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 rerupture [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 recurring 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 [21,22].

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 1b)

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:w=10:7,
Time since surgery: 15 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: 26 ± 7 years,
Height: 173.0 ± 01 cm,
Weight: 80.4 ± 11.1 kg,
BMI: 26.7 ± 2.4, sex: m:w=8:9;
Time since surgery: 16 months (6–53)
*Tegner Activity Scale before the injury: 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 2x 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-SKF 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-SKF (Intern. Knee Documentation Committee Subjective Knee Form); 40 – 80 of 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-SKF 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 per cent (95 per cent CI 0.4 – 6.8 per cent, 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 -9.3 per cent (-12.4 per cent, -6.1 per cent) without a support to -6.0 per cent (-9.2 per cent, -2.8 per cent) 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 5 cm for the injured leg when a support is being worn. (Fig. 1)

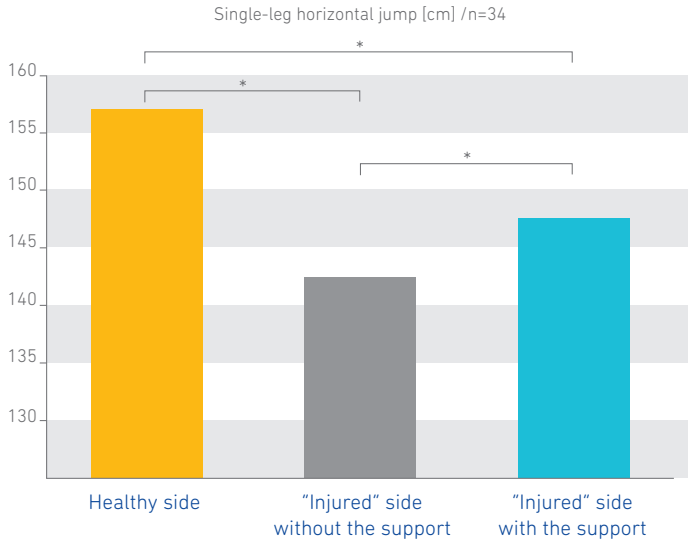

Fig. 1: Single-leg horizontal jump Y axis = jumping length [cm], (α<0.05; power, β=80%; one-way ANOVA)

SINGLE-LEG HORIZONTAL JUMP, LONG-TERM EFFECT:

After 6 weeks of intervention, no significant further increase in jumping ability was measured during the single-leg jump using the injured side when comparing "without" and "with" support. However, a trend can be noticed where the symmetry index in the intervention group (jumping ability; jumping distance with the injured side compared with the healthy side) increased from 92.0 per cent to 95.2 per cent. (Fig. 2)

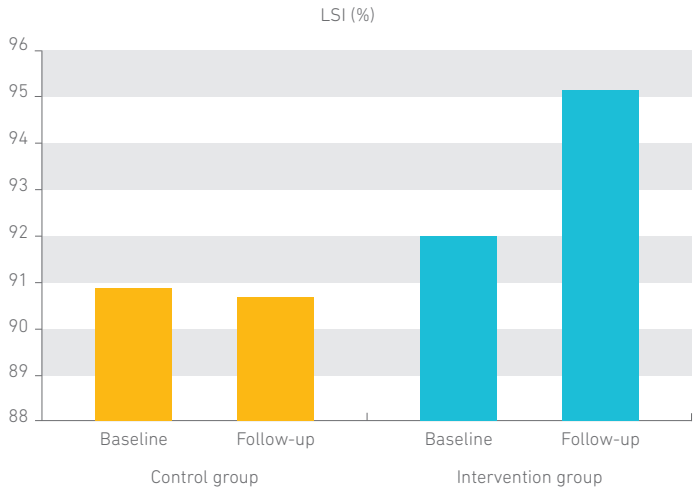

Fig. 2: LSI (Lateral Symmetry Index), comparing the healthy side with the injured side during the acute phase (baseline) and after 6 weeks of wearing the support (follow-up); n=12 KG; n=12 BG

IKDC SCORE, KNEE FUNCTION SELF-ASSESSMENT QUESTIONNAIRE:

There were no significant differences in the overall IKDC assessment between the control group and the intervention group. During the detailed review, however, a significant difference was observed between the control group and the intervention group when asked about an impaired function based on a "locked knee" and/or the knee popping and snapping. In the control group, the number of events was unchanged, whereas the intervention group showed a decrease in the event rate from 71 per cent to 27 per cent after 6 weeks of wearing the support.

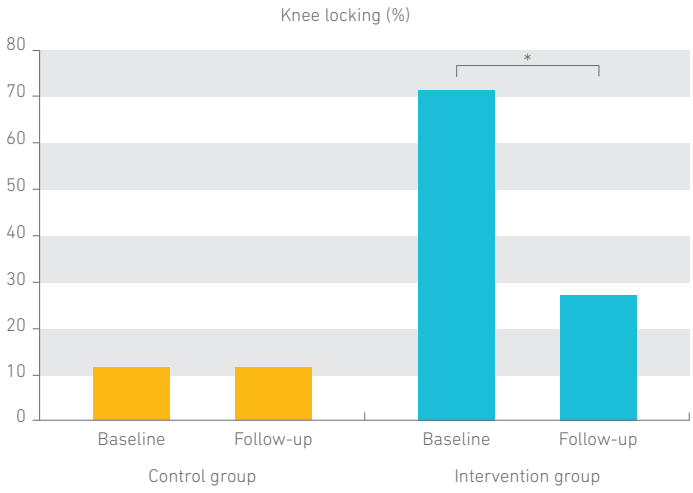

Fig. 3: Comparing knee function before being given the support (baseline) and knee function after 6 weeks of wearing the support (intervention group vs. 6 weeks without a support (control group)), (α<0.05; power, β=80%; McNemar's test), n=16 KG; n=15 BG

DISCUSSION

The single-leg horizontal jump is often used to assess recovery in patients following cruciate ligament reconstruction. It is also used in combination with further tests to determine the timing of a safe return to sporting activities [23,24].
Patients in this study demonstrated lateral symmetry (LSI) of LSI ≥90 per cent in relation to jumping distance, which is often used as a benchmark for returning to exercise. However, the jumping distance of patients using the injured leg without wearing a support was significantly less in this study than the average distance of 187 cm reported in other studies for patients with comparable injuries and age distribution [25].
On the one hand, wearing the knee support can increase performance by 3.6 per cent during the acute phase. This points to an improvement in the functional status of the "injured" knee.

On the other hand, quite a wide dispersion in the individual data (standard deviation; SEM 3 per cent) is documented. In addition, patients reported wearing the support for very different daily durations over the 6 weeks. The time ranges from 1 – 8 hours per day.

The wide range of the Tegner Activity Score from 2 – 9 out of 10 also shows a certain heterogeneity of the groups examined, with some subjects returning to competitive sports (9/10), while others were only just able to walk on uneven surfaces (2/10).

These may be reasons influencing the comparison between the two groups, resulting in no further significant increases in performance being observed over the total of 6 weeks for all patients in the intervention group.
One effect that did continue for the 6 weeks was reflected in the improved symmetry of the injured side compared with the healthy side as well as the notably lower rate of impaired knee function after 6 weeks of wearing the knee support.

Knee supports can be a useful addition to the treatment regimen during rehabilitation and for the ongoing improvement of physical activity.
Based on the evidence of this study data and current existing studies [18 – 22] examining the effectiveness of knee supports, their use should be determined based on individual assessments and the patient's current recovery progress.

CONCLUSIONS

- **GenuTrain increases performance and knee coordination**
- **After 6 weeks of wearing the GenuTrain, there was no decrease in the acute effect**
- **After 6 weeks, there were fewer instances of impaired knee function (knee locking) when using GenuTrain**

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