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INTRODUCTION

Bilateral ligament reconstruction is performed to treat patients with bidirectionally unstable elbows. Surgical options include performing two separate ligament reconstructions one on the medial side and one on the lateral side but it is difficult to tension both symmetrically. Imparting greater medial or lateral tension may lead to a varus or valgus torque that is imparted to the elbow (Fraser 2008). A box loop ligament reconstruction that simultaneously reconstructs both sides with one graft has been advocated instead (Fig 1) (Finkbone 2015).

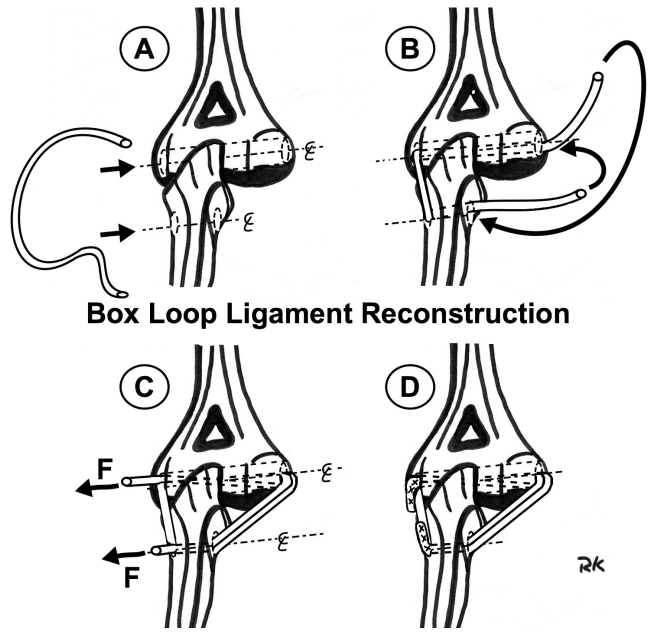


Fig.1. Finkbone "box-loop" Ligament reconstruction employs one long donor tendon graft that is passed through the humerus and ulna and tied back on itself thus creating one continuous loop.

The drawbacks of this "box-loop" technique are that it employs ligament strands that traverse through the humerus and ulna and thus misuses graft material through placement in a location (central distal humerus) where bone to ligament healing is not needed. Another shortcoming is that, due to the friction of graft traversing through the width of the distal humerus and proximal ulna, it is difficult to ensure symmetrical graft tension on the medial and lateral sides of the elbow. Additionally, graft that is located within the humerus can dissipate tensile force over time (stress relaxation due to tendon viscoelasticity) and make it difficult to maintain the initial graft tension. Asymmetric tension can lead to varus and valgus forces being imparted to the elbow.

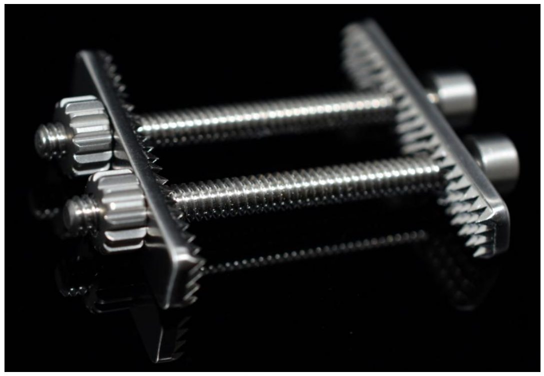


Fig.2. Two plates with aggressive teeth are maintained with two bolts and two nuts that secure the tendon grafts against bone.

The KTE Simultaneous Ligament Reconstruction System (Fig. 2,3) is designed to maintain graft tension after both medial and lateral grafts are simultaneously tensioned. Graft use is minimized by using a Cylindrical Ligament Retention Device (CLRD) that can slide within the hole drilled into the distal humerus. Tendon tensioning is facilitated by allowing the graft limbs to traverse through the eyelets with little friction. To accommodate different distal humerus width dimensions, the CLRD employs a central post in three lengths (Small, Medium, Large).

Fig.3. A cylindrical ligament retention device (CLRD) is employed to affix two ligament grafts. It can pass through a hole drilled within the distal humerus and the CLRD maintains equal tension of each graft limb.

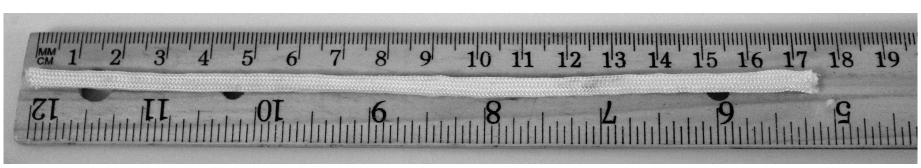


Fig.4. A string demonstrates the length of graft that is needed to reconstruct the elbow if the graft were pulled through the distal humerus and secured with the plates and bolts as shown in Fig. 2. The graft residing within the distal humerus is not biomechanically useful once the limbs have healed to bone.

The goal is to minimize the amount of graft that is used for the ligament reconstruction. If the grafts were allowed to simply pass through the distal humerus then, for an average sized elbow, the required length for each tendon graft would be 17.5 cm. To complete a full medial and lateral ligament reconstruction, two 17.5 cm limbs would be needed.

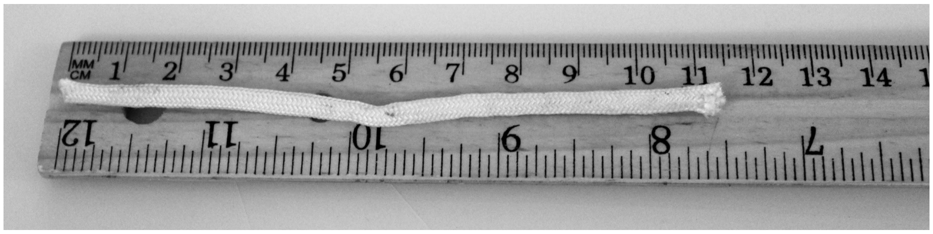


Fig.5. This string demonstrates the length of graft that is needed to reconstruct the elbow if the graft is not pulled through the distal humerus and instead is secured to a CLRD that resides within the distal humerus.

Once a CLRD is used, the required length for each tendon graft would be 11.5 cm. To complete a full medial and lateral ligament reconstruction, two 11.5 cm limbs would be needed. A method was designed for the plates to maintain compression between the tendon graft and bone (Fig.2) The goal was to securely compress the tendon against bone and, in doing so, maximize graft incorporation and healing. Minimizing graft motion through secure stabilization between the graft and bone promotes tendon-to-bone incorporation (Weiler II, 2002).

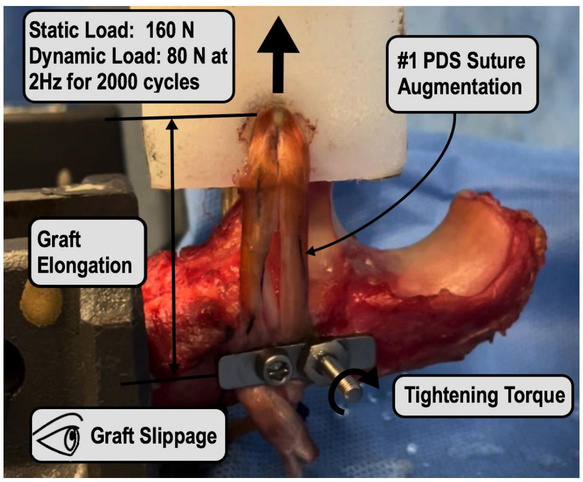


Fig. 6. Biomechanical testing of ligament reconstruction demonstrated no slipping of graft under plate during static and dynamic testing.

Biomechanical evaluation of this technique has demonstrated no measurable graft slipping at the bone plate interface in cadavers during static and dynamic pullout testing. No slipping occurred during static application of 160 N or 2000 cycles of 80 Newton force when two finger tightness was applied to the screw and bolt (Fig. 6) (Gibbs, 2022).

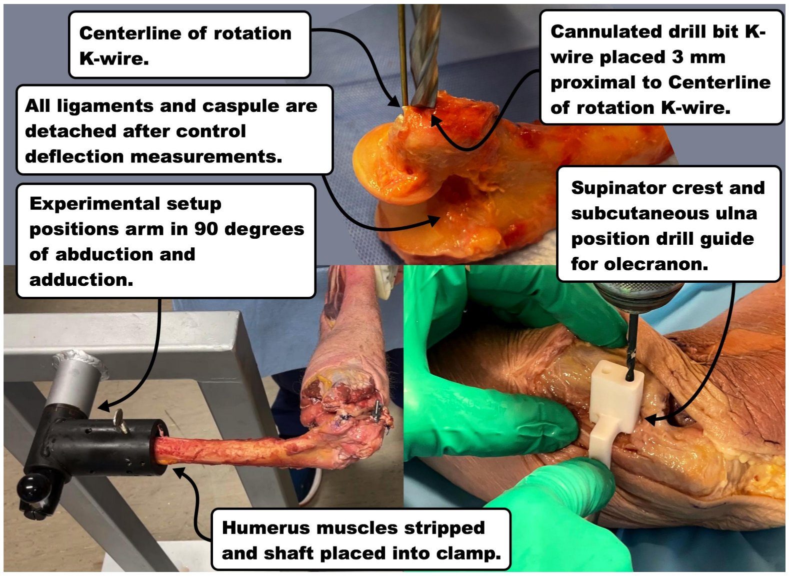


Fig. 7. Static testing of elbow stability in varus and valgus loading environments at different degrees of elbow flexion. The native elbow was measured and then all soft tissue structures were divided and a ligament reconstruction was performed. A repeat static testing demonstrated preservation of native elbow stability.

This ligament reconstruction was employed in cadaver elbows that were subjected to varus and valgus loading. Biomechanical stability of the elbow was restored with this ligament reconstruction after all of the soft tissue connections between the humerus and ulna were separated. The average moment that acted on the elbow was 6.7 Nm. A static force analysis calculated an average medial or lateral force of 268 N, which is split between two graft limbs with each one experiencing 134 N of force. The grafts demonstrated no evidence of slipping or failure at this force (Fig. 7.) (Coutinho, 2023).

INDICATIONS

This technique is designed for treating patients with chronic elbow instability when ligament grafts are needed to restore stability such as may occur in post traumatic environments. Another possible scenario for bidirectional instability may be found when an interposition arthroplasty is considered for patients with elbow arthritis who are too young for a total elbow arthroplasty. The interposition surgery removes the arthritic cartilage from the distal humerus and then resurfaces this region with a soft tissue auto or allograft. This surgical effort invariably destabilizes the elbow.

A complication of interposition arthroplasty is postoperative instability. One report used an Achilles allograft to resurface the distal humerus and then performed a ligament reconstruction with strips from the same soft tissue donor allograft. The ligament reconstruction was protected with an external fixator in 31 of 45 patients. Satisfactory results were noted with preoperative elbow instability leading to poor outcomes despite collateral ligament reconstruction using a continuous loop method (Larson, 2008). Thirteen posttraumatic arthritis patients were treated with interpositional arthroplasty and postoperative hinged external fixation. Although the mean improvement in arc of motion was 60 degrees, poor outcomes were associated with instability. Of the 13 patients, 4 had severe instability (marked subluxation or dislocation), 5 had substantial varus/ valgus instability requiring activity modification, and 4 had slight varus/valgus instability on exam with no functional instability (Nolla, 2008). Thirteen patients with posttraumatic or inflammatory arthritis were treated with distraction interposition arthroplasty using autogenous fascia lata and a hinged external fixator and demonstrated that 9 of 13 patients had satisfactory pain relief. Achievement of elbow stability correlated with post operative success (Cheng, 2000). Seventeen patients that were treated with interposition arthroplasty with or without external fixation had an 88% reoperation rate (excluding removal of external fixation) with 7 patients requiring revision surgery (4 TEA, 2 arthrodesis, 1 revision interposition arthroplasty) at a median follow-up of 54 months. Elbow instability was again associated with a poor outcome (Laubscher, 2014).

In an effort to prevent instability in this setting, a medial epicondyle osteotomy has been described to preserve the medial collateral ligament attachment to bone. An open reduction and internal fixation is then performed to restore stability after the distal humerus has been resurfaced (Hausman, 2004).

Similarly, on the lateral side, an osteotomy that preserves the ligaments may be chosen. One report demonstrates that elbow stability was restored through an open reduction internal fixation of that fragment. Three patients gained an average of 35 degrees of total active motion and all had a decrease in pain. There was no postoperative instability or hardware complications, no infections, and the osteotomy healed in all patients (Walker, 2019). Although good results have been identified using this osteotomy technique, there is a risk of additional complications such as nonunion of the osteotomy or symptomatic hardware, which may require reoperation. Achieving elbow stability is a substantial contributor to the success of this surgery and this simultaneous ligament reconstruction system is designed to impart stability to the grossly unstable elbow and may be a consideration for the treatment of patients with post traumatic arthritis. For the treatment of grossly unstable elbows, we have created this method of treating bidirectional instability.

IMPLANTATION PATIENT POSITION

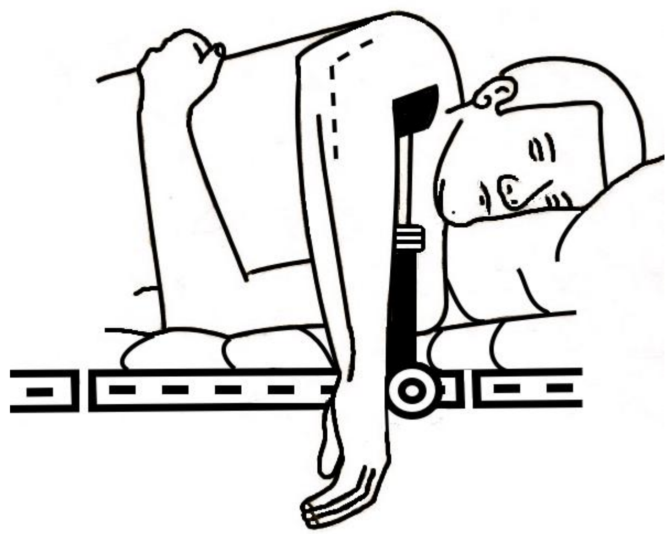


Fig.8. Lateral decubitus position allows for excellent visualization. The ulnar nerve is transposed and the triceps is left attached. Collateral ligaments are reflected off of the medial and lateral epicondyle.

A common patient position is lateral decubitus with the arm supported by an arm holder. Supine patient positioning is also possible.

IMPLANTATION SURGICAL APPROACH

After a dorsal approach is made, the ulnar nerve is transposed. A paratricipital approach is employed and the ECU and Anconeus and the FCU muscles are reflected from the proximal ulna and detached from their proximal origin. The ligaments are reflected off of bone and will later be repaired over the ligament reconstruction. After implantation, these muscles will cover the ligament reconstructions and plates.

IMPLANTATION FINDING CENTERLINE OF ROTATION

Fig. 9. 0.0625” Single tip (1.6 mm) diameter K wires (KI-71-025) are used to establish the centerline of ulnohumeral rotation.

The center of rotation for the medial collateral ligament complex (AMCL) lies on the anterior inferior surface of the medial epicondyle (Azar 2000, Floris 1998, Graham 2017). The center of rotation for the lateral ligament complex (LUCL) occurs around an axis that passes through the center of the capitellum (Moritomo 2007, Olsen 2003, Regan 1991).

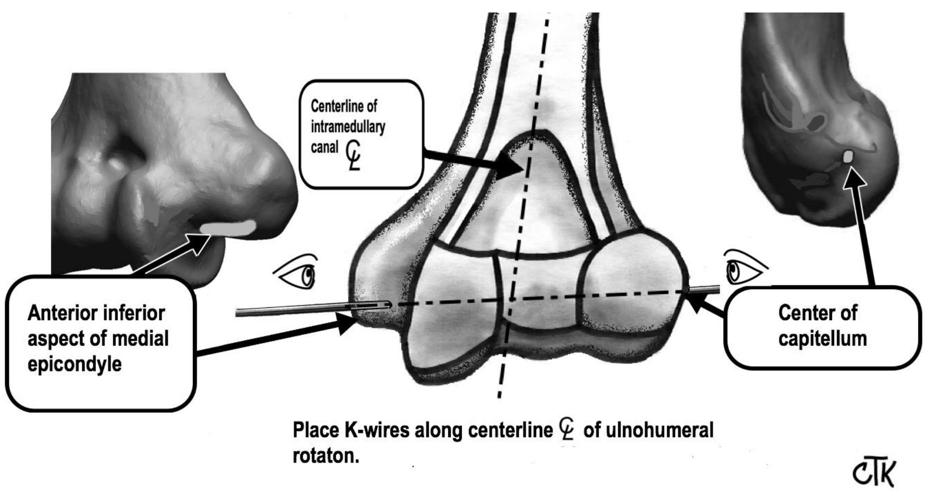


Fig. 10. Bony landmarks are used to identify the centerline of ulnohumeral rotation. A K-wire (KI-71-025) is drilled along this centerline position from the medial side and another from the lateral side. Because the ligament grafts

need to exit through the centerline of ulnohumeral rotation, the hole that is drilled must be both proximal and posterior to this centerline K-wire to accommodate for the radius of the drill bit.

The graft is placed at the centerline of rotation so as to minimize length changes that may occur during elbow motion, which minimizes potential graft impingement, stiffness, stretching, and subsequent failure (Armstrong 2004, Armstrong 2002, Azar 2000, Dodson 2006, Jobe 1986).

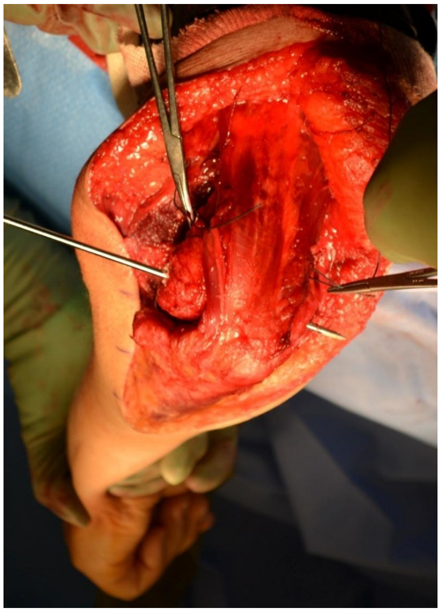


Fig. 11. A K-wire (KI-71-025) is shown at the centerline of ulnohumeral rotation. This K-wire will serve as the reference for placement of parallel medial and lateral K-wires (KI-71-025) posterior and proximal to this centerline of rotation K-wire.

IMPLANTATION DRILLING PARALLEL K WIRE

Successful graft reconstruction requires the grafts to exit bone at the center line of ulnohumeral rotation. This isometric graft placement allows for elbow motion without the limbs being stretched.

Fig. 12. A 6” length cannulated drill bit (KTE-CLRD Drill) has an outer diameter of 0.275” and an inner diameter of 0.094”, which is used to overdrill the K-wire (KI-71-025) placed parallel to the centerline of ulnohumeral rotation.

The CLRD hole that is drilled through the distal humerus uses a cannulated drill bit (KTE-CLRD Drill) (Fig. 12). The CLRD hole through the distal humerus is larger than the graft limbs because it must accommodate the CLRD (KTE-16-S, M, L) and allow for its smooth passage within the distal humerus. This unrestricted passage allows the graft limbs to be tensioned symmetrically and prevents the CLRD or the grafts from getting stuck within the distal humerus.

Fig.13. These two holes are used to place a parallel K-wire (KI-71-025) after the initial medial and lateral K-wires have been drilled into the respective medial and lateral epicondyle. The distance between the K-wires represents the radius of the cannulated drill bit (KTE-CLRD Drill) (Fig 12).

The grafts are expected to heal to bone where they exit the medial and lateral CLRD holes that were drilled. Because the CLRD holes are larger than the grafts themselves, the drill holes must be placed proximal and posterior to the centerline of ulnohumeral rotation to accommodate for the size mismatch between the CLRD drill hole and the graft limbs.

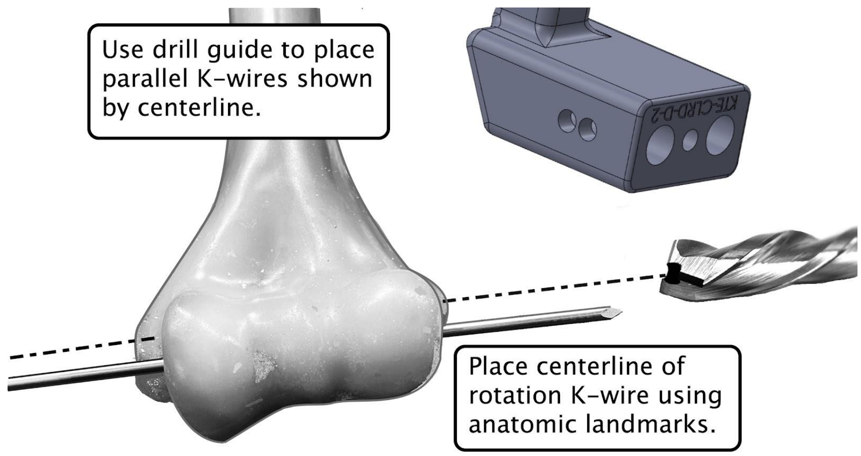


Fig. 14. The original K-wire is shown above. The parallel K-wire location is demonstrated with the dashed line and is created with the assistance of the drill guide (Fig. 13) The cannulated drill bit is shown centered on the dashed line (Second K-wire). Prior to drilling the CLRD hole, the first K-wire is removed and the drill is advanced along the second K-wire (dashed line).

Because the CLRD hole is drilled with a cannulated drill bit (KTE-CLRD Drill) that has a 0.37 " diameter, the hole needs to be placed parallel and proximal to the centerline of rotation with an offset equal to the radius of the cannulated drill bit.

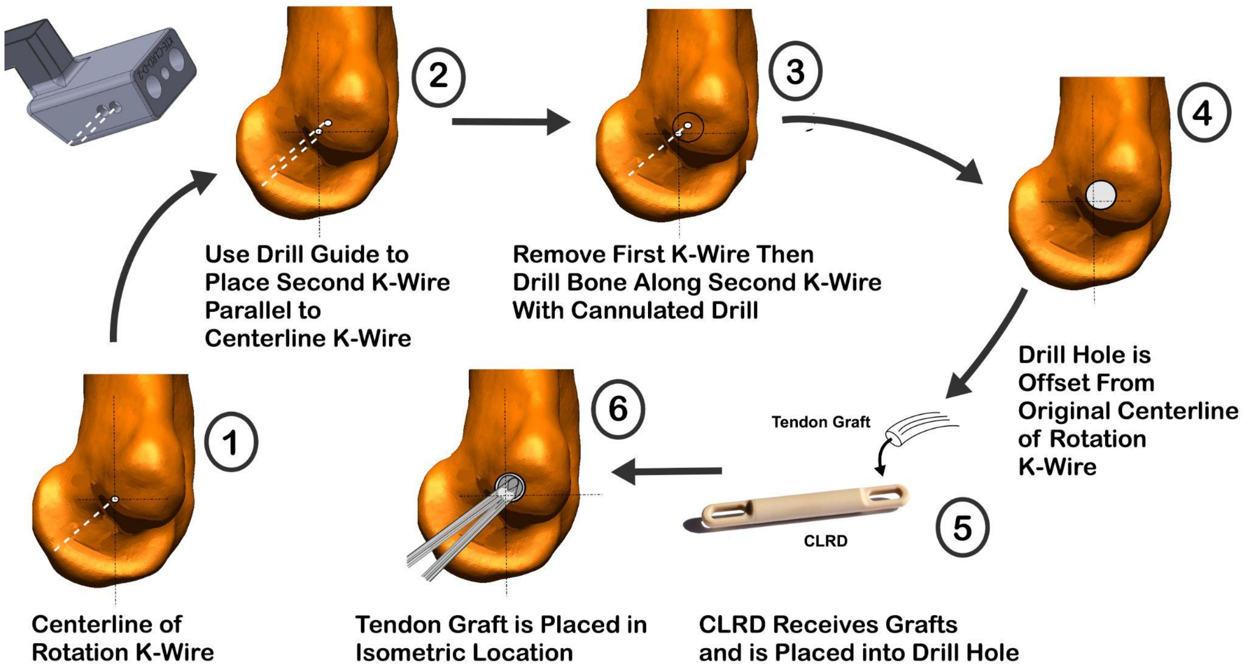


Fig. 15. Step 1: Drill two K-wires into the medial and lateral epicondyle using bone landmarks (Fig 10). Step 2: Use drill guide (KTE-CLRD-D-2) to place another parallel K-wire that is proximal and posterior to the original K-wire. Step 3: Remove the initial K-wires. Step 4: Drill holes using cannulated drill bit (KTE-CLRD Drill) through the medial and lateral epicondyle. The drill is used to connect the two openings and allow for passage of the CLRD (KTE-16-S, M, L). Step 5. Pass the grafts through the CLRD eyelets. Step 6. The grafts are now in an isometric location where they will heal to bone.

The first K-wire is confirmed to represent the centerline of elbow flexion and extension via inspection of projection points and through fluoroscopy. A parallel hole to the first (isometric centerline of rotation) K-wire must be drilled so as to account for the width of the drill hole within the distal humerus. The parallel K-wire is placed proximal and dorsal to the centerline of rotation K-wire in line with the ligament trajectory. When the CLRD drill hole is placed in this manner, the ligament resides at the point of isometry. Placement of the CLRD in this location will ensure that the ligaments, once secured to the ulna, are not subjected to undue stretch during elbow flexion and extension.

IMPLANTATION   DRILLING ULNA BOLT HOLES

Fig. 16. A 4 mm (0.157") diameter drill bit (KTE-CL-Drill) is used to drill the proximal ulna.

Two holes must be drilled into the olecranon for placement of bolts that will maintain compression between the aggressively teethed plates and the bone. The location for these holes is on either side of the supinator crest, which can be palpated on the lateral side and represents the site of origin for the Lateral Ulnar Collateral Ligament.

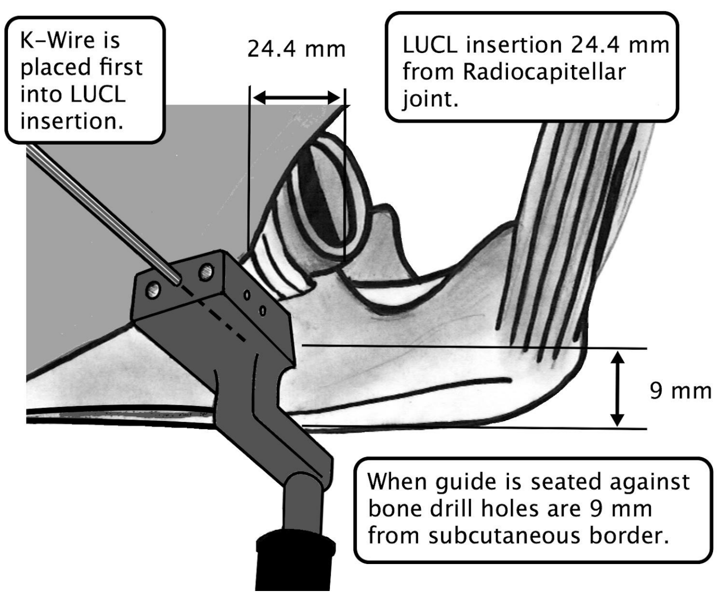


Fig. 17. The supinator crest is used as a guide for drilling the transulnar bolt holes in the proximal olecranon.

Accurate placement of these bolts requires the use of a drill guide (KTE-CLRD-D-2), which assists in positioning the drill holes 9 mm away from the subcutaneous border. The drill guide has a small central hole that is used for the placement of a K-wire. The supinator crest can be used as a landmark or the K-wire can be positioned so as to go through the insertion of the LUCL, which is 24.4 mm (95% CI, 22.7-26.1) distal to the radiocapitellar joint line (Berholdt 2020).

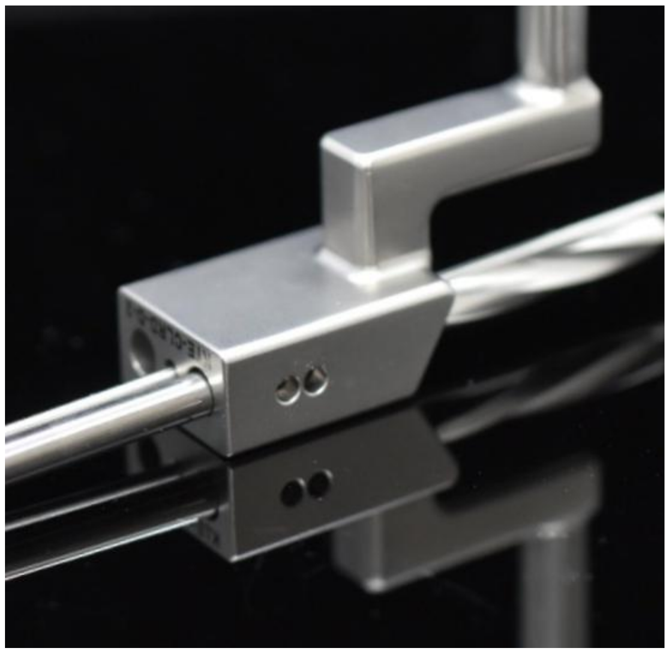


Fig. 18. The drill guide (KTE-CLRD-D-2) is used to drill the holes into the proximal olecranon.

Once the K-wire is deployed, the guide can be removed and the trajectory of the K-wire carefully inspected. Importantly, the distance from the subcutaneous border to the K-wire needs to be equal on medial and lateral sides and it's trajectory can be adjusted if necessary. Once the K-wire is in acceptable alignment, the drill guide allows parallel drilling of holes through the proximal ulna. When the drill holes are placed for the bolts in a position 9 mm away from the subcutaneous border, the screw and plate construct will not be prominent as they are sufficiently removed from the subcutaneous border and are also protected by two muscles that cover this area.

IMPLANTATION SECURING PLATES WITH BOLTS AND NUTS

Fig. 19. The aggressively teethed plates are secured to bone with the transulnar bolts and the splined nuts as shown in this picture.

The plates are secured with bolts and nuts. The bolts are passed through the holes that were drilled into the olecranon and the tendons are passed under the aggressively teethed plates. It is ensured that the bolt hole trajectory allows for the plates to easily be pulled away from the olecranon during subsequent graft passage.

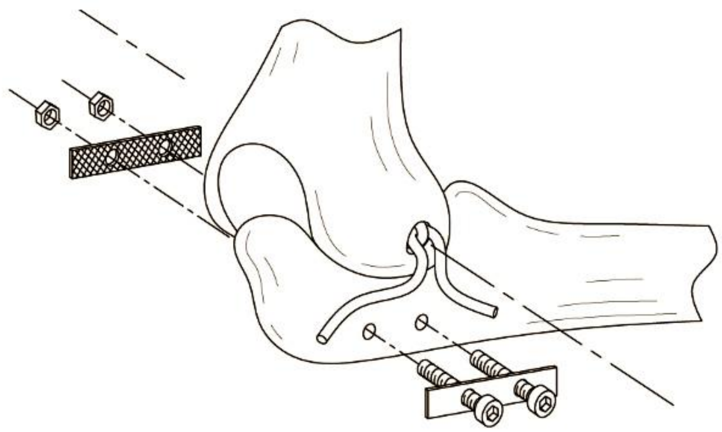


Fig. 20. The plates (RAK-11-M) are secured to the proximal ulna with the nuts (KTE-12) and bolts (RAK-10-M) as shown in this schematic.

IMPLANTATION SELECTING CLRD SIZE

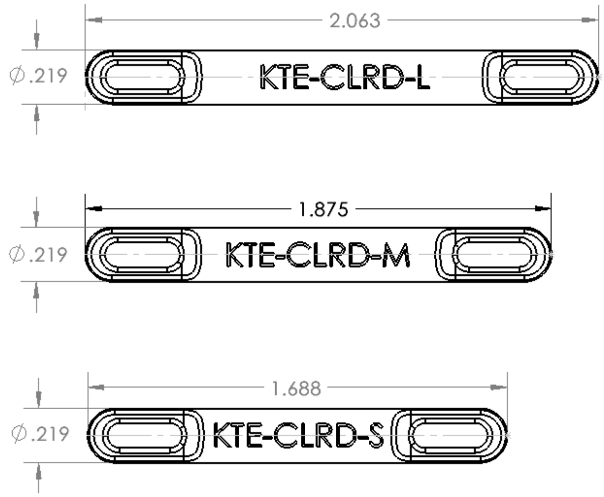


Fig. 21. Three sizes of CLRD (KTE-16-S,M,L) are available and chosen so as to fit within the confines of the distal humerus cortex. The CLRD diameter and eyelets have uniform dimensions and allow for the ligaments to pass through freely.

A CLRD is chosen that is shorter than the width when measured between the medial and lateral drill holes. Three CLRD sizes will allow for the placement of the CLRD that is the appropriate length so that the openings are located just below the cortex, which minimizes graft length.

IMPLANTATION SELECTING GRAFT

Preoperative physical examination will demonstrate whether adequate tendon graft material is present and easily harvested. Reasonable graft options are:

1. Palmaris Longus
2. Contralateral Palmaris Longus
3. Half of the Flexor Carpi Radialis
4. Half of the Flexor Carpi Ulnaris
5. Toe Extensors
6. Plantaris
7. Semitendinosus
8. Gracilis
9. Strip of Triceps tendon

Cadaver testing has shown that various human tendons have biomechanical properties that are suitable for ligamentous reconstruction (Arnout 2013). If insufficient tendon material is present from the aforementioned locations, an allograft tendon such as an Achilles allograft may be employed. This may be particularly advantageous in circumstances where the distal humerus is to be resurfaced with a portion of the Achilles allograft and then two strips are harvested from the same allograft.

IMPLANTATION GRAFT AUGMENTATION CONSIDERATION

If the host graft integrity is considered poor and not able to resist the varus and valgus forces that the elbow will experience in the acute setting (prior to graft incorporation), then a PDS #1 suture (Ethicon, Johnson & Johnson, Raritan, NJ) can be woven into the ligament, which will increase the tensile strength of this construct by transmitting forces through the augmenting suture and away from the graft. Each PDS #1 suture, when woven through the graft and sutured to itself on the dorsum of the ulna, will add 85 +/- 8 N of additional strength in the acute setting. 60% of that strength will be retained at six weeks (Gerber 1994, Metz 1990, Pillai 2010).

Fig. 22. PDS II (Ethicon, Johnson & Johnson, New Jersey, USA) is a sterile synthetic absorbable monofilament suture made from polyester poly(p-dioxanone). An additional 84 +\- 8 N force is imparted with each strand.

The goal is for the absorbable suture to lose its biomechanical properties over a period of time after implantation. While the elbow is most vulnerable in the early stages after implantation, we want to support the reconstruction with suture and prevent the ligaments from experiencing undue forces. After healing has occurred, we want the suture to lose its biomechanical effectiveness so that the ligament reconstruction can experience the usual forces for that environment, which prevents stress shielding of the ligament and allows for the ligament to biomechanically respond to all of the forces that the elbow may experience (Nguyen 2021).

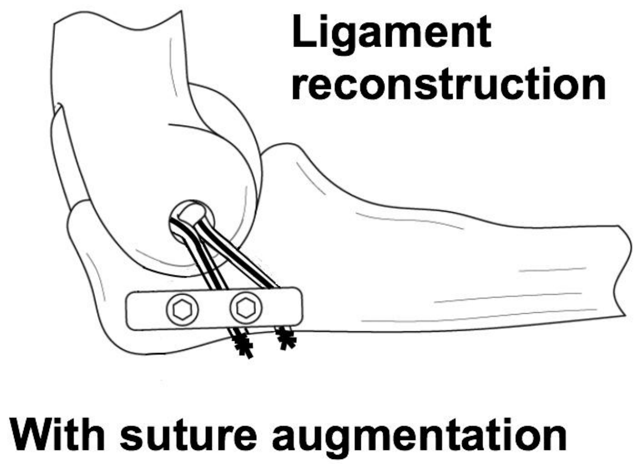


Fig. 23. After graft tensioning has occurred and this tension has been secured with the aggressively teethed plates that apply compression between the graft and bone, the PDS II suture (Ethicon, Johnson & Johnson, New Jersey, USA) that is woven through the tendon graft is sutured to itself.

When absorbable suture augmentation is used, the suture ends are tied over the dorsal aspect of the elbow.

IMPLANTATION PASSING GRAFT THROUGH CLRD

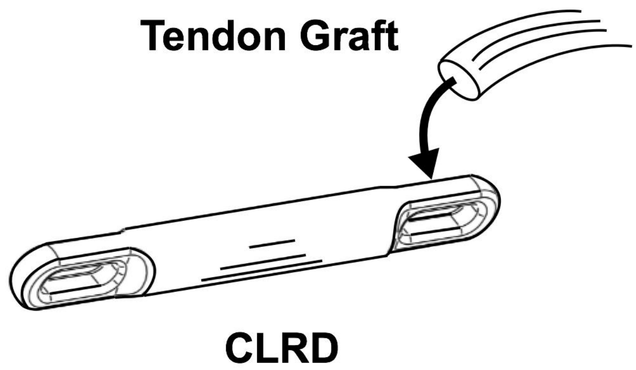


Fig. 24. Tendon grafts are passed through the CLRD eyelets. Grafts are trimmed to pass freely through the opening..

The grafts are passed into the eyelets of the CLRD to ensure that they can glide easily. A tendon graft may need to be trimmed to fit within the eyelet of the CLRD and, yet, a 3.5 to 4 mm graft will comfortably pass through the CLRD. Grafts of this size have been tested with this ligament reconstruction and are able to resist slipping between graft and bone when compressed with the aggressively teethed plates against bone (Gibbs 2023, Coutinho 2023). A palmaris longus tendon graft, which is typically 3-4 mm in diameter, has a stiffness of approximately 42 N/mm and is very capable of withstanding the forces experienced during tendon tensioning (Carlson, 1993).

IMPLANTATION PASSING CLRD THROUGH BONE

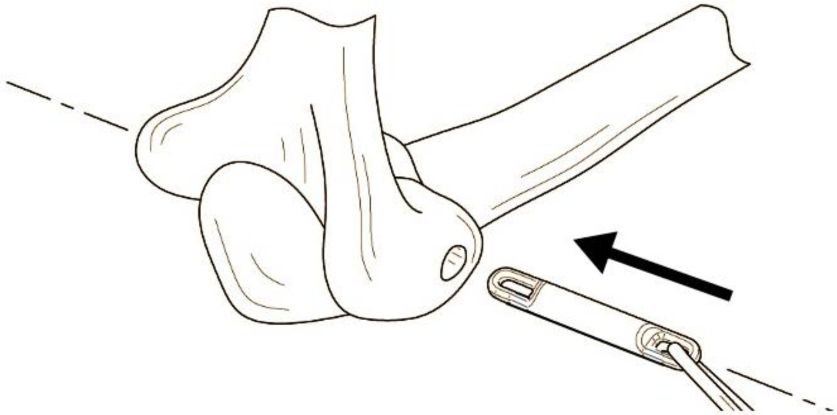


Fig. 25. The CLRD is pushed through the drill hole created by the cannulated drill bit.

The drill hole in the humerus allows easy passage for the CLRD. It slides freely until the CLRD is visible and a new ligament is then passed through the far end eyelet. Once the second tendon is secured, the CLRD is pulled back to lie within the confines of the outside of the distal humerus. Because the CLRD slides within the bone, equal tension can be imparted to the graft when medial and lateral force is applied.

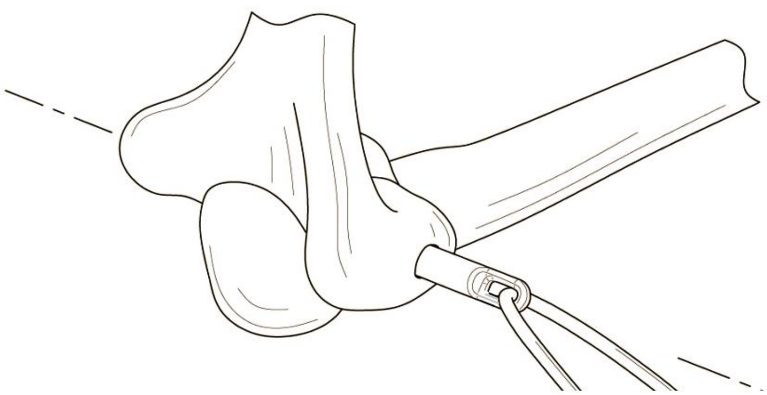


Fig. 26. The CLRD should experience minimal friction as it is pushed across the drill hole, which will facilitate equal tensioning of the ligament grafts.

The Cylindrical Ligament Retention Device (CLRD) is pushed all the way to the other side.

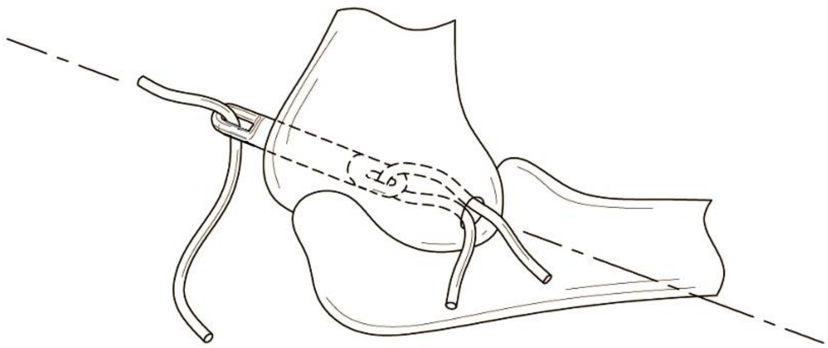


Fig. 27. The other eyelet allows passage of the contralateral graft limb.

It slides freely until the CLRD is visible and a new ligament is then passed through the far end opening.

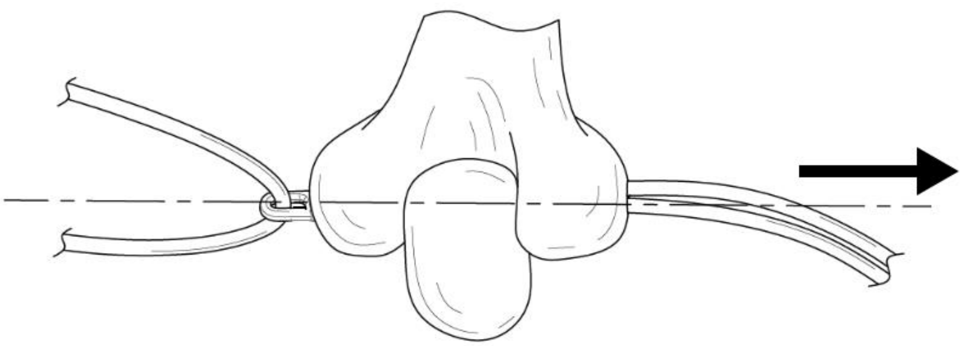


Fig. 28. The CLRD is pulled back into a central location within the distal humerus.

Once the second tendon is secured, the CLRD is pulled back to lie within the confines of the outside of the distal humerus.

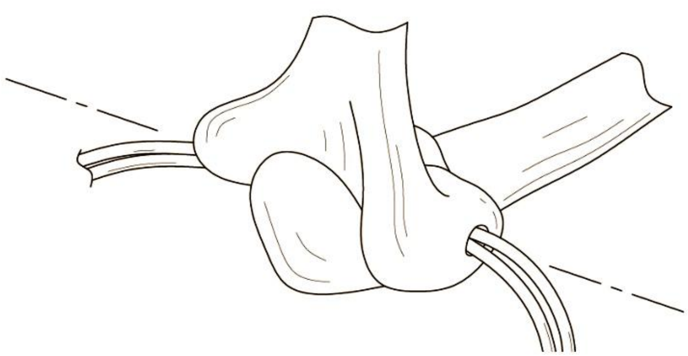


Fig. 29. The CLRD is now centrally located and will secure the graft limbs and allow for equal force transmission during tensioning.

Because the CLRD slides within the bone, equal tension can be imparted to the graft when medial and lateral force is applied.

IMPLANTATION PASSING GRAFT UNDER COMPRESSION PLATE

The four graft limbs are placed under the plates. One limb lies between the bolts and one distal to the distal bolt. The plates gain purchase into these graft limbs with their aggressive teeth.

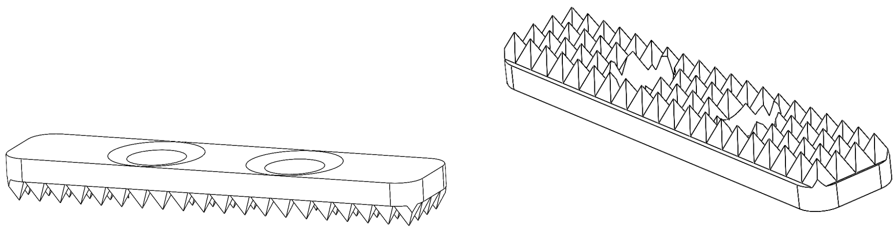


Fig. 30. Aggressively teethed plates are able to secure the graft limbs to bone when compressed with the tightening of the transulnar bolts and splined nuts.

When the bolts are tightened, the plates are pulled into a secure location against the ulna, where substantial pressure is being created between the plate and the olecranon ensuring secure ligament healing.

Fig. 31. Off axis loading of the aggressively teethed plates is possible through the ability of the bolts and nuts to mate with the plates. The plate has two concave mating surfaces that distribute forces when off axis loading may occur.

The bony surfaces of the ulna may not be parallel to the ulnar body component resulting in off axis loading. In order to maximize the contact between both the screw heads and the nuts against the cross locking plates, the mating surfaces were designed to allow for the nuts and bolts to evenly distribute forces during the tightening process.

IMPLANTATION TENSIONING GRAFT

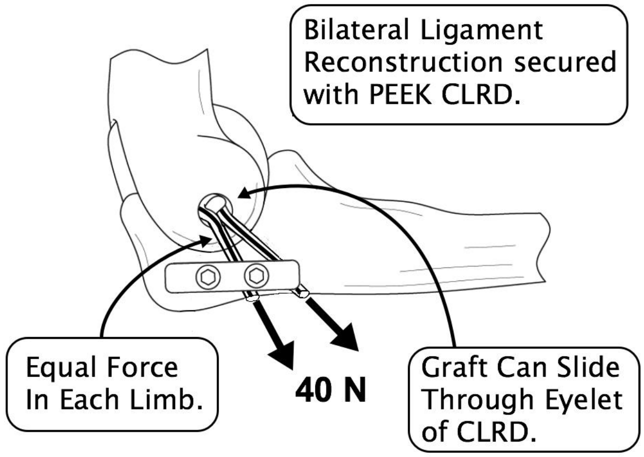


Fig. 32. Medial and lateral sides are each tensioned with 40 N, which results in a combined pull of 80 N. This force is locked in by the compression of the plates against bone.

Each side is pulled with 40 N. Initial joint stability is of paramount importance to ensure excellent graft function. The graft material will never tighten over time and, if anything, only loosens. It is, therefore, imperative to impart significant tension to the graft material and maintain this tension during the healing process. Applying the correct graft tension will prevent under-constraining the elbow as this may lead to residual laxity resulting in subluxation or even dislocation (Sherman 2012).

Over-constraint may lead to increased joint friction resulting in increased joint forces and possibly damage to the joint. The correct tension has been studied with suture repair of the MCL at 20N and 40N reproducing native elbow kinematics, whereas a repair at 60N produced altered kinematics suggestive of overtightening (Pichora 2007).

A cadaver study showed that LCL repair at 20N restored kinematics well and that a greater force may lead to “over tightening” and resultant valgus appearance of the elbow (Fraser 2008).

We will use a 40 Newton force that is applied to both medial and lateral sides. The viscoelastic properties inherent in ligaments will dissipate internal forces and this energy loss (Hysteresis observed in the stress–strain curve) requires force application in an upper range of what would ensure elbow stability. For the purposes of our ligament reconstruction, we recommend 40 N of force to be applied in a reproducible manner to the medial and lateral sides of the elbow. This force is applied by the surgeon who tensions all graft limbs at the same time. The maximum tension applied with a single hand pull by a sports medicine surgeon is 99 N (Cunningham 2002).

Since we require 40 N in each limb, a substantial pull by the surgeon that lies just beneath the surgeon's maximum capability will tension the construct successfully. Since the maximum pull that the surgeon can create (99N) when divided over two graft limbs would provide a limb tension that is 49.5 N, requesting that the surgeon perform a substantial but not a maximal pull will likely approximate the 40 N that is needed on the medial and lateral sides of the elbow (Sherman 2012).

IMPLANTATION TIGHTENING BOLTS TO COMPRESS GRAFT TO BONE

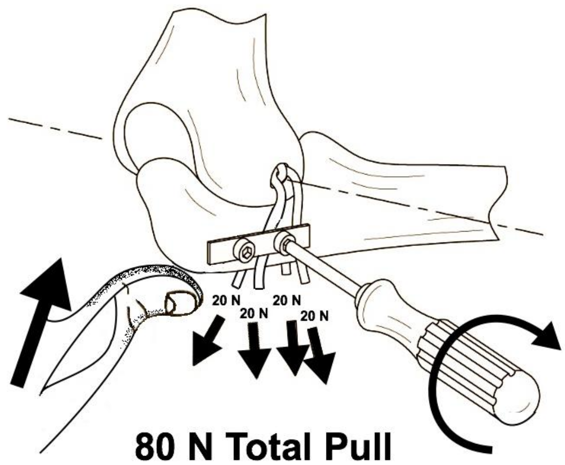


Fig. 33. The ulnohumeral joint is seated with pressure exerted between the ulna and the distal humerus while the tendons are tensioned and the bolts are tightened.

The nuts are tightened on the threaded bolts and compressive force is exerted between the olecranon and the cross locking plate. Substantial compression between the graft and bone is then accomplished, which allows for secure healing of the tendon to the bone which, in turn, recreates stability (Weiler I 2002). Minimizing graft motion through secure stabilization between the graft and bone also promotes tendon-to-bone incorporation (Weiler 2 2002).

IMPLANTATION   BOLT CUTTING

Fig. 34. The transulnar bolts are 0.094 inches (2.4 mm) in diameter and can be tightened with a nut driver.

The transulnar bolts are used to compress the teethed plates against bone. When fully tightened, the bolts will project beyond the splined nut and are in need of cutting.

Fig. 35. Surgical bolt cutters are used to cut the bolt that protrudes beyond the splined nut after tightening.

After the plates are securely compressing the tendons against bone, a bolt cutter is used to cut the bolt flush with the nut and minimize bolt protrusion. A standard 8.5” length double action wire cutter with angled side cutting blades is well suited for this purpose.

Bolt cutters are commonly employed in orthopedic surgery as screws that are too proud on the far side of a bone are frequently cut with bolt cutters (Gehr 2006, Gehr 2006, Suzuki 2010, Gopinathan 2012).

Commonly employed in spine surgery when treating scoliosis and kyphosis, in-situ rod cutting is performed with powerful rod cutters. These implant rods that are attached by bone screws to spinal vertebrae are used to impart structural correction of the spine deformity and are then cut in-situ to the ideal length after the screws have been tightened (Renshaw 1988).

IMPLANTATION DETERMINING ELBOW STABILITY

After implantation, the ulnohumeral joint is moved through a full arc of motion to identify if adequate stability has been achieved. A posterior drawer test is performed to identify whether the ulna can be unseated from the distal humerus. Varus and valgus stress testing should demonstrate no posterolateral rotatory instability as well as no medial joint line opening.

POSTOPERATIVE REHABILITATION

Postoperatively, the arm is placed in a splint in flexion. The patient is often discharged from the hospital on the initial postoperative day. In an effort to maximize tendon to bone healing, the rehabilitation after implantation will be similar to the protocol that is used for a commonly performed elbow ligament reconstruction procedure namely MCL reconstructions (Tommy John surgeries). We will, thereby, create an environment that allows the ligaments to heal and become solid contributors to joint stability.

The time needed for adequate bone-tendon healing lies between 8 and 12 weeks based on animal failure studies. Rodeo et al reported on a canine model that the failure mode was graft pullout at 8 weeks, whereas at 12 and 26 weeks, no pullout failures were noted. An initial layer of cellular, fibrous tissue occurs between the tendon and the bone. This layer progressively matured and reorganized during the healing process. For the first 8 weeks, the ligament to bone connection is the weak link of the biomechanical construct and yet, at 12 weeks, the ligament to bone connection is considered as strong or stronger than the ligament itself (Rodeo 1993). Weiler and colleagues showed in a sheep model that at time 0, the Achilles graft failed by graft pullout, but at 6 and 9 weeks, failure was noted to be intra-ligamentous (Weiler I 2002).

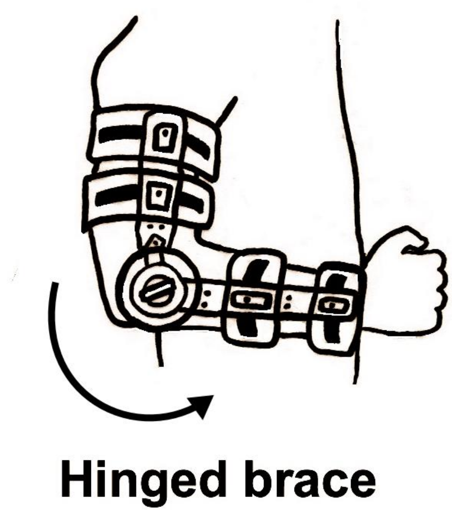


Fig. 36. A hinged elbow brace consists of forearm and arm supports that are connected with a hinge that allows flexion and extension but resists varus and valgus force.

In our postoperative protocol, we will protect the ligament reconstruction through the use of a hinged brace for ten weeks after suture removal at 10 to 14 days. The hinged brace will be employed to only allow 45 to 140 degrees of motion for the first month after the sutures are removed and then full motion for the last six weeks of the initial three month post-operative time period.

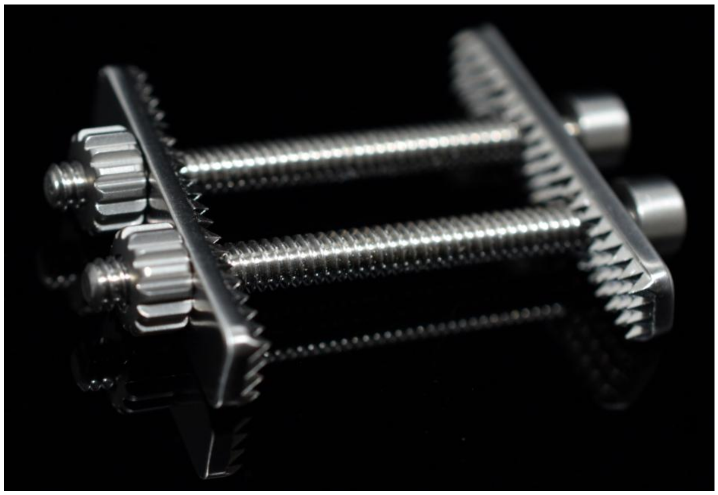
Another option exists for non compliant patients, whereby at two weeks after surgery, we immobilize the arm in a long-arm cast for 3 weeks. A removable thermoplastic splint is then applied for 7 more weeks. It is removed 4 times per day to do overhead range of motion (ROM) exercises in the supine position. Anytime the elbow is moved away from the body, the weight of the forearm is supported by the other hand to prevent inadvertent varus torque during these activities. ROM is progressed as the patient is able to with a goal of achieving full ROM by three months status post surgery.

At 3 months, the focus is shifted toward strengthening the elbow flexors, extensors, pronators, and supinators. Unrestricted activity and return to sport are generally allowed 6 to 12 months after surgery. Formal therapy is generally not instituted.

KTE Ligament Reconstruction System kit contains:

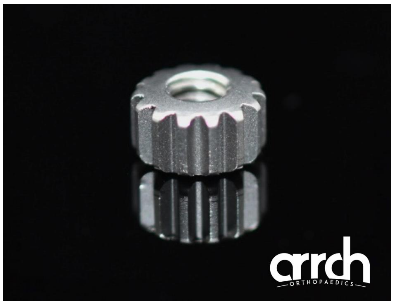
BASIC DESIGN FEATURES:

The Arrch Orthopaedics Bilateral Ligament Reconstruction implants are designed for the reconstruction of ligaments at the elbow.



The ligament grafts are simultaneously tensioned and compressed against the ulna using the assembly shown above.

Illustration	Component	Material of Construction
	**KTE-16-S** Small Cylindrical Ligament Retention Device	PEEK per ASTM F2026
	**KTE-16-M** Medium Cylindrical Ligament Retention Device	PEEK per ASTM F2026

	**KTE-16-L** Large Cylindrical Ligament Retention Device	PEEK per ASTM F2026
	**KTE-12** Splined Nut. 6-32 UNC-2B Thread. 0.151” Width. 0.28” Outer diameter.	Titanium Alloy per ASTM F136
	**RAK-10-M** Transulnar Bolt. 6-32 UNC-2B Thread. ⅛” hexagonal head.	Titanium Alloy per ASTM F136
	**RAK-11-M** Aggressively Teethed Compression Plate.	Titanium Alloy per ASTM F136
	**KI-71-025** 0.625 K-Wire for placement along the centerline of elbow flexion.	ASTM A967 17-4 PH SS

	**KTE-CLRD-Drill** Cannulated Drill Bit for drilling over K-Wire to create a hole for CLRD placement.	ASTM A967 17-4 PH SS
	**KTE-CL-Drill** Drill Bit for drilling holes in olecranon. 4 mm diameter.	ASTM A967 17-4 PH SS
	**KTE-CLRD-D-2** Drill Guide has two functions: 1. Drilling of proximal ulna for placement of transulnar bolts. 2. Placing parallel K-wire to centerline of rotation K-wire.	ASTM A967 17-4 PH SS
	**KTE-10-T** Bolt Driver to tighten **RAK-10-M** Translunar ⅛” hexagonal bolt.	ASTM A967 17-4 PH SS
	**KTE-12-T** Splined Nut driver with socket to hold **KTE-12** splined Nut. 0.394” outer diameter.	ASTM A967 17-4 PH SS

	**1FS19-CO1-P** MedTorq Handle for **KTE-CLRD-D-2** Drill Guide, **KTE-10-T** Bolt Driver and **KTE-12-T** Splined Nut Driver. 1-1/2" Dia x 7" Length.	ASTM A967 17-4 PH SS 302 SS ELASTOSIL® PT SCHWARZ 9005 color paste

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