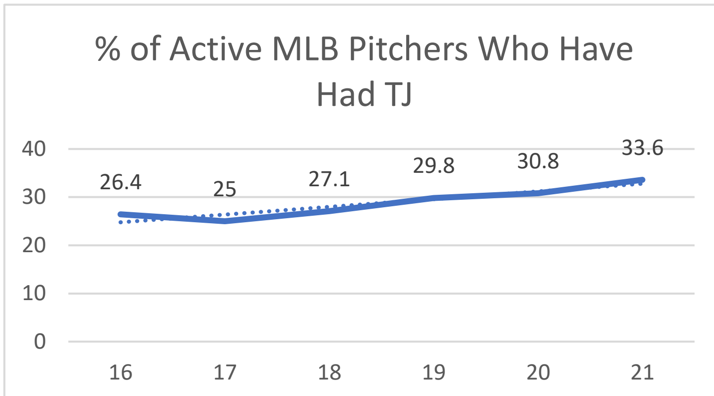
9/25/22

An Evidence-Based Solution to Baseball's UCL Tear Problem

1. <u>Introduction</u>

According to James Andrews, M.D., the rate of UCL tears across baseball has reached near epidemic proportions.

Despite baseball's adoption of workload management strategies and new therapeutic modalities aimed at accelerating post throwing recovery, neither has curtailed what appears to be an ever-increasing rate of Tommy John (TJ) surgeries across MLB. As of 2021, over a third of all MLB pitchers have had a Tommy John surgery at some point in their career.



Source: (A170)

In addition, roughly 50% of all asymptomatic MLB pitchers are estimated to have a partial UCL tear that could turn into a tear requiring TJ at any time (A44).

Amongst pro pitchers, the best case scenario for an MLB pitcher who undergoes UCL reconstruction is he will miss a season, and many will miss two (A56).

While numerous studies report return to play rates at 80-85%, and some as high as 90% to 95%, these studies are misleading as they only reported on return to competition, not whether the pitchers are able to achieve their same level of pre-surgery competitiveness. Three studies over the past decade have examined the percentage of MLB pitchers following TJ who were able to return to their pre-injury levels. The findings of each are alarming.

a) A 2021 study that looked at 63 MLB pitchers who had TJ between 2015-2019 found that a staggering 43% who threw more than 100 pitches in the year prior to their TJ never returned to MLB to throw more than 100 pitches in either their first or second year following TJ (A162).

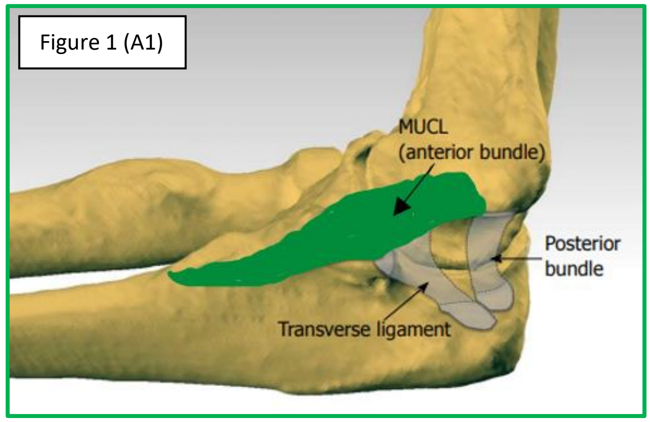
b) A 2014 study that examined the return of 147 pitchers who underwent UCL reconstruction from 1999 - 2011 found that 33% failed to ever return to pitch in more than 10 games (A156).

c) A 2016 study examined the return rates for those who had a second TJ and found that less than 50% returned to pitch in 10 or more games (A168).

Over the past four years, we have consulted with numerous physicians, PhD's, bio-mechanists, physical therapists, athletic trainers, and we have reviewed over 350 clinical studies, all in an attempt to understand the etiology of UCL tears in baseball. Two years into our research, we became confident we could create a device to dramatically reduce the chance a pitcher would ever tear his UCL.

What follows is a summary of our findings.

2. Anatomy of the medial ulnar collateral ligament



The medial ulnar collateral ligament (MUCL) is comprised of 3 ligamentous bundles: the anterior bundle, the posterior bundle, and the transverse or oblique bundle. The anterior bundle (AB) has been shown to be the primary stabilizer of the elbow in valgus stress. It is comprised of 2 bands: the anterior band and the posterior band. The AB originates on the anterio-inferior surface of the medial epicondyle and inserts onto the sublime tubercle of the ulna (Figure 1) (A1). Other than in rare exceptions, substantially all throwing induced MUCL tears occur on the anterior bundle (A8). Therefore, unless otherwise specifically noted, for the remainder of this paper, whenever the term UCL is used, we are referring specifically to the anterior bundle.

3. When UCLs Tear

Dramatically reducing the chance of a UCL tear first requires a thorough understanding of when, why, and where UCLs tear. Thankfully, the literature is filled with studies to answer these questions.

As for "when," contrary to the belief of many that pitchers most often tear their UCL either during extension or deceleration of their throwing arm at, near, or following ball release, the literature is unequivocal. With rare exception, UCL tears occur at maximum external rotation (MER) when peak valgus torque is placed on the elbow and the arm is transitioning from late cocking to early acceleration (A1, 102).

4. Why UCLs Tear

a) At MER, the elbow encounters external valgus torque, which imparts a compressive force on the lateral side of the elbow at the radial humeral joint and a tensile force across both the UCL and several muscle-tendon units (MTUs) overlaying the medial side of the elbow (A163).

b) While pitchers experience differences in the peak torque placed on their elbows attributable to throwing mechanics and anthropometry, the amount of peak valgus torque in Newton meters (Nm) a pitcher experiences on his elbow at MER is roughly equivalent to his velocity in mph. In numerical terms, this means that if a pitcher throws a fastball at 90-100 mph, he is likely placing between 90-110 Nm of torque on the medial side of his elbow (A89, 142, 143).

c) In high velocity throwers, peak torque placed on the elbow often exceeds the capacity of these 3 primary structures to dissipate that torque (A89).

d) Over a career, high torques and forces in the elbow joint stress the UCL, and repetitive valgus overload from throwing may cause microtrauma / microtears (A9).

e) Eventually, this cumulative microtrauma of repetitive near failure tensile stress on the UCL reaches a tipping point where the valgus forces generated by a pitcher exceeds the tensile strength of the UCL, causing a tear (A8, 33).

f) Answering the question of why UCLs tear can be expressed as an algebraic expression where:

A	>	B	+	C	+	D
Peak torque on the elbow (~90-110Nm)		UCL tensile limit (~34-41)		Radial humeral joint compression limit in healthy UCL (~30-36)		Tensile limit of MTUs crossing medial elbow (?)

g) While "A" and "D" are variable, research has identified that "B" (the UCL tensile limit) and "C" (the radial humeral joint compression limit in an elbow with a healthy UCL) are largely fixed.

h) As for "B," the anterior bundle of the UCL is the primary stabilizer in resisting the valgus torque that throwing places on the elbow. According to Drs. Chris Ahmad, Medical Director for the Yankees, and Neal ElAttrache, Medical Director for the Dodgers, the ultimate torque resistance / tensile limit of the anterior bundle of the UCL in an intact elbow ("B") is 34 +/-6.9 Nm (A99).

i) As for "C," the radio-humeral joint is a structural stabilizer that can resist elbow valgus torque. The magnitude of contribution depends on the amount of compression force and the magnitude of the externally applied torque. At 90° flexion, which equates to roughly the position of the elbow at MER, the radial humeral joint compression limit ("C") in an intact UCL is 33% of peak torque or 30-40 Nm (A78).

j) Assuming an average peak torque ("A") of 100 Nm, an upper UCL tensile limit ("B") of 41Nm, and a radial humeral joint compression limit ("C") of 33 Nm, the MTUs which cross the medial elbow must provide at least 34 Nm of varus resistance to prevent a UCL tear.

k) In summary, while the etiology of any individual tear is likely multi-factorial, according to literature there is always a common denominator: torque exceeded the UCL's tensile limit.

There are, however, two compounding factors worth mentioning: velocity and fatigue.

1) Any increase in velocity will almost always lead to an increase in torque placed on a pitcher's elbow (A63), likely explaining why UCL tears have escalated along with the steady rise in fastball velocity over the past decade.

2) Because the tensile limit of the UCL and the compression limit of the radial humeral joint in a healthy UCL are largely fixed, the only variable that can be modified to increase the amount of torque the elbow can safely withstand are the MTUs which cross the medial elbow. If any of these MTUs fatigue, greater stress is placed on the UCL, which can ultimately cause a tear (A2, 95).

   Two recent studies identified the cause and effect impact of fatigue of the MTUs which cross the medial elbow. One study involving 26 college pitchers found that as one of these key muscles, the flexor carpi ulnaris ("FCU"), fatigued, gapping of the medial elbow joint space increased (A159).

   A second 2021 study involving 30 high school pitchers found that the key muscles that overlay the UCL were stretched by an average of 16% in response to the stress of maximum velocity throwing after only 20 pitches. In response to this muscle deformation, strain on the UCL then increased by 12%, which ultimately led to an increase in medial joint space gapping of roughly 4% for every 20 pitches thrown (A156).

   When harmonized, these two studies are significant in light of a recent study involving the Colorado Rockies which found that the risk of UCL injury was 6 times higher in pro players with a medial elbow joint space exceeding 5.6 mm (A149).

5. <u>The Muscle-Tendon Units that Matter The Most</u>

   Physicians universally agree that at MER, the flexor digitorum superficialis (FDS) and FCU are best positioned to provide medial elbow valgus support, making them the greatest contributors to valgus elbow stability. And based on our review of the literature and discussions with several clinicians, we believe a third MTU, the flexor digitorum profundus (FDP), also plays an integral in protecting against distal UCL tears.

   Exhibit 1 highlights the views of numerous iconic physicians about the role of these three MTUs.

   Exhibit 2 identifies the origin, insertion, function, and role of the FDS, FCU, and FDP in protecting the UCL.

   Exhibit 3 contains an illustration of the anatomical footprint of the FDS, FCU, and FDP.

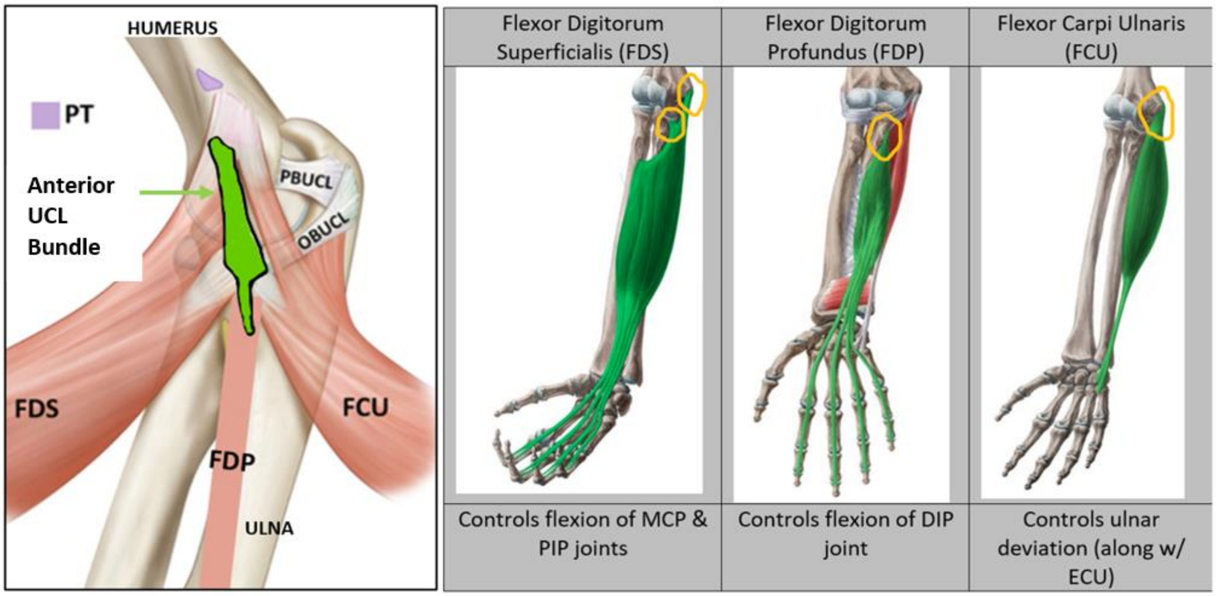
Exhibit 1: Muscle-tendon units best positioned to protect the UCL

Primary Investigator	Quote
Jobe	At MER, the FDS & FCU are best positioned to provide medial elbow valgus support preventatively or therapeutically (A18).
Andrews	When the dynamic stabilizers (FDS, FCU) become fatigued, greater stress is placed on the UCL. Carefully elevate FDP to avoid cutting UCL that lies just underneath (A2).
Ahmad	The FCU and FDS are the primary dynamic stabilizers against elbow valgus torque. To prevent UCL injury, optimize function of FCU and FDS (A64).
Romeo	Muscle fatigue during throwing leaves the UCL unprotected subjecting UCL to forces that can cause tear (A43).
Altchek / Dines	Dynamic stabilization of the elbow is accomplished by strengthening the FCU and FDS. Given their anatomic location overlying the UCL these muscles assist the UCL in stabilizing valgus stress (A11).
Frangiamore	Primary focus should be on strengthening the muscles (FDS, FCU, FDP) surrounding the UCL for injury prevention (A5).
Lin	The FCU & FDS release MUCL strain by generating varus motion, which effectively reduces the MUCL load. Most UCL strain relief at 90° (point of MER) is provided by FCU & FDS (A103).
Awh	Fatigue of dynamic stabilizers (FDS & FCU) can cause UCL tears (A92).
Udall	The FDS and FCU are the greatest contributors to valgus elbow stability. Fatigue of these muscles fatigue causes the MUCL and bony structures of the elbow to undergo a greater load, which can ultimately cause failure of the MUCL (A95).
Dunn	The origin of the FDP overlies the distal ulnar attachment of the UCL (VCOM).

Exhibit 2: Origin, insertion, function, and role of the FDS, FCU and FDP

Muscle	Origin	Insertion	Primary function	Role in protecting UCL
Flexor Digitorum Superficialis (FDS)	1) Medial epicondyle 2) Ulnar ridge	Middle phalanges 2-5	Flex metacarpal & proximal finger joints	Primary UCL dynamic stabilizer by means of direct muscle action with vectors optimally positioned to resist valgus torque (A103)
Flexor Digitorum Profundus (FDP)	Ulna	Distal phalanges 2-5	Flex distal finger joints	Protect distal UCL attachment via overlay origin (A2)
Flexor Carpi Ulnaris (FCU)	1) Medial epicondyle 2) Posterior olecranon	Pisiform	Ulnar deviate wrist	Primary UCL dynamic stabilizer by means of direct muscle action with vectors optimally positioned to resist valgus torque (A103)

Exhibit 3: Illustration of UCL, FDS, FCU, and FDP footprint



Source: (A5)

One other MTU that occasionally gets mentioned by those in the baseball community as being able to protect against UCL tears is the pronator teres. This MTU, along with the pronator quadratus, is primarily responsible for pronation of the forearm. The pronator teres has three attachments: one on the humerus proximal to common flexor attachment and proximal to medial epicondyle (Exhibit 3), a second on the ulna between brachialis and anterior bundle, and a third on the radial shaft. At no point of elbow flexion when torque on the elbow is anywhere near its peak does the pronator teres overlay any portion of the UCL (A18).

This explains why Chris Ahmad M.D., in a study that identified the dynamic contributions of the FDS, FCU, and pronator teres to elbow valgus stability, found that between the three, the pronator teres provides the least dynamic stability (A64).

While there is abundant literature identifying the role of the FDS and FCU protecting the UCL, we could not locate one clinical study over the past 30 years which suggests that the pronator teres plays any meaningful role in contributing to elbow valgus stability. Consequently, in a nod to Occam's razor, we concluded it safe to discard the pronator teres from such consideration.

6. <u>Why Current Approaches to Protect Against UCL Tears Fail</u>

Because excess torque on the UCL is always the cause of a UCL tear, any approach that seeks to protect against a UCL tear must prevent torque from ever exceeding the UCL's tensile limit. The baseball community has attempted to accomplish this with four approaches. Given baseball's steadily increasing rate of UCL tears, it's safe to say all have been at best only marginally effective. What follows is a brief review of each approach along with its shortcomings.

a) Improved mechanics

Various studies have identified that the following results in more torque begin placed on the elbow:

1) Decreased balance on the drive and plant legs on Y test (A39)
2) Trunk rotation before front foot contact (A14)
3) Shoulder abduction angles greater than 109° at front foot contact (A15)
4) Elevated elbow extension angle at MER (A15)
5) Excessive contralateral trunk tilt (A42)

Given these findings, it is only logical that clinicians and coaches alike have sought to instill "perfect" mechanics in every pitcher in hopes of preventing UCL tears. Unfortunately, thus far, chasing torque reduction on the elbow / UCL through improved mechanics has not appeared to represent a plausible approach to reduce the rate of UCL tears for a variety of reasons:

1) The "flawed" mechanics that a pitcher employs often contribute to his success or are so neurologically engrained that pitchers are either unwilling or unable to make the types of mechanical changes necessary to reduce torque on their elbow.

2) According to Stan Conte, senior director of medical services for the Marlins and previously the Dodgers and Giants, while almost universally agreed upon poor mechanics such as dropping the elbow, the inverted W, and opening the front side too soon will increase stress and torque on the UCL, no study has shown a direct relationship between their existence and injury (A43).

3) Those deemed to have "good" mechanics also frequently tear their UCL (Walker Buehler, Kershaw, Yu Darvish, Hunter Greene, Verlander, etc.)

4) If "good" mechanics were capable of preventing UCL tears, it's highly unlikely over a third of all active MLB pitchers would have reconstructed UCLs (A170) and 50% of all asymptomatic pitchers would have partial tears that could turn into a tear requiring TJ at any time (A44).

b) Workload management

First identified in 1975 (A34) and then popularized in 2015, an Australian research team found that a soccer player's acute to chronic workload is a greater predictor of injury than either acute or chronic workload separately (A35). Simply put, athletes with high chronic workloads are more resistant to injury. As this study gained traction within the sports community, in hopes of protecting against elbow and shoulder injuries, most in baseball came to three realizations:

1) Not throwing enough can be just as harmful as throwing too much.
2) Breaks from throwing are not wise if pitchers are not given ample time to slowly ramp up to previous levels of endurance.
3) Any form of throwing places valgus load on the medial elbow.

Those seeking to institute an acute to chronic workload (ACW) management system to protect pitchers against UCL tears set prescribed time for pitchers to ramp up before increasing the frequency or intensity of their throwing. Once a desired level is achieved, pitchers are then instructed to throw with a consistent frequency and intensity to avoid falling outside of what would be considered a “safe” range.

As with mechanics, thus far, applying an ACW management system has not appeared to meaningfully alter the rate of UCL tears. Of note, in 2018, a team of researchers examined 161 MLB starting pitchers who made at least 5 starts between 2010 and 2015 to determine whether there was an association between average pitch count per game, cumulative pitch counts, cumulative innings pitched, or cumulative number of starts over a multi-year period and the subsequent risk of injury. Their conclusion: there is no association between preceding years of cumulative pitches, starts, innings pitched, or average pitches per start and being placed on the [IL] for any musculoskeletal reason (A167).

c) Fatigue management / recovery

Recognizing that muscle fatigue of the flexor pronator mass leaves the UCL unprotected and subjects it to forces that can cause it to tear (A43), many have sought to reduce post throwing fatigue using a variety of therapeutic modalities (e.g., ice, heat, contrast, BFR, TENS, E-Stim). While it is beyond the scope of this paper to evaluate the efficacy of each, provided any such modality has clinical support, we believe that any form of intervention that reduces muscle fatigue is both logical and worth pursuing. However, in terms of their efficacy at protecting against UCL tears, all such modalities have two shortcomings:

1) None offer any mechanism to identify the recovery state of the three MTUs best positioned to protect the UCL

2) At best, a perfectly administered post throwing recovery intervention will only restore the MTUs best positioned to protect the UCL to their baseline state. Because players seeking to throw harder - which we suspect conservatively represents at least 95% of all pitchers - will place increasing amounts of torque on their elbow (A63), any solution must increase the torque bearing capacity of the three MTUs best positioned to protect the UCL.

d) Conventional strength & conditioning exercises / practices

There are 20 extrinsic muscles in the forearm that primarily control flexion, extension, pronation and supination of the wrist and fingers. Extensive clinical research, much of it referenced in this paper, has shown that only a few of these muscles are anatomically positioned to support the UCL at maximum external rotation where torque is at its peak.

Most conventional S&C approaches to improve forearm strength employ a variety of exercises such as plate holds, tennis ball or hand grip squeezes, fingertip push-ups, wrist rollers, forearm curls, or various rice bucket exercises. A steady diet of these exercises my produce enlarged forearms but, except for those that involve finger flexion, will have no impact on reducing the risk of a UCL tear because they do not target the MTUs anatomically positioned to protect the UCL at maximum external rotation.

As for those that do involve finger flexion, these may prove only mildly beneficial at best as they only target the FDS, while missing the FCU and FDP entirely. This omission is hugely problematic for two reasons:

1) Numerous studies have identified that despite the FDS having nearly twice the calculated potential for direct valgus force transmission as does the FCU, the FCU is anatomically further posterior, which places it in a more functionally advantageous position directly over the anterior aspect of the UCL to protect against injury (A 18, 64, 103, 159).

2) Roughly 40% of all tears occur distally at the sublime tubercle attachment (A166) where only the FDP is positioned to reduce the load on the UCL. Ideally, any solution should protect the UCL across its entire footprint.

Additionally, even those aforementioned exercises that do stimulate the FDS will likely fail to achieve the minimum 70% maximum voluntary contraction (MVC) requirement routinely over a 12 week period to alter its stiffness / Young's modulus.

In closing on this topic, the inarguable truth is that if doing the litany of exercises identified above could protect the UCL, MLB pitchers would rarely ever tear their UCLs, because every organization already has their pitchers do them religiously. But the current incidence rates indicate these exercises are not the answer.

7. <u>The Roadmap as defined by the literature</u>

a) The guiderails

1) UCL tears occur whenever torque on the elbow exceeds the maximum combined capacity of 3 structures: the UCL, the radial humeral joint, and the MTUs overlaying the UCL.

2) The anterior bundle of the UCL has 2 attachments - one proximal at the medial epicondyle and the other distal on the sublime tubercle of the ulna.

3) The FCU and FDS overlay the humeral and mid-belly footprint of the UCL (Exhibit 3, A103).

4) The FDP overlays the distal UCL attachment (Exhibit 3, A2).

5) Preventing UCL tears can best be accomplished by reducing UCL strain when torque on the elbow is at its peak (i.e., MER) (A8, 33).

6) Of the UCL, the radial humeral joint, and the MTUs overlaying the UCL, the only variable that can be altered is the capacity of the MTUs crossing the UCL elbow to withstand greater levels of torque.

7) UCL tears have a bi-polar distribution: 48% of tears occur proximally at the medial epicondyle, 40% occurring distally at the sublime tubercle attachment,

and only 12% occurring along the mid-belly of the UCL (A166). Thus, ideally, any solution should protect the UCL across its entire footprint.

b) Understanding muscle-tendon unit strain reduction

1) Muscles and tendons act as functional stabilizers to reduce strain placed on ligaments due to their stiffness (A96).

2) The FDS, FCU and FDP are the 3 MTUs best positioned to dynamically stabilize the UCL at MER: the FDS and FCU to the proximal and mid belly of the UCL by means of direct muscle action with vectors optimally positioned to resist valgus torque (A103), and the FDP to the distal UCL attachment (A2). The role of the FDP in protecting against distal tears is vital considering the FDS and FCU tendons only overlay 45.6% and 20.9% of the distal (ulnar) footprint of the UCL (A5).

3) In general, as muscles fatigue, they become 16-21% less stiff (A148).

4) If the FDS, FCU and/or FDP fatigue, their stiffness decreases and they offload less torque on the UCL. This increases strain on the UCL and subjects it to forces that can cause a tear (A43, 103). Any UCL strain increase is then accompanied by an increase in gapping of the medial elbow joint space (A159), and with it, a potentially six times greater risk of UCL injury (A149).

5) Any intervention that increases the stiffness and reduces the fatigue of the FCU, FDS, and FDP will create the best chance to prevent a UCL tear.

c) Increasing the stiffness and endurance of a muscle-tendon unit

With the proper stimulus, the following findings of a 2022 meta-analysis of 61 studies identify the factors that impact increasing the stiffness and endurance of a muscle-tendon unit (A164):

1) Tendons are highly responsive to changes in mechanical load and can become stiffer and stronger with sustained increases in loading.

2) A stiffer tendon experiences less strain at a given load and resists a greater external load prior to failure.

3) High-intensity resistance training protocols (≥70% 1 rep MVC) regardless of contraction mode (concentric, isometric, eccentric, and concentric/eccentric) produced large increases in tendon stiffness and Young's modulus.

4) Training durations of 3x per week for at least 8 weeks were effective in inducing increases in tendon stiffness and Young's modulus, but greater increases occurred in high intensity protocols with training duration of ≥ 12 weeks.

5) This alteration of the mechanical function of the tendon was primarily explained by a change in Young's modulus independent of hypertrophy.

6) Gains in MTU stiffness / Young's modulus move linearly with but trail strength gains.

   A seminal study by Kubo, a world renowned MTU expert, found that 12 weeks of isometric strength training at > 70% of 1RM increased average muscle-tendon MVC by 39%, and stiffness by 51%. But while MVC increased 5% and 28% after 1 and 2 months respectively, tendon stiffness showed no increase after 1 month and only 12% after 2 months. It was not until after month 3 when MVC had increased 39% that stiffness increased 51% (A132).

7) Unlike stiffness, training induced reductions in MTU fatigue are primarily influenced by neurological adaptations, not strength gains (A100).

   As such, training which reduces MTU fatigue plateaus after 4 weeks. In 2013, a team of researchers measured the baseline fatigue rate of the triceps over 5 sets of 10 maximum effort elbow extensions, and then sought to improve it. Following a 10 week training protocol, the fatigue rate of all participants was retested. The initial fatigue rate, defined as the percentage decrease of the average value of the 5^{th} set vs the 1^{st} set went from 39% before training to only 12% after 10 weeks (so a 44% improvement). Nearly all gains occurred after the first 4 weeks of training (A100).

d) Harmonizing muscle-tendon unit research findings relevant into a device and app

1) It takes 3 months of strength training at ≥70% MVC, regardless of contraction mode (i.e., concentric, isometric, eccentric, or concentric/eccentric) to elicit the greatest changes in MTU stiffness (A77).

2) It is the stiffness of an MTU that reduces strain on a ligament (in this case the UCL). Strength gains merely serve as the mechanism to increase MTU stiffness / Young's modulus (A103, 148).

3) The MVC force produced by a finger in a multi-finger task is on average 32% less than the MVC force produced by finger in a single finger task (A146).

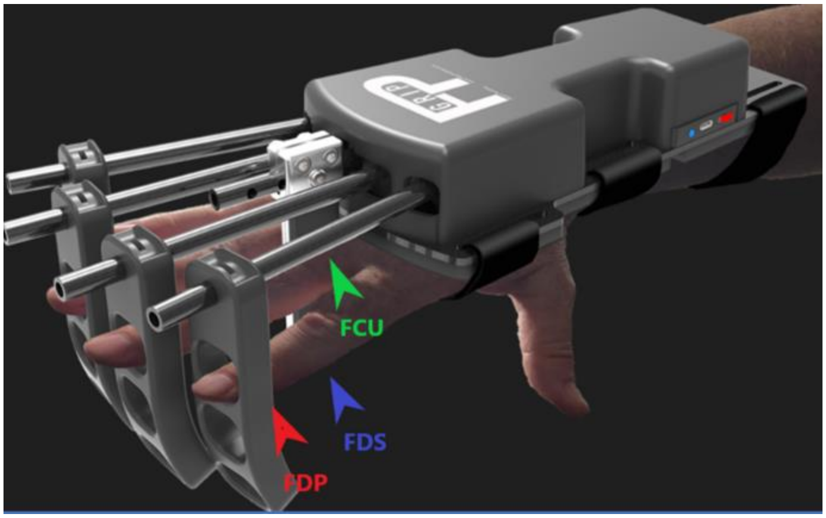
4) Harmonizing points 1, 2, and 3, single digit FDS and FDP strength training for 2-3 months is required to achieve optimal UCL protection.

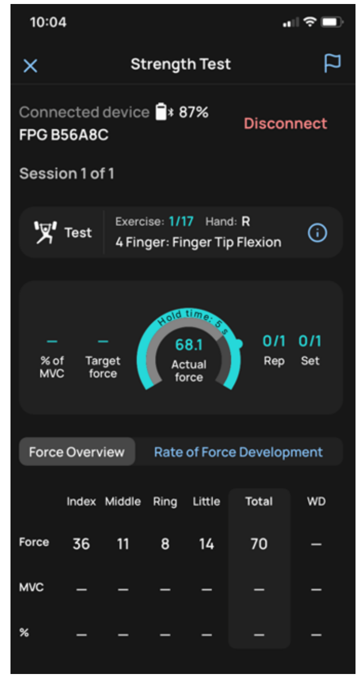
5) 80% of increased muscle-tendon stiffness will be lost after 12 weeks of de-training (A132).

6) 4 weeks of endurance training at ≥90% MVC can produce significant muscle endurance gains from neurological adaptations (A100).

8. The solution

a) The FlexPro Grip device / app





	Feature	Benefit
1	The device allows for isometric application of force in four directions: flexion, extension, ulnar deviation, and radial deviation	Training in 4 directions protects against asymmetry
2	Flexion force can be applied at any point along the distal or intermediate phalanges. EMG testing of FPG device revealed: i. applying flexion force from the distal attachment applies roughly 60% more stress to FDP than FDS ii. applying flexion force from mid-finger attachment primarily targets the FDS	Allows for optimal targeting of FDS or FDP to protect against proximal and distal tears
3	Flexion and extension force can be applied by any combination of digits	Force of fingers in multi-finger task represents only 60-70% of individual finger MVC (A146). Single digit training ensures the ≥70% MVC training thresholds necessary to alter stiffness / Young's modulus of FDS and FDP are met.
4	Device allows for application of ulnar deviation isometric force	Enables users to alter the Young's modulus of the FCU, the muscle tendon unit that offers the greatest protection against UCL tears (A 18, 64, 103, 159)
5	App displays objective force measurements for each digit and wrist deviation	Enables users to train at target thresholds ≥ 70% MVC to alter stiffness / Young's modulus of FDS, FDP, and FCU

6	App sets training thresholds for each user based on strength levels for each session	Makes load adjustments based on normal ebbs and flows to ensure training targets for each workout match changing MVC strength levels.
7	App provides evidence-based Strength, Endurance, and Readiness protocols	Eliminates any uncertainty as to what a user should do to achieve optimal results. Readiness testing identifies fatigue immediately to prevent throwing when UCL is exposed to excessive load

9. Results of non-peer reviewed trial

In October 2021, the four finger MVC strength and endurance levels of 30 MiLB pitchers were tested on the FlexPro Grip device. To administer the baseline Strength Test, we first familiarized all players with the device by having them perform a series of warmup exercises where they were instructed to first apply 25% of their maximum perceived effort, then 50% of their maximum perceived effort. They then were instructed to ramp up their application of force over 3-5 seconds to 100% of their MVC. Two repetitions were performed with 12 seconds of rest between each repetition. The highest peak force in either repetition was recorded. Players were tested at both the distal and proximal joints on both hands.

After a day of rest, players then completed a baseline Endurance Test. To administer this test, we again familiarized all players with the device by having them perform a series of warmup exercises where they were instructed to first apply 25% of their maximum perceived effort, then 50% of their maximum perceived effort. They then were instructed to ramp up their application of force as fast as possible to 100% of their MVC and hold this force for 4 seconds. Players performed 24 repetitions in 4 sets of 6, with 4 seconds of rest between each repetition and 15 seconds between each set. Their peak force at 4 seconds after each repetition was recorded. Only the throwing hand of each player was tested.

After a day of rest, players then began a 4 week Strength Training protocol where they trained 2 or 3 times per week only with their throwing hand. The protocol required the players to perform 5 repetitions of 5 exercises in 3 day cycles. Day 1 of the training protocol targeted the FDP by requiring the players to perform fingertip flexion of all 4 fingers, then the index, middle, ring, and little fingers, in that order. Day 2 of the training protocol aimed to protect against flexion to extension imbalance by requiring the players to perform fingertip extension of all 4 fingers, then the index, middle, ring, and little fingers, in that order. Day 3 of the training protocol targeted the FDS by requiring the players to perform mid-finger flexion of all 4 fingers, then the index, middle, ring, and little fingers, in that order.

As for the 5 repetitions of the 5 exercises in each training session, the first repetition of each exercise was performed at 100% of MVC as was done for the Strength Test. The remaining 4 repetitions required the player to apply 70% of the first rep MVC and hold that for 5 seconds. The 70% target force was calculated by the FlexPro Grip app and viewable throughout each repetition. Players were given a 12 second rest between each repetition.

After 4 weeks of training, the baseline Strength and Endurance Tests were re-administered, with a day of rest between each test. Players were re-tested for Strength on both hands and Endurance on only their throwing hand.

All players continued their normal throwing schedules while training.

Results:

a) The average MVC gain in 4 finger fingertip flexion (FDP) for the throwing hand was 23%.

b) The average MVC gain in 4 finger fingertip flexion (FDP) for the non-throwing, untrained hand was 17%.

c) The average MVC gain in 4 finger fingertip extension for the throwing hand was 25%.

d) The average MVC gain in 4 finger fingertip extension for the non-throwing, untrained hand was 19%.

e) The average MVC gain in 4 finger mid-finger flexion (FDS) for the throwing hand was 21%.

f) The average MVC gain in 4 finger mid-finger flexion (FDS) for the non-throwing, untrained hand was 15%.

g) Endurance was measured as the change in the force applied from the first set highest repetition to the force applied in the fourth set lowest repetition.
    1) The average baseline rate of decline in force output was 33%.
    2) The average rate of decline in force output for all 30 players after 4 weeks of performing the Strength Training Protocol was 20%.
    3) After excluding the eight (8) players who threw live in a game or a max effort pen within 48 hours of their re-test, the average rate of decline in force output for the remaining 22 players after 4 weeks of performing the Strength Training Protocol was 12%.

h) Anecdotally, the player with the lowest FDP strength that was tested on the FlexPro Grip device in October 2021 suffered a distal tear to his UCL in the 2022 season. He only tested on the device. He did not complete any training protocol.

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419-280-1566

10. References

1	Understanding the MUCL of the elbow: Review of native ligament anatomy and function Joshua R Labott, William R Aibinder, Joshua S Dines, Christopher L Camp. World J Orthop 2018 June 18; 9(6): 78-84
2	UCL Injuries in the Throwing Athlete. Jeremy R. Bruce, MD, James R. Andrews, MD. The American Academy of Orthopaedic Surgeons. 2014.
5	Qualitative and Quantitative Analyses of the Dynamic and Static Stabilizers of the Medial Elbow: An Anatomic Study. Salvatore J. Frangiamore, MD, Gilbert Moatshe, MD, Bradley M. Kruckeberg, BA, David M. Civitarese, BS, Kyle J. Muckenhirn, BA, Jorge Chahla, MD, PhD, Alex W. Brady, MSc, Mark E. Cinque, BS, Morten Lykke Oleson, MD, Matthew T. Provencher, MD, Thomas R. Hackett, MD, and Robert F. LaPrade, MD, PhD. 2017.
8	Analysis of Pitching Velocity in Major League Baseball Players Before and After UCLR. Jimmy J. Jiang, MD, and J. Martin Leland, MD. University of Chicago Medical Center 2014
9	UCLR vs Repair With Internal Bracing Comparison of Cyclic Fatigue Mechanics. Christopher M. Jones, MD, David P. Beason, MS, and Jeffrey R. Dugas, MD. ASMI, Birmingham, AL 2018.
11	Elbow UCL injuries in athletes: Can we improve our outcomes? Lauren H Redler, Ryan M Degen, Lucas S McDonald, David W Altchek, Joshua S Dines. World J Orthop 2016 April 18; 7(4): 229-243
14	Correlation of Throwing Mechanics With Elbow Valgus Load in Adult Baseball Pitchers. Arnel L. Aguinaldo, MA, ATC, and Henry Chambers, MD. From the Center for Human Performance and Motion Analysis Laboratory, Rady Children’s Hospital, San Diego, California. 2009.
15	Relationship between throwing mechanics and elbow valgus in professional baseball pitchers. Sherry L. Werner, PhD, Tricia A. Murray, Richard J. Hawkins, MD, FRCS, and Thomas J. Gill, MD, 2002.
18	Functional Anatomy of the Flexor Pronator Muscle Group in relation to the MCL of the Elbow. Davidson, MD, Pink PT, Perry MD, Jobe MD. 1995
33	Optimal management of UCL injury in baseball pitchers. Elizabeth E Hibberd, J Rodney Brown, Joseph T Hoffer, Department of Health Science, The University of Alabama, Tuscaloosa, AL, USA; Department of Intercollegiate Athletics, The University of Alabama, Tuscaloosa, AL, USA. 2015
34	Banister, E., Calvert, T., Savage, M., 1975. A systems model of training for athletic performance. Aust J Sports Med, 7, pp.57-61
35	The acute: chronic workload ratio predicts injury: high chronic workload may decrease injury risk in elite rugby league players Billy T Hulin,1,2 Tim J Gabbett,3,4 Daniel W Lawson,2 Peter Caputi,5 John A Sampson1. BJSM Online First, published on October 28, 2015.
39	Baseball Players Diagnosed With UCL Tears Demonstrate Decreased Balance Compared to Healthy Controls. J. Craig Garrison, PT, PhD, ATC, SCS, Amanda Arnold, PT, DPT, SCS, OCS, Michael J. Macko, PT, DPT, OCS, John E. Conway, MD. 2013
42	Biomechanical Estimation of Elbow Valgus Loading in Throwing Athletes as a Means to Reduce Injury Risk. Ryan L. Crotin, PhD, CSCS, Sarah A. Zinamon, BS, John D. Kelly IV, MD, Josh R. Baxter, PhD. 2016
43	Panel discusses elbow UCL injury in throwing athletes: Orthopedics Today, March 2015 Roundtable Participants
44	MRI Predictors of Failure in Non-operative Management of UCL Injuries in Professional Baseball Pitchers: Article in The Orthopaedic Journal of Sports Medicine. July 2016. Frangiamore, MD, T. Sean Lynch, MD, Vaughn, MD, Soloff, MS, Forney, MD, Styron, MD, and Schickendantz, MD

56	Performance, Return to Competition, and Reinjury After Tommy John Surgery in Major League Baseball Pitchers A Review of 147 Cases. Article in The American Journal of Sports Medicine · April 2014
63	Fastball Velocity and Elbow-Varus Torque in Professional Baseball Pitchers. Jonathan Slowik, PhD; Kyle T. Aune, MPH; Alek Z. Diffendaffer, MS; E. Lyle Cain, MD; Jeffrey R. Dugas, MD; Glenn S. Fleisig, PhD. 2019
64	Dynamic Contributions of the Flexor-Pronator Mass to Elbow Valgus Stability. Maxwell C. Park and Christopher S. Ahmad. J. Bone Joint Surg. Am. 86:2268-2274, 2004.
77	Human tendon adaptation in response to mechanical loading: a systematic review and meta-analysis of exercise intervention studies on healthy adults. Sebastian Bohm, Falk Mersmann and Adamantios Arampatzis* Bohm et al. Sports Medicine - Open (2015) 1:7
78	Articular and ligamentous contributions to the stability of the elbow joint. Morrey, Kai-Nan, Mayo clinic. The American Journal of Sports Medicine. Volume 11. Number 5. 1983
89	Computing muscle, ligament, and osseous contributions to the elbow varus moment during baseball pitching. James H. Buffi, Katie Werner, Tom Kepple, Wendy M. Murray. Ann Biomed Eng. 2015 February
92	MRI Web Clinic — January 2010. UCL Tears of the Elbow. Mark H. Awh, M.D.
95	Effects of flexor-pronator muscle loading on valgus stability of the elbow with an intact, stretched, and resected medial UCL. John H. Udall, MD, Michael J. Fitzpatrick, MD, Michelle H. McGarry, MS, Thu-Ba Leba, MD, Thay Q. Lee, PhD*. Journal of Shoulder Elbow Surg. 2009
95	Effects of flexor-pronator muscle loading on valgus stability of the elbow with an intact, stretched, and resected medial UCL. John H. Udall, MD, Michael J. Fitzpatrick, MD, Michelle H. McGarry, MS, Thu-Ba Leba, MD, Thay Q. Lee, PhD*. Journal of Shoulder Elbow Surg. 2009
96	Effect Of Increased Quadriceps Tensile Stiffness of Peak ACL Strain During a Simulated Pivot Landing. David B. Lipps, Ph. D, Youkeun K. Oh, Ph. D2, James A. Ashton-Miller, Ph. D1,2,3, and Edward M. Wojtys, M.D. Orthop Res. 2014 March; 32(3): 423–430
99	Biomechanical evaluation of a new UCL reconstruction technique with interference screw fixation. Ahmad CS[1], Lee TQ, ElAttrache NS. Am J Sports Med. 2003 May-Jun;31(3):332-7.
100	Changes in Strength, Endurance, and Fatigue During a Resistance-Training Program for the Triceps Brachii Muscle. Journal of Athletic Training 2013. Jelena Z. Popadic Gacesa, MD, PhD; Aleksandar V. Klasnja, MD, MSc; Nikola G. Grujic, MD, PhD
102	Segmental Power Analysis of Sequential Body Motion and Elbow Valgus Loading During Baseball Pitching Comparison Between Professional and High School Baseball Players. Arnel Aguinaldo, PhD, ATC, and Rafael Escamilla, PhD, PT, CSCS. The Orthopaedic Journal of Sports Medicine, 2019
103	Muscle contribution to elbow joint valgus stability. J of Shoulder and Elbow Surg 2007. Fang Lin, DSc, Navjot Kohli, MD, Sam Perlmutter, BS, Dohyung Lim, PhD, Gordon W. Nuber, MD, and Mohsen Makhsous, PhD.
132	Time course changes in muscle and tendon properties during strength training and detraining. Kubo et. al. Journal of Strength and Conditioning Research 2010.
142	The influence of mound height on baseball movement and pitching biomechanics. Alek Z. Diffendaffer, Jonathan S. Slowik, Nicholas J. Lo, Monika Drogosz, Glenn S. Fleisig. Journal of Science and Medicine in Sport 22, 2019.
143	The influence of baseball pitching distance on pitching biomechanics, pitch velocity, and ball movement. Alek Z. Diffendaffer, Jonathan S. Slowik, Karen Hart, James R. Andrews, Jeffrey R. Dugas, E. Lyle Cain Jr., Glenn S. Fleisig. Journal of Science and Medicine in Sport 23, 2020.

146	Coordinated force production in multi-finger tasks: finger interaction and neural network modeling. Vladimir M. Zatsiorsky, Zong-Ming Li, Mark L. Latash. Biological Cybernetics. 1998
148	Changes in joint, muscle, and tendon stiffness following repeated hopping exercise. Keitaro Kubo & Toshihiro Ikebukuro. Department of Life Science, The University of Tokyo, Meguro, Tokyo, Japan. Physiological Reports. August 2019
149	Using SUS to Understand the Risk of UCL Injury Among Professional Baseball Pitchers Based on Ligament Morphology and Dynamic Abnormalities. Shanley PhD, Smith MD, Mayer MD, Bailey PhD, Thigpen PhD, Tokish MD, Kissenberth MD, and Noonan MD. The Orthopaedic Journal of Sports Medicine. 2018.
156	Ulnar Collateral Ligament Laxity After Repetitive Pitching Associated Factors in High School Baseball Pitchers. Hiroshi Hattori, PT, PhD, CSCS, Kiyokazu Akasaka, PT, PhD, Takahiro Otsudo, PT, PhD, Toby Hall, PT, PhD, Katsunobu Sakaguchi MD, PhD, and Yomei Tachibana, MD, PhD. Investigation performed at Saitama Medical University, Saitama, Japan. The American Journal of Sports Medicine April 8, 2021
159	Elasticity of the Flexor Carpi Ulnaris Muscle After an Increased Number of Pitches Correlates With Increased Medial Elbow Joint Space Suppression Akira Saito, Yusuke Namiki, and Kyoji Okada. Journal of Strength and Conditioning Research 00(00)/1–8. 2021 National Strength and Conditioning Association. July 2021
162	Return to Performance After UCLR in MLB Pitchers: A Case-Control Assessment of Advanced Analytics, Velocity, Spin Rates, and Pitch Movement. Fury MD, Oh MD, Linderman MS, Wright-Chisem MD, Scarborough PhD, and Berkson MD. 2021. Orthopedic Journal of Sports Medicine
163	The UCL loading paradox between in-vitro and in-vivo studies on baseball pitching. Bart Van Trigt, Liset Vliegen, Ton Leenen & DirkJan Veeger. International Bio-Mechanics 2021, VOL. 8, NO. 1, 19–29
164	Mechanical, Material and Morphological Adaptations of Healthy Lower Limb Tendons to Mechanical Loading: A Systematic Review and Meta-Analysis. Stephanie L. Lazarczuk, Nirav Maniar, David A. Opar, Steven J. Duhig, Anthony Shield, Rod S. Barrett, Matthew N. Bourne. Sports Medicine. April 2022.
166	Adolescent Baseball Pitchers with UCL Tears Exhibit a High Proportion of Partial Tears. Eric Goodrich, DO, Benjamin Cox, DO, Hillary A. Plummer, PhD, ATC, Achraf Cohen, PhD, James R. Andrews, MD, and Michael Saper, DO, ATC, CSCS. American Journal of Sports Medicine. 2022
167	How many innings can we throw: does workload influence injury risk in Major League Baseball? An analysis of professional starting pitchers between 2010 and 2015. Saltzman, MD, Mayo, MD, Higgins, BS, Gowd, BS, Cabarcas, BS, Leroux, MD, Basques, MD, Nicholson, MD, Bush-Joseph, MD, Anthony A. Romeo, MD, Verma, MD. Journal of Shoulder Elbow Surg (2018) 27, 1386–1392
168	Outcomes in revision Tommy John surgery in Major League Baseball pitchers. J Shoulder Elbow Surg. 2016 Jan;25(1):90-7. Joseph N Liu, Grant H Garcia, Stan Conte, Neal ElAttrache, David W Altchek, Joshua S Dines
170	John Rogele @MLBPlayerAnalys