abduction, then forward flex it to check the scapulothoracic translation. At the same time, palpate the rotation and rolling of the reconstructed clavicle. Recheck the position of the fracture fragments under the image intensifier in both A-P and the oblique views to make necessary adjustments before removing the guide wire. If correct-handed CRISP-G is applied, any unwinding between 0-to-45 degrees of clavicle rotation will be tightened automatically upon returning the arm to its neutral anatomical position.

Take the final intraoperative image in the anterior-posterior direction perpendicular to the plane of the fixed clavicle and cephalo-caudal 30–45-degree oblique views to confirm that the implant is within the medullary canal and extends adequately across the fracture site. Achieve wound haemostasis before a meticulous layer-by-layer closure, avoiding crushing of the tissues with haemostatic tension. Bury the head of the CRISP-G under the periosteum and muscle layers. There is no need for a drain if the dissection, haemostasis and closure are meticulous.

Apply the appropriate-sized shoulder immobilizer to prevent sudden arm movement while the patient is waking up. To ensure pain relief and correct immobilization during the first week, provide an appropriately sized shoulder immobilizer that allows unloaded underarm use of the hand for feeding and hygiene purposes.

19.0 Retrograde technique:

The method for closed fracture reduction, preparation of trabecular medulla, implant insertion, and intraoperative clinical and radiographic assessment are the same for the retrograde technique as for the antegrade approach. The retrograde approach is from the acromial end of the clavicle on its posterior convex surface, just lateral to the conoid tubercle **(Fig. 14)**.

Make a 3-5 cm long skin incision starting at the palpable vertex of the lateral curvature. Extend it laterally over the acromion, directed dorsally towards the angle of the acromion, to create sufficient space for instrumentation and direct the trajectory in line with the medial curvature, making it easier to negotiate the reduction trocar and cannula across the fracture site into the medial fragment. After cutting the skin, spread the subcutaneous tissue with blunt artery forceps, protecting the acromial branches of the Supraclavicular nerve (**Fig. 14B**). Retract the subcutaneous tissues to expose the insertions of the Occipitocleidal trapezius and Cleidobrachialis deltoideus muscles on the superior surface of the clavicle. Sharply incise between them, including the periosteum, with a scalpel blade rather than a cautery. Then, raise the periosteum along with the insertion of the attached muscles, exposing the superior and posterior surface lateral to the conoid tubercle. Under the image intensifier, with a 2.5 mm drill bit, open the cortex lateral to the conoid tubercle at the centre of the convex posterior surface. Take care not to damage the insertion of the coracoclavicular ligament on the conoid tubercle and trapezoid ridge. Avoid skidding off the drill bit by starting perpendicular to the bone surface rather than at an acute angle.

Retrograde access is more difficult than antegrade access because of limited access in the angle between the clavicle and the acromion. Still, it is feasible with proper wound retraction and by extending the skin incision laterally. Open the cortex to reach a depth of 2-3 cm into the medulla. Check the trajectory angle under the image intensifier, aligned with the medial curvature. Proceed with the 2 mm cannula and trocar reduction instrument. After reaching the fracture site, check its position and toggle the lateral fragment with appropriate movements of the shoulder complex to realign the two fragments and enter the medulla of the medial fragment. Continue by oscillating movements, avoiding posterior and inferior directions of the reduction tool, to prevent injury to the subclavian vessels and the brachial plexus, even though separated by the Subclavius.

Once past the fracture site, continue into the medial fragment to a depth of 3 to 5 times the average external diameter of the clavicle at the fracture site. Check the length of the reduced clavicle clinically and radiographically against the contralateral side. Measure the length of CRISP-G against the cannula. Ensure the cannula is within the medulla of both the fragments on anterior-posterior and cephalocaudal oblique views. Once satisfied, remove the trocar, introduce the guidewire and ream the medulla over the guidewire, to allow the largest possible major

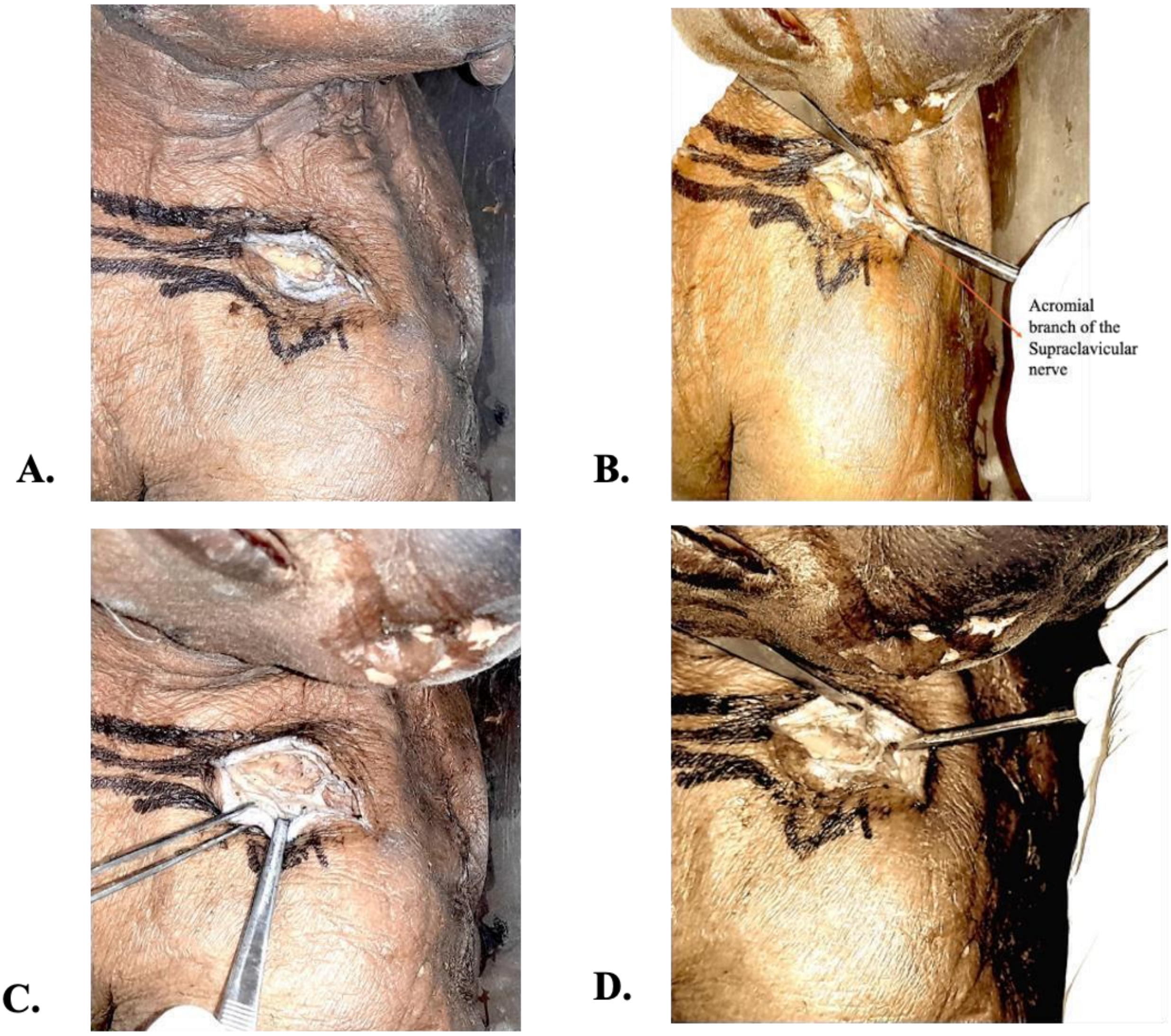


Figure 14. The author's dissection demonstrates a retrograde approach. **A**. Subperiosteal exposure; **B**. Revealing an acromial branch of the Supraclavicular nerve; **C.** Showing the posterosuperior surface of the lateral curvature; **D.** An awl perforating the posterior convex surface.

Figure 15 Lengthening of the clavicle upon application of a rigid intramedullary CRISP-G in a 5/10 station osteotomy of a Sawbone© clavicle.

diameter of the CRISP-G implant. After reaming, check the position of the guide wire before threading the selected CRISP-G implant. Once in the medial fragment, check its position under the image intensifier and drive it home carefully to avoid excessive hoop stresses. Avoid excessive interfragmentary compression, and, once again, check the length to prevent shortening.

As the rigid straight CRISP-G moves across the medial curvature, it may extend the curvature increasing its radius of curvature and lengthening the medial curvature segment by a few millimetres (**Fig. 15**). The lengthening could have been avoided by choosing the antegrade approach for the given mid-diaphyseal osteotomy at the 5/10th station. A few millimetres of lengthening of the clavicle are not detrimental to the kinematics of the clavicle and the glenohumeral range of motion and strength. Check the stability of the fracture site by elevating the arm in abduction and forward flexion and assess scapulothoracic translation for any incongruency. Once satisfied, close the wound in layers without undue tension, ensuring that the head of the CRSIP-G is seated against the posterior cortex of the lateral convexity and buried under the Occipitocleidal Trapezius muscle. After dressing the wound, place the arm in a shoulder immobilizer. Take control of the arm as the patient wakes from anaesthesia.

20.0 Postoperative rehabilitation program:

Postoperative care following the CRISP-G intramedullary implant procedure is part of the overall perioperative care plan of a patient with the clavicle fracture. It begins during preoperative care at the time of consent for surgical intervention. Make the patient aware of the pros and cons of the surgery, including the likely complications and the expected pain level, which varies significantly between patients. Most importantly, educate the patient about the postoperative rehabilitation programme, preferably in the company of caring relatives while in hospital and later at home after discharge.

The immediate postoperative period is crucial. The surgeon should be vigilant for complications to ensure the patient is not deprived of timely intervention for the best outcome. At the time of discharge, the patient should receive clear instructions, preferably a printed protocol with specific modifications depending on the quality of fracture fixation, until the first follow-up visit, which should be between 10 and 14 days. The protocol should inform the patient about the early signs and symptoms of commonly occurring complications and the restrictions on the operated extremity during social, work, and leisure activities. A manual labour must understand the likelihood of income loss.

Better pain control and lack of unpleasant sensory experiences improve patient compliance, mobility of the operated extremity, and acceptance of the anticipated return to work and play. Excessive pain and unpleasant sensory and emotional upset are associated with potential tissue damage(Ryf & Araf, 2007). Such signs and symptoms lead to deleterious physiological consequences and morbidity due to unexpected complex regional pain syndrome, which may be the result of unevenly tensioned wound closures that trap superficial nerve fibres and poor pain control in the immediate postoperative period.

20.1 Patient-specific rehabilitation schedule:

Patient-specific rehabilitation will largely depend on the quality of fracture fixation, whether it was stable or unstable, and on intraoperative congruency of scapulothoracic and acromiohumeral synsarcoses, with glenohumeral movements before wound closure. This helps to determine the duration of the initial period of maintaining shoulder immobilizer. In a case of stable fixation and routine wound healing, if the radiographic appearance of the fracture site shows the beginning of circumferential woven callus and implant position is maintained at the end of the second week, the patient can begin gentle underarm shoulder movements including abduction under 90 degrees, internal and external rotation with flexed elbow out of the shoulder immobilizer over the next 3-4 weeks, increasing active use of the arm without carrying weights. In an unstable fixation, continue with the shoulder immobilizer until sufficient provisional callus becomes evident.

The shoulder immobilizer can be abandoned at the end of the fourth week, gradually increasing overhead movements without weight. In cases where the fracture fixation was not considered reasonably stable, the duration of the shoulder immobilizer should be extended depending on the radiographic progress of the provisional fracture callus formation and the state of the implant. Modify the rehabilitation protocol and investigate the cause of delay in fracture healing to prevent non-union. In delayed healing, rule out the likelihood of infection and loosening of the bone-implant construct and treat accordingly. If no apparent reason exists, after the sixth week with further callus formation, arrange a supervised physiotherapy program for a range of motion at the glenohumeral articulation. Followed by strengthening of the abductors and rotators after the eighth week. In addition, recommend an active assisted exercise program to maintain congruency of the scapulothoracic synsarcosis over the next 6-8 weeks, and continue radiographic follow-up until the pain-free union and an active multiplanar arm elevation are achieved.

The surgical team is responsible for arranging competent follow-up with sufficient information on when to return to full-time work and athletic activities. Expect improved patient compliance as recovery progress throughout the rehabilitation period. Generally, in cases of stable fixation and the absence of risk factors that impair fracture healing, a return to full-time sedentary work at the end of the third week is possible. A rigid rehabilitation plan may not be followed successfully by an uninformed and non-compliant, overconfident patient with risk factors leading to delayed and non-union. Advise overhead manual and sporting activities after implant removal in 3-4 months, in most cases, following a flexible programme.

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Declaration: This is to declare that the design and development of the CRISP-G is the intellectual property of the author Dr. Harjeet Singh Gandhi.

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