Gait of stance control orthosis users: The Dynamic Knee Brace System

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Abstract
Individuals with weak or absent quadriceps who wish to walk independently are prescribed knee-ankle-foot orthoses (KAFOs). New stance control orthosis (SCO) designs automatically release the knee to allow swing phase flexion and extension while still locking the joint during stance. Twenty-one participants were fitted unilaterally with the Dynamic Knee Brace System (DKBS), a non-commercial SCO. Thirteen subjects were experienced KAFO users (average 28 ± 18 years of experience) while eight were novice users. Novice users demonstrated increased velocity (55 vs. 71 cm/sec, p = 0.048) and cadence (77 vs. 85 steps/min, p < 0.05) when using the DKBS over the traditional locked KAFO. Experienced KAFO users tended to have reduced velocity and cadence measures when using the SCO (p < 0.10). Knee range of motion was significantly greater for the novice group than for the experienced group (55.2 ± 4.8 vs. 42.6 ± 3.8°, p = 0.05). Peak knee extension moments tended to be greater for the experienced group (0.29 ± 0.21 vs. 0.087 ± 0.047 Nm/kg, p = 0.09). This report describes gait changes during the introductory phase of DKBS adoption. Experienced KAFO users undoubtedly had ingrained gait patterns designed to compensate for walking with a standard locked KAFO. These patterns may have limited the ability of those users from taking full and immediate advantage of the SCO capabilities. Also, alternate SCO systems may engender different results. Comparison studies and longer term field studies are needed to clarify benefits of the various bracing options.

Keywords: KAFO, stance control orthosis, gait

Introduction
Long-leg braces or knee-ankle-foot-orthoses (KAFOs) are prescribed for individuals with significant quadriceps weakness. The orthosis is intended to provide knee joint stability during standing and walking. In the USA, approximately 989,000 people wear knee braces (Russell et al. 1997). The diagnoses of people requiring knee braces include polio, neurovascular incidents, and neurological and developmental defects. The real utility of such assistive devices has been shown to be dependent upon the individual’s estimation of effectiveness (Phillips and Zhao 1993). KAFO users naturally perform cost-benefit analyses encompassing their unique capabilities, needs, and expectations. In many cases the benefits do not equal the real-life day-to-day costs with 58 – 79% of KAFOs being abandoned (Phillips and Zhao 1993; Kaplan et al. 1996).
Recently KAFO design has been advanced by the introduction of mechanisms that provide stance phase control and swing phase freedom (Travolta 2002). These are referred to as stance control orthoses (SCO). By stance phase control it is meant that knee joint flexion is restricted during stance, the weight bearing phase of the gait cycle. These mechanisms are designed to release the knee, allowing both flexion and extension during swing, the non-weight bearing phase of the gait cycle. The intent is to allow a more normal, energy efficient, and cosmetically appealing gait. The potential benefits of a knee brace design that would allow swing phase motion while providing stance phase knee joint control has been recognized since 1918 and is gaining attention as designs are brought to the commercial market for clinical application (Windler 1918; Travolta 2002). Over 20 device patents have been filed in the USA and internationally which purport to have solved this problem. Objective reports on potential versus actual benefits in the field are less plentiful. In general, previous studies report improved gait symmetry and reduced energy consumption when using a SCO (Lehmann and Stonebridge 1978; Malcolm et al. 1980; van Leerdam 1993; Kaufman et al. 1996; Suga et al. 1998; van Leerdam and Kunst 1999; McMillan et al. 2004; Rietman et al. 2004).

The objective of this report is to document gait in a large cohort of subjects receiving an SCO.

Methods

The Dynamic Knee Brace System (DKBS) used in this study is a stance control orthosis. It is comprised of a custom designed wrap spring clutch (Irby and Kaufman 2002), an electromechanical release, and sensors at the knee and footplate, all fit to a conventional KAFO (see Figure 1) (Irby 1994; Irby et al. 1999a, 1999b). The wrap spring clutch is designed to provide 113 Nm of braking capability about the joint axis while withstanding 100 Nm of varus/valgus loading and/or 35 Nm of transverse (i.e., axial) moments. The clutch along with the electromechanical release mechanism measures 22 x 10 x 5 cm. The control circuitry is housed in a case measuring 11 x 8 x 2 cm and is typically mounted on the lateral border of the thigh shell of the KAFO. A typical DKBS KAFO weighs approximately 3.1 kg of which 1.1 kg is the clutch, electromechanical release, and electronic circuitry. The remainder of the weight is due to that of a typical KAFO with thermoplastic thigh and shank sections, stainless steel uprights, and a single stainless steel hinge. The lateral hinge is replaced by the wrap spring clutch assembly. A battery pack providing approximately two full days of use, measuring 13 x 7 x 2 cm, weighs 0.37 kg, is carried by the user in a waist pack. Two sensors provide input to the control circuit. One at the knee joint provides knee angle information while the second provides foot-floor contact information.

Research participant recruitment, consent and testing procedures were approved by the local institutional review board prior to subject enrollment. Twenty-one research participants (15 males: six females) were recruited based upon the inclusion and exclusion criteria shown in Table I. None of the participants required or used bilateral knee bracing. The KAFOs were fabricated by certified professional orthotists. The style of ankle joint for all subjects was determined by consensus between the orthotist and the research participant. Proper fit was carefully evaluated and modifications made as needed to eliminate problems with orthosis alignment and fit.

Each patient was assessed by a licensed physical therapist experienced in range of motion and manual strength testing techniques. A zero to five strength rating scale was used with 0 = absent and 5 = normal strength. This physical examination encompassed the bilateral function of the hips, knees, and ankles. Testing was conducted using a single DKBS even though in some cases patients had asymmetric bilateral involvement. In those cases the
Figure 1. The Dynamic Knee Brace System is comprised of a custom designed wrap spring clutch, an electromechanical release, a control box, and sensors at the knee (not shown) and footplate (shown), all fit to a conventional KAFO. A rechargeable lithium-ion battery pack is typically carried using a waist pack.

Table I. Criteria for research subject enrollment.

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<tr>
<th>Inclusion criteria</th>
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<tr>
<td>Primarily dependent on a KAFO for walking and use an orthosis on a daily basis, or does not use an orthosis, but has a collapsing knee which must be stabilized by a hand on the knee and/or forward trunk lean</td>
<td>Impaired cognitive powers which would interfere with cooperation during the tests or impair assessment of the orthotic system</td>
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<td>May use either one or two KAFOs for ambulation</td>
<td>Disturbance of equilibrium sufficient to interfere with safety in experimental testing of the orthotic system</td>
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<td>Must require that the KAFOs be locked for community ambulation</td>
<td>Painful condition of the back or limbs sufficient to interfere with the tests</td>
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<td>Must demonstrate the ability to walk a minimum of 100 m (crutches or walker can be used if needed)</td>
<td>Minimal contractures at hip (15–20°), knee (10°), or ankle (5° dorsiflexion) interfering with optimum orthotic fitting</td>
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<td>Must have sufficient hip flexor strength to advance the limb</td>
<td>Inability or unwillingness to walk with present orthosis</td>
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weaker limb was fitted with the DKBS. None of the enrolled participants required bracing of their stronger limb for community ambulation.

Objective gait measurements were acquired with a computerized real-time video motion analysis system utilizing 10 infrared cameras (EvaRT 4.0, Motion Analysis Corporation, Santa Rosa, CA, USA). The spatial distribution of the cameras was optimized to yield reliable motion data at the hip, knee, and ankle, bilaterally. A set of 21 reflective markers were placed on each subject as described by Kadaba et al. (1989) (see Figure 2). Markers were placed bilaterally on the acromion processes, lateral epicondyle of the elbows, centre of the dorsum of the wrists, anterior superior iliac spines (ASIS), lateral femoral condyles, lateral malleoli, the spaces between the first and second metatarsal heads, heels, on 5 cm wands placed at mid-thigh and mid-shank, and on the sacrum. The markers placed at bony prominences were used for establishing anatomic coordinate systems for the pelvis, thigh, shank, and foot. The motion analysis system was calibrated prior to each gait analysis, the calibration volume being 5 x 3 x 2.5 m. One set of data corresponding to the standing position (static data) were recorded in order to calculate the location of the joint centres. Where orthosis componentry were interposed, careful records of the offsets were documented for subsequent correction of joint centres during post-processing. After a brief orientation session, the subject was instructed to walk on the laboratory walkway. Participants were allowed to choose ambulatory

Figure 2. Research participant prepared for automated 3D gait analysis. Bilateral 3D motion analysis data were collected for each participant.
aides befitting their ambulatory status and confidence. Floor reaction forces were recorded using two AMTI force plates (Advanced Mechanical Technology, Inc., Watertown, MA, USA; model BP2416) and two Kistler force plates (Kistler Instrument Corp., Amherst, NY, USA; model 9281B) embedded in the floor in the centre of the calibration volume. The 3D marker coordinates and force plate data were used as input to a commercial software program, OrthoTrak 5.0 (Motion Analysis Corp., Santa Rosa, CA, USA), to calculate the joint kinematics and kinetics. The OrthoTrak 5.0 program was used to create the joint centres and segment coordinate systems from the 3D marker trajectories, as well as the subsequent rigid body kinematic/kinetic calculations. Embedded right-hand Cartesian coordinate systems were used in this model to describe the position and orientation of the lower limb rigid body segments. The intersegmental joint forces and moments were derived based on these measurements. Joint moments reported are internal moments normalized by body mass (kg). The temporal-distance factors such as stride, cadence, and velocity were calculated from the kinematic data. Gait cycle periods were selected by heel-strike to heel-strike events. All gait events were expressed as a percentage of the gait cycle, irrespective of the actual time for a stride, to yield a normalized gait cycle.

Statistical analyses were performed with a commercial analysis package (JMP 5.1, SAS Institute Inc., Cary, NC, USA). Data were lumped together as well as stratified according to the subject's current KAFO status. The ‘Experienced’ group routinely used a locked KAFO for ambulation. The ‘Novice’ group did not use a locked KAFO for ambulation. Physical examination data were analysed using a Wilcoxon ranked-sum test. Motion analysis data were analysed using a paired t-test to compare ‘Locked’ versus ‘SCO’ conditions. A one-way analysis of variance analysis was used to compare between ‘Experienced’, ‘Novice’, and aggregate groups. Statistical significance was set at $p = 0.05$.

**Results**

The average age for the 21 research participants was 53 ± 15 years ranging from 11 – 76 years. Body weight averaged 84 ± 20 kg ranging from 51 – 127 kg. Body-Mass Indices (BMIs) ranged from 19 – 40 with an average of 29 ± 6 (CDC 2004). According to the CDC the study group consisted of five ‘normal’, eight ‘overweight’, and eight ‘obese’ participants. Twelve had polio while the balance of patients had other pathologies or trauma including neuropathies, incomplete spinal cord injuries, spina bifida, multiple sclerosis, and muscular dystrophy. Thirteen currently used a locked KAFO and were designated ‘experienced’ users. The average age for the experienced group was 48 ± 15 years ranging from 11 – 68 years; their average KAFO experience was 28 ± 18 years ranging from 6 – 50 years; and they weighed 80 ± 21 kg ranging from 51 – 113 kg. The average BMI for this group was 28 ± 6 ranging from 19 – 40. The remaining individuals had chosen to manage their ambulatory needs up to this point without the aid of a KAFO. Average age for this ‘novice’ group was 61 ± 10 years ranging from 47 – 76 years. They weighed 91 ± 18 kg ranging from 72 – 127 kg. BMI for the novice group was 31 ± 5 ranging from 25 – 38. The entire novice group had articulated or ‘free’ ankle joints. Of the 13 experienced users, six had ‘rigid’ ankles and seven had articulated or ‘free’ ankle joints.

The research participants generally demonstrated mild to moderate strength loss. Average hip flexor strength of the involved leg was 2.7 with data ranging from 0 – 4.5 (0 = absent, 5 = normal strength) (see Figure 3).

Average hip flexor strength of the uninvolved leg was 3.8 (range 0 – 5). Average hip extensor strength of the involved leg was 2.1 (range 0 – 4). Average hip extensor strength of the uninvolved leg was 3.3 (range 2 – 5). Both flexor and extensor differences between involved and uninvolved limbs were statistically significant. Stratification based upon KAFO
experience showed novice group hip flexors of the involved limbs tended to be stronger than those of experienced users (3.4 vs. 2.2) but not significantly so ($p = 0.08$) (see Figure 4).

However, hip extensors of the involved limbs of novice users were shown to be significantly stronger than the experienced group (3.0 vs. 1.5). Knee strength differed between involved and uninvolved limbs as well as between the novice and experienced groups (see Figure 5).

**Figure 3.** Manual muscle test results for all subjects at the hip and knee. Strength was rated on a 0 (absent) to 5 (normal) scale. The involved limb was braced using the Dynamic Knee Brace System. The uninvolved limb in many cases was not ‘normal’ but was simply the stronger leg. * indicates a statistically significant difference was found. Standard error bars are shown for reference.

**Figure 4.** Strength test results for the hip by KAFO experience. Research subjects who did not regularly use a locked KAFO for ambulation at the beginning of the study were categorized as ‘Novice’. All other subjects were categorized as ‘Experienced’. * indicates a statistically significant difference was found. Standard error bars are shown for reference.
Average knee extensor strength for the involved limb was significantly lower than the uninvolved limb for both experience groups and the aggregate. The average knee extensor strength ratings for all subjects were 1.8 (range 0–5) for the involved limbs and 4.5 (range 2.5–5) for the uninvolved limbs. A significant difference was also found between the novice and experienced groups for the involved knee extensor strength. The novice knee extensor strength average was 2.6 (range 1–5) and the experienced group measured 1.3 (range 0–3.5). Ankle dorsiflexor strength was significantly different for the subject aggregate between the involved and uninvolved limbs measuring 2.0 (range 0–5) and 4.4 (range 0–5) respectively. No significant difference was found between limbs in the novice group but was found in the experienced group (see Figure 6). Average ankle dorsiflexor strength for the involved and experienced limbs was 0.9 (range 0–3.5) and 4.1 (range 0–5) for the uninvolved limbs. A statistically significant difference between novice and experienced groups for the involved limb average ankle dorsiflexor strengths was found. The average values of involved limbs of novice users was 3.7 (range 1–5) while that of experienced users was 0.9 (range 0–3.5).

Temporal-distal measures of velocity, cadence, stride length, and single support time were analysed. Novice users showed significant changes between the locked KAFO and SCO conditions for three of the four measures. Velocity increased from 55.3–59.0 cm/sec ($p = 0.034$) (see Figure 7). Cadence increased from 76.8–84.9 steps/minute ($p = 0.042$) (see Figure 8). Stride length increased from 86.3–99.2 cm ($p = 0.072$) (see Figure 9). Single limb support time increased from 27.0–30.3% but this was not significant ($p = 0.072$). Experienced users tended to reduce velocity and cadence during this early SCO testing ($p = 0.10$) but not significantly so. On aggregate, there were no significant changes between the locked KAFO and SCO conditions.

Kinematic data for the hip, knee, and ankle were analysed for differences across locked and SCO conditions as well as between experienced and novice KAFO users. Maximum pelvic obliquity for the novice group was significantly reduced (mean difference $2.8^\circ$, $p = 0.04$) and
the overall range of motion tended to be reduced with SCO use (mean difference $1.7^\circ$, $p = 0.08$). Hip flexion was significantly increased for the novice group with the SCO use (mean difference of $5.3^\circ$, $p = 0.001$) while experienced users demonstrated a significant increase in hip extension with SCO use (mean difference of $3.8^\circ$, $p = 0.008$). Hip abduction measures demonstrated no changes for the aggregate or stratified data sets. Dynamic knee range of motion was significantly increased for the aggregate, experienced and novice groups.

Figure 6. Strength test results for the ankle by KAFO experience. * indicates a statistically significant difference was found. Standard error bars are shown for reference.

Figure 7. Self-selected walking velocities for novice KAFO users, experienced KAFO users, and for the aggregate of all subjects tested. The * pairing indicates a statistically significant change between the ‘Locked KAFO’ and ‘SCO’ conditions. Standard error bars are shown for reference.
with SCO use. Also average knee range of motion was significantly greater for the novice group than for the experienced group (55.2 ± 4.8° vs. 42.6 ± 3.8°, p = 0.05) (see Figure 10).

Maximum contralateral ankle plantarflexion (i.e., vaulting) was significantly reduced with SCO use for both experienced (mean difference of 1.4°, p = 0.02) and novice groups (mean difference of 2.5°, p = 0.04). Average foot orientation for the aggregate was 15° external to the line of progression ranging from 13° internal to 51° external. No significant differences were observed in foot orientation between experience groups or locked versus SCO test conditions.

Figure 8. Self-selected cadence for novice KAFO users, experienced KAFO users, and for the aggregate of all subjects tested. The * pairing indicates a statistically significant change between the ‘Locked KAFO’ and ‘SCO’ conditions. Standard error bars are shown for reference.

Figure 9. Single limb support for novice KAFO users, experienced KAFO users, and for the aggregate of all subjects tested. The * pairing indicates a statistically significant change between the ‘Locked KAFO’ and ‘SCO’ conditions. Standard error bars are shown for reference.
Kinetic data analysis included peak contralateral hip abduction and ipsilateral extension moments during swing, peak knee extensor moments during stance, knee moment at foot-off, and peak contralateral ankle plantarflexion moment during stance. No significant differences in maxima for net internal hip abduction or extension moments were demonstrated across experience or knee joint status. They equaled 0.66 ± 0.21 and 0.093 ± 0.11 Nm/kg respectively on aggregate. Peak knee extension moment tended to be greater for the experienced group in the locked condition (0.32 ± 0.23 vs. 0.066 ± 0.087 Nm/kg, p = 0.06) and in the SCO condition (0.29 ± 0.21 vs. 0.087 ± 0.047 Nm/kg, p = 0.09) (see Figure 11).

In absolute terms the experienced group demonstrated a peak knee extension demand of 25 Nm and 7.0 Nm for the novice group. The maximum demand on the DKBS recorded in laboratory testing was 67 Nm. Average peak knee moment for all subjects was 20 ± 18 Nm. Knee moments at foot-off were 6.2 ± 1.7 Nm for the novice group and 3.8 ± 2.3 Nm for the experienced group. Average knee moments at foot-off for the SCO condition were 0.11 ± 0.068 Nm/kg (6.2 ± 1.7 Nm) for the novice group and 0.048 ± 0.029 Nm/kg (3.8 ± 2.3 Nm) for the experienced group. This difference was not statistically significant. On aggregate knee moment at foot-off was 4.5 ± 2.3 Nm. Average peak contralateral ankle plantarflexion moment in stance (i.e., vaulting moment) for the subject aggregate was 0.95 Nm/kg ranging from 0.14–1.7 Nm/kg. No significant differences were observed between the experience groups or locked versus SCO conditions.

Discussion
This study represents the first comprehensive quantitative analysis of a stance phase control orthosis. Twenty-one participants were enrolled representing a wide range of demands upon
the knee brace system. Objective laboratory data included physical examination of lower limb strength and automated 3-D motion analysis providing both kinematic and kinetic measures collected at the point of readiness for release into the community for independent, unsupervised use. Results show that the DKBS, a stance control orthosis, provided significant improvement in self-selected walking velocity for novice KAFO users. Both novice and experienced users demonstrated increased peak knee flexion in swing, with a concomitant reduction in compensatory motions such as vaulting and dynamic pelvic obliquity. Temporal-distal outcome measures at the early stage of SCO use were demonstrated to depend in part on the experience level of the individual. Many experienced users were uneasy with the swing phase knee joint freedom, having walked with a locked KAFO for decades previously. For the SCO condition they tended to adopt a more cautious walking pattern resulting in lowered velocity and stride length measurements. The novice users however demonstrated significant improvements in these measures when comparing the locked versus SCO conditions.

Kinematic measurements of the hip, knee, and ankle also demonstrated a difference in outcome based upon KAFO experience as well as between the KAFO locked and SCO test conditions. Motion analysis data were collected to document changes in the three primary compensations employed to manage a stiff knee during gait:

1. Hip hike (pelvic obliquity);
2. Circumduction (hip abduction); and
3. Vault (contralateral ankle plantarflexion in stance).

Of these three compensations only the peak ankle plantarflexion angle was changed with SCO adoption for the experienced group. Peak pelvic obliquity and hip abduction measures remained unchanged. The novice group however demonstrated significant changes in both

Figure 11. Internal knee flexion/extension moments of novice (thick traces) and experienced (thin traces) groups. Values > 0 tend to flex the knee joint. Normal moments (± 1 SD) shown for comparison.
pelvic obliquity and ankle plantarflexion between the locked and SCO conditions. These differences may be attributable to the novice group not having ingrained compensatory movement patterns, and, as a result, were able to quickly adapt to the SCO condition.

Peak joint moments at the hip, knee, and ankle showed no significant changes between test conditions demonstrating that the DKBS provided appropriate knee joint support in stance. Statistically significant differences were shown to exist between the experience groups. The novice group generally managed their knee moments during stance so that they tended to extend the braced limb. The experienced group however relied upon the DKBS more heavily (figuratively and literally) to provide knee joint stability during stance.

Industrial standards are not yet in place for SCO designs. The authors have located only one specific pass/fail criteria for a standard knee joint locking mechanism. The proof test is a static load of 100 Nm in the sagittal plane on a single locking hinge design. Alternatively, comparisons may be made to research data. Johnson et al. (2004) has published multi-centre research data with average maximum knee joint extension moments of 33 Nm. These values differ from the 20 Nm measurements reported here. Reported walking velocities were roughly equal at 68 cm/s (Johnson et al. 2004) versus 63 cm/s for this study. The Johnson subject population weighed 66.6 kg on average while the group reported on herein average 84 kg, a difference of 26%. The remaining parameters of limb segment lengths and knee angle during stance are not available for comparison. Knee moments at foot-off are not generally reported in the literature: however this joint moment needs to be recognized in SCO design (Kaufman et al. 2004). In late stance, when preparing for foot-off, both the hip and knee are in extension. Lacking knee extensor strength gravity and hip flexors naturally combine to create a knee flexing moment. In this report they averaged 3.8 and 6.2 Nm for the experienced and novice groups respectively and 4.5 Nm on aggregate.

Shortcomings of the current study are DKBS size and packaging and limited user experience with the device. The current DKBS is too large to fit under some trouser designs. Many prospective and enrolled research participants remarked on the large size and weight of the DKBS. At 1.1 kg, the clutch is a significant additional weight. However, this particular design is able to match or exceed the static strength of materials typically used in KAFO construction and provide over a 100 Nm of braking capacity. Although commercially available SCO systems do not provide absolute brake or lock specifications, several give quantitative patient selection criteria. Body weight restrictions for these commercial SCOs range from 80 – 120 kg and stipulate that the user has either no knee flexion contracture or contractures must be $< 10^\circ$ depending upon the design. Only 10 of the participants in this study weighed 80 kg or less. Eleven weighed between 80 and 127 kg. All interested applicants were accommodated without any mechanical failures. Enrollment criteria for this study included that any knee contracture must be $< 10^\circ$. Functionally, however, four of the 21 participants regularly had stance phase knee flexion measures $> 20^\circ$ (see Figure 10). Many users, particularly those in transition to a KAFO, will not need 100 Nm of braking capability but may succeed with only half or one quarter of that capability. Reducing the braking capacity will allow the physical size and weight to be reduced to levels acceptable to a wider population. Nevertheless, the capacity of the clutch used in this study is required for some subjects. Only half of the research participants in this cohort would have met current commercial SCO fitting guidelines and been able to receive a SCO.

Research subjects were provided varying levels of training and supervision based upon their accommodation to the DKBS. Some individuals were able to walk independently using the DKBS within 10 minutes. Others required multiple training sessions utilizing parallel bars and one-on-one coaching. Laboratory-based data were collected immediately after the individual proved him or herself capable of independent ambulation. As such this
protocol provides only initial changes observed in the adoption of an SCO and in particular the DKBS.

Future reports should examine changes in gait over time. The authors expect to see changes as individuals become familiar with the DKBS. Future study designs may also include comparisons between the various stance control orthosis designs to see how they impact walking ability. In the meantime, DKBS development will continue.

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