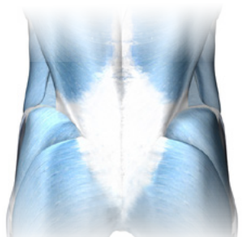
BAUERFEIND®

COLLECTED STUDIES
ORTHOPEDICS

Non-interventional studies using Bauerfeind supports and orthoses

CONTENTS

HAND/ARM



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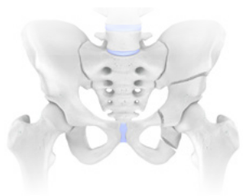

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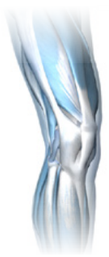


KNEE

ManuTrain®
CONSERVATIVE TREATMENT OF WRIST PROBLEMS

INTRODUCTION

Compression supports can be a useful aid to reduce pain, improve hand strength, and restore hand function in patients suffering from acute wrist problems with different causes.
Existing studies, however, present limited evidence of the effectiveness of conservative as well as post-operative rehabilitation measures designed to alleviate clinical signs and symptoms in the wrist.

This study was conducted with the goal of evaluating the clinical outcome for patients with regard to stabilization, relief, physical performance, and quality of life. Pain reduction and pain medication consumption were also documented.
During the study, patients suffering from acute wrist problems with different causes, such as tendovaginitis, ganglion, athralgia, and sprains, were treated conservatively using a bi-elastic compression support for the wrist.

METHOD

From August 2022 to January 2023, 23 patients were treated conservatively for wrist pain, using the ManuTrain support.
10 patients were diagnosed with tendovaginitis, 5 had sprained wrists. 2 patients were diagnosed with ganglion, 3 with athralgia, and one patient each with osteoarthritis, wrist instability, and ulnar styloid impaction syndrome. Before starting the study, 18 patients received analgesics, 3 used pain relief creams, and one patient underwent manual therapy.

Initial data was collected during the first medical appointment. Another survey was taken after 4 to 6 weeks. Using a DASH questionnaire, the functionality of the hand and wrist during everyday activities was analyzed, for example. The Mayo-Wrist questionnaire was used to evaluate the wrist's physiological functionality. The pain level as well as the perceived state of health were recorded using a 10-point VAS scale, and the ability to work was documented.

The evaluation included how often the support was worn, how easy the support was to use, how comfortable it was to wear, as well as how well it fit the patient, and how effectively it stabilized the wrist. Patients were also asked about their use of pain medication and how effectively they felt the support reduced pain.

Source: Neusser, M., et al., Non-interventional study; Bodensee Sports Clinic, Center for Orthopedics and Sports Medicine; Bauerfeind, internal data

RESULTS

Patients wore the support for an average of 5 weeks. They stated that they wore the support during the day for an average of 7.3 hours when being physically active. Most participants wore the support during the day (15 patients). Four patients wore it during the day and at night. About a third of patients wore the support when exercising, and another third during leisure activities. (Fig. 1)

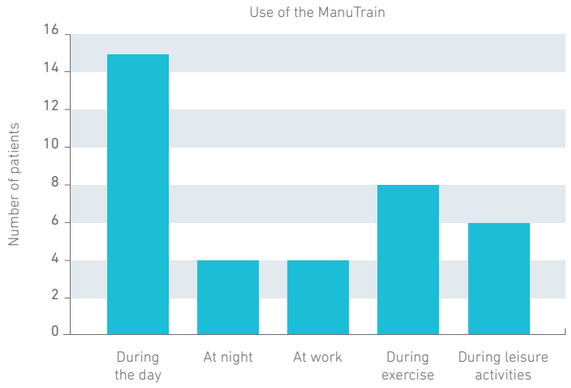


Fig. 1: Use of the ManuTrain from T1 to T2, after an average of 5 weeks, (patients; n total = 22; several answers are possible)

Patients themselves were able to assess their general state of health using a scale from 1 to 10: 1 representing "the worst state", 10 representing "the best state". Over the course of treatment, the general state of health improved by 1 to 5 points on the evaluation scale in 11 patients. 2 patients did not notice any difference, and the general state of health slightly deteriorated in 2 patients. On average, patients' perceived state of health improved from 5.9 to 7.5 on the scale. (Fig. 2)

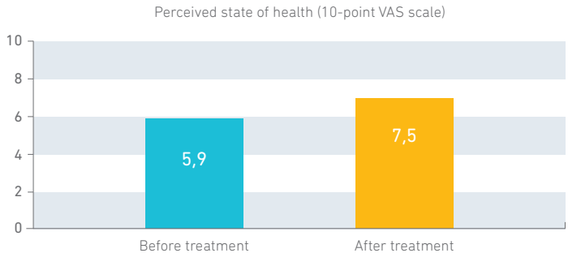


Fig. 2: Perceived state of health during T1 before treatment and during T2 after an average of 5 weeks

RESULTS

On a 10-point VAS scale, patients rated their wrist pain at a median of 7. (Min. = 4; 1st quartile = 6; median = 7; 3rd quartile = 8; max. = 10) (Fig. 3).

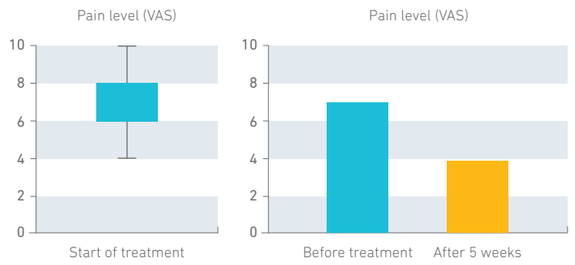


Fig. 3: Patients' pain level at the beginning of treatment
Fig. 4: Pain level at the beginning and after 5 weeks of treatment

At the beginning of the study (T1), the pain level was rated at an average of 6.9 on the 10-point VAS scale. After treatment, the pain was rated at an average of 3.9 on the 10-point VAS scale. This represents a pain reduction of 43 percent. 19 of 25 patients rated the pain reduction attributed to using the ManuTrain as "good" to "very good".
Wrist stabilization provided by the support was rated by 82.6 percent of patients as "very good".
The fit was rated by 91.3 percent of patients as "good" and "very good", donning of the product worked very well for 56.5 percent of patients. (Fig. 5)

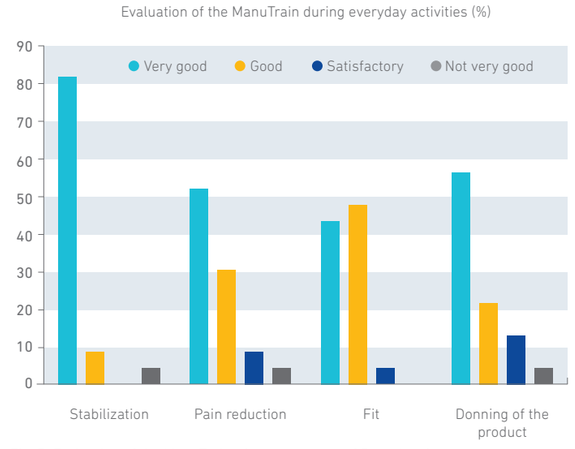


Fig. 5: Evaluation of the ManuTrain after an average of 5 weeks of treatment

The support's wearing comfort during everyday activities was predominantly rated as "good". 11 of 22 patients stated that they had "no restrictions", and 8 of 22 patients said they had "no significant restrictions". (No fig.)

Patients were surveyed before and after treatment using the Mayo questionnaire. It showed an improvement from 77 to 93 points out of a maximum of 100 possible points. (Fig. 6) The Mayo score basically describes the physiological functionality of the wrist. 100 points mean full range of motion and unrestricted wrist functionality. After being treated with the ManuTrain, patients reached a very high ("excellent") level of mobility and functionality with 93 points. All sub-scores included in the Mayo questionnaire demonstrated an improvement in functionality over the course of treatment. Pain was reduced, and grip strength as well as mobility of the wrist increased.

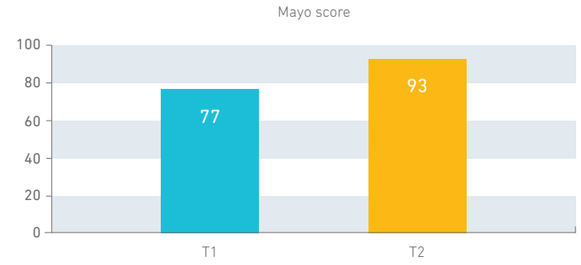


Fig. 6: Mayo score during T1 before treatment and during T2 after an average of 5 weeks of treatment with the ManuTrain (patients; n total = 22)

RESULTS

The DASH questionnaire records the performance of everyday activities before and after treatment. The DASH score shows an improvement, i.e. a reduction from 35.5 to 8.3 points.
The minimal DASH score of 0 points means full functionality during everyday activities, such as opening a jar with a screw cap or turning a key in a lock. The maximum of 100 points, on the other hand, means significant limitations during everyday activities. They can be carried out only with major problems or patients are not able to do them at all. At the beginning of treatment, patients were noticeably restricted in everyday functionality, which is reflected by the score of 35.5 points. After an average of 5 weeks of treatment, significant improvement was recorded, with the score reaching 8.3 points. (Fig. 7) This represents almost full functionality during everyday activities. Patients were able to perform important actions almost without restrictions again. This includes personal hygiene and independent housekeeping.

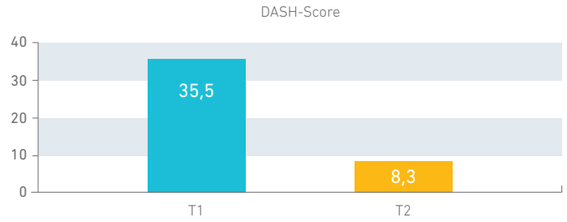


Fig. 7: DASH score during T1 before treatment and during T2 after an average of 5 weeks of treatment with the ManuTrain (patients; n total = 20)

ADVERSE REACTIONS, ADVERSE EVENTS

None of the 23 patients suffered any adverse effects for the 4 to 6 weeks of wearing the support. Neither did any adverse events occur in any of the patients.

DISCUSSION

During the conservative treatment of wrist problems, the use of compression supports is designed to stabilize the wrist and reduce pain, for example. Another clinical study showed that gymnasts who suffered from wrist problems and who wore a wrist support during training on the pommel horse, floor, and beam, were in significantly less pain than without a medical aid. [1] The patients in this study also noticed a significant pain reduction when using the ManuTrain.
Another treatment goal is the restoration of full wrist functionality and the associated ability to carry out everyday activities independently and entirely. **Conservative treatment using the ManuTrain showed that patients confirmed excellent effectiveness related to stability perception and the ability to carry out everyday activities.**
In cases of serious injuries, such as a distal radius torus fracture, the use of a wrist support in children aged 4 to 15, also showed the same outcome as treatment using a rigid orthosis or a plaster cast with regard to pain, functionality, quality of life, complication rate, and days off school. [Daniel C Perry, et al.]
Because the product is "inconspicuous" and does not cause adverse effects, this study also demonstrated that using the **ManuTrain is low-risk, in addition to its proven effectiveness.**
Further data acquisition is desirable to confirm the existing findings.

CONCLUSIONS

- Pain reduction by 43 percent on average with the ManuTrain
- Significant improvement in wrist stability with the ManuTrain
- The ManuTrain provides an excellent perception of stability
- The ManuTrain provides excellent wearing comfort

We would like to thank Dr. med. Markus Neusser and Dr. med. Diesch †,
Bodensee Sports Clinic, Center for Orthopedics and Sports Medicine, for conducting the study.

Sources: [1] B., Trevithick, R., Mellifont, M., Sayers, **Wrist pain in gymnasts: Efficacy of a wrist brace to decrease wrist pain while performing gymnastics**, Journal of Hand Therapy 33 (2020) 354e360;
D., C., Perry. et al., **Offer of a bandage versus rigid immobilisation in 4- to 15-year-olds with distal radius torus fractures: the FORCE equivalence RCT.**
Health Technol Assess. 2022 Jul; 26(33): 1–78., doi: 10.3310/BDNS6122

ManuLoc® long

POST-OPERATIVE TREATMENT OF A DISTAL RADIUS FRACTURE WITH THE MANULOC LONG ORTHOSIS

Dr. med. Peter Katzmaier,
MVZ Oberstdorf

INTRODUCTION

Distal radius fractures nearly always occur when patients put their hand out to cushion their fall. Symptoms include pain, especially when rotating the hand outward (supination) and rotating the forearm, loss of strength, sensation or function problems, or visible misalignment and/or swelling in the forearm.

METHOD (REFERENCE TO MVZ OBERSTDORF)

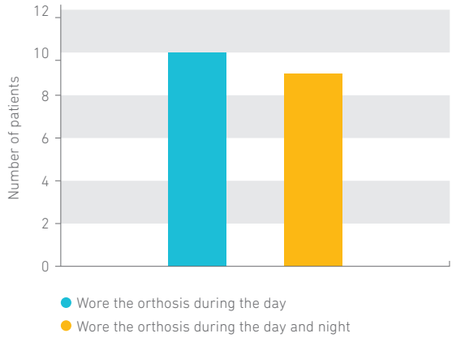
Between October 2015 and March 2016, 13 patients were supplied with the ManuLoc long orthosis on the first day after surgery to correct a distal fracture of the forearm. The patients were examined when they were discharged from hospital (Day 2 after surgery), when they had their sutures removed (Day 12 after surgery), and after 6 weeks. X-rays were taken of the wrist during the first and third data collection appointments.

All patients were treated using palmar locking-plate osteosynthesis for distal forearm or radius fractures near a joint. Officially, patients were advised not to move their arm for two weeks. After two weeks of uninterrupted immobilization of the affected arm, patients were allowed to exercise their arm without the splint. Patients were able to choose whether to continue using the splint.

The study recorded the patients' DASH score, the Mayo wrist score, pain sensation (VAS), patient rating of their general state of health (VAS), and their ability to work. In each case, data on how often the orthosis was worn, how easy the orthosis was to handle, how comfortable it was to wear, and how well it fit the patient and stabilized the arm was recorded. Patients were also asked about their use of painkillers and how well they felt the orthosis reduced pain.

RESULTS[1]

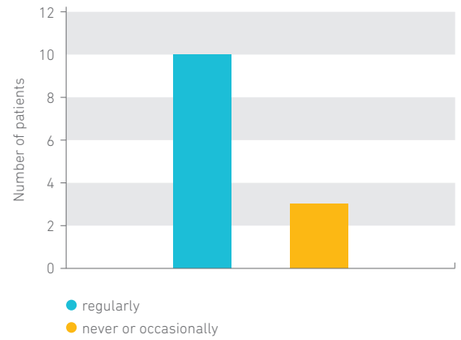
ManuLoc wearing period
Time: six weeks after surgery



As it was so comfortable to wear, patients continued to wear the orthosis even after it was no longer required by their physician.

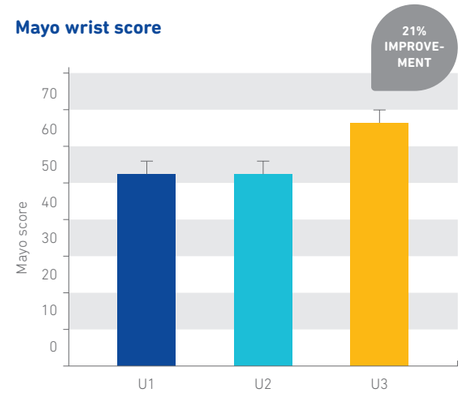
RESULTS

ManuLoc long compliance
Time: six weeks after surgery

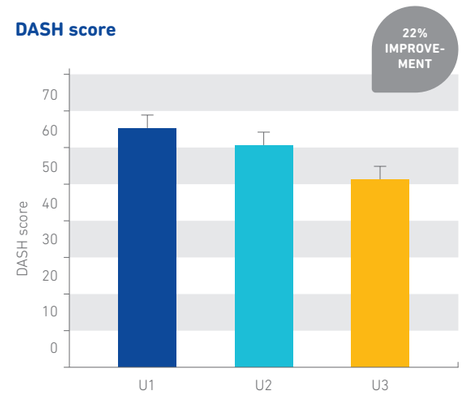


Nearly 80 percent of patients regularly wear the orthosis even after the six-week period as it stabilizes the arm well and is extremely comfortable to wear.

Mayo wrist score



DASH score



The Mayo and DASH scores improve over the course of the treatment with ManuLoc long, which corresponds to the healing process in treatment with a cast.

CONCLUSIONS with reference to post-operative treatment using the ManuLoc long orthosis

- High level of wearing comfort and the perfect fit
- Significant pain reduction
- High hand functionality
- Protection whilst rebuilding strength

1 First published in Bauerfeind Life issue 3 in 2016. The full article can be accessed at bauerfeind-life.de.

ManuLoc® long

EFFECTS OF A HAND ORTHOSIS ON PATIENTS SUFFERING FROM VARIOUS WRIST PROBLEMS

INTRODUCTION

The wrist must be stabilized and immobilized in the case of many injuries and conditions to alleviate pain, accelerate healing, or secure the outcome of surgery.

There are various options to stabilize the wrist: a classic plaster cast or an immobilizing orthosis as an alternative.

The objective of the study is to describe and evaluate the practical use of a hand orthosis for different indications.

METHODOLOGY

Between January 2019 and September 2019, 86 patients were supplied with the ManuLoc long orthosis in 26 orthopedics practices. About two thirds of the patients were female, one third was male. The average age was 52.5 years. 50 percent of patients were between 36 and 67.5 years old. (Fig. 1)

In each case, data on how often the orthosis was worn, how easy it was to handle, how comfortable it was to wear, and how well it fit patients was recorded. Patients were also asked about stabilization, support of the hand function, and how effectively they felt the orthosis reduced pain. Data was recorded by the treating physicians as well as by patients.

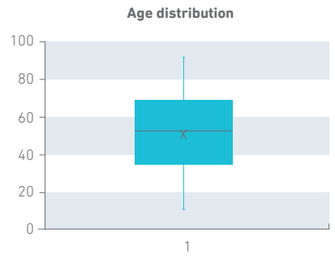


Fig. 1: Age distribution of patients treated, n = 86, box plot illustration, y axis = age in years

RESULTS

Treatment with the ManuLoc long took an average of 5.4 weeks, with 50 percent of all treatment being between 4 and 7.25 weeks. During the treatment period, the ManuLoc long was worn for at least 3 hours by 8 percent of patients, around 40 percent wore it for 5-8 hours, and more than 50 percent wore it for over 8 hours. (Fig. 2)

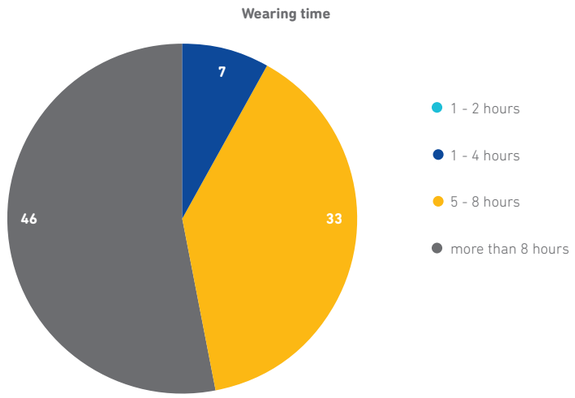


Fig. 2: Number of patients – orthosis wearing duration in hours/day

RESULTS

The two most common indications were post-traumatic, such as "distal radius fracture" and "tenosynovitis". (Fig. 3, Fig. 4)

The ManuLoc long was used in a pre-operative setting in 11 percent of cases, post-operatively in 31 percent, and 58 percent of patients were treated conservatively. (No fig.)

68 percent of patients were also treated with an additional or several concomitant therapies. For the majority, anti-inflammatories, analgesics, and/or physiotherapy were prescribed in addition to the ManuLoc long. In some cases, manual therapy or stimulating electrical current was administered.

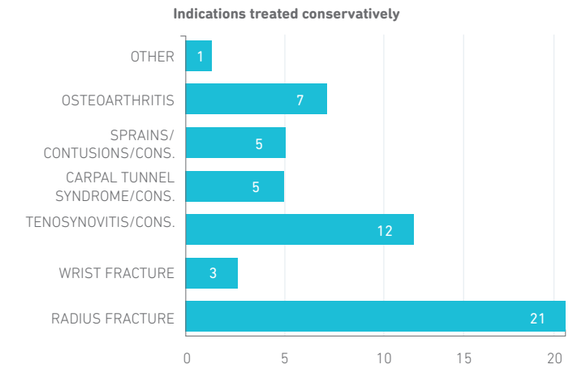


Fig. 3: Number of patients treated conservatively

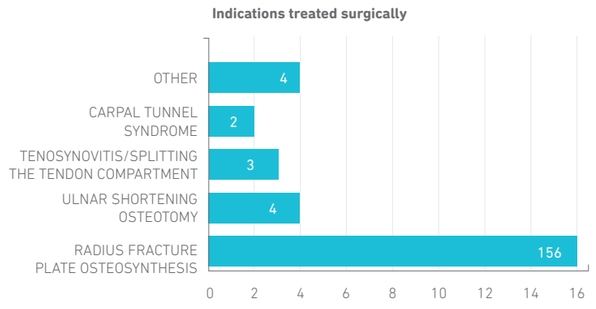


Fig. 4: Number of patients treated post-operatively

ASSESSMENT BY PHYSICIANS

Physicians rated stabilization by the ManuLoc long orthosis as good to very good in 97 percent of cases. (Fig. 5)

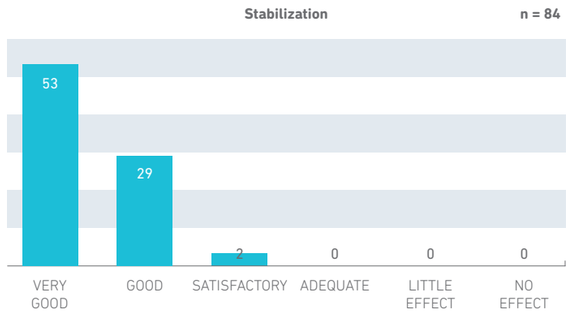


Fig. 5: Assessment of stabilization by the treating physicians

The treating physicians believed that in 87 percent of indications in this study, early functional treatment using the ManuLoc long would be possible to very much possible. (Fig. 6)

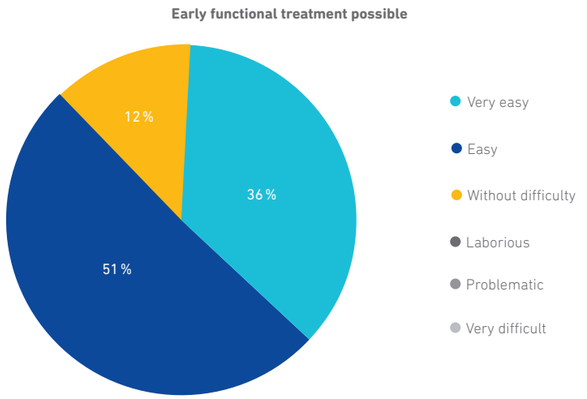


Fig. 6: Assessment of early functional treatment by the physicians

In 100 percent of cases, the physicians rated the ManuLoc long as a good to very good alternative to a plaster cast.

Source: Bauerfeind, internal data

PATIENT ASSESSMENT

94 percent of patients rated the stabilization and the feeling of protection exerted by the ManuLoc long as good to very good. (Fig. 7)

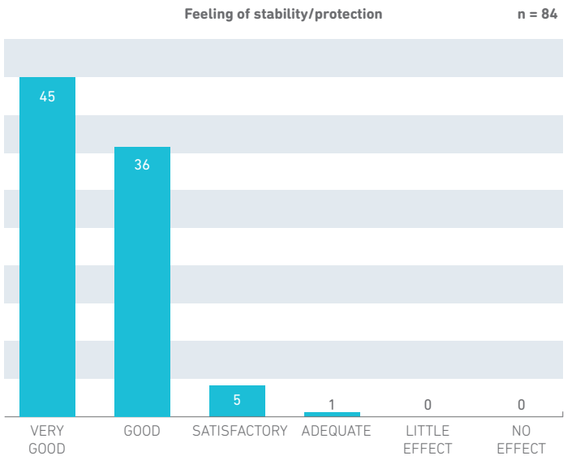


Fig. 7: Patient assessment relating to feeling of stability

On average, pain felt by patients before treatment was rated 6 using the VAS scale.
After an average of 5.4 weeks, 73 of 86 patients reported that they experienced less to significantly less pain when wearing the ManuLoc long. 11 patients actually felt no pain after the treatment period. (Fig. 8)

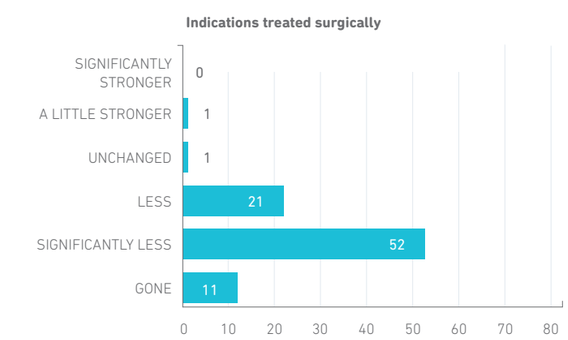


Fig. 8: Pain perception after 5.4 weeks of treatment using the ManuLoc long

26 percent of patients rated wearing comfort, such as breathability, skin friendliness, or weight of the orthosis as excellent, 64 percent as good.

91 percent of patients rated the fit as good to excellent.

Donning and doffing of the ManuLoc long was rated as easy to very easy by 91 percent of patients.

77 percent of patients were able to perform everyday activities, such as light work in the kitchen or garden, shopping, etc., without restrictions, or perform them well when using the ManuLoc long. (Fig. 9)

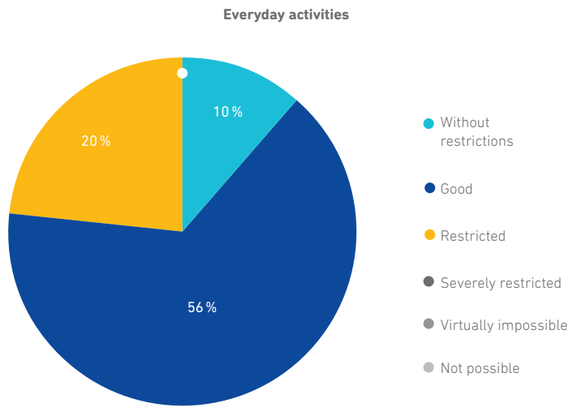


Fig. 9: Number of patients; how possible the use of the hand is during everyday activities

When asked about grasping movements with the fingers, e.g. to hold a comb, pen, or cutlery, about 85 percent of patients reported that this was possible without restrictions or that they were able to do it well using the ManuLoc long.

CONCLUSIONS

- → Rated as good to very good by physicians and patients in most cases
- → Stabilizes the wrist in extension/flexion as well as in a radial/ulnar direction
- → Excellent wearing characteristics, such as fit, breathability, and skin-friendliness
- → Significant pain reduction in most patients

LumboLoc® Forte

THE EFFECT OF A LUMBAR ORTHOSIS ON PAIN PERCEPTION AND MOBILITY IN PATIENTS SUFFERING FROM LUMBAR BACK PAIN

BACKGROUND

Lightweight lumbar orthoses following the orthopedic design of a traditional lumbar support brace are anatomically contoured. Thanks to the reinforcements/stays or pads integrated at the back, they provide the spine with effective stabilization and relief, and have a muscle-activating effect.

One of the goals of the study is to determine the extent of lightweight lumbar orthosis use. We are also interested in finding out what additional treatment is implemented in combination with a back orthosis. Furthermore, data is recorded showing the clinical effect of the back orthosis and how patients perceive it.

METHODOLOGY

Study design:	Non-interventional, clinical, prospective cross-sectional study; case series, one-arm
Study director:	Prof. Dr. med. Alexander Katzer; Orthopedics and Trauma Surgery; ORTHOCLINIC HAMBURG
Sample:	**n = 100 patients;** Age: 59.3 ± 18 years Gender: male = 36 female = 64
Test orthosis:	LumboLoc Forte (Bauerfeind AG)
Measurement systems and test procedures:	Data collection using a questionnaire
Investigation period:	Data collection took place after the second visit T2, on average after five weeks, following initial diagnosis, T1.
Data assessment:	Descriptive statistics for the different points in time using the overall data
Inclusion criteria:	Diagnosis of an indication relevant to the back orthosis
Exclusion criteria:	Additional, acute injuries and/or conditions that have a direct impact on the parameters of the data collected

RESULTS

Indications for a lumbar orthosis
Out of 100 patients who were treated with a lumbar orthosis, 30 percent were diagnosed with low back pain, followed by 16 percent who were diagnosed with lumbago. 19 percent of indications were SI joint syndrome. These three indications make up around two thirds of observed conditions that are treated with lumbar orthoses.
Other indications where lumbar orthoses are prescribed are intervertebral disk conditions (protrusion and prolapse 7 percent), root irritation (6 percent), and facet syndrome or spondylolysis (5 percent) as well as vertebral displacement (4 percent).
For other, less common indications, see Fig. 1.

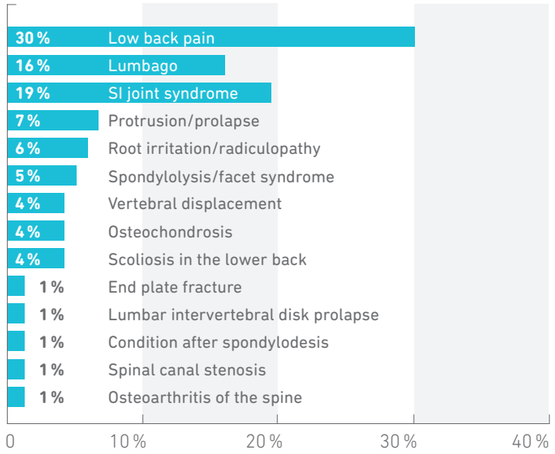


Fig. 1: Indications for lumbar orthosis use, 100 patients surveyed

TREATMENT REGIME

In 34 percent of cases, only a lumbar orthosis was prescribed, in 66 percent of cases, at least one other intervention in addition to the lumbar orthosis was implemented.
28 percent of patients also did physiotherapy. Analgesics (4 percent), manual therapy (3 percent), or acupuncture (2 percent) were prescribed less often as a second treatment measure in addition to the orthosis.
In 29 percent of cases, **two** other treatment measures were implemented in addition to the orthosis, with the most common combinations being orthosis plus analgesics and acupuncture (6 percent), and orthosis plus analgesics and physiotherapy (6 percent). Overall, at 44 percent, physiotherapy is the most frequently prescribed treatment in addition to a lumbar orthosis. (Fig. 2)

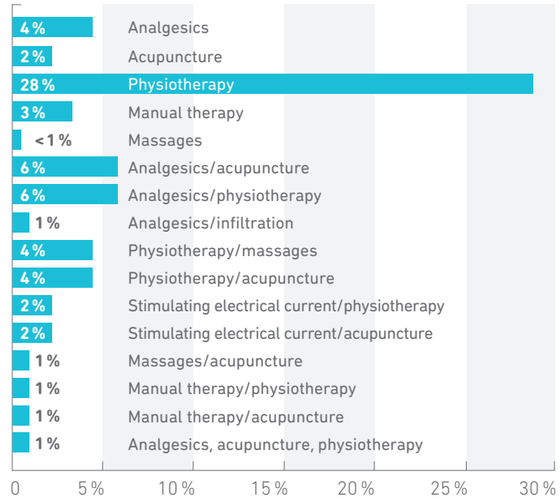


Fig. 2: Frequency of additional treatment options prescribed together with a lumbar orthosis in [%], n = 100

Source: Bauerfeind, internal data

TREATMENT GOALS

The three treatment goals most often mentioned, and therefore most important, were pain reduction (85 percent), improvement of mobility (49 percent), and the associated increase of patient mobility (42 percent). Achievement of the goal was rated as good (rating 2.29 to 2.05) after an average of five weeks (5.13 / +- 1.63 calendar weeks) of treatment. (Fig. 3)

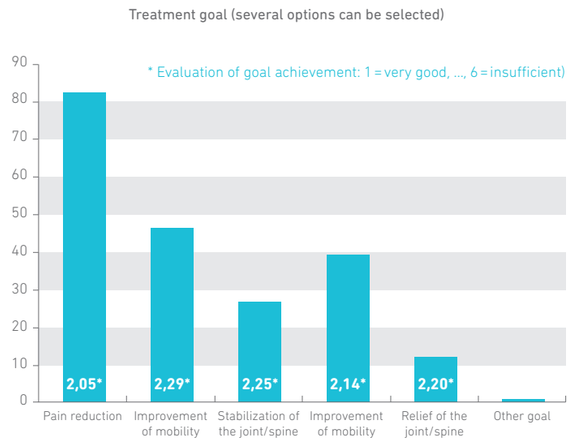


Fig. 3: Treatment goal for prescribing the lumbar orthosis, y axis = number of mentions, n = 97

COMPLIANCE

The majority of patients (61 percent) indicated that they wore the orthosis for 3 to 4 hours per day. About a third of patients (29 percent) indicated that they wore the orthosis for 5 to 8 hours per day.
Few patients (6 percent) wore the orthosis only occasionally for 1 to 2 hours per day. 4 percent of patients wore the orthosis more than 8 hours per day. (Fig. 4)

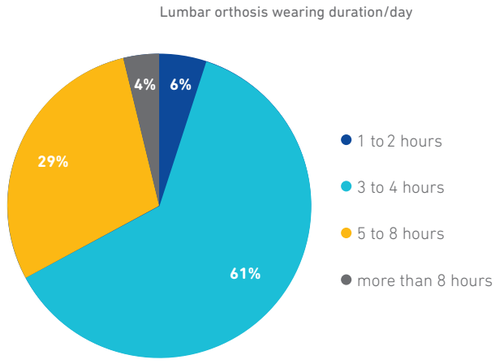


Fig. 4: Proportional distribution of the wearing duration of the orthosis/day, 100 patients surveyed according to their own reports, n = 100

ORTHOSIS USE

A quarter of patients used the lumbar orthosis for the entire day. The majority of patients (41 percent) used the orthosis at work. 13 percent of patients wore the orthosis during leisure activities, 5 percent during exercise, and 2 percent even at night. (Fig. 5)

93 percent of patients rated the handling of the orthosis as without difficulty or very easy (average rating = 2.3). 79 percent of patients rated the fit as good to excellent, 19 percent of patients rated it as satisfactory (average rating = 2.2).
68 percent of patients rated the wearing comfort as good to very good, 29 percent of patients rated it as satisfactory (average rating = 2.3) (no fig.).

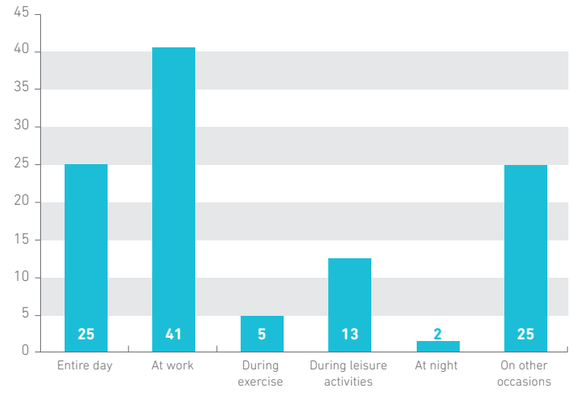


Fig. 5: Situations in which patients wore the lumbar orthosis during an average period of five weeks, n = 100, several options could be selected; (y axis = number of mentions)

STABILIZATION AND FEELING OF PROTECTION

78 percent of patients rated the perceived stabilization of the orthosis and the associated feeling of protection as good to very good, 20 percent rated it as satisfactory. 2 percent of patients noted very little to no stabilization as a result of wearing the orthosis. (Fig. 6)

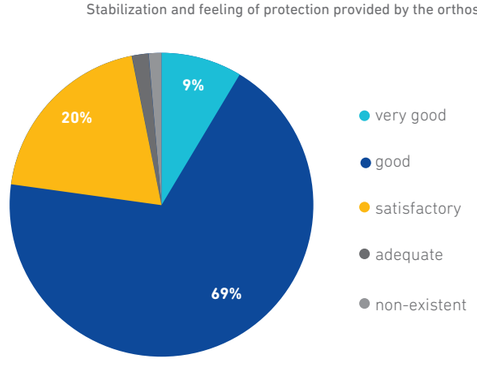


Fig. 6: Assessment of stabilization and feeling of protection provided by the orthosis, rated by 100 patients after an average orthosis wearing duration of five weeks, n = 100

PAIN REDUCTION

The 100 patients surveyed before treatment with a lumbar orthosis rated their pain level at an average of 6.5 on a 10-point VAS scale. After using the orthosis,
pain perception significantly reduced by 2.2 to 4.3 on the 10-point VAS scale after an average of five weeks. (Fig. 7)
50 percent of patients indicated that they were not taking pain medication in addition to their treatment with the orthosis.
1 percent of patients indicated that they were taking pain medication three times a day, 26 percent once to twice a day, 14 percent every other day, and 9 percent only once a week.
Since only 18 percent of patients were prescribed analgesics, the other patients (32 percent) must have been taking additional pain medication at their own discretion.
Of the 50 patients who took pain medication, 72 percent indicated that they were able to reduce their previous pain medication consumption as a result of wearing the orthosis.

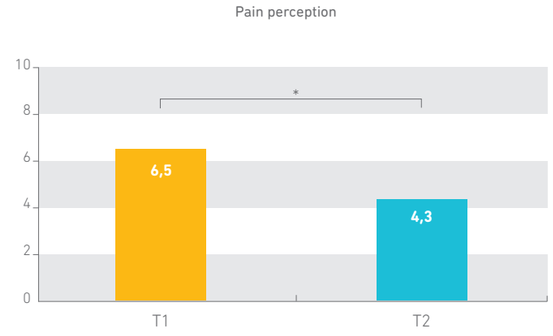


Fig. 7: Pain perception, averages; at T1 (before treatment with the lumbar orthosis) and at T2 (after an average of five weeks' treatment with the orthosis), y axis: 10-point VAS scale; n = 100; (* $p < 0.001$, $\alpha < 0.05$; power, $\beta = 80$ percent; paired t-test)

MOBILITY

Before treatment, patient mobility was rated at an average of 5.1 on a 10-point VAS scale. After five weeks of treatment with the lumbar orthosis, patient mobility increased significantly. On average, an improvement by 1.3 points, i.e. a value of 6.4 was reported. (Fig. 8)

69 percent of patients reported no problems or restrictions when carrying out everyday activities with the orthosis, 28 percent of patients reported minor restrictions only (no fig.).

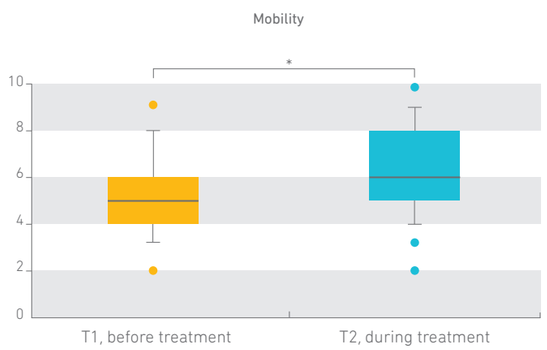


Fig. 8: Box plot showing: Median with quartiles; comparing patient mobility before treatment with the lumbar orthosis and after an average of five weeks' treatment with the orthosis, y axis: 10-point VAS scale; n = 95; (* $p < 0.001$, $\alpha < 0.05$; power, $\beta = 80$ percent; Wilcoxon Signed Ranks Test)

DISCUSSION

Previous studies already showed a clinical effect of lumbar orthoses.
Even during an observational period of two weeks, wearing an orthosis in cases of acute, subacute, and chronic low back pain (LBP) resulted in an improvement of the self-assessed functionality of avoidance posture as well as patients' pain perception. [1]
This corresponds to patient statements from this study concerning pain perception and mobility with both comparable indications as the previous study and additional indications in the lumbar spine area, see Fig. 1.

Another study with patients suffering from degenerative lumbar spinal stenosis proved a mobilizing effect as a result of wearing the orthosis. Neurogenic claudication was improved so much by wearing an orthosis that patients' pain-free walking distance significantly increased compared with walking without an orthosis. [2]

Effects of lumbar orthoses were also confirmed during extended treatment of several months. Significant improvements were observed when examining the functional status of patients being treated with orthoses for subacute LBP for three months, compared to patients who did not receive an orthosis. [3]
Additionally, the study recorded decreased consumption of LBP-related medication in patients who were treated with an orthosis. This observation was also made in this study where the majority of patients reported that they were able to decrease their pain medication, thanks to the lumbar orthosis.

CONCLUSIONS

- The LumboLoc Forte lumbar orthosis is used for a **wide range of indications.**
- Overall, the majority of patients (71 percent) was **happy to very happy with the orthosis.**
- The orthosis provides **clinically relevant pain reduction**. This also manifested in the fact that, according to patients, **wearing the orthosis** decreased **consumption of pain** medication.
- **Less pain, additional stabilization, as well as an improved feeling of protection all resulted in a significantly noticeable increase in patient mobility.**

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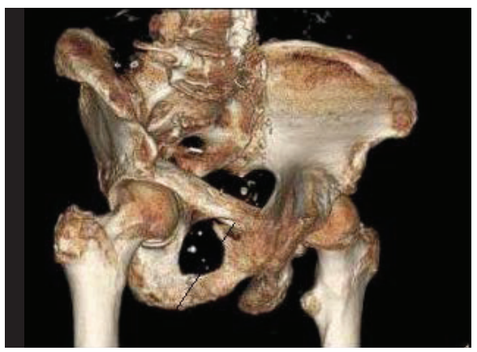
SacroLoc®
USING THE PELVIC ORTHOSIS TO TREAT PELVIC BRIM FRACTURES

Prof. Dr. med. Rolf Haaker,
Orthopedics Clinic, St. Vincent Hospital, Brakel

INTRODUCTION

Unlike complete pelvic ring fractures, pelvic brim fractures are characterized by the fact that they are isolated to the upper pubic rami or ischium and usually only affect one side, but can also be bilateral injuries [1]. Pelvic brim fractures are particularly painful as the walking load applied to the sacroiliac joint during the nutation movement causes movement in the area of the fracture. In the past, patients have generally been immobilized for 14 to 21 days as a result of the severe pain they experienced. The period of immobilization caused by pain is long in cases of an isolated pubic rami fracture in an elderly person in particular and mobilization is a slow process, even when pressure is relieved from the leg of the affected side of the pelvic rami [1].
The aim of this study was to investigate the influence of a pelvic orthosis (SacroLoc) on immobilization time and the consumption of pain medication in patients with pelvic brim fractures.



3D reconstruction of upper pubic rami fracture

STUDY DESIGN

Case series

METHODOLOGY

Sample:	n = 18, Age: 64 – 90 years, 16 women and 2 men
Indications:	17× stable pelvic fractures, most of which were osteoporotic in nature 1× unstable pelvic fracture with concomitant os sacrum fracture
Treatment:	· Pain therapy with opiates · Physiotherapeutic early mobilization on crutches from the fifth or sixth day as an inpatient · Pelvic orthosis
Test orthosis:	SacroLoc (Bauerfeind AG)
Data assessment:	Descriptive statistics

RESULTS

In all 18 cases, in comparison to the previous procedure in which the patients were immobilized for 14 to 21 days, a significantly earlier start of mobilization was achieved after 8 to 10 days with the protection offered by the SacroLoc orthosis (Fig. 1).
Patients also reported a reduction in pain on weight-bearing which was reflected in a significantly reduced opiate requirement, in most cases until the day of discharge on day 8 to 10 (no fig.).

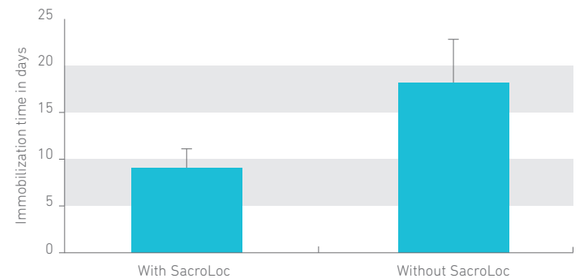


Fig. 1: Immobilization time with and without SacroLoc

DISCUSSION

Due to the changing age structure of the population with increasing prevalence of senile osteoporosis, a rapid increase in pelvic brim fractures and unstable pelvic ring fractures is observed [2]. Furthermore, pubic rami fractures are not only common in geriatric patients in the context of accidents involving minimal force, they also occur in rare cases as fatigue fractures in athletes [2].
The use of the SacroLoc pelvic orthosis in this observational study led to earlier mobilization and lower pain medication consumption in patients with pelvic brim fractures. The effect of the orthosis can be explained in terms of an external compression of the pelvic girdle with reduction of the scissor movements when the leg is standing and swinging [2]. In a study by Sichting et al., it was shown using a computer model that the compressive force exerted by the pelvic orthosis causes a counternutation in the sacroiliac joint (SI) joint, thereby restricting the scope of physiological movement [3]. This effect is also reflected in the stress applied to the ligaments involved in this movement. The stretching of the ligaments in the posterior pelvic ring is significantly reduced as a potential site for nociceptive input. These results indicate that the use of a pelvic orthosis such as the SacroLoc can reduce pain in the area of the pelvis and thus allow earlier mobilization of patients.
In summary, it can be assumed that an extension of the SacroLoc indication to include pelvic brim fractures is sensible and appropriate [1].

CONCLUSIONS

- → Early mobilization
- → Lower consumption of pain medication

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Rev. 1 – 2020- 04

CoxaTrain®
CONSERVATIVE TREATMENT OF HIP PROBLEMS

INTRODUCTION

Osteoarthritis is the most common joint condition in the world. During advanced stages in particular, it results in pain and loss of joint movement.

The percentage of those suffering from osteoarthritis significantly increases with age; from the age of 65, almost half of all women in Germany (48.1 percent) and nearly a third of men (31.2 percent) are affected.[1] The development of effective conservative treatment strategies is key because joint replacement, in cases of osteoarthritis of the hip for example, is only indicated in the final stage. Hip orthoses are a possible element in the conservative treatment of osteoarthritis of the hip.

This non-interventional study was conducted with the goal of evaluating the clinical outcome for patients with regard to pain reduction, joint stability, and mobility. Data collection also included the situations in which the orthosis was worn, what patients thought about wearing comfort, and how easily everyday activities could be performed.

To this end, patients suffering from different severities of osteoarthritis of the hip were conservatively treated with a flexible hip orthosis.

METHOD

From June 2022 to November 2023, 57 patients (34 women/ 23 men) with hip pain were conservatively treated with the CoxaTrain orthosis.

44 patients were diagnosed with osteoarthritis of the hip, six had coxalgia. Three patients were diagnosed with impingement of the hip joint, three with trochanteric bursitis, and one patient with labrum lesion. Some patients were diagnosed with several conditions, such as additional muscle imbalance, a feeling of instability, and/or hip dysplasia or osteoarthritis of the hip together with impingement of the hip joint.

19 patients took analgesics before participating in the study, 13 patients underwent physiotherapy. Nine additionally took part in rehabilitation exercise. A third each of nine patients were treated with shockwave therapy, infiltration therapy, or acupuncture.

When data was collected, the treating physicians asked patients about treatment goals. The three most common goals for the conservative treatment of osteoarthritis of the hip included: reducing pain, relieving the hip joint, and maintaining mobility. (Fig. 1)

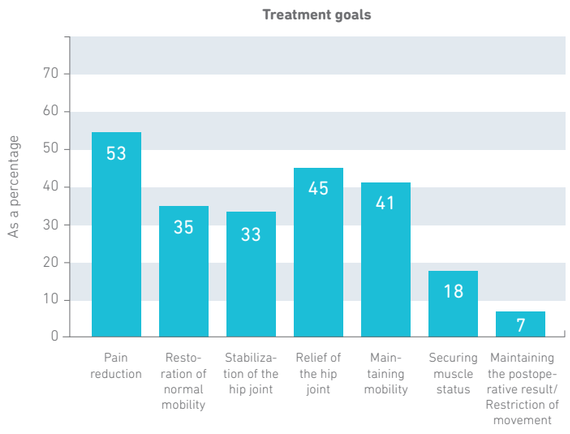

Fig. 1: Treatment goals, treating physicians' assessment, several answers possible

During the patients' follow-up appointment, physicians were asked how effective they thought treatment using the hip orthosis was, on a scale of 1 = excellent to 5 = poor.

Achieving the three most common treatment goals was rated by physicians as 1.9 on average. The four additional treatment goals were rated as 2.0. to 2.2 on average.

Source: Non-interventional study, 5 orthopedics practices Bauerfeind, internal data

RESULTS

The investigation period for each patient using the orthosis was 7.6 weeks on average. Patients stated that they wore the orthosis for an average of 4.6 hours per day.

When asked in which situations patients donned the orthosis (several answers were possible), 49.1 percent stated during leisure activities, 21.1 percent wore it the entire day, 38.6 percent at work, 19.3 percent during exercise, and 1.8 percent at night. (Fig. 2)

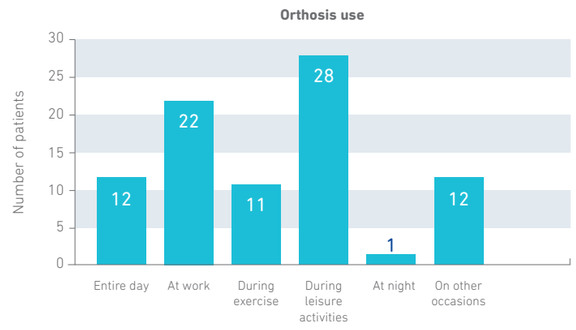

Fig. 2: The diagram shows in which situations the orthosis was worn. (Patients n total = 57, several answers were possible)

Pain perception was recorded using a 10-point VAS scale. Pain reduced by an average of 3.1 points, from 6.5 to 3.4. This represents a pain reduction by 47.7 percent (Fig. 3)

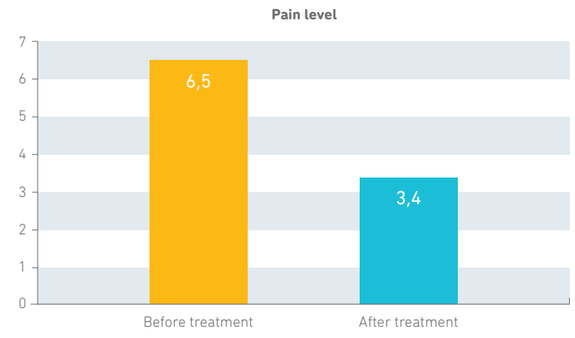

Fig. 3: Pain perception rated on a 10-point VAS scale; 0 = no pain to 10 = extremely serious pain

27 patients regularly took pain medication.
13 of these were able to reduce the amount of pain medication during treatment, thanks to the orthosis, seven stayed with the same amount. Seven patients did not provide information.

22 patients (38.6 percent) stated that the orthosis provided good to very good support and confidence during treatment. 11 patients (19.3 percent) felt it was satisfactory, 14 patients (24.6 percent) adequate, four patients (7 percent) felt they were not supported very well.

The following assessments were made on a 10-point VAS scale:
the feeling of stability when walking on even, firm ground improved by an average of 2.3 points on the scale with the orthosis.
The feeling of stability when walking on uneven ground increased by an average of 2.6 points.
The feeling of stability when walking downstairs improved by an average of 2.5 points with the orthosis.
The feeling of stability when standing improved by an average of 2.1 points on the scale with the orthosis. (Fig. 4)

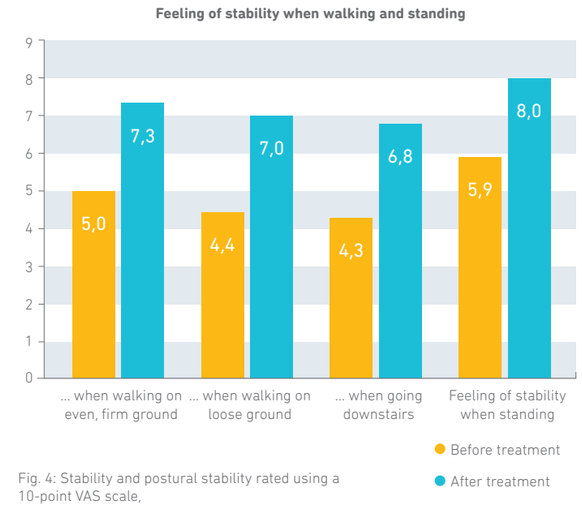

Fig. 4: Stability and postural stability rated using a 10-point VAS scale,
0 = very bad feeling to 10 = very good feeling

When asked about the estimated maximum walking distance without pain, the following statements were made:
The walking distance without pain was rated as 4.1 on a 10-point VAS scale without the orthosis (0 = short/10 = long), with the orthosis, the average was 6.6 – which is an additional 61 percent. Wearing the orthosis increased the pain-free walking distance significantly (no fig.).

When asked: "How good is your mobility during everyday and leisure activities?", patients stated an average of 4.2 without the orthosis and 7.2 with the orthosis on a 10-point VAS scale. This represents an improvement in mobility of 71.4 percent. (Fig. 5)

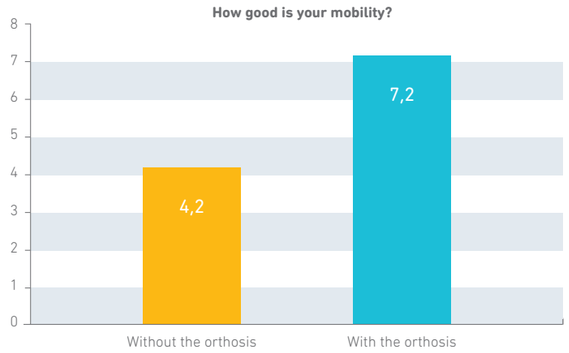

Fig. 5: Mobility rated using a 10-point VAS scale,
0 = very bad to 10 = very good

During gentle everyday activities and activities that subject the body to more strain, patients faced major limitations before being treated with the orthosis.

Patients gave a rating of 5.1 on average for gentle activities without the orthosis. With the orthosis, the situation improved to 6.9, which represents an additional 35.3 percent. Everyday activities that subject the body to more strain were rated as 4.4 without the orthosis and as 6.2 with the orthosis, which is an additional 40.9 percent (Fig. 6).

The orthosis helps perform everyday activities better with noticeably fewer limitations.

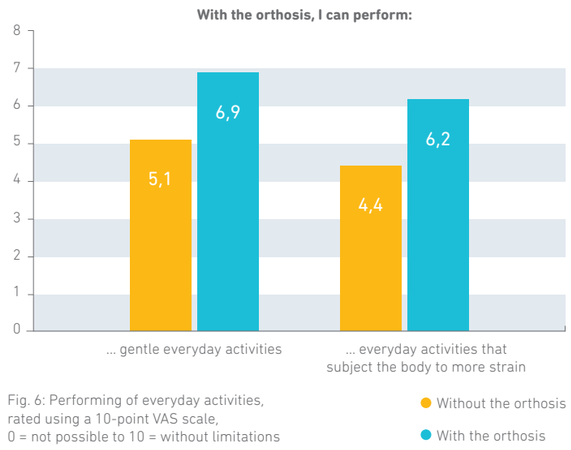

Fig. 6: Performing of everyday activities, rated using a 10-point VAS scale,
0 = not possible to 10 = without limitations

Handling/donning of the orthosis was perceived as easy to very easy by 70.2 percent, without problems by 17.5 percent, and as strenuous to problematic by 12.3 percent; nobody found it very difficult.
The fit and non-slip properties of the orthosis during movement were rated as good to excellent by 57.9 percent, as standard by 33.3 percent, and by 8.8 percent as not very good. Nobody rated them as poor.
Patients rated the wearing comfort with regard to breathability as 2.4 on average, skin friendliness as 2.3, and weight of the orthosis as 2.3. (Fig. 7)

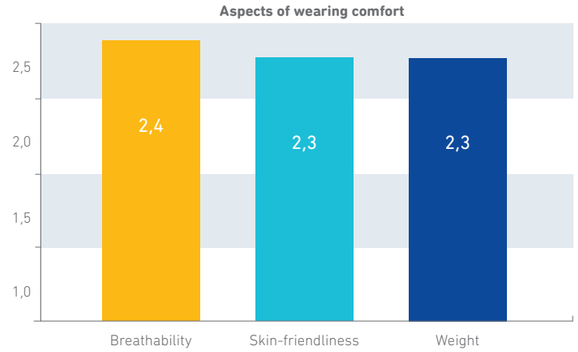

Fig. 7: Assessment of wearing comfort on an ordinal scale from 1 to 6,
1 = excellent to 6 = not adequate

ADVERSE REACTIONS, ADVERSE EVENTS

None of the 57 patients suffered any adverse effects caused by the orthosis for the wearing duration.

CONCLUDING OBSERVATION:

In order to guarantee the efficiency of orthoses as a treatment option, patients must be educated. Patient education should include information about goals and modes of treatment as well as about possible risks and adverse reactions. Patients should be encouraged to get in touch with the relevant professional if an adjustment is required, in cases of intolerances, or if they have questions about the medical aid.[2]

During conservative treatment of osteoarthritis of the hip, the use of hip orthoses is designed to reduce pain, for example. A clinical study (Evidence Level 1b) substantiated that the CoxaTrain reduced pain at night as well as during the day.[3] The patients in this study also noticed significant pain reduction when using the CoxaTrain.

Another treatment goal is the improvement of hip functionality and the associated ability to carry out everyday activities independently and entirely. Patients who underwent conservative treatment using the CoxaTrain confirmed an improved feeling of stability as well as increased mobility. Furthermore, they were able to perform everyday activities more easily with the orthosis. These results correspond to the results of the clinical 1b study that has already been conducted. Patients suffering from moderate osteoarthritis of the hip showed that their mobility improved over time when wearing the CoxaTrain. Stride length as well as walking speed significantly increased, with an increased maximum extension moment being recorded.[3] Gait normalized when the hip orthosis was worn.[4]

Because the product is "inconspicuous" and does not cause adverse effects, this study also demonstrated that **using the CoxaTrain is low-risk, in addition to its proven effectiveness**.

Further data acquisition is desirable to confirm the existing findings.

CONCLUSIONS

- Pain reduction by an average of 47.7 percent when using the CoxaTrain
- Significant improvement in patient mobility by 71.4 percent
- The CoxaTrain provides an excellent feeling of stability
- The CoxaTrain offers exceptional wearing comfort

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Rev. 0 – 2024-07

GenuTrain® OA

EVALUATION OF EFFECT AND THERAPEUTIC SAFETY OF THE KNEE ORTHOSIS

BACKGROUND

The joint most frequently affected by osteoarthritis is the knee (gonarthrosis). The condition becomes more prevalent with age, it affects patients' quality of life and their ability to cope with everyday tasks. It also generates high costs for the healthcare system (1).

The goal of the study was to determine the effectiveness of the relieving GenuTrain OA knee orthosis, which has been designed to treat osteoarthritis of the knee, measured using parameters such as perception of pain and stability as well as mobility, from being provided with the medical product to the next appointment. Additionally, data was collected relating to compliance, wearing characteristics, handling, and fit of the orthosis. The data recorded by the physician was used to make possible assumptions about medical treatment goals and to what extent they were achieved.

METHODOLOGY

Study design:	Non-interventional, clinical study; case series, one-arm (evidence level 3)
Sample:	8 orthopedics practices n = 113 patients; Age: 64.4 ± 11 years Gender: 41 percent male; 59 percent female
Test orthosis:	GenuTrain OA (Bauerfeind AG)
Treatment duration:	On average 5.4 calendar weeks (± 1.4 calendar weeks)
Timing of being provided with the orthosis:	Non-surgical care 81 percent After surgery 16 percent Before surgery 3 percent
Test method:	Data collection using a questionnaire
Investigation period:	Initial diagnosis at T1 and data collection during the second appointment T2
Data assessment:	Inductive statistics: paired t-test
Inclusion criteria:	Medial or lateral osteoarthritis of the knee
Exclusion criteria:	Patients who are mentally and/or physically unable to guarantee the safe use of the orthosis

TREATMENT GOALS AND THEIR ACHIEVEMENT AS IDENTIFIED BY THE PHYSICIAN

Data was collected in seven different practices. The most important treatment goals as identified by physicians were, in decreasing order, pain reduction (93 percent), knee joint relief (67 percent), knee joint stabilization (55 percent), and the restoration of normal patient mobility (29 percent). Achievement of the goal was rated as good (rating 2.20 to 1.87) after an average of five weeks (5.4 / +- 1.4 calendar weeks) of treatment. (Fig. 1)

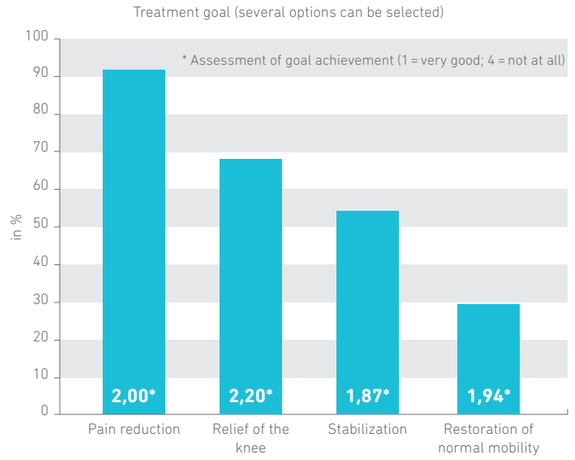


Fig. 1: Treatment goal and its achievement as a result of being provided with the GenuTrain OA

COMPLIANCE

A quarter (25.2 percent) of patients wore the orthosis for more than 8 hours every day. The majority (38.3 percent) reported that they wore the orthosis for 5 to 8 hours every day. 23.4 percent wore the orthosis for 3 to 4 hours, and 13.1 percent for 1 to 2 hours every day (Fig. 2).

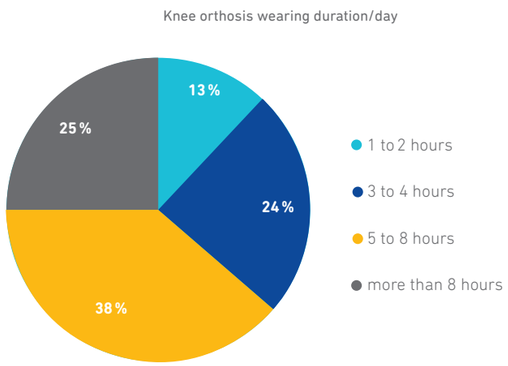


Fig. 2: Proportional distribution of the wearing duration of the orthosis; n = 107

SUPPORT AND STABILITY PROVIDED BY THE ORTHOSIS

Patients rated on a scale of 1 to 6 (1 = very good, 6 = none at all) whether the orthosis supported treatment and provided stability. On average, patients gave a rating of 2.2. This means the support provided by the orthosis was good (n = 107).

STABILITY, MOBILITY, AND PAIN PERCEPTION

During treatment, pain reduced to 3.4 as a result of using the orthosis, compared with 7 before treatment, measured using a 10-point VAS. The feeling of stability in the knee increased from 3.8 to 7.3 as a result of wearing the orthosis.
Patient mobility increased to 6.9 during treatment, compared with 3.2 before treatment. This also manifested in the pain-free walking distance that increased from 3.2 to 6.9 on a 10-point scale (1 = short, 10 = long). All changes are statistically significant and clinically relevant (Fig. 3).

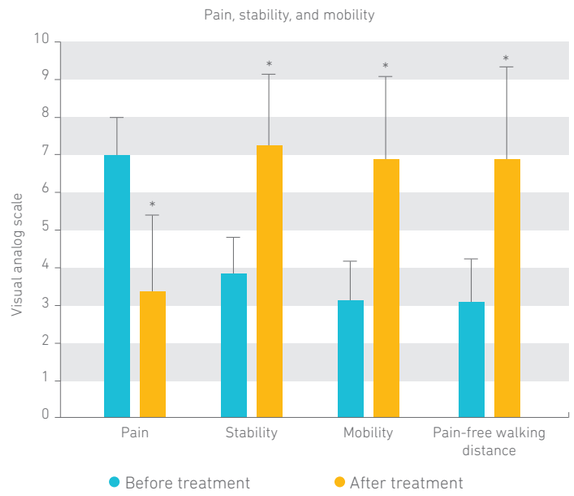


Fig. 3: Pain, stability, mobility, and pain-free walking distance before treatment with the orthosis and after treatment with the orthosis (an average of 5.4 weeks), specified using a visual analog scale. Showing averages with standard deviation; * p<0.001 (paired t-test)

CONSUMPTION/REDUCTION OF PAIN MEDICATION

44 percent of patients indicated that they were taking pain medication at least once a week (n = 112). When asked whether consumption of pain medication could be reduced as a result of wearing the orthosis, 77 percent of patients said "Yes" (n = 75).

PATIENT SATISFACTION

Handling or donning the orthosis was described by 92 percent of patients as very easy, easy, or without difficulty. The fit was rated as excellent or good by 79 percent of patients. The majority of participants (73 percent) also rated the non-slip characteristics as excellent or good (Fig. 4).

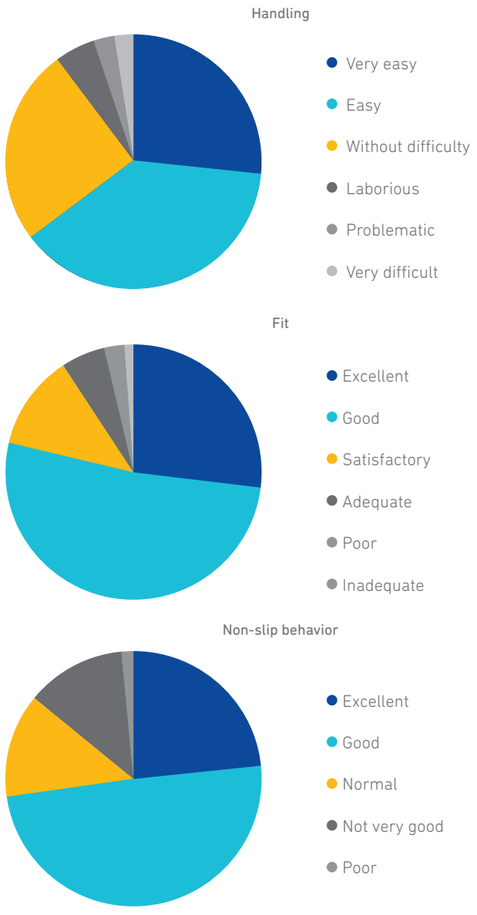


Fig. 4: Patient assessment of handling, fit, and non-slip characteristic of the orthosis

Wearing comfort, for which specifically skin-friendliness, breathability, and weight were asked about, was rated by patients on average with good (2.2) (1 = very good, 6 = poor).

When asked when they were wearing the orthosis, 50 percent of patients reported that they wore the orthosis during their leisure time, 43 percent the entire day, 41 percent during work, 19 percent during exercise, and nobody at night (multiple selection possible).

27 percent of those asked were able to carry out everyday activities without restrictions when wearing the orthosis. The majority (47 percent) was able to carry out everyday activities easily. 21 percent indicated that they were restricted during everyday activities, and 3 percent were severely restricted. One patient (0.9 percent) reported that he or she was not able to carry out everyday activities when wearing the orthosis.

With reference to care of the orthosis, 61 percent of patients rated it as easy, 36 percent as average, and 2 percent as difficult.

Using a 10-point scale, patients were also asked to what extent they expected the orthosis to be slim and that it can be worn beneath clothing (0 = unimportant, 10 = very important). The average was 7.2 ± 2.97, meaning this is an important criterion for patients. Overall, when patients weighed up all "Pros" and "Cons", there was a clear indication that they were happy with the orthosis (average: 2.1; n = 110).

HOW SATISFIED ARE PATIENTS WITH THE GenuTrain OA

DISCUSSION

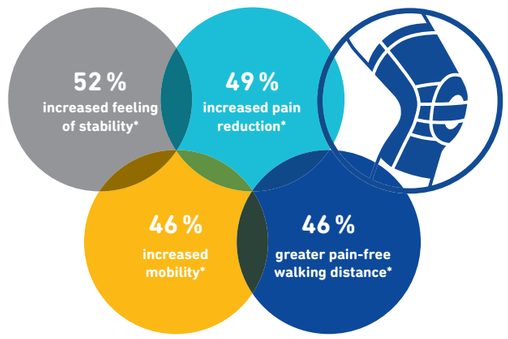
In order to reduce knee strain, hard-frame orthoses are often used as part of non-surgical treatment. For this orthosis design, previous studies have shown pain reduction, mechanical joint relief, as well as improved function in those affected (2, 3). The low level of wearing comfort, however, poses a problem because it leads to insufficient patient compliance (4).

As part of an observational study, this study was able to show that the GenuTrain OA combines both: it provides stabilization, reduces pain by means of targeted relief, and increases patient mobility. At the same time, its wearing comfort, great fit, non-slip characteristics, and easy handling ensure a high level of compliance. This, in turn, increases the effectiveness of the orthosis and therefore patient satisfaction.

CONCLUSIONS

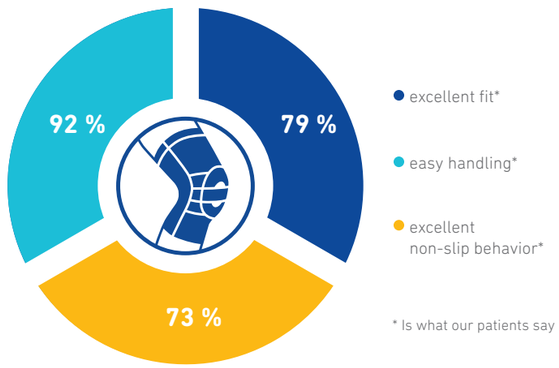
- In patients suffering from osteoarthritis of the knee, the GenuTrain OA leads to a significant and clinically relevant reduction of pain as well as increased stabilization and mobility.
- Thanks to its wearing comfort, the GenuTrain OA results in a high level of compliance, which helps with the clinical effect of the orthosis.
- Overall, the majority of patients (74 percent) was happy or very happy with the orthosis, and the treating physician rated the achievement of the treatment goals as good.

Stability, mobility, pain perception, and walking distance



* compared with not wearing an orthosis

Patient satisfaction



* Is what our patients say

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SecuTec® Genu

INVESTIGATION INTO THE EFFECT OF KNEE ORTHOSES ON THE OUTCOME FOLLOWING KNEE JOINT SURGERY

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Ingo Friedl, Sanitätshaus Altenburg GmbH

INTRODUCTION

The use of a knee orthosis is a fixed element of the treatment regime for certain injuries affecting the knee joint and the adjacent structures, whether this forms part of conservative treatment or part of the follow-up therapy 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 injuries in the knee joint, following meniscus repair surgery or surgery to stabilize a dislocated patella, and both prior to and following anterior or posterior cruciate ligament reconstruction. Alongside the active principle of four-point stabilization for femoro-tibial instability, an orthosis can be fitted and worn in order to limit the affected joint's range of motion. This prevents instability, especially during postoperative management, thus safeguarding the surgical outcome. The orthosis allows for flexibility in limiting the range of motion, meaning that it can be adapted to the injury profile and adjusted as healing progresses. Satisfying these characteristics by means of a hard-frame orthosis is a key element as regards therapeutic success and a functional outcome.
The aim of the case series was to investigate the use of the SecuTec Genu knee orthosis in conservative and postoperative therapy for knee injuries. A number of parameters were investigated, including the fit and any slipping by the orthosis, joint stabilization, and pain levels.

METHODOLOGY

Sample:	72 patients were given a knee orthosis following surgery (45 men, 27 women, age: 42 +- 18 years)
Indications:	27 x ACL tear, 11 x collateral ligament injury, 9 x patellar dislocation, 7 x quadriceps tendon tear, 6 x patellar fracture, 4 x instability in osteoarthritis of the knee, 3 x tibial plateau fracture, 3 x distal femur fracture, 1 x popliteus tendon rupture, 1 x instability following total knee replacement There was an almost equal division between the left and right knee.
Product:	SecuTec Genu (Bauerfeind AG)
Examination dates:	Documentation form completed by the physician, orthotist, and patient T0: conservative and postoperative (1–4 days postoperative) T1: postoperative (4–8 weeks postoperative) The intervals between the examinations were selected by the treating physician, based on the indication and the expected regeneration time.
Data assessment:	Descriptive statistics for the different points in time using the complete data
Inclusion criteria:	• Patients regardless of age and weight • Patients with a knee injury or condition with a postoperative indication

RESULTS

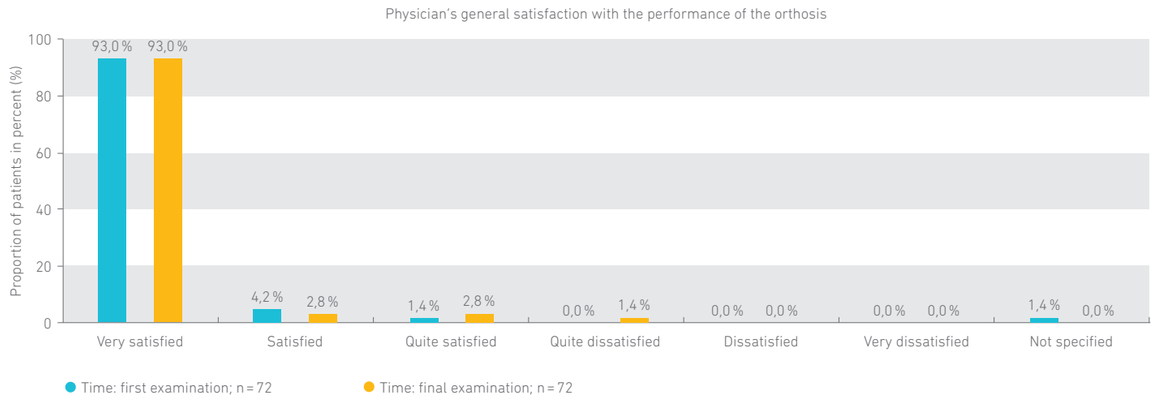

Fig. 1: Treating physician's assessment of the orthosis

The treating physician was very satisfied with the performance of the orthosis during the follow-up therapy in 93 percent of all 72 cases. The performance of the orthosis includes the characteristics of pain reduction, stabilization of the knee joint, and restoration of the mobility of the knee joint. The rapid mobility of the patient due to the orthosis was referred to as particularly positive. In five cases, use of the orthosis meant that an operation was successfully avoided during the time frame of the study.

52 patients were also receiving physiotherapy at the time of the follow-up examination, while 29 patients were being given drug therapy. According to the survey conducted by the physician, 97.2 percent of the 72 patients were very satisfied with the knee orthosis at the time of the follow-up examination (no fig.).

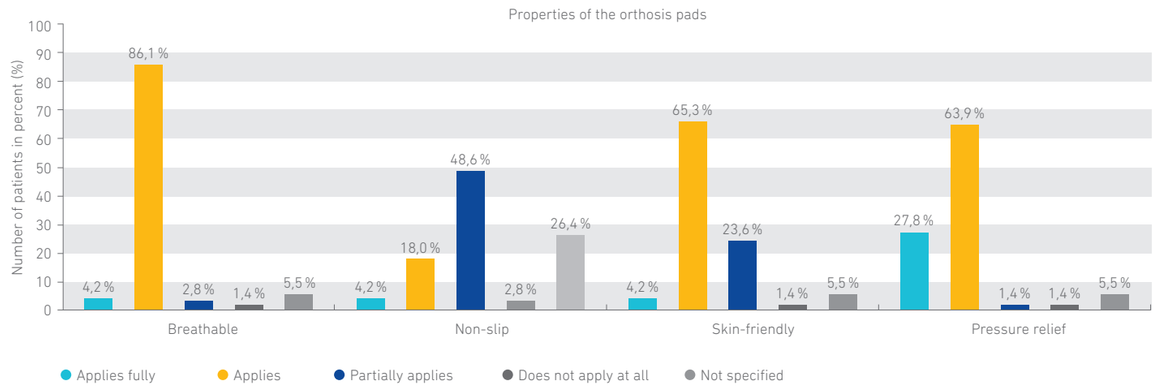

Fig. 2: Orthotist's assessment of the orthosis pads

The orthotist rated the orthosis on the basis of the product supplied to the patient and by inspecting the SecuTec Genu at the times of the examinations.
Good breathability of the pads was documented in 90.3 percent of cases. In 22.3 percent of cases, the non-slip behavior was rated as good, while this was rated as partially applicable in 48.6 percent of cases. Inadequate muscles may be mooted here as a possible cause. The skin-friendliness of the pad material and the pressure relief provided by the pads were rated as good to very good in 69.5 percent and 91.7 percent of cases respectively.

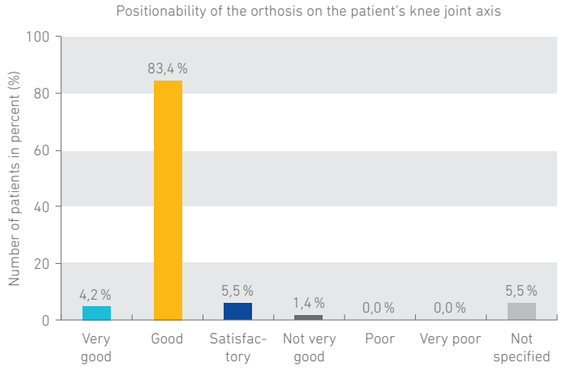

Fig. 3: Orthotist's assessment of the individual adaptability of the orthosis

The orthotist rated the positionability of the orthosis and, therefore, the adjustability of the orthosis hinges to the patient's individual compromise axis of rotation as good to very good in 87.5 percent of cases.

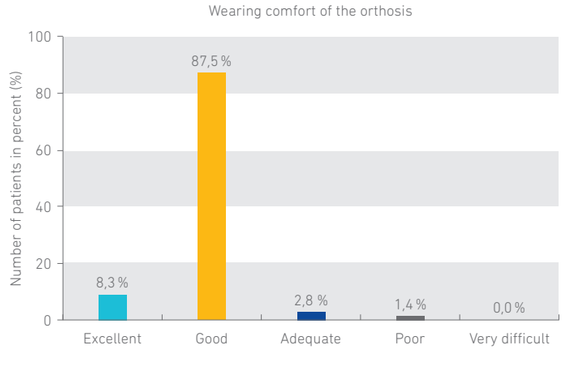

Fig. 4: Wearing comfort at the time of the follow-up examination

95.8 percent of patients rated the wearing comfort as good to very good. Wearing comfort is one of the aspects that determine good patient compliance. An orthosis can only be effective if it is actually worn.

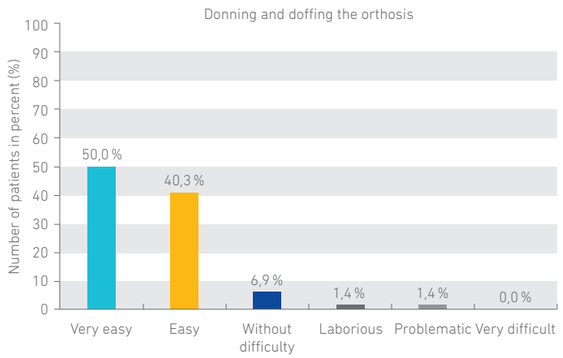

Fig. 5: Assessment of the handling of the knee orthosis at the time of the follow-up examination

90.3 percent of patients described the orthosis as easy or very easy to handle. This aspect plays a role in the straightforward use of the orthosis on an everyday basis.
The fact that the orthosis can be placed on the knee joint from the front means that there is no need to bend the leg sharply.

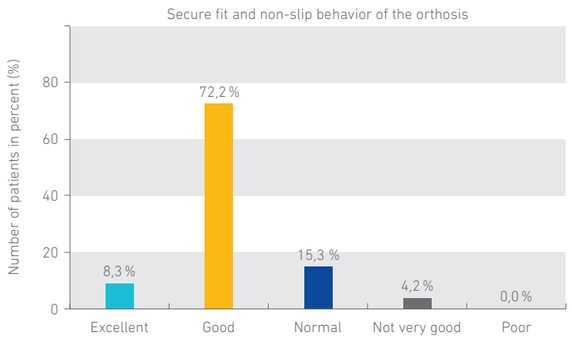

Fig. 6: Secure fit of the orthosis during movement at the time of the follow-up examination

80.5 percent of patients rated the secure fit and precise position of the knee orthosis as good or very good. This has a positive effect on the experience of wearing the orthosis and helps to avoid stress on the cruciate ligaments.

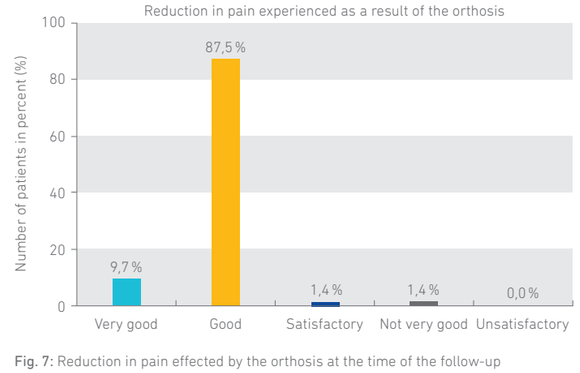

Fig. 7: Reduction in pain effected by the orthosis at the time of the follow-up examination compared to the initial examination

The reduction in pain resulting from the use of the orthosis was rated as good or very good by 87.5 percent and 9.7 percent of patients respectively.

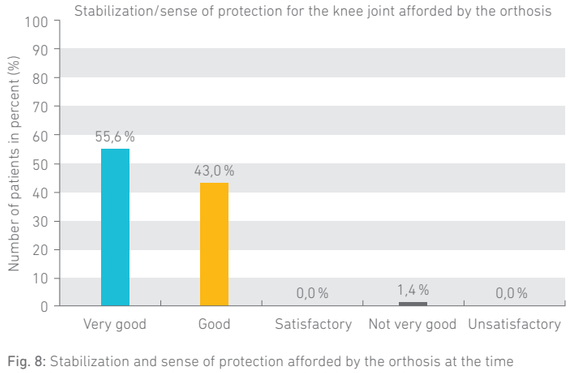

Fig. 8: Stabilization and sense of protection afforded by the orthosis at the time of the follow-up examination compared to the initial examination

The SecuTec Genu provides reliable stability and gives the patient a strong sense of protection. This was confirmed by 98.6 percent of patients. These factors are important for the early mobilization of patients. They help to prevent dystrophy and promote the build-up of muscle during the follow-up treatment phase.

SUMMARY & DISCUSSION

In the largest number of cases, the SecuTec Genu was used in this non-interventional study postoperatively following cruciate ligament surgery (n = 27).
The orthosis was used in the case of a further 19 operations that also treated various soft tissues in the knee joint. This accounts for a much larger proportion of the postoperative use cases compared to the use cases following surgery on bony parts (including cartilage) of the knee joint (n = 23). The aim of postoperative knee orthosis use is to safeguard the surgical outcome over a period of up to nine months, and longer in certain situations such as at work or when playing sport, to boost the sensorimotor system, and support the build-up of muscle. In the case of ligament reconstruction, for example, this is essential for the healing processes and the morphological restructuring processes of the new ligament [Rupp et al 1998; Jannsen et al. 2011].

Stabilizing knee orthoses such as the SecuTec Genu enable activities to be performed within a range of motion (ROM) that prevents both pain and harmful movements. In addition, orthoses help to promote the economy of movement processes [Kamada et al. 2017]. As both physician and patient surveys and clinical studies show, knee orthoses can reduce the risks of reinjury and ensure mechanical and neuromuscular joint stability [Strutzenberger et al. 2012]. The reduction in pain achieved by wearing a knee orthosis helps considerably in the rehabilitation process and boosts the patient's mobility.
In view of the properties described, knee orthoses are a useful element of postoperative follow-up care.

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CONCLUSIONS

- 97.2 percent very happy patients
- 98.6 percent of patients confirmed good to very good stabilization of the knee joint
- 97.2 percent of patients experienced significant pain reduction
- Supports early mobilization

Rev. 0 – 2018- 02

SecuTec® Genu

EFFECTS AND WEARING CHARACTERISTICS OF THE DORSAL VERSION OF THE 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.

METHODOLOGY

Study design:	Non-interventional, clinical study; Case series, one-arm (Evidence Level 3)	
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 treatment:	Physiotherapy	58 percent
	CPM dynamic splint	47 percent
Test method:	Data collection using a questionnaire	
Investigation period:	Initial diagnosis at T1 and data collection during the second appointment T2	
Data assessment:	Descriptive statistics	

Source: Case series, Norddeutsches Knorpelzentrum (North German Cartilage Center, COVZ), Quickborn, Bauerfeind, internal data

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 ± 1.9 weeks).

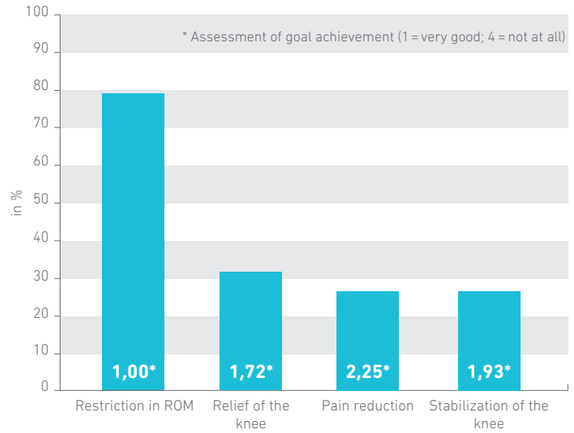

Fig. 1: Treatment goals and achievement of goals when wearing the SecuTec Genu dorsal version (several options can be selected)

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).

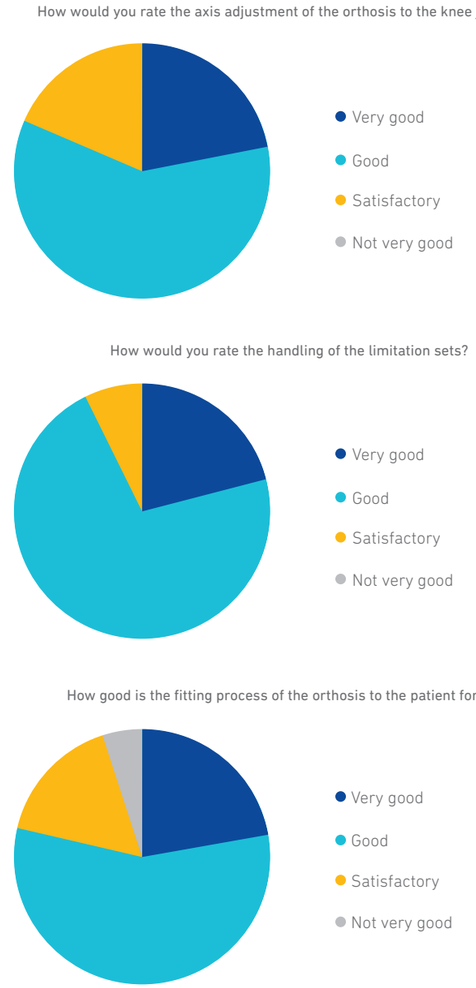

Fig. 2: Orthotist's assessment of the axis adjustment, handling, and fitting of the orthosis

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 relief	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 donning of 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 donning the orthosis 3.7 (= not very good) by patients. The secure positioning was rated 2.4 (= good) on average (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).

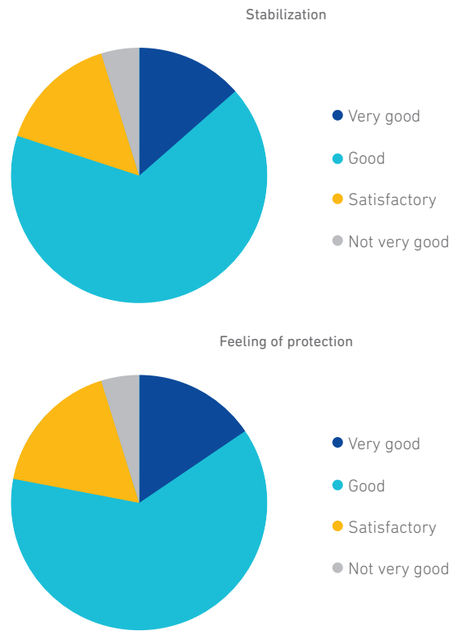

Fig. 3: Patient feedback about the effects of the dorsal version of the SecuTec Genu knee orthosis

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.

CONCLUSIONS

- 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.

We would like to thank "Norddeutsches Knorpelcentrum"
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