

# STUDY PUBLICATION OF SELECTED RESULTS

## EFFECTS AND WEARING CHARACTERISTICS OF THE DORSAL VERSION OF THE SecuTec® Genu KNEE ORTHOSIS

### BACKGROUND

The use of a knee orthosis is an established element in the treatment of certain injuries affecting the knee joint and the adjacent structures, whether this forms part of conservative treatment or of the follow-up care after surgery. The stabilizing properties of a hard-frame orthosis can be used for a wide variety of indications, such as in the treatment of collateral ligament lesions in the knee joint, following meniscus repair surgery, or surgery to stabilize a dislocated patella, as well as both prior to and following anterior or posterior cruciate ligament reconstruction (ACL and PCL). Alongside the active principle of four-point stabilization for femoro-tibial instability, an orthosis can be fitted and worn in order to limit the joint's range of motion. This prevents instability, especially during post-operative care, thus safeguarding the surgical outcome. The SecuTec Genu dorsal version is a Z splint, which is particularly suitable for patients suffering from knee injuries and a sensitive tibial edge. This knee orthosis is also available as a frontal version. The choice between the two versions provides increased flexibility when treating ligament and meniscus injuries as well as complex instabilities.

The aim of this non-interventional study was to investigate the use of the dorsal version of the SecuTec Genu knee orthosis in the conservative and post-operative treatment of knee injuries. The treating physician and orthotist as well as the patients were surveyed. The study examined parameters such as treatment goals and achieving the specified goals, handling and fitting of the orthosis, as well as fit, non-slip properties, and joint stabilization provided by the orthosis.

### STUDY DESIGN

Non-interventional, clinical study; case series, one-arm (evidence level 3)

### METHODOLOGY

Sample:	n = 38 patients; Age: 47.1 years ± 12.4 years Gender: 34 percent male; 66 percent female
Test orthosis:	SecuTec® Genu, dorsal version
Treatment duration:	On average 5.9 calendar weeks (± 1.9 calendar weeks)
Indication:	Ligament surgery/ syndesmoplasty 5.3 percent ACL/PCL rupture 5.3 percent Fracture of the patella 5.3 percent Instability 7.9 percent Restriction in the range of motion 76.3 percent
Additional treatments:	Physiotherapy 58 percent CPM dynamic splint 47 percent
Test method:	Data collection using a questionnaire
Study period:	Initial diagnosis at T1 and data collection during the second appointment T2
Data assessment:	Descriptive statistics

### SOURCE

Non-interventional study, unpublished data, Bauerfeind AG 2021

### TREATMENT GOALS AND THEIR ACHIEVEMENT AS IDENTIFIED BY THE PHYSICIAN

Data was collected in one practice. The physician's most important treatment goal was the restriction in the range of motion (ROM) for 79 percent of the patients. Furthermore, pain reduction (26.3 percent), knee joint relief (31.6 percent), and knee joint stabilization (26.3 percent) were important treatment goals. The achievement of the goal "restricting range of motion" was universally rated as "very good" (1.00) (Fig. 1). The achievement of the goals "pain reduction", "knee joint relief", and "knee joint stabilization" was rated as "good" (1.72 to 2.25) after an average of 6 weeks' treatment ( $5.9 \pm 1.9$  weeks).



Fig. 1: Treatment goals and achievement of goals when wearing the SecuTec Genu dorsal version (several options can be selected)

### PHYSICIAN'S SATISFACTION WITH THE ORTHOSIS

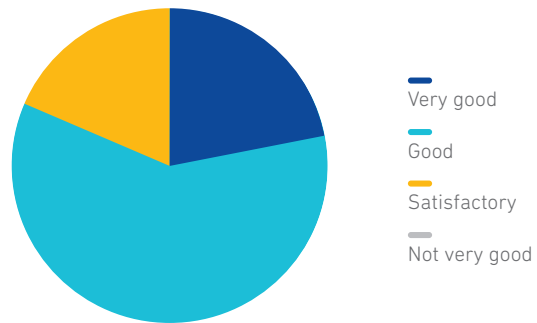


Overall, the treating physician was satisfied with the orthosis, even though, in 29 percent of cases, the physician reported that the orthosis was not easy to put on and was associated with major effort for the patient.

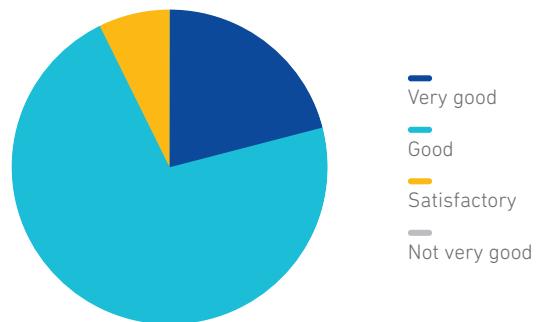
### ORTHOTIST'S ASSESSMENT OF THE ORTHOSIS

Both the axis adjustment and the handling of the limitation sets, as well as the fitting of the orthosis to the patient were, on average, rated as "good" by the orthotist (Fig. 2).

How would you rate the axis adjustment of the orthosis to the knee joint axis?



How would you rate the handling of the limitation sets?



How good is the fitting process of the orthosis to the patient for you?

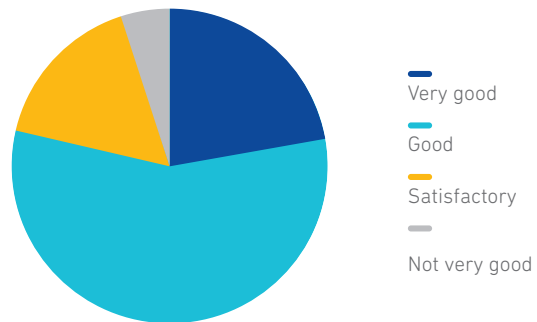


Fig. 2: Orthotist's assessment of the axis adjustment, handling, and fitting of the orthosis

The properties of the cushioning of the orthosis were largely rated as positive, and pressure relief, skin-friendliness, non-slip characteristics and breathability described as "applies" or "applies completely" (Tab. 1).

	Pressure relieving	Skin-friendly	Non-slip	Breathable
Applies completely	20.51%	28.21%	20.51%	25.64%
Applies	74.36%	71.79%	64.10%	74.36%
Applies to a lesser degree	5.13%	0.00%	15.39%	0.00%
Does not apply	0.00%	0.00%	0.00%	0.00%

Tab. 1: Orthotist's assessment of the cushioning

The dorsal design of the orthosis is highlighted as a positive characteristic in 13 percent of cases. In 28 percent, however, it is seen as a negative feature that makes putting on the orthosis harder.

## PATIENTS' ASSESSMENT OF THE ORTHOSIS

**Wearing duration:** On average, the orthosis was being worn for 18.3 hours, both during the day (97.4 percent) and at night (94.7 percent).

On average, the wearing comfort of the orthosis was rated 2.4 (= good), the fit 2.6 (= satisfactory), and putting on the orthosis 3.7 (= not very good) by patients. The secure positioning was rated 2.4 on average (= good) (Tab. 2).

	Wearing comfort	Fit	Donning of the orthosis	Secure positioning
Good / very good	60.53%	63.16%	23.68%	60.53%
Satisfactory	23.68%	23.68%	10.53%	28.95%
Not very good	13.16%	10.53%	36.84%	10.53%
Poor / very poor	2.63%	2.63%	28.95%	0.00%

Tab. 2: Patient feedback about the dorsal version of the SecuTec Genu knee orthosis

50 percent of participating patients perceived the weight of the orthosis as light; 50 percent as normal. The breathable cushioning made of microfiber was perceived by 2.6 percent of patients as "very pleasant" on the skin, by 26.3 percent as "pleasant", by 44.7 percent as "normal" and by 26.3 percent as "not very pleasant".

The knee joint stabilization provided by the orthosis was rated by 13.2 percent as "very good", by 68.4 percent as "good", by 15.8 percent as "satisfactory" and by 2.6 percent as "not very good". The feeling of protection provided by the knee orthosis was rated in 15.8 percent of cases as "very good", in 63.2 percent as "good", in 18.4 percent as "satisfactory" and in 2.6 percent as "not very good" (Fig. 3).

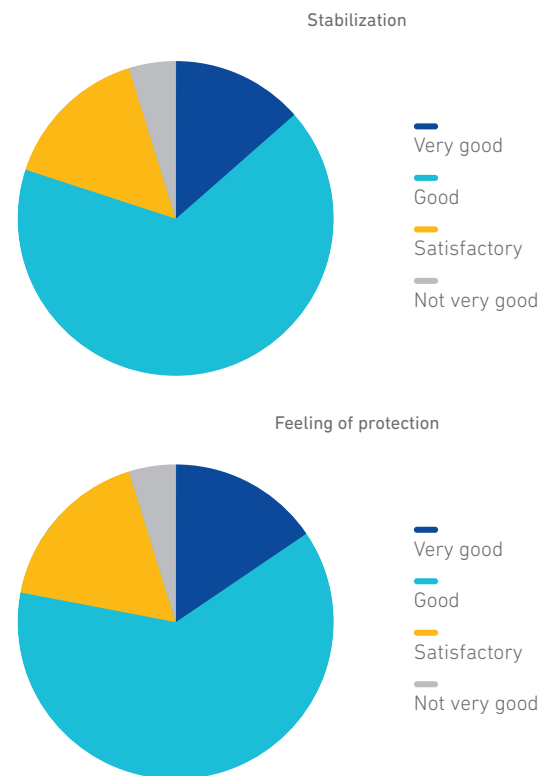


Fig. 3: Patient feedback about the effects of the dorsal version of the SecuTec Genu knee orthosis

89 percent of patients would continue to wear the orthosis if their physician recommended it. Furthermore, the majority (84.2 percent) was "satisfied" or "quite satisfied" with the orthosis in general.

## PATIENT SATISFACTION WITH THE ORTHOSIS



## DISCUSSION

Functional knee orthoses are used, for example, for the treatment of instabilities and in the post-operative recovery phase. They are designed so that usual joint kinematics are not restricted but the joint is protected from unintentional movement. Stabilizing knee orthoses enable activities to be performed within a range of motion (ROM) that prevents both pain and harmful movements.

As early as 2017, a non-interventional study demonstrated the significance of the SecuTec Genu in post-operative care [Whitepaper SecuTec Genu, Dr. Baum; 2017]. When data was collected, the frontal version was used exclusively, which is placed on the injured knee from the front and then secured. The study under consideration also showed that the SecuTec Genu dorsal version provides stabilization and an excellent feeling of protection.

These are important factors for early patient mobilization to counteract dystrophy and promote the development of muscles during follow-up care.

During treatment, the choice between the two SecuTec Genu versions, frontal and dorsal, therefore increases the physician's flexibility when prescribing a medical product.

## CONCLUSION

- +** The physician's primary goal, i.e. restriction of movement in the knee joint, is 100 percent achieved by the dorsal version of SecuTec Genu orthosis.
- +** Orthotists are satisfied with the handling, axis adjustment, and fitting of the dorsal version.
- +** The SecuTec Genu provides patients with stabilization and an excellent feeling of protection.
- +** The choice between a frontal and dorsal version of SecuTec Genu increases flexibility when selecting the right product.

## ACKNOWLEDGEMENT

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