TITLE: KRONOS Versus Breg T-Scope Post-operative Knee Braces Following Anterior Cruciate Ligament (ACL) Reconstruction

NCT07090616

DATE: 29 April 2025

PROTOCOL TITLE: A Randomized Controlled Trial of the KRONOS Versus Breg T-Scope Post-operative Knee Braces Following Anterior Cruciate Ligament (ACL) Reconstruction

PRINCIPAL INVESTIGATOR:
Name: Jorge Chahla, MD, PhD. Jonathan Gustafson, PhD
Telephone Number: : (312) 432-2818

Email Address: cartilage.restoration@rushortho.com

VERSION DATE: 04/25/2025

STUDY SUMMARY:

Investigational Agent-s -Drugs or Devices	None
IND / IDE / HDE #	N/A
Indicate Special Population-s	☐ Children ☐ Children who are wards of the state ☐ Adults Unable to Consent ☐ Cognitively Impaired Adults ☐ Neonates of Uncertain Viability ☐ Pregnant Women ☐ Prisoners -or other detained/paroled individuals ☐ Students/Employees
Sample Size	40
Funding Source	Department of Orthopedic Surgery
Indicate the type of consent to be obtained	☒ Written Main and Assent Form ☐ Verbal/Waiver of Documentation of Informed Consent ☐ Waiver of HIPAA Authorization ☐ Waiver/Alteration of Consent Process
Site	☒ Single Site Research Study ☐ Data Coordinating Center -DCC
Research Related Radiation Exposure	☐ Yes ☒ No
DSMB / DMC / IDMC	☐ Yes ☒ No

ACRONYMS & ABBREVIATIONS:

ACL- Anterior Cruciate Ligament
BMI- Body Mass index
IKDC- International Knee Documentation Committee
KOOS-Knee Injury and Osteoarthritis Outcome Score
MOR – Midwest Orthopedics at Rush
MRI – Magnetic Resonance Imaging
PRO – patient reported outcome
PROMIS-Patient-Reported Outcomes Measurement Information System
ROM – Range of Motion
RTS- Return to Sport

RTW-Return to Work

RUMC – Rush University Medical Center
VAS pain- Visual Analog Pain Scale
VR/SF 12-Veteran RAND 12-Item Health Survey

Purpose of the study –

The purpose of this study is to evaluate the clinical efficacy of the KRONOS postoperative knee brace compared with the standard Breg T-scope hinged brace following anterior cruciate ligament (ACL) reconstruction surgery.

Background & significance –

Anterior cruciate ligament (ACL) injuries of the knee are prevalent and frequently treated with surgical reconstruction of the ligament using a graft to restore knee function and stability.[1] Postoperatively, early rehabilitation is critical to successful surgical outcomes, preventing postoperative complications, and returning to an active lifestyle.[2] However, care must also be taken to protect the implanted graft against strain that may disrupt tendon-to-bone healing, and ultimately cause premature failure of the graft. Consequently, over 60% of surgeons who perform ACL reconstruction recommend and prescribe rehabilitative postoperative knee braces locked in extension to limit extension/flexion motion, varus and valgus (inward and outward) movements at the knee, and help patients regain extension range of motion (ROM.[2]

Despite widespread clinical use, evidence on the efficacy of current bracing technologies remains controversial and inconclusive. Some randomized controlled trials and systematic reviews have concluded that rehabilitative bracing provided no clinical benefit with respect to knee ROM, knee laxity, pain, or quadriceps (large thigh muscle group) strength in the early postoperative period or at mid-term follow-up.[2–4] In contrast, Melegati et al[5] demonstrated improved extension after one week postoperatively among a group that used a rehabilitative brace locked in full extension, compared to a group that

used the same brace locked from 0-90°. This variability may be in part due to significant limitations present across several of the previous studies, including lack of compliance data and power calculation to determine necessary sample sizes.[2 6]

The KRONOS postoperative unloader brace features a new bracing technology that combines the capability of hyperextension immobilization with additional benefits of offloading up to 60 lbs off the knee joint. The adjustable tensioning system in the KORNOS brace offers promising potential to significantly alleviate patient discomfort and pain, facilitate quicker return to a higher level of activity, and ultimately contribute to improved surgical outcomes. The primary purpose of this study is to evaluate the clinical efficacy of the KRONOS postoperative unloader knee brace compared with standard Breg T-scope hinged brace in improving range of motion and other complications following anterior cruciate ligament (ACL) reconstruction surgery.

Hypothesis

We hypothesize that subjects randomized to receive the KRONOS postoperative unloader knee brace will reach full extension sooner and have reduce extension deficits compared to subjects randomized to receive the standard Breg T-scope hinged brace. In addition, it is hypothesized that the KRONOS subjects will require fewer additional treatments for extensions deficits including, but not limited to, additional therapy, intra-articular injections, oral corticosteroids, manipulation under anesthesia, or arthroscopic revision surgery.

Selection of Subjects –

Patients scheduled to undergo primary ACL reconstruction as indicated via CPT 29888 from the Athena electronic medical record (EMR) will be identified and eligible for enrollment in this study. Following the informed consent process outlined below, we will prospectively enroll and randomize 20 participants to one of the two study arms (KRONOS versus Breg T-scope post-operative knee brace), totaling 40 participants in each group.

Inclusion Criteria:

- Subjects > 18 years of age
- English-speaking
- Scheduled to undergo primary anterior cruciate ligament reconstruction surgery
- No history of prior knee surgery on the operative knee
- No concomitant ligamentous repair or reconstruction procedures (i.e. ligamentous pathology aside from anterior cruciate ligament).
- Subjects undergoing concurrent partial meniscectomy or meniscus repair that would not alter postoperative weight-bearing status or rehabilitation protocol would be eligible for inclusion.

- Clinical and radiographic examination (MRI) consistent with an acute full thickness ACL tear

Exclusion Criteria:

- Age < 18 years of age
- Non-English speaking
- Revision ACL reconstruction
- Multi-ligamentous injury, including concomitant posterior cruciate ligament, medial collateral ligament and fibular collateral ligament injuries
- Concomitant meniscal or cartilage injury that would alter postoperative weight bearing status or rehabilitation protocol
- Inability to comply with the proposed follow-up clinic visits
- Subjects lacking decisional capacity
- Worker's compensation subjects
- Requiring a custom-sized brace

Consent process –

Potential participants are identified using medical chart and case review. The study eligibility requirements will be reviewed by the PI and study staff. The potential participant is pre-selected as tentatively meeting the eligibility requirements for the study. Research study staff will reach out to eligible patients through a phone call explaining the study. Randomization to the treatment (KRONOS postoperative brace) or control group (Hinged knee brace) will occur at the time of informed consent

Informed Consent Discussion
Investigator and/or PI and research study staff will contact the patient in clinic or via telephone to discuss the research study with them. Ideally, the informed consent discussion should be conducted when the study staff and potential participant has time to ask and answer questions. Information provided to the patient includes the rationale for the study procedure or treatment, the number of study visits and the study activities they will need to complete, risks involved, expected benefits, and alternatives to treatment.

The process may occur over a period of several discussions, culminating in the signing of a consent form in the office (Ipad or paper) or sent to their verified email address. The informed consent discussion will be documented in the patient profile or chart.

If the patient agrees to participate, their email addressed will be verified. The consent will be obtained electronically sent through the secured platform called Patient IQ to their email. The potential subject will then be prompted to reply with the appropriate passcode in order to access the consent form, and then provide the passcode again with their

signature (secured). No research activities will be performed prior to execution of the consent. A copy of the time stamped document will be sent to the study team through the electronic platform and a copy will be sent to the participant.

Study Design & Procedures–

This is a randomized controlled trial.

We estimate 40 particpants (20 Kronos: 20 T-Scope) will be enrolled in the study.

Primary outcome variable

- Rates of extension deficit (as measured by the fraction of patients with reduced extension compared to the contralateral knee, determined by heel height and goniometric measurements of knee extension)

Bracing Protocol

Both treatment groups will progress according to a standard of care postoperative rehabilitation program regardless of the group to which the patient is randomized.

KRONOS Bracing Group

Subjects randomized to the treatment group will be measured and fitted with the KRONOS knee brace at their initial clinic visit after study enrollment. The patient will be instructed to use the brace preoperatively and bring it to their surgery, after which the brace will be placed again on the patient postoperatively at the conclusion of their procedure. Subjects will be instructed to wear the brace until symmetric terminal extension is achieved as indicated by side-to-side comparison with the non-surgical limb. This will be under the supervision and approval of the providing physician. Subjects will be instructed to use the brace (locked in extension and under high tension) at night during sleep and ambulation, though removal for therapy and rehabilitation exercises will be permitted.

Control Group – Standard Breg T-Scope Postoperative Bracing

Subjects will be placed in a standard postoperative hinged knee brace in the operating room that will be locked in full extension. Subjects will be instructed to use the brace locked in extension while sleeping for 6 weeks and when ambulating until the patient is able to perform a straight leg raise with no extension lag outside of the brace, at which point the brace may be worn unlocked during ambulation.

Table 1. Study timeline.

Preop	Surgery	2	6 weeks	12	6 months	12	

			weeks		weeks		months
Patient Recruitment	●						
Informed Consent and Randomization	●						
Physical Exam (i.e. Heel height and goniometer measurement of active extension, passive flexion, passive extension)	●	●*	●	●	●	●	
Circumferential thigh measurement (including healthy knee at pre-op)	●		●	●	●	●	
Brace Placement	●**	●					
PROMs	●				●	●	●
Brace compliance survey		●**	●	●			

*Passive flexion and extension ROM only under anesthesia prior to beginning surgery

** Only for patients randomized to the KRONOS brace treatment group

PROMs will include: IKDC, KOOS, VR-12, PROMIS Depression, PROMIS Physical Function, PROMIS Pain Interference, Return to Sport (RTS) and Return to Work (RTW), Resilience scale and brace compliance survey.

Study Interventions –

Prospective Data Collection

Timeline of Events

1. Once subjects are indicated for ACL surgery, a review of inclusion criteria will be undertaken, and subjects will be offered the opportunity to participate in the study.
2. Pre-operative physical exam findings including Pivot-shift, Lachman, and range of motion data will be recorded.
3. Range of motion measurements (ROM), including heel height[7,8] and goniometric measurements of 3 types of ROM (active extension, passive flexion, and passive extension) will be done at the initial visit, preoperatively on the day of surgery, *intraoperatively under anesthesia before the initiation of the surgery* (passive flexion and passive extension only), and at the designated postoperative timepoints indicated in Table 1 (1 week, 2 week, 6 week, 12 weeks, 6 months, and 12 months).

4. Thigh circumference will also be measured with tape measure at the mid-thigh and

suprapatellar levels on the operative knee as a surrogate for quadriceps atrophy, as previously done[10–12], pre-operatively and at the designated postoperative visits in Table 1 (1 week, 2 week, 6 week, 12 weeks, 6 months, and 12 months). Thigh circumference of the nonoperative healthy knee will also be measured pre-operatively for baseline comparison

5. Informed consent will be obtained. Prior to surgery (preoperative) subjects will be asked to complete standard of care patient reported outcomes questionnaires including IKDC, KOOS, PROMIS (Depression, Pain Interference, Physical function) , VAS pain, VR/SF 12, RTS, RTW and brief resilience scale.

6. Brace compliance survey A survey assessing patient compliance with bracing instructions will be administered at the designated postoperative timepoints indicated in Table 1.

7. Subjects will proceed with operative management of their ACL tear, including appropriate treatment and documentation of concomitant injuries.

8. Subjects will be appropriately fitted for the brace corresponding to randomization on the day of surgery. All braces will be placed on the subject in the operating room at the conclusion of the procedure. All subjects will begin a standard of care physical therapy protocol on postoperative day 1-14.

9. Subjects will undergo standard of care follow up at 1-week, 2-week, 6-weeks, 12-weeks, 6-months, and 12 months. At these standard of care visits, range of motion, including goniometric angle and heel-height measurements, will be made at all postoperative time points.
   Time-to-achievement of full symmetric extension relative to the non-surgical knee will be monitor and recorded. Additional physical exam of the knee will be performed at all follow-up time points.
10. At 12 weeks, 6 months, and 12 months, subjects will also be asked to complete standard of care patient reported outcomes questionnaires including IKDC, KOOS, PROMIS, VAS pain, VR/SF 12, and brief resilience scale. Subjects will also be asked to answer standard of care questions regarding return to work and return to sport throughout the 1-year postoperative period.

Retrospective Data Collection

The following data will be abstracted from secured electronic medical record databases (Epic, Athena, Opal, Patient IQ) and electronically recorded on coded data collection tool for this study:

- Demographic information (age, sex, body mass indes (BMI), laterality)
- Chief Complaint
- History of present illness

- Physical Exam

Opal and Joints will be used to capture the following:

Surgical approach

Arthroscopic diagnoses

Techniques used

Fixation device / technique

Preoperative imaging including but not limited to MRI

The following outcome variables will be taken from Athena and Patient IQ:

- Postoperative complications
- Failure of primary reconstruction
- Need for a revision or subsequent procedure
- Preoperative / postoperative patient reported outcomes (PRO) including:

IKDC, KOOS, VR-12, PROMIS Depression, PROMIS Physical Function, PROMIS Pain Interference, Return to Sport (RTS) and Return to Work (RTW), Resilience scale

Other outcomes variables of interest:

- Time-to-achievement of full extension
- Degree of extension loss
- Time to walking without a limp
- Quad circumference difference
- Frequency of brace use
- Number of postoperative physical therapy visits up to one year post-op
- Standard of care Breg T-scope group: time to unlocking the brace
- Kronos group: time to no quad assist (no dial engaged)

Rehabilitation Protocol

The rehabilitation program will be started on the day after surgery according to the providing physician's standard protocol.

Risk/benefit assessment –

There is no direct benefit to the patient for his/her participation in this study.

The results will contribute to the optimization postoperative bracing and rehabilitation protocols following ACL surgery. This study will help determine if the KRONOS postoperative knee brace is an efficacious and safe methodology to improve range of motion and reduce extension deficits following ACL reconstruction.

Potential risk may include having the participant's privacy or confidentiality compromised. The participant's identities will not be identifiable in publications resulting from this investigation. Every reasonable effort will be made to protect the participant's information while their data is used as part of this study.

The alternative to participation in this study is not to participate.

Costs to the subject–

A brace will be provided to each study participant free of cost regardless of what group they are in– a standard of care Breg T-Scope brace or a Kronos brace.

No insurance coverage will be offered for regularly scheduled standard of care postoperative visits. However, any additional visits scheduled solely for the purpose of this study will be covered at no cost to the patient.

Compensation of subjects–

No compensation will be offered to study participants.

Data Analysis and Statistical Considerations –
Power analysis was based on data published by Mikkelsen et al.[6] as part of an ACLR randomized controlled trial of a hyperextension brace. A priori power analysis was conducted to determine the sample size required to detect a significant difference in the proportion of patients experiencing a loss of full knee extension of ≥2° between the straight brace and hyperextension brace groups. Using the observed proportions from the study ($p1=0.545$ for the extension group and $p2=0.091$ for the hyperextension group), the following parameters were used in G*Power for the calculation: **Statistical test**: Fisher's exact test (two independent groups); **Effect size**: $w= 0.57$; **Significance level (α)**: 0.05; **Power ($1-\beta$)**: 0.8. The analysis indicated that a total sample size of **32 participants** (16 per group) would be required to achieve 80% power to detect a statistically significant difference in the proportions of patients experiencing knee extension loss at $\alpha=0.05$. To account for potential loss of subjects to follow-up, a total of 40 subjects will be eligible to be enrolled.

The statistical software *R* will be used for analyses and calculation of relevant p-values, standard deviation, correlation coefficients, and confidence intervals. Categorical variables will be analyzed via Chi-squared test, while quantitative variables will be analyzed via students' t-test for parametric data and Wilcoxon Mann-Whitney test for nonparametric data.

Data & Safety monitoring

There is minimal risk to the subjects except the potential for loss of privacy and confidentiality, but every reasonable effort will be made to protect the patient's information while their data is used as part of this study.

Data storage & confidentiality –

Participant information will be collected and maintained in a excel data sheet housed on the Midwest Orthopedics at Rush (MOR) server, which is dual-factor authentication protected and accessible only to research staff. Subjects identity will be coded via the use of a separate document key (electronic excel spreadsheet) correlating subjects' Rush medical record numbers with a study ID assigned for the sole purpose of this study. This key electronic document will be maintained as a separate electronic file (excel spreadsheet) from data collection tool and will be housed in the Midwest Orthopaedics at Rush server, which is dual-factor authentication protected and accessible only to research staff.

Files will not be shared with non-study personnel.

According to (Rush policy OP-0432 and CC-G04) and study data must be maintained for 10 years in accordance with Illinois State Law. After this time the data will be destroyed by permanently and securely deleting electronic files on the Master key document (PHI) and the coded data collection tool.

References:

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