STOKO K1
SUPPORT VERIFICATION

Stoko Design Inc.

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Date: 01/04/2020
Revised: 06/09/2021

The purpose of this document is to compare the levels of support provided by conventional knee braces and the Stoko K1.

Abstract

Background: Knee injury and instability is a common occurrence for many active individuals. Braces and supportive products are frequently used either in response to an injury or to a chronic condition; however, different devices have varying levels of support and ability to positively impact user outcomes. Our aim was to create a test fixture, which quantified the support knee braces provided to the knee in order to test and refine our knee brace - Stoko K1.

Methods and Materials: A Knee test fixture (KTF) and validation methodology was developed to quantify the support level of competitive braces on the market and compare to the Stoko K1. We benchmarked three competitive products representing three classes of knee bracing: rigid hinge (Ossur Custom CTi), soft sleeve with hinge (Donjoy Hinged Knee), and soft sleeve (Bauerfeind GenuTrain) against the K1 through valgus and varus deviations. All four braces were evaluated for the average valgus or varus load reduction through the entire range of motion, knee laxity limits (4°), and injury threshold (9°).

Results: A clear delineation appeared between the support level of each brace. The CTi custom provided the highest average valgus support (3.75Nm), the hinged soft sleeve achieving a mid-level of support (1.49Nm), and the soft sleeve having minimal effect (0.85Nm). The Stoko K1 achieved an average of (3.29Nm). The braces provided similar average varus support values of 2.67Nm, 1.68Nm, 0.63Nm, and 2.23Nm, respectively.

Conclusion: The Stoko K1 soft brace provided a comparable level of valgus/varus support to the rigid hinged class and outperformed both the soft sleeve with hinge and soft sleeve classes. Stoko K1 should be considered for indications requiring rigid hinged class levels of support.

Introduction

With any medical device, validation is an important step in the design cycle. It is essential to prove that devices function as designed and fulfill their intended use both for consumers and medical device regulators. Knee bracing products, and specifically the Stoko K1, are intended to be used by patients who have knee instability, most commonly from injury. In order to validate our device, we must prove that it supplements the natural supportive structures of the body and reduces joint loading patterns.

Exploration of this nature has been done by every major medical bracing company in the market - Ossur, Bauerfeind, DonJoy, etc. The validation that is public for these companies is their exploration via formal academic study and self-published white papers. Examples of such studies include gait analysis (1–3), mechanical validation (4–7), and clinical trials (8,9). These examples have informed the scoping of our internal validation, design decisions, and testing, and we intend to conduct exploration via formal academic study shortly.

To effectively test prototypes, quantifiable metrics and testing methodology were developed. In knee brace testing literature, braces are evaluated by quantifying lower limb dynamics, joint loading, or musculature response among others (2,4,10). These studies often utilize custom apparatuses built by each institution to execute testing (4,5,11). This body of literature became the basis by which we informed the creation of our own test devices and testing methodology. Stoko produced an internal test fixture which could reliably test the efficacy of our prototypes, and benchmark fair comparisons against the industry's current best solutions.

The purpose of this White Paper is twofold. First, to present Stoko's Knee Test Fixture and test methodology, and second, to determine the efficacy of the Stoko K1's valgus/varus support against other bracing options on the market. Based on our understanding of the injury biomechanics and market solutions designs, we hypothesized that the Stoko K1 would offer similar levels of support to the current 'gold standard' rigid bracing options.

Methods and Materials

Knee Test Fixture

It became apparent that a standard method to test and validate design decisions was necessary during the development of the K1 brace. A thorough investigation of literature was conducted, and many test fixtures were studied in detail (4,5,11–20). This exploration was used to evaluate the merit of each testing configuration, balance those against our objectives, and draw design inspiration. It was determined that the KTF would be modeled off the principles of Pierrat and his colleagues' device, as it appeared to be the most effective design, and aligned well with our needs (5). The main consideration for this decision was the ability to isolate and test all possible axes of motion, and therefore, reproduce many injury mechanisms of the knee reliably and repeatedly.

We conducted a full engineering design cycle and fabricated the KTF. The finalized and assembled KTF is shown in Figures 1 and 2.

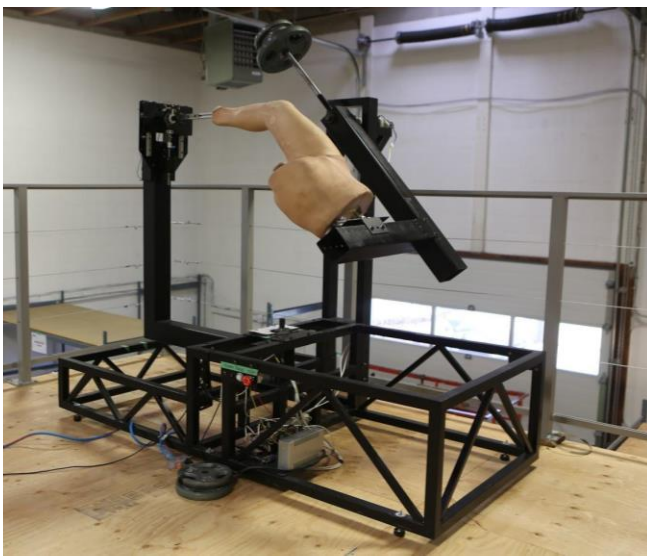

Figure 1. KTF Including a rigid frame, four instrumented and motor actuated axes, and an anatomical leg model.

The KTF is comprised of:

1. Varus/Valgus Arm – Stepper actuated and torque cell instrumented arm which produces and measures varus and valgus moments at the knee.
2. Flexion/Extension Arm – Stepper actuated and torque cell instrumented arm which produces and measures flexion and extension moments at the knee.
3. Internal/External Rotation Stage – Stepper actuated and torque cell instrumented stage which produces and measures internal and external moments at the knee.
4. Anterior/Posterior Drawer Platform – Stepper actuated and load cell instrumented platform which produces and measures anterior and posterior drawer translation loads at the knee.
5. An anatomically accurate human leg model with an implanted anatomical knee model.
6. Highly rigid frame which minimizes deflections during testing.

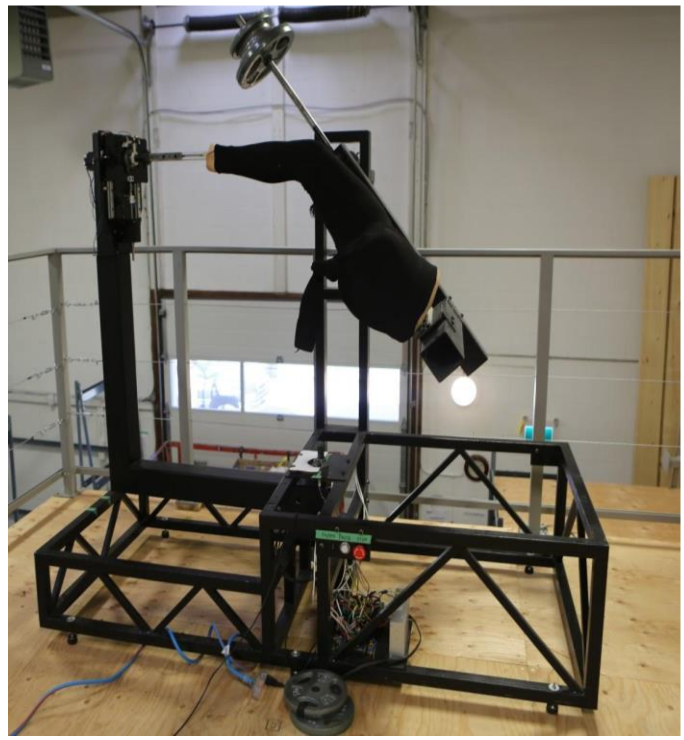

Figure 2. KTF Alternative angle with K1

With these components, testing of the K1 and competitor braces in a rigorous way is possible. We have the capability to do simple tests of a single axis in order to isolate specific motions and functions of the garment, as well as produce complex motions representative of injury mechanisms experienced in sport (21,22).

KTF Testing Methodology

The method employed for testing is outlined below:

1. The leg model is positioned at a zero or starting point.

2. The leg model is moved through a predetermined range of motion while the position and load cells are measured at 16 Hz.
3. The leg model is returned to the zero position.
4. Steps two and three are repeated multiple times (three to ten iterations depending on test purposes).
5. Stoko's K1 and other market knee braces are applied to the leg model and steps two through four are repeated.

The resultant load cell data is calibrated for the respective axes as either: a moment about the knee joint in newton meters and an angular displacement in degrees; or a load on the knee joint in newtons and translational displacement in millimeters (2,3). Positional feedback can be derived from the driving motors of each axis. The returned data is then processed to report the effect each brace has on reducing the knee load.

The data processing that occurs after these tests is what gives visibility to the load reduction of each brace. By doing the initial steps of one through three, a baseline of the leg model is established. From this information, we are able to subtract the baseline loading from each of the subsequent brace trials, and can derive the amount of load that the brace is supporting, or the load reduction, at each point throughout the motion.

KTF Valgus and Varus Testing

The KTF testing methodology was used on the Stoko K1, and three additional knee braces: Ossur Custom CTi, DonJoy Hinged Knee, and Bauerfeind GenuTrain. The KTF was moved through 11° of valgus and 9° of varus for baseline reading and each brace. Each test condition was repeated four times to determine the repeatability and standard deviation of the fixture. As described in the KTF testing methodology, the load reduction was calculated for each of the four products. For support comparisons, the Stoko K1 was used as the datum product.

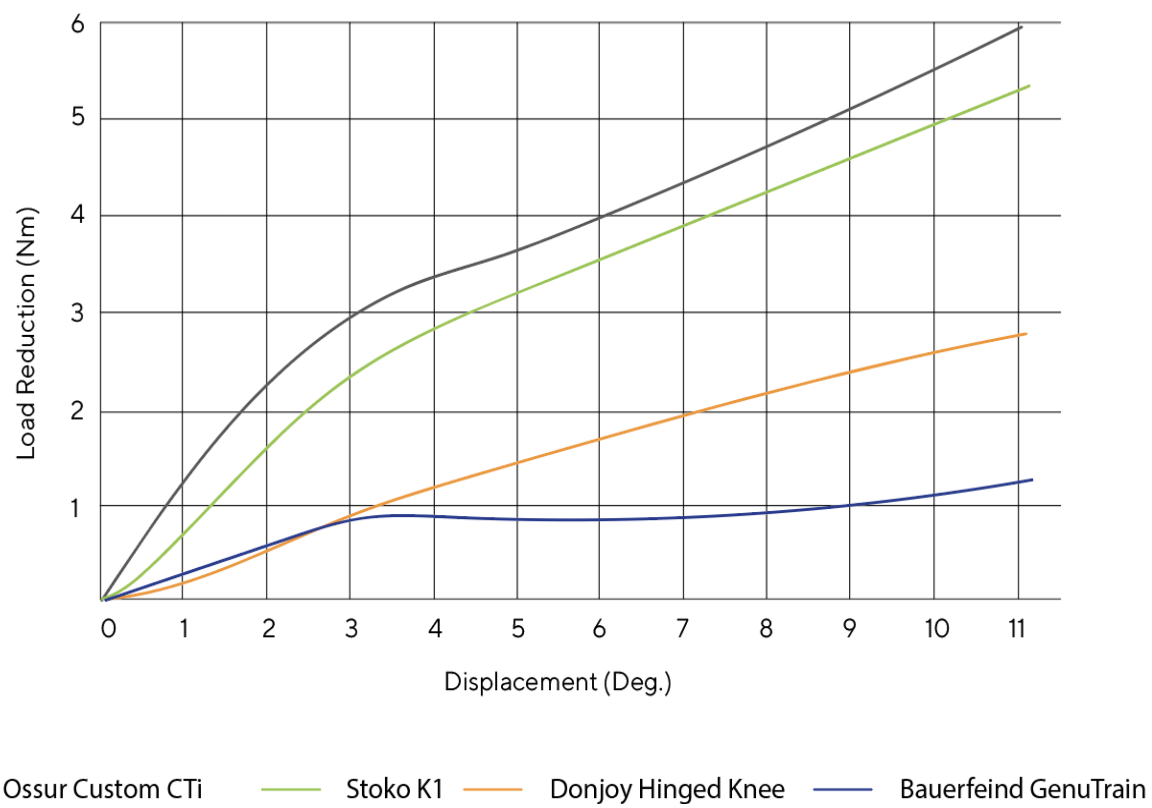

Figure 3. Comparison of knee valgus loading of various braces with respect to load on Stoko's KTF.

Results

Results from KTF valgus and varus testing are shown in Figures 3 and 4.

Figure 3 shows the different bracing product's average load reduction throughout valgus deviation from 0 to 11°. The results show comparable performance between the Stoko K1 and Ossur Custom CTi through the entire range. The CTi has a slightly faster initial rate of load reduction (Nm/°) until approximately 1°, after which, the two braces trend similarly resulting in a 11% difference in load reduction at maximum displacement. The Donjoy Hinged Knee and Bauerfeind GenuTrain also follow similar trends to that of the other braces, albeit with a lesser magnitude of load reduction achieved throughout the entire region of displacement.

Figure 4 shows the different bracing product's average load reduction throughout varus rotation from 0 to 9°. All of the devices follow a similar loading trend. The Stoko K1 and the Ossur Custom CTi achieve comparable levels of support, however, the CTi has a faster rate of load reduction (Nm/°) through the entire displacement region. This results in a 20% difference in load reduction at maximum displacement. The Donjoy and Bauerfeind braces achieve a lesser magnitude of load reduction throughout the entire region of displacement.

A picture of the individual braces performance starts to emerge when looking at three different variables, and the percent change in those variables with respect to the Stoko K1: average load reduction through the entire displacement range, load at average human knee laxity for valgus and varus deviations respectively (4°) [23,24], and load at typical ligament tear point (9° - representative of medial collateral ligament and anterior cruciate ligament) (23). This data is presented in Table 1 and Table 2 below.

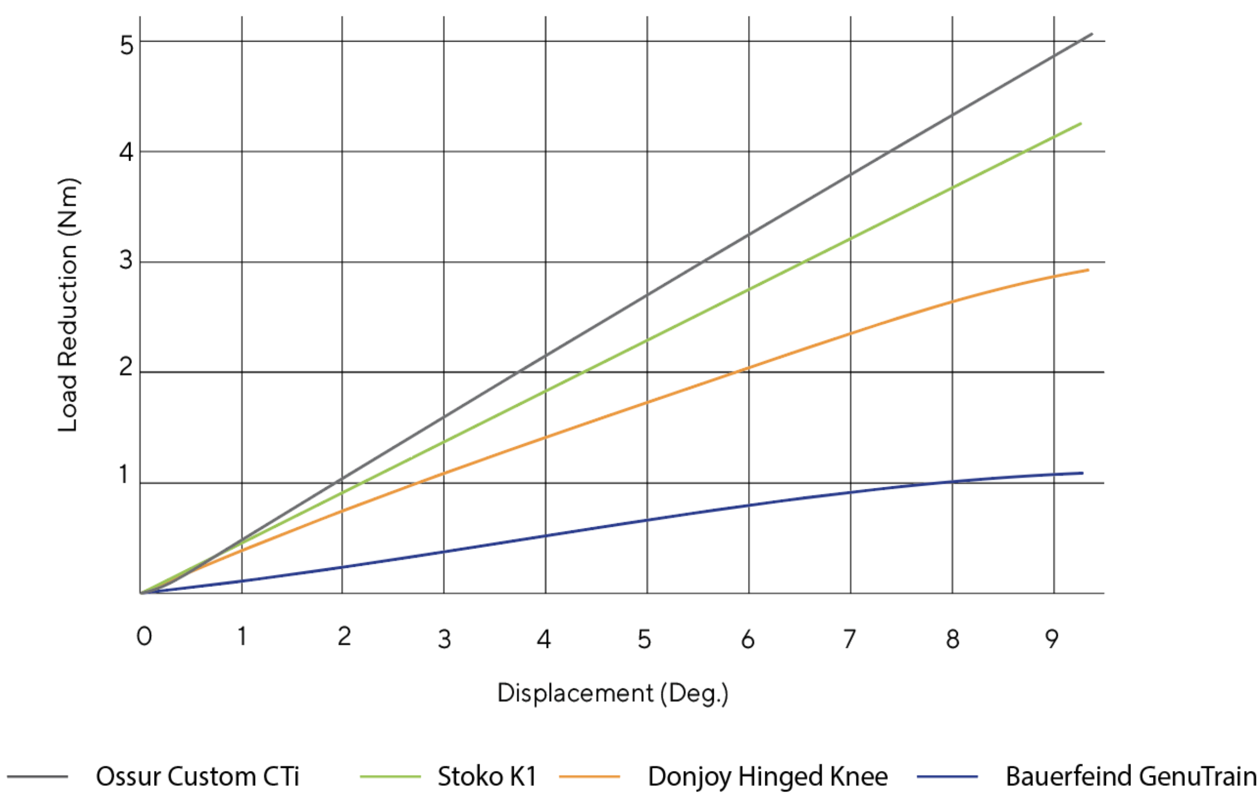

Figure 4. Comparison of knee varus loading of various braces with respect to load on Stoko's KTF.

Cycling each brace within a trial produced a high level of repeatability. The standard deviation of the trials for each brace is presented in Table 3.

Table 1. Average valgus load reduction, load at average valgus knee laxity (4°), load at average ligament tear point (9°), and percent change between brace load reduction with respect to Stoko K1. *K1-Stoko K1, Ossur-Ossur Custom CTi, Donjoy-Donjoy Hinged Knee, Bauerfeind-Bauerfeind Genutrain.

Valgus	K1	Ossur	Donjoy	Bauerfeind
Average (Nm)	3.29 (-)	3.75 (114%)	1.49 (45%)	0.85 (26%)
Laxity at 4° (Nm)	2.77 (-)	3.24 (117%)	1.11 (40%)	0.90 (33%)
Tear at 9° (Nm)	4.56 (-)	5.08 (111%)	2.26 (50%)	1.03 (23%)

Table 2. Average varus load reduction, load at average varus knee laxity (4°), load at average ligament tear point (9°), and percent change between brace load reduction with respect to Stoko K1. *K1-Stoko K1, Ossur-Ossur Custom CTi, Donjoy-Donjoy Hinged Knee, Bauerfeind- Bauerfeind Genutrain.

Varus	K1	Ossur	Donjoy	Bauerfeind
Average (Nm)	2.23 (-)	2.67 (120%)	1.68 (75%)	0.63 (28%)
Laxity at 4° (Nm)	1.8 (-)	2.17 (120%)	1.43 (79%)	0.53 (29%)
Tear at 9° (Nm)	4.05 (-)	4.86 (120%)	2.86 (71%)	1.07 (26%)

Table 3. Average standard deviation (SD) of load within trials of each product tested. Each trial consists of a sample N=4. *K1-Stoko K1, Ossur-Ossur Custom CTi, Donjoy-Donjoy Hinged Knee, Bauerfeind-Bauerfeind Genutrain.

	Baseline	K1	Ossur	Donjoy	Bauerfeind
Valgus (Nm)	0.16	0.2	0.29	0.17	0.14
Varus (Nm)	0.07	0.2	20	0.14	0.14

Discussion

From the KTF results, a clear delineation appears between the different "classes" of knee bracing products with the rigid hinged (Ossur Custom CTi) performing the best, the hinged soft sleeve (Donjoy Hinged Knee) achieving a mid-level of support, and the soft sleeve (Bauerfeind GenuTrain) having minimal structural support. The Stoko K1 was able to achieve a comparable level of support to the rigid hinged class of knee braces, all while maintaining its novel form factor, support mechanism, and being sold off the shelf.

As seen in Table 1 and 2, this performance was evaluated at two key points: average deviation laxity, and average deviation for ligament tear. In order to effectively test the different braces, our model had to have constraints to make it reasonably representative of the biological system and avoid deforming or destroying itself and the braces. This ended up being approximately 10° for both varus and valgus deviation because it captured the key ranges of laxity and tear (23–25), and was the limit at which the model could be cyclically deformed and still produce results that were reliable and repeatable. The former two evaluation points, laxity and tear, are important because they demonstrate the region and limits where a brace can be effective, help the body mitigate loads, increase user stability, and reduce the risk of injury.

Support throughout the entire range of motion is critical as the severity of injury differs based on biological variability and loading rate of the ligaments (23). Additionally, although complete collateral ligament tears happen at 9°, grade one and two tears (partial tears) can occur with less displacement (26). By inspecting the load reduction throughout the entire range of motion, and the points of interest, the relative performance emerges.

Throughout the entire range of motion, the Stoko K1 proves to be an effective method of mitigating loads on the ligaments. Its performance in both varus and valgus most closely aligns with the performance of the Ossur Custom CTi, or the rigid hinged brace category in the knee orthotics space. This class is typically considered the “gold standard” in prophylactic and functional knee bracing. With respect to the K1, the CTi maxed out at a support level of 120% throughout varus, and a minimum difference of 111% at the tear point in valgus (9°). Between the two braces, there is consistency of this result indicating that, in terms of structural support, the Stoko K1 and Ossur Custom CTi offer similar outcomes.

The Stoko K1 outperforms the soft sleeve brace class by a significant margin. The Bauerfeind Genutrain achieved a support level ranging between 23% to 33% of the K1. The support level was consistent through both valgus and varus, with a maximum difference of 4% at the 4° laxity threshold.

The hinged soft sleeve class was similar, however there was less agreement between varus and valgus. With respect to the K1, Donjoy’s Hinged Knee averaged a 50% support level in valgus, but a 75% support level in varus. These results demonstrate that the K1 provides more support throughout both deviations but provides higher relative performance in valgus deviations. The Hinged Knee's improved performance in varus may be because it is the only product, outside of a sleeve, with a symmetrical support mechanism. Both the K1 (through the cable pathways), and CTi (lateral arms), have asymmetric support mechanisms. However, on the Hinged Knee the medial and lateral aluminum arms are symmetric and may lead to additional support in the varus mechanism.

Although the Stoko K1’s support level was the most similar to the Custom CTi in the rigid hinged class, it did provide slightly less support (11-20%) across all conditions. Although we have not benchmarked other rigid hinges brace, the CTi is widely considered one of the stiffest and most protective knee braces on the market. Its support level makes it ideal for extreme sports such as motocross and wakeboarding. Considering how similar the K1 performed against the CTi, we believe that it will provide more support than many other rigid hinged braces in the category. This combination of comfort and stability makes the K1 an ideal product for many indications.

The data presented is from hundreds of hours of testing that occurred over the course of eight months to validate the Stoko K1 with respect to other market braces and test the effect of different design decisions. Trends in performance were consistent and highly repeatable.

Future Actions

Testing

Further testing and validation is always a priority. Top of the list is to further explore evaluation of different axes and complex motions. Some initial exploratory work has been executed on anterior and posterior drawer, and internal and external rotation, however, much more consultation of the relevant literature, validation of our preliminary results, and volume of trials are necessary before any substantive conclusions can be drawn.

In addition to this work, a further exploration of the current market solutions will be done. Exploring other brace designs and evaluating their performance is vital for or team to understand the merits and flaws of bracing design decisions and improve the efficacy of the Stoko K1.

Third-Party Validation

In parallel with internal validation efforts, academic Institutions and test houses have been approached to explore third party testing of the K1. Currently, a gait analysis is being pursued and we anticipate results in the calendar year of 2021. This activity is important to validate our in-house findings, and produce data which validates the product in the marketplace.

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