

## SUMMARY OF SELECTED RESULTS

# INTERNATIONAL OBSERVATIONAL STUDY ON THE EFFECTIVENESS OF THE EPITRAIN IN THE CONSERVATIVE AND POSTOPERATIVE TREATMENT OF SPORTS INJURIES

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### ABSTRACT

Both nationally and internationally, sports activities form an important part of a healthy lifestyle and play a key role in staying healthy<sup>1</sup>. However, these health benefits come with the risk of injury. Every year, 1.25 million sports players injure themselves badly enough to need medical treatment<sup>1</sup>. In addition to injuries, problems can also result from the increased risk of inappropriate or excessive mechanical stress. A sports medicine study conducted by Priest at Vic Braden College in California investigated epicondylopathy in tennis players. 31 percent of the 2,516 tennis players involved in the study reported elbow problems. These were found to be caused by biomechanical factors such as technical faults during movement sequences (such as backhand shots), holding the racket, or especially powerful shots<sup>2</sup>. A number of treatment regimes, such as supports and orthoses, physical therapy, and painkillers, are used in conservative treatment.

The aim of the observational study was to investigate the use of the EpiTrain in the conservative and postoperative treatment of sports injuries. It focused in particular on the parameters of pain level, range of motion, and everyday activities.

### STUDY DESIGN

prospective, transnational, multicenter observational study

### METHODS

Sample:	The study centers were recruited from various international Bauerfeind companies. Nine international medical specialists (Germany, Austria, Poland, Canada, the Middle East, Singapore, Hungary, Italy) from the fields of orthopedics, surgery, trauma surgery, and sports medicine were involved. 176 patient cases were treated using the EpiTrain.
Product:	EpiTrain elbow support (Bauerfeind AG)
Data collection:	July 2015 – March 2016 Documentation form filled in by physician and patient Measurement of patient's range of motion using the neutral-zero method <sup>3</sup> T0*: Time before injury T1*: Initial examination (prescribing of aid, or shortly after aid is dispensed to the patient) T2*: During recovery T3*: Final examination (recovery is foreseeable) * The intervals between these dates were defined by the examiner based on the indication and the expected regeneration time.
Study dates:	Descriptive statistics for the different points in time a) based on the overall data b) investigation of effectiveness based on treatment regime clusters: product without additional prescription, product and physiotherapy, product and painkillers, mix (product, physiotherapy, painkillers)
Evaluation of data:	• Documentation of at least two of the three visits
Inclusion criteria:	• Patients with a sports injury: Instability (functional instability, instability due to anatomical deficits e.g. ligament insufficiency, ligament rupture), joint pain with restriction of movement due to inappropriate or excessive mechanical stress (e.g. tendomyopathy, injuries to the capsular ligament, bruising, compression injuries, sprains), inflammation (e.g. tendinitis) • ≥ 29 prescriptions

<sup>1</sup> EuroSafe, Injuries in the European Union, Report on injury statistics 2010-2012, Amsterdam, 2014

<sup>2</sup> Priest JD ; The Elbow and Tennis, Part I: An Analysis of Players with and without Pain. The Pphysician and sportmedicine, Vol 8, No 4:81-91

<sup>3</sup> Neutral-zero measurement: standardized orthopedic evaluation and documentation index for joint mobility

## RESULTS

The demographic data of the patients treated with the EpiTrain showed the following:

**Fig. 1: Demographic data**

<b>Prescriptions</b>	n = 176
<b>Age</b>	45.2 ± 15.0 years
<b>Men</b>	88
<b>Women</b>	87
<b>Countries</b>	Germany, Austria, Poland, Canada, the Middle East, Singapore

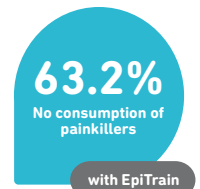
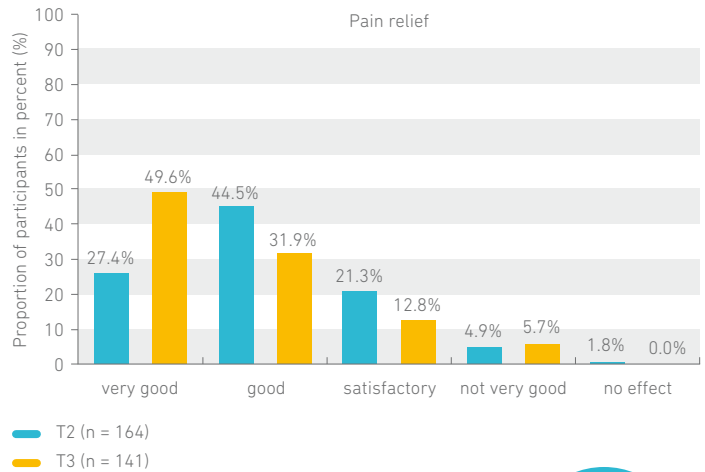
The EpiTrain was prescribed to the majority of patients due to joint pain (n = 110). It was prescribed in fewer instances for joint inflammation (n = 15) and once for instability (n = 1).

**Fig. 2: Patient symptoms**

<b>Symptoms</b>	Joint pain n = 110
	Joint inflammation n = 15
	Joint instability n = 1

Before injury, 58% of the patients practiced recreational sports. Between the initial and final examinations, a positive trend was observed in the range of motion (ROM), with an increase in the flexion angle of the elbow joint from  $122.3^\circ \pm 29.9$  (T1) to  $132.8^\circ \pm 31$  (T3). Extension was possible from the start of treatment onward. The trend for supination showed an improvement of  $9.5^\circ$  (T1:  $64.3^\circ \pm 24.6^\circ$ ; T3:  $73.9^\circ \pm 22^\circ$ ). The range of motion for pronation improved from  $65.7^\circ \pm 23.6^\circ$  (T1) to  $73.1^\circ \pm 23.3^\circ$  (T3). The level of pain experienced was also examined. At the time point T2, 71.9% of patients reported pain relief to be "good" to "very good" when wearing the EpiTrain. At the point of foreseeable recovery (T3), 81.5% of patients rated the pain relief as "good" and "very good."

**Fig. 3: Assessment of patients' pain relief (T2, T3)** Overall data (options: no effect, not very good, satisfactory, good, very good)



The consumption of painkillers was also closely linked to pain relief.

At the time of injury (T1), 73.6% of patients took painkillers occasionally to up to three times a day. This figure had dropped to 68.3% by T2. At the time of recovery (T3), the majority of patients (63.2%) no longer used painkillers.

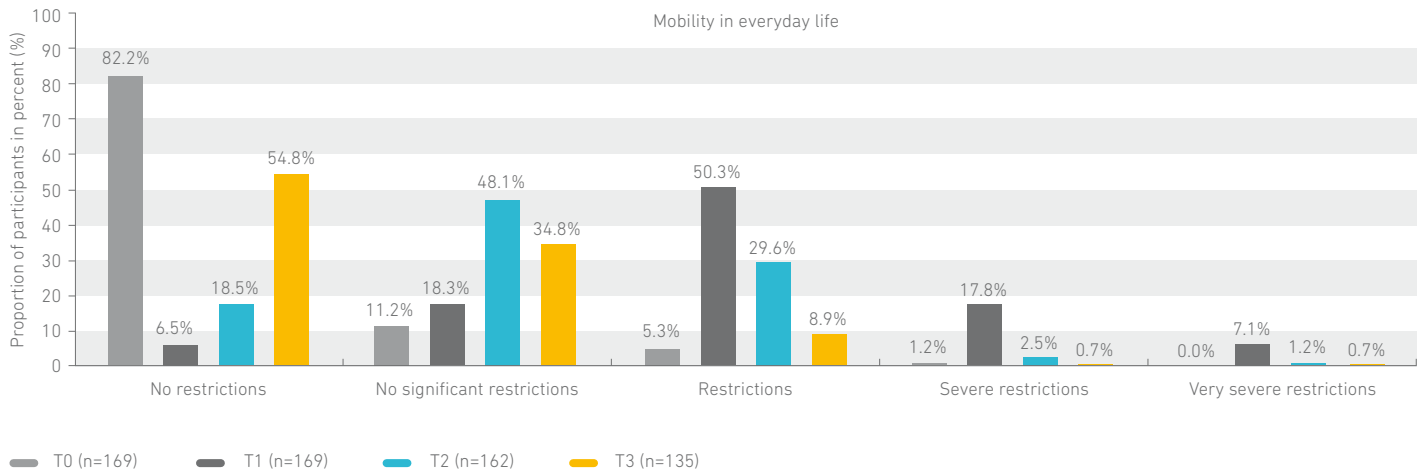


The treatment, supported by the EpiTrain, improved patients' perceptions of their mobility in their daily lives.

At the start of treatment (T1), 25% of patients stated that they were experiencing severe to very severe restriction of movement in their daily lives. A further 50.3% of patients reported restrictions in everyday movements. Over the course of treatment (T2), this figure decreased to 33.3%. By additionally wearing the EpiTrain to go about their daily activities, the majority of patients (93.4%) were able to master virtually all everyday movements without restriction by the end of treatment (T3).

**Fig. 4: Evaluation of mobility in everyday life (T1, T2, T3)**

Overall data

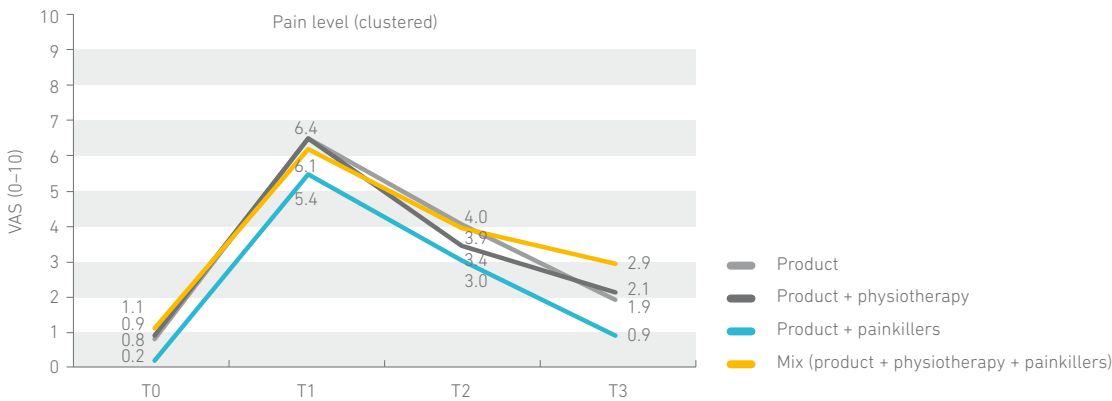


The effect of different treatment regimes on the parameter 'pain' was also investigated.

In relation to prescribing practices, the results showed that the EpiTrain was most frequently prescribed in combination with physiotherapy and painkillers ("mix" treatment regime). This was followed by prescribing the product on its own and additional physiotherapy. Supplementary painkillers were prescribed the least often.

For comparable joint pain at the time of injury (T1) (VAS: 6.4), similar pain-reduction effects were achieved for prescribing the product without further measures and for prescribing it alongside physiotherapy (VAS: 1.9 and 2.1). At the time of foreseeable recovery, the "Mix" prescription combining all three treatment regimes resulted in a lower perceived reduction in pain (VAS: 2.9).

**Fig. 5: Pain level T0-T3** – clustered by treatment regime (product, product and physiotherapy, product and painkillers, mix (product, physiotherapy and painkillers))



In addition, the patients rated the EpiTrain with a high level of wearing comfort (8 out of 10 points on the VAS) at two points in time (T2, T3). Over the course of treatment and once treatment had ended, 90% of patients said that the support was “easy” to “very easy” to handle.

## SUMMARY & DISCUSSION

Severe twisting of the arm or hyperextension of the elbow, for example during sports activities, can put excessive strain on the elbow joint. This results in pain and restriction of movement<sup>4</sup>.

The aim of this observational study was to investigate the therapeutic use and the effect of the EpiTrain in sports-related injuries. More than half of the study group practiced recreational sports. The majority of patients were prescribed the EpiTrain to ease joint pain. Far fewer patients were given the support to treat instability and joint inflammation. The most frequent diagnosis was humeral epicondylitis. According to the available studies, the most effective form of treatment for humeral epicondylitis is unclear<sup>5</sup>. This is also reflected in the prescribing practices among international specialists. In order to make an impact on the symptoms reported by patients, they most frequently prescribe a combination of support, physiotherapy and painkillers. The evidence suggests differentiated prescribing practices at the international level.

A study conducted by Solveborn reported that physiotherapeutic stretching of the forearm is more effective than simply prescribing a support for pain caused by humeral epicondylitis<sup>5</sup>.

A further study by Clements showed that, again, the combination of physiotherapy and support led to the greatest reduction in symptoms<sup>6</sup>.

With regard to the effectiveness of the treatment regime, the observational study showed comparable pain-relieving effects when the EpiTrain was used as the sole treatment method or was prescribed in combination with physiotherapy (VAS (product): 1.9, VAS (product and physiotherapy): 2.1). The proven high effectiveness in pain reduction when wearing the EpiTrain was boosted by the additional use of painkillers (VAS: 0.9 (T3)).

An earlier study by Valle Jones and Hopkin-Richards also documented the pain reduction experienced when wearing the EpiTrain.<sup>4</sup> A significant reduction in pain and increase in joint stability with the EpiTrain was recorded in patients with acute, recurring and persistent elbow pain<sup>4</sup>.

Alongside this pain reduction, the results also showed that the patients' use of painkillers decreased as the study progressed. It is not possible to make any statements regarding the types of painkillers used.

As the study concerns documentation of treatment, the duration of the treatment or the point of full recovery could not be recorded precisely. Based on the study design, a period of 8 to 12 weeks can be assumed.

Finally, the use of the EpiTrain as a first priority in response to pain can be postulated in an international context.

<sup>4</sup> Valle-Jones J-C, Hopkin-Richards H; Controlled trial of an elbow support (EpiTrain) in patients with acute painful conditions of the elbow: a pilot study. *Cum. Med. Res. Opin.*, 12, 224-233, (1990) (

<sup>5</sup> SOLVEBORN S.A. – Radial epicondylagia (tennis elbow) treatment with stretching or forearm band: a prospective study with long-term followup. *Scan J Med Sci Sports* 1997; 7:229-237. zitiert von promanu, 2. Auflage 2010)

<sup>6</sup> CLEMENTS L.G., CHOW S. – Effectiveness of a custom-made below elbow lateral counterforce splint in the treatment of lateral epicondylitis (tennis elbow). *Can J Occup Ther* 1993; 60:137-144. zitiert von promanu, 2. Auflage 2010)