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Representative Survey among 3,000 Patients

Demonstrates the Subjective Protective Function of a Knee Orthosis
in Critical Everyday Situations

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The aim of the survey was to investigate the benefit of an orthosis in patients with knee injuries in critical everyday situations. The data entry form included questions regarding indication, treatment, incidence of critical events during rehabilitation, and wearing comfort of the orthosis. A total of 2,956 patients with knee injuries were included in the survey, of whom 76% had surgery and 24% conservative treatment. Up to 94% of the participants confirmed that the knee orthosis provided security and protected them from critical everyday situations that could jeopardise the result of surgery. 63% of the patients reported that they actually experienced a critical event during the rehabilitation phase and attributed a protective function to the orthosis in these situations; 94% of users would recommend the orthosis to others. The representative survey thus confirmed the protective function of a knee orthosis in critical everyday situations.

Key words: critical everyday situations, knee orthosis, protective function, patient survey, rehabilitation

Introduction

The use of knee orthoses is the subject of controversial discussions among experts. Studies also present a heterogeneous picture, in particular when it comes to the application of functional orthoses after anterior cruciate ligament reconstruction [1, 2]. Most studies of the postoperative use of orthoses focus on clinical endpoints such as stability of the knee joint, function (ROM), pain or muscle activity. Furthermore, the chosen time of the study endpoints frequently lies in the late rehabilitation phase [1, 2]. Evidence for the use and benefit of an orthosis in the early rehabilitation phase on the other hand is scant, among other things because this

aspect is rarely investigated in studies. Critical incidents can occur in particular during the initial weeks and up to twelve months after the operation, with the consequence of re-ruptures or contralateral injuries [3]. These aspects including the subjective protective function of a knee orthosis were not adequately considered in past clinical studies, and cannot be clearly proven by examining objective clinical parameters alone [2]. That is why two aspects should always be examined separately from each other in evaluating the postoperative benefit of a knee orthosis:

1. The aspects of transplant selection (semitendinosus, patellar or quadriceps tendon), the use of an adequate tendon diameter, positioning of the drill channels and fixation techniques among others are decisive for an optimal result of the operation [4]. An orthosis has no influence on this clinical result.

2. Protection against critical everyday movements that can subsequently put the result of the operation at risk is decisive for the orthosis. Thus the orthosis primarily has the function of protecting the result of the operation in the early rehabilitation phase rather than improving it. A knee orthosis is also recommended in case of a combined injury of the anterior cruciate ligament and medial collateral ligament. Here a surgical measure for the treatment of the anterior cruciate ligament injury and conservative treatment for the collateral ligament injury including an orthosis is preferred. Thus the orthosis not only protects the result of the operation but also supports healing of the collateral ligament injury [5, 6].

The orthosis can also be of psychological significance in addition to its protective function, but the psychological components of treatment are rarely investigated in studies [1, 2]. A study has proven a positive influence

of the knee orthosis in the early postoperative phase after anterior cruciate ligament reconstruction. One reason among others was the psychological effect, which boosted the patient's confidence in their physical weight carrying capacity, thereby resulting in increased physical activity and the improvement of mobility [7]. In anterior cruciate ligament rupture patients with conservative treatment, a study also showed that patients with an orthosis perceived a significantly higher feeling of stability and positive effects on rehabilitation than patients in the control group without an orthosis [8].

Especially in the return to sports, the fear of a repeat injury plays a major role: only about 50% of athletes with a rupture of the anterior cruciate ligament regained their original level of sports activity notwithstanding physical rehabilitation. Among the patients that did not return to their sports performance level, the validated Tampa Scale of Kinesiophobia (TSK) showed



Fig. 1 „M.As®comfort“ rigid-frame orthosis from Medi.



Fig. 2 Subjectively perceived protective function of the knee orthosis in critical everyday situations: level of agreement with statements (A), (B) and (C) on a scale of 1 (= „disagree“) to 6 (= „fully agree“); information in percent of surveyed patients.

that this patient sub-population had more fear of a renewed injury [9]. A current study confirms this result: reduced anxiety – measured by lower kinesiophobia values four weeks after anterior cruciate ligament reconstruction – correlates with improved rehabilitation progress after 12 weeks [10]. That is why fear of renewed injury during the rehabilitation phase should be given more consideration, both in the real life setting and in clinical studies [9]. Regarding the aspect of return to sports, the validated ACL-Return to Sport after Injury score (ACL-RSI) with 12 items was already developed for this purpose in 2008 [11].

The currently available scores are aimed at fear of movement and physical activity, especially in the context of sports. However, the fear of renewed injury due to critical situations and its possible negative influence on the rehabilitation process is not limited to athletes but applies to any patient regardless of patient-specific factors such as age, gender, sports activities or body mass index. That is why this study was conducted in a real life setting in order to best reflect the reality of patient care and the clientele in the context of knee injuries. The goal of the patient survey was to initially identify and document critical everyday situations subjectively perceived by patients, and then to examine the protective function of an orthosis for patients with knee injuries.

Materials and methods

The voluntary survey was conducted within the scope of the “Medi Worry-Free Package” (return of the knee orthosis after successful treatment). The questionnaire generated specifically for this survey was included with the “M.4s comfort” (Fig. 1) and

“M.4 X-lock” rigid frame orthoses, and contained questions about the indication, aetiology of the injury, therapy, frequency of critical incidents during rehabilitation, and the use and wearer comfort of the orthosis. Multiple responses were possible in part. Patients were informed regarding participation and had the option to respond online or by mail. The survey period was from March to September of 2018. LamaPoll was used for the anonymised evaluation.

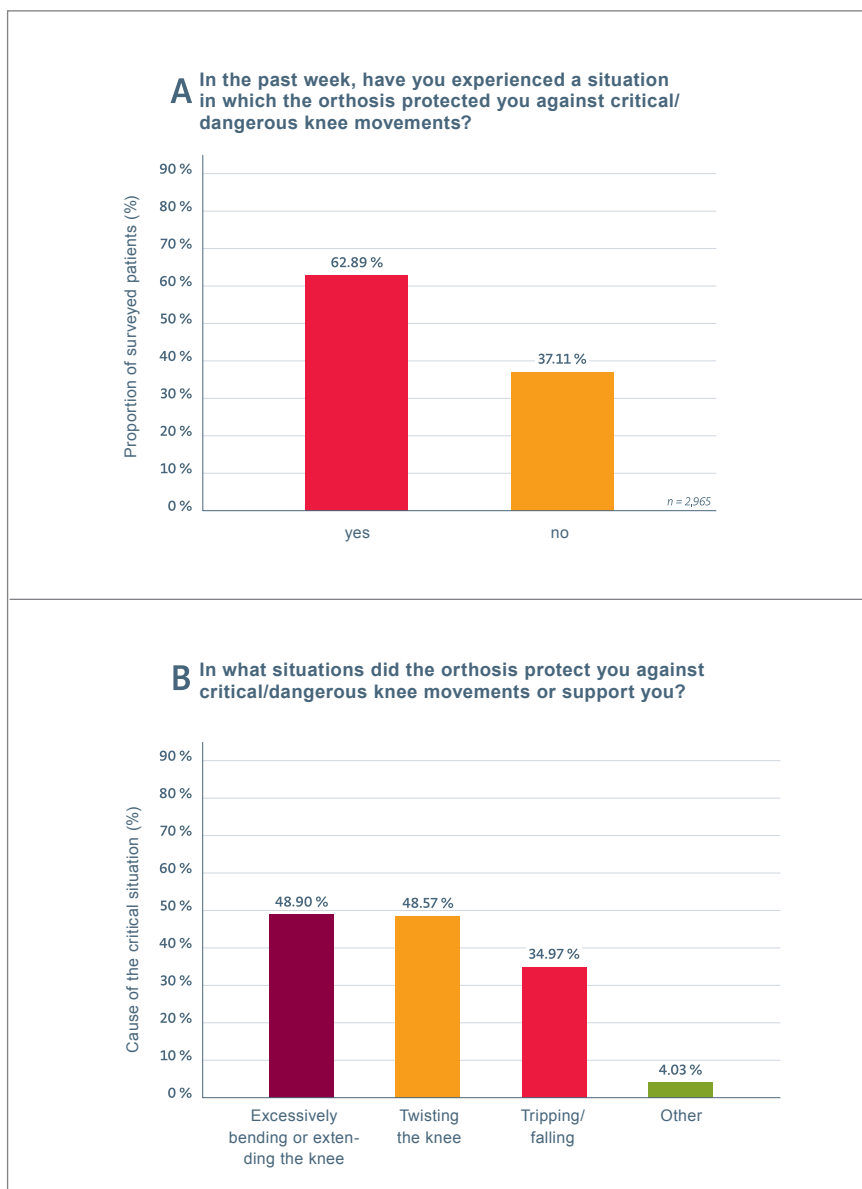


Fig. 3 Occurrence of critical everyday situations among knee injury patients; A) Identification of patients who answered the question about actually experienced critical situations and the protective function of the orthosis with „Yes“ or „No“ (information in percent of surveyed patients); B) Documentation of the critical everyday situations (information about the causes of critical situations in percent).

Results

Patients

A total of 2,956 patients with injuries in the area of the knee joint took part in the voluntary survey. Indications for the doctor's prescription of a knee orthosis were as follows (multiple selections possible in case of combined injuries): anterior cruciate ligament injury 47%, meniscus injury 32%, collateral ligament injury 18%, patellar/quadriceps tendon injury 12%, carti-

lage injury 11%, knee instability 15%, posterior cruciate ligament injury 5%, other 10%.

The causes of injury included winter sports (23%), football (17%), other sports (19%), household accidents (11%), occupational accidents (8%), traffic accidents (3%) and other (19%). After the diagnosis, 76% of patients indicated they received surgical treatment and 24% of the patients received conservative treatment. Aside from the prescription of an orthosis for postoper-

ative or conservative use, the patients indicated additional therapy measures (multiple selections possible): physiotherapy 90%, manual lymph drainage 55%, medication therapy (such as painkillers) 41%, CPM device 31%, medical compression sock 25%, heat/cold therapy 22%, acupuncture 1%, other 9%.

In response to the question about sports activity, 73% of participants indicated that they did sports before the injury, with the following intensity: up to four hours per week 46%, four to eight hours per week 36%, eight to twelve hours per week 14% and more than twelve hours per week 4% of the patients.

Subjective protective function of the orthosis

To assess the benefit of the orthosis perceived by patients in everyday life, the following statements were evaluated on a scale from 1 (= "disagree") to 6 (= "fully agree"): 94% of the patients agreed or fully agreed (scale 5 and 6, Fig. 2A) with the first statement "The orthosis supported me during therapy and gave me confidence". 87% of the patients agreed or fully agreed (scale 5 and 6, Fig. 2B) with the second statement "The orthosis gave me confidence to properly extend/bend the knee". 92% of the participants agreed or fully agreed (scale 5 and 6, Fig. 2C) with the third statement "The orthosis protected me against critical/dangerous knee movements". Thus most of the patients positively assessed the subjectively perceived protective function of the knee orthosis. Regarding the identification of critical incidents in everyday life, 63% of the patients affirmed that they actually experienced critical situations and confirmed that the orthosis supported and protected them at the time (Fig. 3A). Patients were given the following critical incidents to choose from in the questionnaire: a) "Excessively bending or extending the knee", b) "Twisting the knee", c) "Tripping and/or falling" and d) "Other" (with the option to enter free text). "Excessively bending or extending the knee" (49%), "Twisting the knee", (49%) and "Tripping and/or falling" (35%) were the most commonly noted critical incidents, among other things while climbing stairs or getting into or out of the car (multiple selections possible, Fig. 3B).

Wearer comfort and recommendation rate

The participants were able to rate the quality, wearer comfort and handling of the orthosis on a scale from 1 (= “unsatisfactory”) to 6 (= “very good”): 93% of patients assessed the quality of the orthosis as good to very good (scale 5 and 6, Fig. 4A); 77% indicated good to very good wearer comfort (scale 5 and 6, Fig. 4B) and 84% perceived the handling as good to very good (scale 5 and 6, Fig. 4C). This means that most of the patients were satisfied with the workmanship and application of the orthosis, which is also reflected by the recommendation rate: 94% of the users would recommend the orthosis to other patients.

(Scale 5 “likely” and 6 “highly likely”, Fig. 5). Nearly 10% of the patients want to continue wearing the orthosis during sports or in everyday life even after rehabilitation. The main reasons were the responses “Gives me confidence in sports/everyday life” (61% of respondents) and “Stabilises my knee” (50%), followed by the responses “I trust in being able to load/extend my knee” (25%) and “Reminds me to be cautious” (25%, multiple selections possible).

Discussion and conclusions

According to the author’s state of knowledge, the study presented here is the first large patient survey in Germany to document the occurrence of subjectively perceived critical incidents and their frequency among nearly 3,000 patients with injuries in the area of the knee joint. Until this time many studies on the use of a knee orthosis focused on clinical endpoints such as the degree of stability, function/ROM, pain and muscle activity aimed primarily at improving the result of the operation and on long-term consequences, and less on protecting the result of the operation and on the conservative treatment of possible accompanying injuries in the (implant) healing phase [1, 2].

In the area of the knee joint, the rupture of the anterior cruciate ligament is among the most frequent traumatic ligament injuries, which was also confirmed in this study with almost 50% of the participating patients. Extensive rehabilitation measures are required with such injuries in order to obtain a good

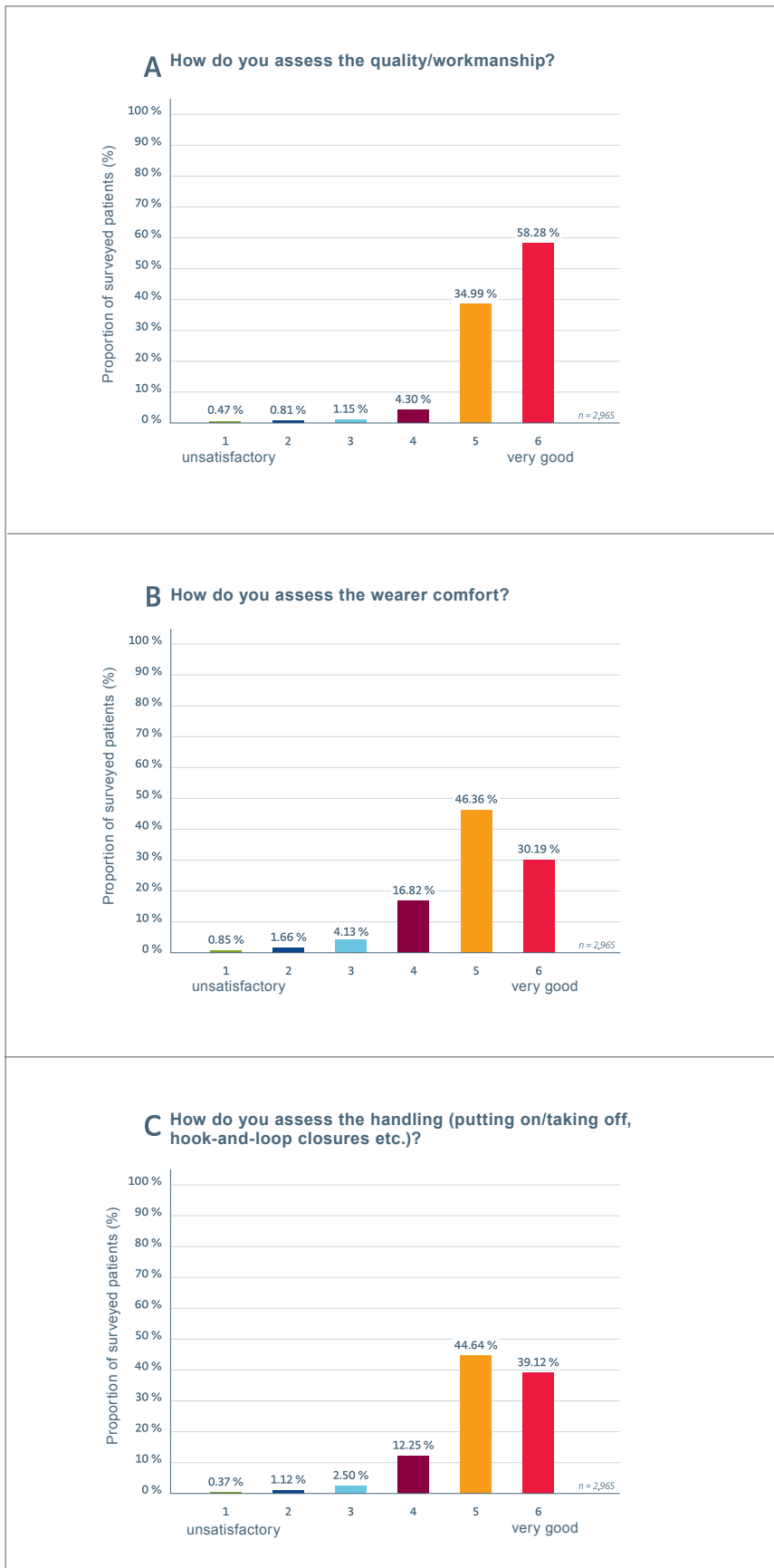


Fig. 4 Assessment of the quality (A), wearer comfort (B) and handling (C) of the knee orthosis on a scale from 1 (= „unsatisfactory“) to 6 (= „very good“); information in percent of surveyed patients.

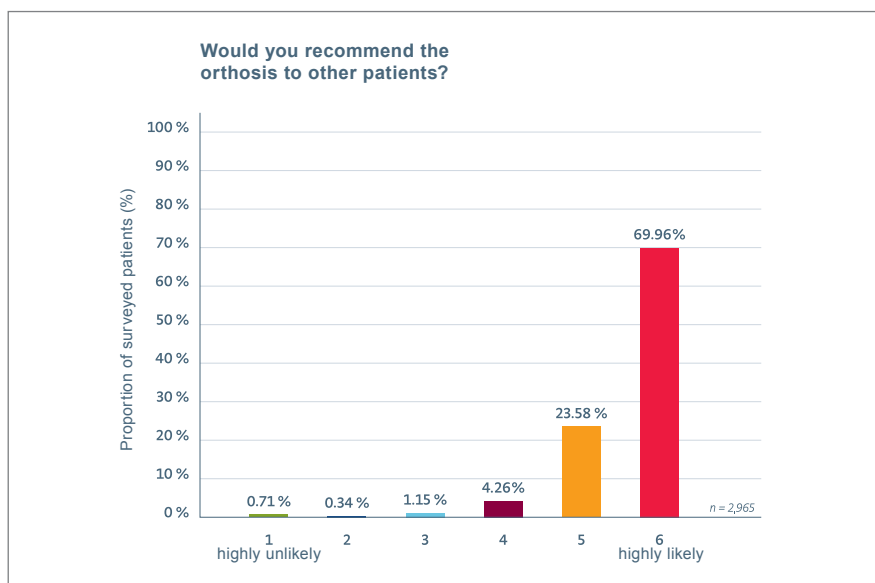


Fig. 5 Recommendation rate for the orthosis on a scale from 1 (= „highly unlikely“) to 6 (= „highly likely“); information in percent of surveyed patients.

long-term result [12]. Using a knee orthosis is a fixed element of these measures, both in conservative therapy and after an operation. Using the orthosis is particularly crucial in the early rehabilitation phase. Thus orthoses are used in the follow-up treatment of cruciate ligament replacement surgery to ensure the healing of the transplant, since it must be protected against excessive loads in the time after transplantation [12]. Reasons for such detrimental stresses may include premature reintegration into sports as well as everyday, unconscious and unforeseeable incidents such as tripping or falling while climbing stairs, slipping on ice or twisting the knee while getting into and out of the car.

That is why the objective of the study presented here was to illuminate the benefit of an orthosis that is relevant for patients, which is often underrepresented in studies – namely the subjectively perceived protective function – in real-life situations. Nearly 3,000 patients in various age classes and with different sports activity levels participated in the survey. Although a large proportion of the participants actively engaged in sports before the injury (73%) and more than half the injuries were caused by sports (nearly 60%), the survey also included participants with no sports activity and with other causes of injury so that an all-encompassing examination of real life situations is assured.

The survey showed that the orthosis is of major significance and relevance

for the patient. In a first step, the patients were asked about their general subjective assessment of the protective function provided by the orthosis. Here about 90% of the patients respectively agreed with the general statements about the subjective safety and protective function. When the patients were asked specifically about the actual occurrence of critical incidents in everyday life in a next step, it is interesting to note that nearly two-thirds of the patients affirmed this question and emphasised that the orthosis fulfilled its function as a “safety belt” in these cases. A simple but readily comprehensible comparison is provided in a publication from 2017: similar to the safety belt when driving a car – not needed as long as nothing happens, but capable of saving your life when something does – the orthosis serves to protect the transplant/result of the operation [13]. The psychological effect of the orthosis should not be disregarded either, since a significant number of the surveyed patients reported an increased feeling of safety when wearing an orthosis, among other things because the patients had the confidence to load the knee. Among others the validated questionnaires “ACL-RSI Score” [14] or “Tampa Scale of Kinesiophobia” [15] as patient-reported outcomes (PRO) are suitable for investigating the psychological effect of an orthosis in studies. Some patients in the current study also indicated that the orthosis reminded

them to be cautious. Therapists in particular also see this reminder function with the use of a knee orthosis [13].

A recent structured, anonymised online survey among instructors of the AGA (Society for Arthroscopy and Joint Surgery) examined the standards in follow-up treatment after anterior cruciate ligament replacement in German-speaking regions. The key insights of the study were that the majority of surgeons do not require a prolonged period of relief after the operation and prescribe a postoperative orthosis: 82.8% of the respondents protected the joint with an orthosis after operating, most commonly with a rigid-frame orthosis (77.8 %) [16]. This survey confirms the meaningful use of an orthosis by patients with a knee injury. The results of the voluntary survey provide initial evidence that patients feel more confident and perceive a subjectively higher level of stability due to the orthosis – possibly in combination with the body’s own protective mechanisms. The increased feeling of safety can enable faster mobilisation and return to everyday activities and work. The benefit of an orthosis as well as its contribution to the reduction of possible recurring trauma resulting in injuries is therefore not only relevant from the patient and clinician’s point of view, but also from the perspective of health economics. In addition to the objective clinical parameters, suitable validated subjective questionnaires and possibly objective parameters that remain to be defined to investigate the protective function should therefore be considered in the design of clinical studies, picking up on the results of the survey presented here to confirm them and, in particular, study them in clinical practice.

*Kinesiophobia is excessive fear of movements and physical activities because they are associated with a painful injury or repeat injury. The validated Tampa Scale of Kinesiophobia (TSK) was developed for the quantification of kinesiophobia.

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Reviewed paper

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