



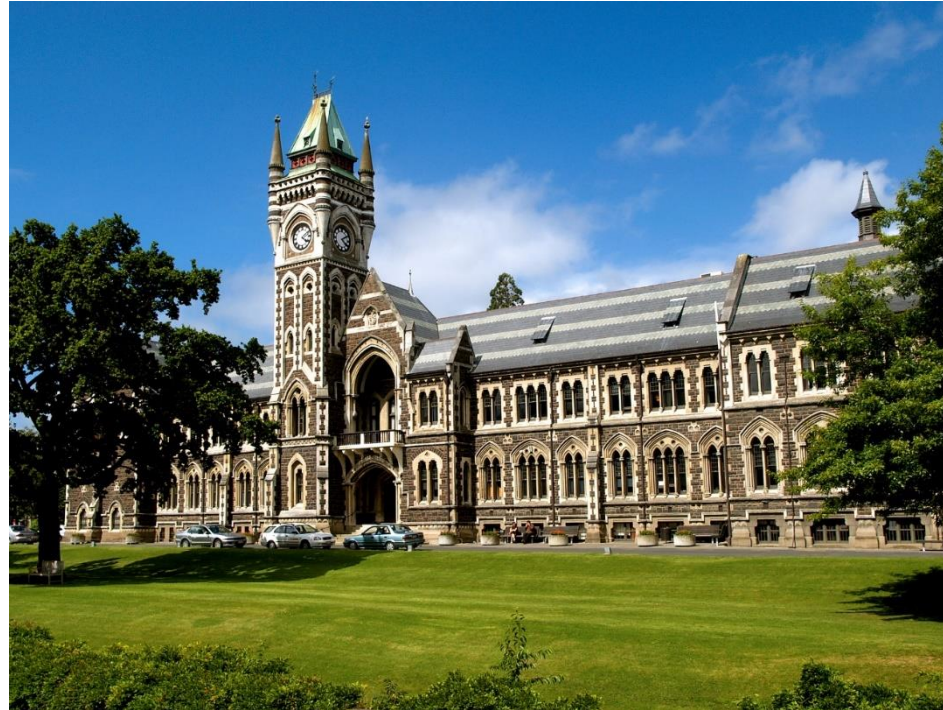
Study of chronic instability / GenuTrain



Prof. Dr. Gisela Sole



Prof. Dr. med. Nils Hammer*



University of Otago, New Zealand



Study of chronic instability / GenuTrain



Sample:

Part 1: Acute effect: n = 34 patients (crossover, randomised).
Part 2; 6 weeks wearing time: n = 17 with bandage = BG = intervention group,
n = 17 without support = KG = control group

Intervention group:

Age: 27 ± 7 years, height 173.0 ± 10 cm, weight 72.9 ± 10.7 kg.

BMI 24.4 ± 3.2 , sex; m:w=10:7; time since surgery: 15 mon. (7-44)

Wearing time of the bandage/day: at least one hour

TengerActivityScale before injury: 7 (3-10)

TengerActivityScale since injury post OP: 4 (2 - 9)

Inclusion criteria:

- A.) Patients with ACL rupture and with a following **ACL ligament reconstruction at least 5 months to 5 years,**
- B.) **Functional deficits** as measured by the IKDC-SKF (Intern. Knee Documentation Committee Subjective Knee Form); 40-80 out of 100 points.

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Acute effect of the bandage / single leg jump [cm] /n=34

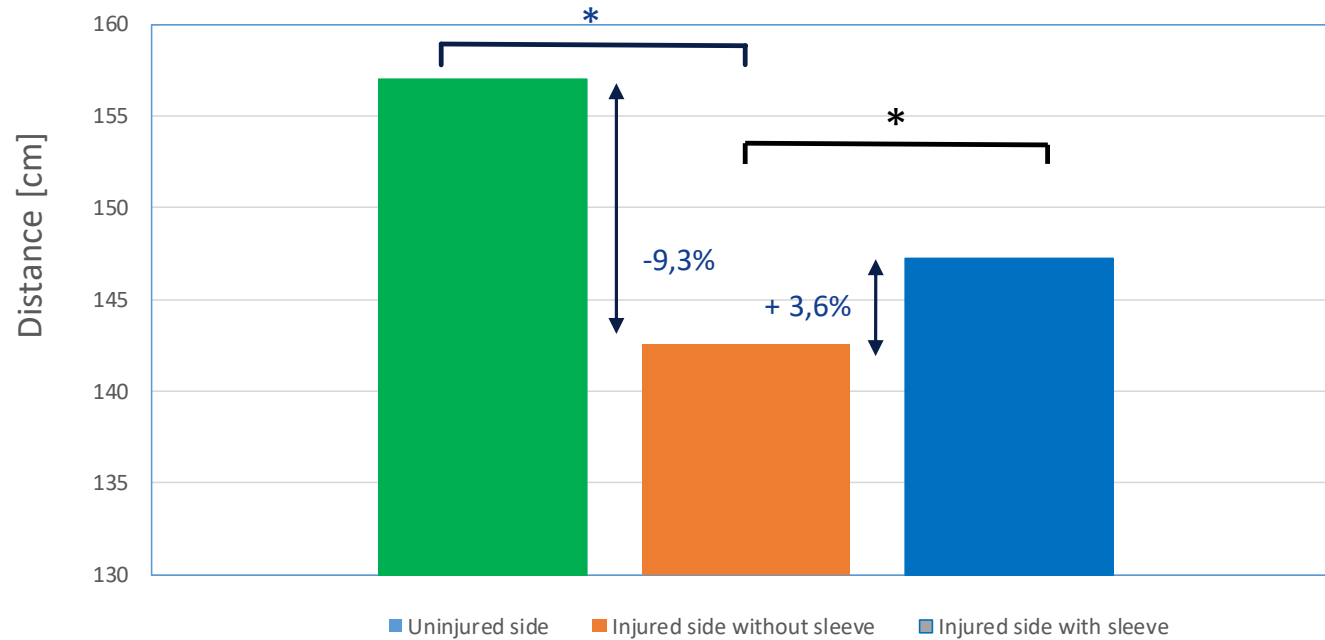
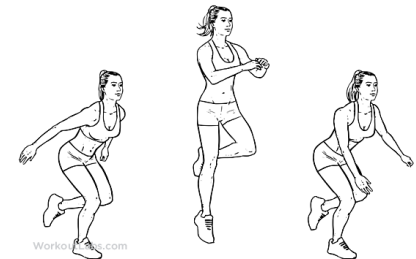


Abb.: Distance-single leg jump / y-Axis = Length of the jump [cm], ($\alpha < 0,05$; Power, $\beta = 80\%$; One Way ANOVA)



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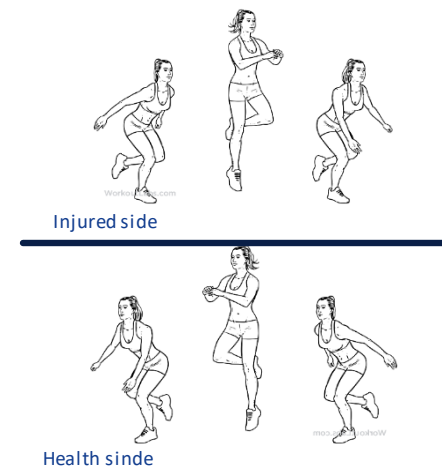
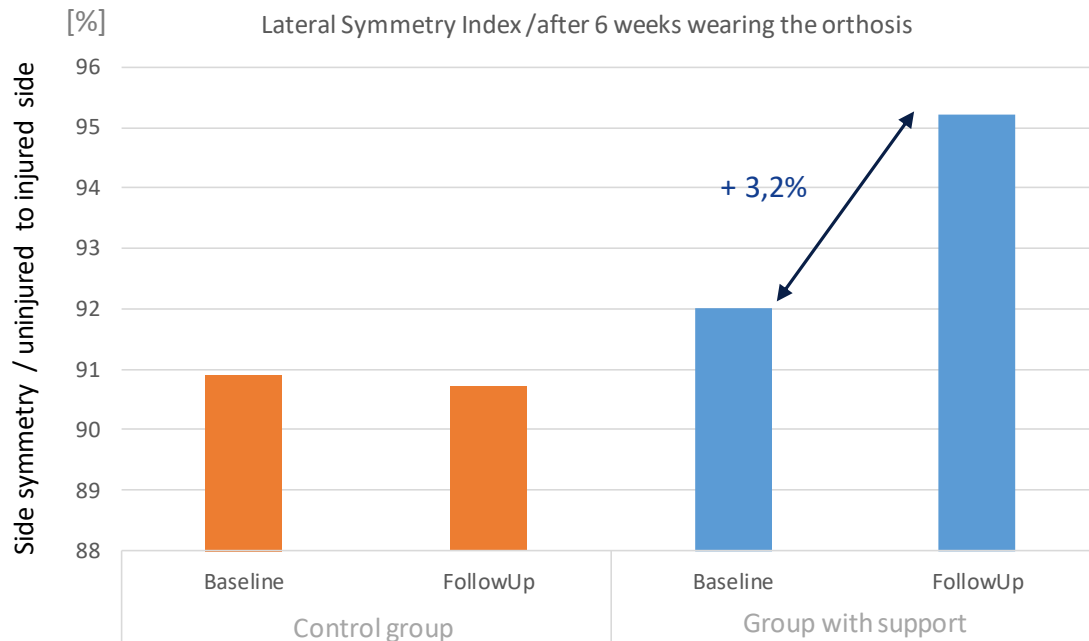


Fig.: LSI (Lateral Symmetry Index), comparison of the healthy side with the diseased side in acute application (baseline) and after 6 weeks of wearing the support (follow-up); n=12 CG Control group; n=12 BG Group with support LSI = injured side/uninjured side * 100; [%].

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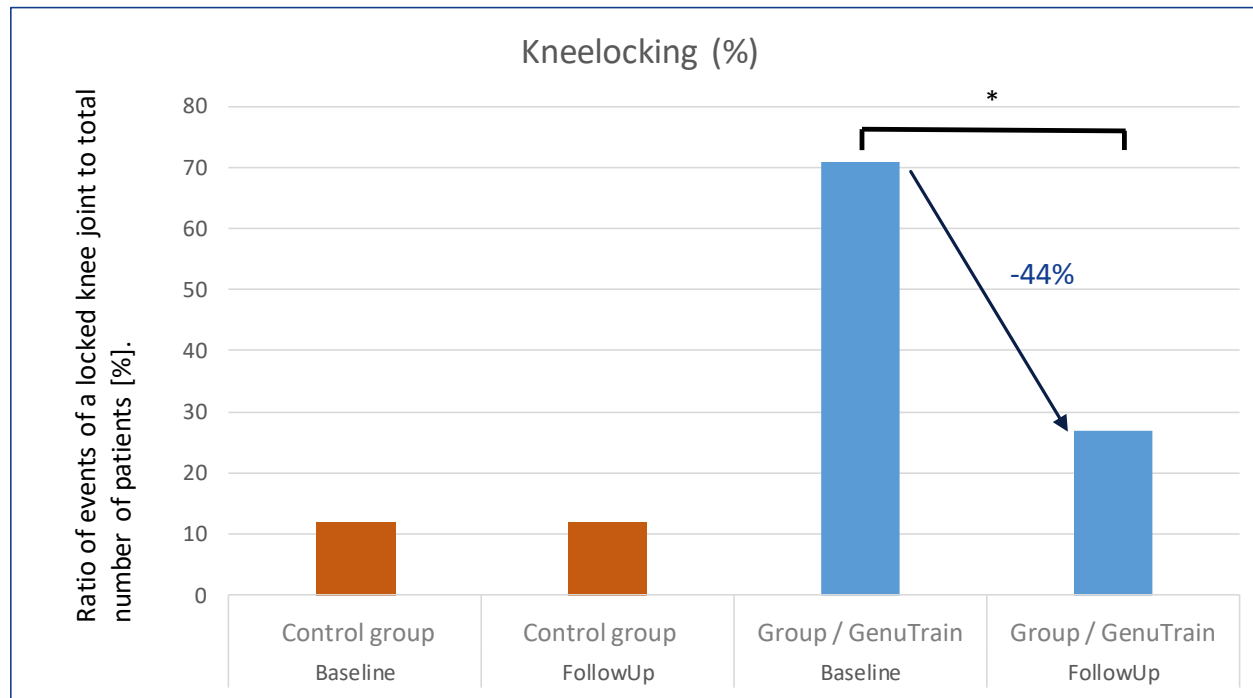


Fig.: Comparison of knee function before fitting with the support (baseline) with knee function after 6 weeks. Intervention with the support (support group or 6 weeks without support (control group), ($\alpha < 0.05$; power, $\beta = 80\%$; Mc Nemar test), $n = 16$ KG; $n = 15$ BG

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White Paper



STUDY PUBLICATION OF SELECTED RESULTS

EFFECTIVENESS AND LONG-TERM EFFECT OF A KNEE SUPPORT IN PATIENTS WITH CHRONIC INSTABILITY FOLLOWING ACL RECONSTRUCTION

BACKGROUND

The surgical reconstruction of a torn cruciate ligament with subsequent rehabilitation is the most commonly pursued treatment in young, active patients. [1] The annual incidence rate for ACL reconstructions per 100,000 is 68.6 in the US [2], 58.2 in New Zealand [3], 52.0 in Australia [4] and 32.0 in Sweden. [5] The incidence is higher in populations playing team sports than for people who do not exercise. [6]

In the post-operative setting, reports show medium-term to long-term impairment of and restriction in knee functionality in addition to the risk of re-rupture [7] or the development of osteoarthritis of the knee [8]. Clinical studies suggest that potential consequences following cruciate ligament reconstruction may include persistent thigh muscle deficits [9-10], abnormal gait [11] and reduced physical activity [12]. Activity levels also seem to decrease over time [13], with excessive body weight playing a part as well [14].

A long-term decrease in the quality of life related to knee function, fear of re-rupturing cruciate ligament tears and diminishing confidence are potential developments that have been observed in patients following cruciate ligament ruptures [10,15-17].

Studies report on the use of elastic supports in individual patients during the rehabilitation phase and when returning to exercise following ACL reconstruction [18]. It has been discussed that supports may improve/normalize gait by improving proprioception and sensorimotor control [19,20], thus increasing knee joint function and the patient's confidence in their own knee [1, 21].

The objective of the study was to examine the stabilizing effect of the GenuTrain knee support in patients with chronic instability (at least 5 months after surgery) following ACL rupture and ligament reconstruction at baseline as well as 6 weeks after wearing the product.

STUDY DESIGN

Crossover design for the acute effect; two-arm, randomized, controlled clinical study with 6-week long-term follow-up (evidence level II)

METHODS

Sample: n=34 patients; Part 1: acute effect: n=34 (crossover, randomized) Part 2: 6 weeks of wearing the product: n=17 with support + BG = intervention group, n=17 without support + KG = control group

Intervention group: Age: 27 ± 7 years, Height: 173.0 ± 10 cm, Weight: 72.9 ± 10.7 kg, BMI: 24.4 ± 3.2, sex: m=10, f=7, Time since surgery: 16 months (7-44) Wearing duration of the support/day: at least one hour *Tegner Activity Scale before the injury: 7 (3-10) *Tegner Activity Scale since injury, after surgery: 4 (2-9)

Control group: Age: 28 ± 7 years, Height: 173.6 ± 10 cm, Weight: 86.4 ± 11.1 kg, BMI: 28.7 ± 2.4, sex: m=6, f=9, Time since surgery: 16 months (6-53) Wearing duration of the support/day: 9 (6-10) *Tegner Activity Scale since injury, after surgery: 5 (3-9)

*Tegner Score: 0 – Unable to participate in sports/activities because of knee problems; 5 – Recreational exercise is possible, jogging on uneven surfaces 3x week; 10 – Competitive national or international sports, team sports (football, rugby)

METHODS

Test supports: GenuTrain® (Bauerfeind AG)

Measurement systems and test procedures:

Horizontal jump: Single leg jump from standing on one leg and landing on one leg, average of 3 attempts, healthy side, injured side without and with the support LSI Lateral Symmetry Index (Injured side/healthy side * 100) IKDC SKI International Knee Documentation Classification Subjective Knee Form = function, max. points: 100

Investigation period:

1st measurement: Acute effect, measurement on the day the support was handed out followed by 6 weeks of wearing the support for BG, n=17 and KG n=17 without a support 2nd measurement: 6 weeks after 1st measurement

Inclusion criteria:

Patients with ACL rupture and ACL reconstruction at least 5 months to 5 years in the past, functional deficits, measured using the IKDC SKI (Intern. Knee Documentation Committee Subjective Knee Form); 40-80 or 100 points

Exclusion criteria:

Patients with revision procedures or previous ACL ruptures on the other knee Patients with problems related to the pelvis or lower back as well as the lower extremities Conditions that required medical treatment during the past 6 months or that caused a restriction in daily activity Neurological or cardiovascular conditions BMI above 30 or IKDC SKI value < 40 or > 80

RESULTS

Single-leg horizontal jump, acute effect: During jumps with the support on the injured leg, the distance increased significantly by 3.6% (95% CI 0.4-6.8%, p=0.025) compared with jumping without a support on the injured leg.

A reduction in different jumping abilities was also observed between the healthy and the injured side of: 2.3% (12.8%, -4.1%) without a support to -0.9% (-9.2%, 7.8%) when wearing the support. During the acute phase, the deficit on the injured side compared with the healthy side decreases by a third when wearing the GenuTrain. This corresponds to an increase in jumping ability of 8 cm for the injured leg when a support is being worn. (Fig. 1)

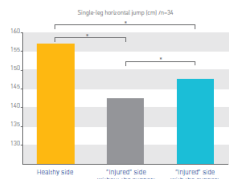


Fig. 1. Single-leg horizontal jump. Values = jumping length (cm), n=34; p < 0.05, p=0.025, p=0.001, one-way ANOVA.



GenuTrain increases the performance and coordinative abilities of the knee joint



No decrease in acute effect after six weeks of wearing the GenuTrain



After six weeks, fewer malfunctions of the knee joint (knee locking) due to GenuTrain



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Publication



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BMC Musculoskeletal Disorders

RESEARCH Open Access

Immediate and 6-week effects of wearing a knee sleeve following anterior cruciate ligament reconstruction: a cross-over laboratory and randomised clinical trial

Gisela Sole^{1*}, Peter Lamb², Todd Pataky³, Stefan Klimt⁴, Pierre Navaro^{5,6} and Nils Hammer^{7,8}

Abstract
Background: Rehabilitation following anterior cruciate ligament (ACL) reconstruction is based mainly on comprehensive progressive exercise programmes using a multi-dimensional approach. Elastic knee sleeves may be useful adjuncts to rehabilitation. The aim of this study was to determine the immediate and 6-week effects of wearing a knee sleeve on person-reported outcomes and function in participants who had undergone an ACL reconstruction and who had residual self-reported functional limitations.
Methods: Individuals with ACL reconstruction in the previous 6 months to 5 years were recruited. Immediate effects of a commercially-available elastic knee sleeve on single-leg horizontal hop distance were explored using a cross-over design. Following this first session, participants were randomised into a Control Group and a Sleeve Group who wore the sleeve for 6 weeks, at least 1 h daily. Outcome measures for the randomised clinical trial (RCT) were the International Knee Documentation Classification Subjective Knee Form (IKDC-SKF) score, the single-leg horizontal hop distance, and isometric quadriceps and hamstring peak torque. Linear mixed models were used to determine random effects. Where both limbs were measured at multiple time points, a random measurement occasion effect nested within participant was used.
Results: Thirty-four individuals (16 women) with ACL reconstruction completed the cross-over trial. Hop distance for the injured side during the sleeve condition increased by 3.6% (95% CI 0.4–6.8%, $p = 0.025$). There was no evidence of differential changes between groups for the IKDC-SKF (Sleeve Group $n = 15$; Control Group $n = 16$, $p = 0.327$), or relative improvement in the injured side compared to the uninjured side for the physical performance measures (Sleeve Group $n = 12$; Control Group $n = 12$; three-way interaction $p = 0.533$ [hop distance], 0.381 [quadriceps isokinetic peak torque], and 0.592 [hamstring isokinetic peak torque]).
Conclusions: Single-leg hop distance of the ACL-reconstructed side improved when wearing a knee sleeve. Wearing the knee sleeve over 6 weeks did not lead to enhanced improvements in self-reported knee function, hop distance and thigh muscle strength compared to the control group.

* Correspondence: g.sole@bmc.lu.se
¹Center for Health, Activity and Rehabilitation Research (CHAR), School of Health, Behavior and Society, University of Colorado Boulder, New England Hall, 1050 Lincoln Drive, Boulder, CO 80502, USA

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trial) only, a sequence effect. Analyses for the IKDC, hop distance and muscle strength are from linear mixed models using Restricted Maximum Likelihood (REML) to estimate random effects. A random participant effect and, where both limbs are measured at multiple time points, a random measurement occasion effect nested within participant. For hop distance, quadriceps and hamstrings peak torque, interaction effects for injured leg with sleeve at follow-up (three-way interaction and interaction effect for sleeve at follow-up (two-way interaction) are presented as ratios of the geometric means. Reported effects are for changes and, for Part 2, baseline values were incorporated in the model. These analyses were performed with Stata (16.1, StataCorp LLC, College Station, Texas, USA).

Results
 One hundred and twenty-eight volunteers responded to community ($n = 50$) and TriFracts ($n = 78$) advertising. Of those, 34 were eligible and were assessed at baseline (Part 1). Reasons for exclusion are provided in Additional file 1: Appendix 2. Two participants of the Sleeve Group withdrew from the study following that assessment due to knee re-injuries, unrelated to use of the knee sleeve (Fig. 1). A further eight participants were affected by the COVID-19 lockdown in New Zealand in March/April 2020: one control participant withdrew from the RCT; seven (Sleeve Group $n = 3$; Control Group $n = 4$) continued and completed their physical activity diaries during lockdown. They completed the follow-up IKDC-SKF, but could not attend the second laboratory session. Post-lockdown, recruitment continued and seven participants were included in the study (total $n = 34$). Thirty-one participants completed the follow-up IKDC-SKF (primary outcome for the RCT), of which 24 participants completed the follow-up biomechanical laboratory session (Fig. 1). Demographic data of the participants are provided in Table 1.

Part 1 Cross-over trial immediate effects of wearing the knee sleeve
 Hop distance increased during the sleeve condition on the injured side by 3.6% (95% CI 0.4–6.8%, $p = 0.025$)

Fig. 1 Flowchart of participant recruitment, allocation and follow-up. *Participants were lost to the laboratory-based follow-up data collection due to the COVID-19 lockdown in March/April 2020. IKDC-SKF International Knee Documentation Classification Subjective Knee Form.



MOTION IS LIFE.