SHOULDER

Stability of mid-shaft clavicle fractures after plate fixation versus intramedullary repair and after hardware removal

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Abstract

Purpose Operative treatment for middle-third clavicle fractures has been increasing as recent data has demonstrated growing patient dissatisfaction and functional deficits after non-operative management. A controlled biomechanical comparison of the characteristics of locked intramedullary (IM) fixation versus superior pre-contoured plating for fracture repair and hardware removal is warranted. Therefore, the purpose of the present study was to investigate potential differences between these devices in a biomechanical model.

Methods Thirty fourth-generation composite clavicles were randomized to one of five groups with 6 specimens each and tested in a random order. The groups tested were intact, repair with plate, repair with IM device, plate removal, and IM device removal. The lateral end of the clavicles was loaded to failure at a rate of 60 mm/min in a cantilever bending setup. Failure mechanism, energy (J), and torque (Nm) at the site of failure were recorded.

Results Failure torque of the intact clavicle (mean ± standard deviation) was 36.5 ± 7.3 Nm. Failure torques of the IM repair (21.5 ± 9.0 Nm) and plate repair (18.2 ± 1.6 Nm) were not significantly different (n.s.) but were significantly less than the intact group ($P < 0.05$). Failure torque following IM device removal (30.2 ± 6.5 Nm) was significantly greater than plate removal (12.9 ± 2.0 Nm) ($P < 0.05$). No significant differences were observed between the intact and IM device removal groups (n.s.).

Conclusion The results of the current study demonstrate that IM and plate devices provide similar repair strength for middle-third clavicle fractures. However, testing of the hardware removal groups found the IM device removal group to be significantly stronger than the plate removal group.

Keywords Mid-shaft · Middle-third · Clavicle fracture · Plate fixation · Intramedullary fixation · Hardware removal

Introduction

Clavicle fractures are a common injury of the shoulder girdle, and a vast majority of these injuries encompass the middle-third of the clavicle [13, 21, 23, 24]. In the past, these fractures were commonly treated non-operatively because they were thought to heal with a low rate of malunion and functional deficits [15, 20, 29]. However, a trend towards operative management of certain fracture types has been observed recently due to studies indicating increased patient dissatisfaction and functional deficits of the shoulder complex following non-operative treatment [2, 11, 17, 25, 35]. Today's literature suggests that some degree of malunion universally occurs if any fracture displacement is present [30] and symptomatic malunion may be more common than previously reported [16, 17, 22]. Furthermore, a recent prospective randomized trial showed improved functional outcomes and lower non-union and malunion rates for surgical fixation [1]. Operative treatment has also been reported to have financial benefits for

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the patient due to expedited return to work, decreased pain medication consumption, and less time spent in physical therapy [2]. Therefore, a biomechanical evaluation of surgical treatments for mid-shaft clavicle fractures has become necessary to assist clinicians in deciding the optimal surgical method for treatment.

Surgical management of middle-third clavicle fractures may include various techniques for reduction and fixation of the injury. Plate fixation is considered the "gold standard" of operative treatment, providing immediate rigid fixation [5, 16, 32, 33]. Intramedullary (IM) fixation devices are another option, which can be accomplished with less soft tissue dissection, more cosmetic incisions, and they may permit callus formation due to the relative stability with a different complication profile from plate fixation [7, 18]. These complications include plate loosening, plate angulation, plate breakage, irritation of the brachial plexus, infection, delayed union, malunion, nonunion, and re-fracture [4, 15]. In addition, complications with IM fixation have been reported and include hardware prominence, implant migration, implant breakage, infection, and re-fracture [19, 31]. The advantages of IM fixation, such as smaller incisions, less dissection and soft tissue stripping, relative protection of the supraclavicular nerves, the load sharing nature of the device, and the ability to remove the implant with the patient under local anaesthesia have been demonstrated in the literature [3, 18, 28, 31, 34].

To date, little biomechanical data are available investigating and comparing the clinical application and clinically relevant biomechanical strength of plate fixation and locked IM devices. Additionally, no biomechanical data has been reported on the strength of the healed clavicle following hardware removal. The purpose of this study was to biomechanically evaluate the repair strength of a superior locking clavicle plate and a new generation locked IM fixation device for middle-third clavicle fractures in a composite bone model. Comparison between the two constructs to the natural intact state was used to evaluate the biomechanical characteristics of the devices. In addition, the biomechanical stability of the intact clavicle after hardware removal of both devices was assessed. Plate repair was hypothesized to provide higher strength than IM device repair, and IM device removal was predicted to result in higher strength relative to plate removal.

Materials and methods

Testing was performed with thirty 175 mm fourth-generation composite clavicles to represent the shape, size, and strength properties observed in human clavicles (Pacific Research Laboratories, Vashon, WA, USA). Previous studies have reported comparable failure modes, stiffness, and strength between composite bones and cadaveric bones, without the anatomical variability present in cadaveric models [8, 10]. As is the case for any study performed in a composite bone or in vitro model, the in vivo biologic aspects for healing were not present, and the results were predictive of a repair at time-zero. Clavicles were randomized to one of the five testing groups, with 6 specimens per group. The groups tested were intact, repair with plate, repair with IM device, plate removal, and IM device removal. For the repair groups, a mid-shaft 1 cm butterfly fracture was simulated with a saw and custom jig to hold the clavicles in place and repeatedly create the same fracture at the same location and angle. The apex of the fracture was located 90 mm from the lateral tip.

Devices and surgical repair techniques

Biomechanical testing was performed on clavicles to reproduce a time-zero repair of a simulated mid-shaft butterfly fracture. Devices used for repair were a 74 mm six-hole pre-contoured locking plate (Acumed, Hillsboro, OR, USA) and a 120 × 4.0 mm IM clavicle fixation device (CRx, Sonoma Orthopedics, Santa Rosa, CA, USA) (Fig. 1). For the hardware removal groups, devices were installed on intact clavicles and then removed to simulate the clinical situation after hardware removal following union of the fracture. All procedures were performed by a board certified orthopaedic surgeon. All devices were implanted according to the techniques recommended by the device manufacturers.

Intramedullary clavicle pin

The supplied 2.0 mm diameter drill was used to create a 2.0 mm starter hole in the medial segment of the clavicle. The diameter of the starter hole was then increased using a 3.5 mm diameter drill. The 3.0 mm curved trocar was then introduced, followed by the 4.5 mm curved cutting awl, which was advanced until a 50 mm depth was achieved. The 2.0 mm drill was again used to create a 2.0 mm starter hole in the lateral segment of the clavicle, and a 4.5 mm aiming awl was seated in the canal. A 1.6 mm diameter K-Wire was driven through the aiming awl so that it exited the clavicle posterolateral to the conoid tubercle. The aiming awl was removed, and the K-Wire was retained. The 4.5 mm diameter cannulated drill bit was placed over the K-Wire, and a channel was drilled through the lateral segment in the medial direction. The K-Wire was removed, and the drill bit was retained. A J-Tip guide wire was back loaded through the 4.5 mm drill bit. The bit was removed, and the guide wire was retained in the lateral segment. The guide wire was seated into the medial segment, and the

Fig. 1 Fracture repairs and hardware removals were performed with an IM device (CRx, Sonoma Orthopedics, Santa Rosa, CA, USA) (*left*) and six-hole pre-contoured locking plate (Acumed, Hillsboro, OR, USA) (*right*)

fracture was reduced. The flexible reamer was reamed over the guide wire from lateral to medial. A 120 mm implant was selected as the appropriate size for all specimens. The implant was fully advanced across the fracture. The grippers were deployed with the actuation driver, and the lateral screw was placed.

Locking superior mid-shaft clavicle plate

The fracture was reduced using two reduction forceps on the medial and lateral fragments. A 74 mm six-hole narrow profile locking plate was selected as the appropriate size for repair, placed over the fracture, and stabilized with clamps. The plate was centred over the fracture site to ensure that three screws could be placed into intact bone medially and laterally. Screw holes were pre-drilled using a 2.8 mm diameter drill, and locking guides were used when appropriate. Two 3.5 mm fully threaded cortical screws were then placed in the middle compression holes both medial and lateral to the fracture site. The bone clamps were then removed, and the remaining four holes were filled with 3.5 mm locking screws to secure the plate. All screws were placed in a bicortical fashion.

Hardware removal

In addition to testing the biomechanical strength of the repairs provided by the IM and plate devices, the strength of the intact clavicle following hardware removal was investigated to simulate removal of the devices following union of the fracture. For both hardware removal groups, the devices were installed in intact clavicles with no previous fracture and then removed according the manufacturers' recommendations.

Biomechanical testing

The medial and lateral 2 cm of the specimens were potted in polymethylmethacrylate (PMMA) (Fricke Dental International, Inc., Streamwood, IL, USA) within custom-made cylinders. For all specimens, the medial aspect of the potting was in line with the long axis of the clavicle. The

lateral aspect of the potting was perpendicular to the long axis of the clavicle. This was performed to ensure that during testing and under deflection, the normal force applied by the flat-bottom actuator was always in the direction exactly perpendicular to the medial aspect of the clavicle axis where it enters the potting. The lateral potting cylinder extended anterior, posterior, and equidistant on either side of the long axis of the clavicle so that the load did not induce a rotational moment (Fig. 2). Prior to potting, screws were drilled into the medial and lateral aspects of the clavicles to ensure rigid fixation in the PMMA. None of the devices overlapped with the potted regions.

Biomechanical testing was performed in a dynamic tensile testing machine with custom-made jigs (Instron ElectoPuls E10000, Instron Systems, Norwood, MA, USA). The accuracy for this system has been calibrated and verified to be equal to or better than ±0.25 percent of the indicated force and ±30 μm of the indicated position. The medial aspect of the clavicle was rigidly held perpendicular to the actuator using a custom fixture after a box level was used to adjust the jig to ensure the clavicle was parallel to the base (Empire Level, Empire Tools, Mukwonago, WI, USA). Grease was applied to the bottom surface of the actuator jig and top surface of the lateral potting to reduce friction while the surfaces were in sliding contact during testing. The flat-bottom jig was attached to the actuator of the tensile testing machine, which was used to apply a bending load to the lateral aspect of the clavicle in the superior to inferior direction. This setup has been reported to be the most comparable to in vivo loading conditions [27], and similar methodologies have been described in the literature [6, 27]. The actuator was aligned with the superior most aspect of lateral PMMA cylinder on the clavicle, and the testing was started. The clavicles were then loaded to failure at a rate of 60 mm/min. The failure mechanism, location, and load were recorded, while energy (J) and failure torque (Nm) were calculated. The ultimate failure load was multiplied by the distance from the actuator loading point to the location of fracture to find the torque at the time and location of failure. The deflection of the lateral tip of the clavicle was plotted against the applied load, and the energy absorbed by the clavicle was calculated by finding the area under the force–
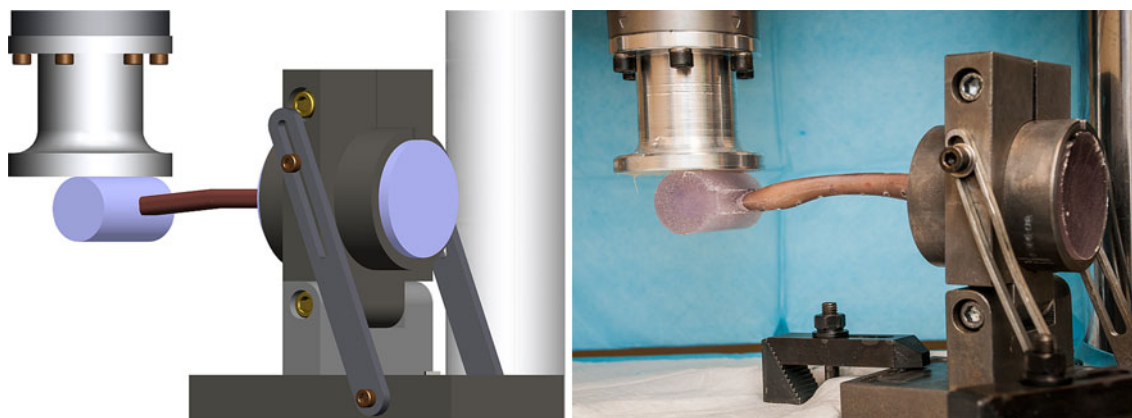
Fig. 2 Cantilever bending test setup modelled with CAD (*left*) and in the laboratory setting (*right*)

deflection curve. Average tip deflection at the time of failure for the intact group was 23.0 mm (range 17.5–27.6 mm). This value was used to define clinical failure, because excessive deformation in vivo could result in damage to surrounding structures. Energy for the remaining groups was calculated up to the point of failure or to 23.0 mm of deflection, whichever came first.

Statistical analysis

Statistical analysis was performed with the use of Predictive Analytics Software (PASW) Statistics Version 18 (IBM Corporation, Armonk, NY, USA). The study compared data for each group using a one-way analysis of variance (ANOVA). For ANOVA's that demonstrated a statistically significant difference, a post hoc Tukey's HSD (Honestly Significant Difference) test was conducted to assess the location of the means that were statistically significant between the groups. Significant difference was determined to be present for $P < 0.05$.

Results

Ultimate failure torque

Failure torque of the intact clavicle (mean ± standard deviation) was 36.5 ± 7.2 Nm. Failure torques of both repair groups were significantly less than the intact group ($P < 0.05$). Average torques for the IM and plate repair groups were 21.5 ± 9.0 and 18.2 ± 1.6 Nm, respectively. No significant differences were observed between the two repair groups (n.s.).

No significant differences were observed between the intact and IM device removal groups (n.s.); however, the plate removal group experienced significantly less torque at the time of failure than the intact group and IM device removal group ($P < 0.05$). Failure torques for the IM and

plate removal groups were 30.2 ± 6.5 and 12.9 ± 2.0 Nm, respectively (Fig. 3).

Energy

Energy resulting in failure of the intact clavicle (mean ± standard deviation) was 3.4 ± 1.2 J. Energies for both repair groups were significantly less than the intact group ($P < 0.05$). Average absorbed energies of 1.4 ± 0.3 and 1.3 ± 0.1 J were observed for the plate repair and IM device repair groups, respectively. No significant differences were observed between the two repair groups (n.s.).

No significant differences were observed between the intact and IM device removal groups (n.s.); however, the plate removal group required significantly less energy to fail than the intact group and IM device removal group ($P < 0.05$). The average amount of energy absorbed by the IM and plate removal groups was 2.5 ± 0.8 and 0.9 ± 0.1 J, respectively (Fig. 4).
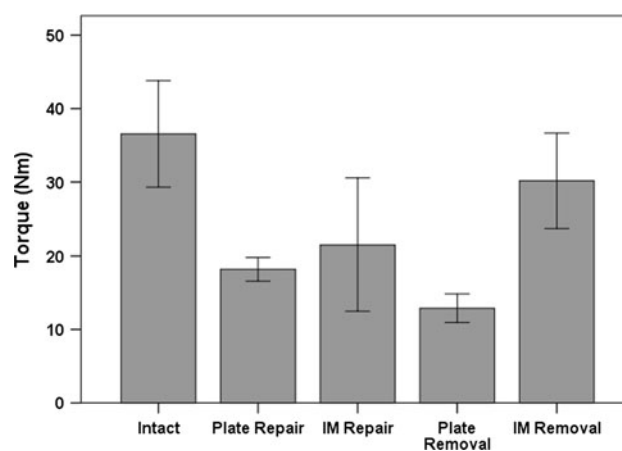

Fig. 3 Failure torque (Nm) of the intact and all repair and hardware removal groups. With the exception of the IM Removal group, all specimens failed at significantly lower loads than the intact specimens ($P < 0.05$)
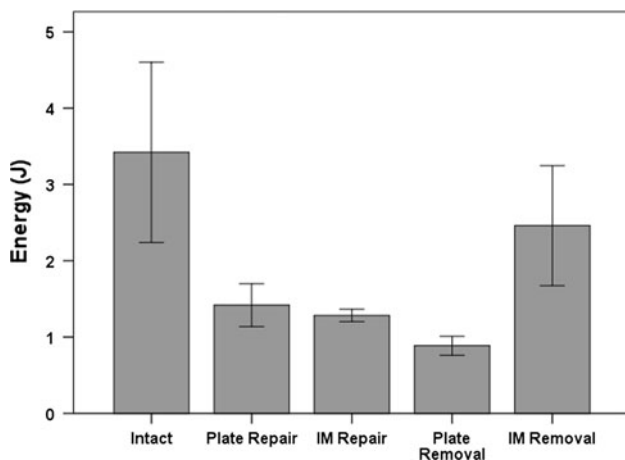
Fig. 4 Energy absorbed by the intact and all repair and hardware removal groups. With the exception of the IM Removal group, all specimens absorbed significantly less energy before failing than the intact specimens ($P < 0.05$)

Failure mode

Five of the intact clavicles failed due to fracture at the medial potting and one failed due to mid-shaft fracture. All plate repair specimens failed due to fracture through the medial most screw hole. Three of the IM repair specimens failed due to fracture at the medial potting, two failed due to the device breaking through the bone at the medial aspect of butterfly fracture, and one failed due to fracture at the device's lateral fixation screw. All plate removal specimens failed due to fracture through one of the screw holes: two through the 2nd most medial hole, three through the 3rd most medial hole, and one through the 4th most medial hole. Four of the IM device removal specimens failed due to mid-shaft fracture, while the remaining two specimens failed due to fracture at the medial potting (Fig. 5).

Discussion

The most important finding of the present study was the superior strength observed following IM device removal compared to plate removal. The results demonstrate that IM and plate constructs provide similar repair strengths of middle-third clavicle fractures in response to bending load to failure, contradictory to the expected result. However, testing of the hardware removal groups to simulate device removal after fracture union found the IM device removal group to be significantly stronger than the plate removal group. This may have implications for clinical practice.

Previous biomechanical studies have reported on the repair strength of plate and IM devices [6, 9, 27]. In 2011, Drosdowech et al. [6] evaluated a reconstruction plate (Synthes, West Chester, PA, USA), limited contact dynamic compression plate (Synthes, West Chester, PA, USA), locking compression plate (Synthes, West Chester, PA, USA), and IM device (Rockwood, DePuy, Warsaw, IN, USA) for repair strength of middle-third fractures of the clavicle using a cantilever bending test. Similar to the current study, no significant differences were observed between the failure strength (Nm) of the IM device, dynamic compression plate, and locking compression plate repairs. A noted limitation of the study by the authors was the lateral fragment of the clavicle rotating about the IM device during testing, which initially weakened the repair construct until the rotational moment was minimized.

In 2010, Renfree et al. [27] reported a study which biomechanically evaluated repairs of clavicle fractures using a pre-contoured unicortical locking plate (Acumed, Hillsboro, OR, USA), pre-contoured bicortical nonlocking plate (Acumed, Hillsboro, OR, USA) and an IM device (Rockwood, DePuy, Warsaw, IN, USA), using cantilever and 3-point bending tests. This study found that during cantilever bending the IM repair group failed at significantly lower loads than the plate repair groups; a result of the lateral fragment rotating about the IM device. Similar to the current study, the IM group experienced larger tip deflections prior to failing. The 3-point bending test added stability to the repair construct and resulted in the IM repair failing at significantly higher loads than the plate repair groups. The IM repair group still experienced the largest deflections prior to failing. The plate repair groups all failed through the medial most screw hole, consistent with the current study.

Regarding the testing protocol, the cantilever bending setup was chosen to biomechanically evaluate the plate and IM repair techniques, as it is most similar to in vivo loading of the clavicle with the medial aspect fixed at the sterno-clavicular joint, and the weight of the arm loading the lateral end [27]. The two aforementioned studies [6, 27] with similar cantilever bending test setups both noted that the s-shape of the clavicle resulted in an unintentional rotational moment about the long axis of the clavicle, which caused the lateral fragment to spin about the IM devices and negatively affected the performance of these devices during testing. This variable and unquantified torque was present during testing and affected the outcome of these prior studies. While the authors of the current study acknowledge that clinically the clavicle sees both bending loads in addition to some rotational forces in vivo, the objective of this study was to compare strength in response to pure bending loads only. To obtain a true direct comparison between the bending strength of different devices, loading conditions must be consistent and unintentional, variable, and unquantified additional loads cannot be present. The rotational moment was observed during pilot testing in the current study and corrected for with a potting
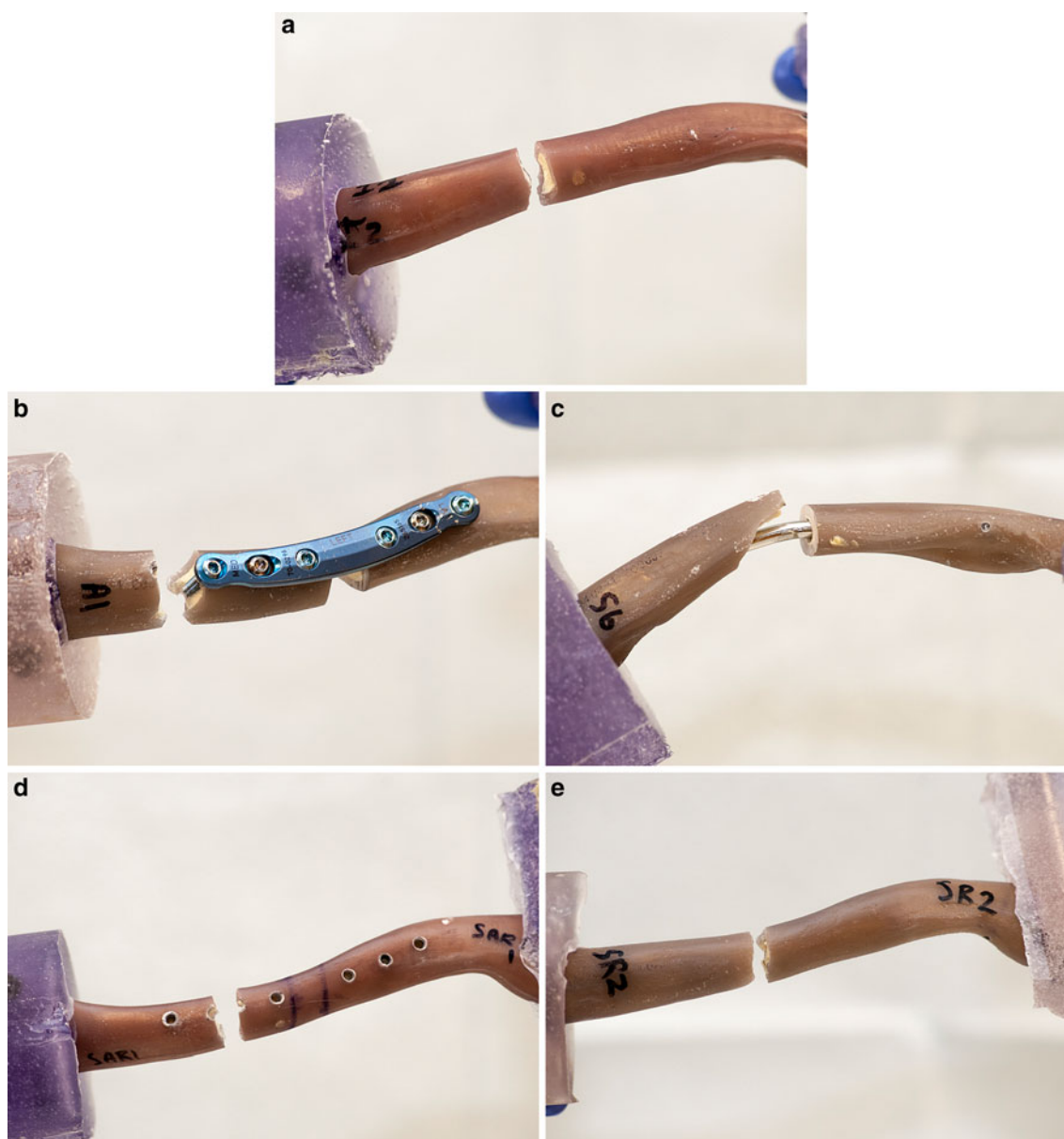
Fig. 5 Example failure modes of the intact (**a**), plate repair (**b**), IM repair (**c**), plate removal (**d**), and IM removal (**e**) specimens

technique on the lateral side which created a loading area that extends beyond the long axis of the clavicle in the anterior and posterior directions. Therefore, the current study was able to eliminate the rotational moment and load both the IM and plate groups in pure bending.

While a limited number of studies have biomechanically compared the repair strength of IM and plate devices, none of the aforementioned studies and no other study in the literature have yet reported on the biomechanical properties of a clavicle after implant removal. Biomechanical studies have previously investigated stability after implant removal in other bones [12, 14, 26], but this has not been accomplished in the clavicle. The strength of a bone after removal of an implant is of great importance for clinicians in terms

of decision making regarding weight bearing, motion, and return to contact sports. Therefore, one purpose of the current study was to provide some objective information about clavicle failure strength after hardware removal of plate constructs compared to IM device repairs. The results show significantly higher failure strength and energy absorption for the IM devices ($P < 0.05$). This knowledge may help to better define the point in time for return to full contact sports after hardware removal of either device and hence potentially decrease the rate of re-fracture.

A limitation of this study, as for any study applying a biomechanical examination to a clinical problem, is the ability of the test setup to accurately reproduce the anatomical constraints and loading conditions experienced in

the shoulder. The clavicle has multiple muscle and ligament attachments and experiences complex loading conditions with the sternoclavicular and acromioclavicular joints allowing for motion. It is also a time-zero study and does not account for any of the biologic aspects that occur with healing. However, the current study has the advantage of being clinically relevant, well controlled, and reproducible. It uses a clinically applicable biomechanical model in order to make a consistent evaluation of these devices and appropriately investigates the hypotheses of the study. Additionally, hardware removal testing was performed in intact clavicles with no previous fracture to simulate the healed clavicle following fracture union. While bone strength at the fracture union site may not be equivalent to intact bone depending on time removed from the injury, the use of intact clavicles served as a consistent and reproducible model to identify weaknesses in the bone directly caused by the hardware.

Comparable repair strengths and associated mechanical properties for the tested devices may be expected clinically at time-zero. Additionally, the healed clavicle following IM device removal may be able to withstand higher forces without subsequent fracture relative to plate removal. Clinical interpretation of these results should be performed cautiously.

Conclusions

The results of this study demonstrate that IM and plate constructs provide similar repair strength for middle-third clavicle fractures in response to bending load to failure. Testing of the hardware removal groups to simulate device removal after fracture union found the IM device removal group to be significantly stronger than the plate removal group.

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