ottobock.

Dyna Ankle





Clinical Study Summaries

This document summarizes clinical studies conducted with the Dyna Ankle. The included studies were identified by a literature search made on PubMed and within the journals *Hefte zur Unfallheilkunde, Orthopädieschuhtechnik, Schweiz. Zeitschr. Sportmed., Sportverletzung – Sportschaden, Orthopädische Praxis,* and *Medizinisch Orthopädische Technik.*

ottobock.

Table of content:

| 1 Overview table | рЗ |
|-----------------------------------|--------|
| 2 Summaries of categories | p 4-8 |
| Functional tests | р5 |
| Satisfaction | p7 |
| 3 Summaries of individual studies | p 9-13 |
| Matussek et al. 2000 | p 10 |
| 4 Copyright | p 14 |

1 Overview table

The summaries are organized in three levels depending on the detail of information. The overview table (Level 1) lists all the relevant publications dealing with a particular product (topic) as well as researched categories (e.g., gait analysis, clinical effects, satisfaction, etc.). By clicking on underlined categories, a summary of all the literature dealing with that category will open (Level 2).

For those interested to learn more about individual studies, a summary of the study can be obtained by clicking on the relevant reference (Level 3).

| | | | | | Category | | | |
|---------------|------|-----------------------------------|---|-------|----------|------------------|------------------|---------------------|
| Refere | ence | | Functions and Activities | | | | | Participation |
| Author | Year | Biomechanics – Static measures | <u>Biomechanics –</u> <u>Gait analysis</u> | X-Ray | EMG | Functional tests | Clinical effects | <u>Satisfaction</u> |
| Matussek | 2000 | | x | | | X | | X |
| Total number: | 1 | 0 | 1 | 0 | 0 | 1 | 0 | 1 |

2 Summaries of categories

On the following pages, you find summaries of categories researched in several studies (e.g. gait analysis, clinical effects, satisfaction, etc.). At the end of each summary, you will find a list of reference studies contributing to the content of the particular summary.

Functional tests / Biomechanics (deep jump)

Major Findings

With Dyna Ankle:

→ highest reduction (6.7° or 60.5%) of supination angle of all competitor orthoses in comparison to barefoot situation





■ barefoot; ■ soft orthoses; ■ semi-rigid orthoses; ■ rigid orthoses (Matussek et al., 2000)

| Clinical Relevance | The literature shows the advantages of early functional therapy over conservatively immobilizing therapy in the treatment of injured ankle ligaments (Lohrer, 1990; Dahners et al., 1989; Wetz et al., 1987; Zwipp, 1986; Zwipp et al., 1988). Tension tests of the outer ligaments showed that they are only slightly tensioned in the range of of 10° dorsal extension and 20° plantar flexion. Orthoses should therefore not only have an antisupinatory effect, but also limit plantar flexion beyond 20° (Wirth et al., 1978). Sufficient scarring of injured structures is only possible if maximum stress on the scar is avoided while maintaining moderate stress stimuli. (Segesser et al., 1986) |
|--------------------|--|
| Summary | Matussek et al. (2000) analyzed eight orthoses available on the market and one tape bandage with regard to their protective abilities during the supination stimulus, which was triggered in the landing phase after a deep jump. The orthoses were divided into three groups according to their design characteristics: |
| | In the soft orthoses, the reduction of the supination angle is approx. 30%, whereby the mode of action is mainly to be interpreted by stimulating the proprioceptive protective reflexes. The semi-rigid orthoses offer an average 39% reduction in the supination angle due to their mechanical stabilizers. The rigid orthoses have an antisupinatory effect and only allow plantar flexion up to approx. 10°-15°. This makes them suitable for the functional treatment of acute rupture of the outer ligaments. |

| | The result of the evaluation of the ankle foot orthoses was not unexpected. Dynamic, sudden supination events are not completely prevented by any of the tested splints (Scheuffelen et al., 1993; Segesser et al., 1986). |
|-------------------------------------|--|
| | The maximum reduction effect of approx. 61% was achieved with the Dyna Ankle from the group of rigid orthoses. Due to their design, they are also able to prevent plantar flexion of more than 20°, which is why they can be used in the acute treatment of external ligament injuries. (Matussek et al., 2000) |
| References of summarized studies | Matussek, J.; Bröcker, L.; Mellerowicz, H.; Neff, G. (2000). Sprunggelenksorthesen- prüfung unter Einsatz eines neuen plyometrischen Testverfahrens – Versuchsbe- schreibung und Analyse der Daten. Testing ankle orthoses by means of a new plyometric technique. <i>Medizinisch Orthopädische Technik</i> , 120: 72-81. |
| Other References | Dahners, L. E.; Torke, M. D.; Gilbert, J. A.; Lester, G. E. (1989). The effect of motion on collagen synthesis and fiber orientation during ligament healing. 35 th Annual Meeting, Orthopaedic Research Society, Las Vegas, Nevada |
| | Lohrer, H. (1990). Mittelfristige Ergebnisse operativ versorgter lateraler Kapsel- bandrupturen am oberen Sprunggelenk – ein Vergleich immobilisierender und funktioneller Nachbehandlung. <i>Orthopädische Praxis</i> ,26:675-679. |
| | Scheuffelen, C.; Gollhofer, A.; Lohrer, H. (1993). Neuartige funktionelle Untersu- chungen zum Stabilisierungsverhalten von Sprunggelenksorthesen. <i>Sportverlet-</i> <i>zung – Sportschaden,</i> 7: 30-36. |
| | Segesser, B.; Jenoure, P.; Feinstein, R.; Vogtsartori, S. (1986). Wirkung äußerer Sta- bilisationshilfen bei fibulärer Distorsion. <i>Orthopädieschuhtechnik,</i> 7: 342-363. |
| | Wetz, B.; Steffen, R.; Raemy, H.; Jakob, R. P. (1987). Spätergebnisse nach konser- vativer Therapie fibulotalarer Bandläsionen mit der Aircastschiene. <i>Scheweiz.</i> <i>Zeitschr. Sportmed.</i> , 35: 115-118. |
| | Wirth, C. J.; Küsswetter, W.; Jäger, M. (1978). Biomechanik und Pathomechanik des oberen Sprunggelenkes. <i>Hefte zur Unfallheilkunde</i> 131: 10-22. |
| | Zwipp, H. (1986). Die anterolaterale Rotationsinstabilität des Oberen Sprungge- lenks. <i>Hefte zur Unfallheilkunde</i> 177. |
| | Zwipp, H.; Tscherne, H.; Hoffmann, R.; Thermann, H. (1988). Riß der Knöchelbän- der: Operative Versorgung oder konservative Behandlung. <i>Deutsches Ärzteblatt</i> 42: 2897-2902. |

↑ Back to overview table

Satisfaction

Major Findings

With Dyna Ankle:

- → high sense of security in 15 of 19 subjects
- → good wearing comfort in 16 of 19 subjects
- → easy to learnable handling in 18 of 19 subjects
- \rightarrow low to moderate feeling of restriction in 15 of 19 subjects



Perceived sense of security

Clinical Relevance

Satisfaction can be measured to determine the general well-being of a person and the fulfilment of his expectations to the medical device. It is a very meaningful parameter to investigate since it has a direct impact on the patient's well-being and compliance. It is influenced by additional categories and can therefore be seen as a summary of possible pain reduction and better performance of ADLs.

Additionally, the patients' satisfaction is also correlated with the usage of the medical device. Studies on the non-use of devices suggest that, on average, a third of all devices provided are not used (Scherer 2002). The lack of consumer involvement or consumer dissatisfaction with the device were shown as predictors of non-use (Wielandt & Strong, 2000). In addition, a number of problems have been identified as reasons for non-use: inadequate performance of the product; poor function of the product; difficulty in operating the product; and the high cost of the products and their maintenance (Batavia & Hammer 1990, Goodacre & Turner, 2005). Obtaining user perspectives is therefore fundamental to address these issues.

| Summary | Each of the orthoses tested gives most test persons a sense of safety. As expected, this is often described as "high" in the rigid and semi-rigid orthoses. |
|-------------------------------------|--|
| | As expected, wearing comfort with soft and semi-rigid orthoses was also described more frequently as "hardly irritating". Within the group of rigid orthoses, the Dyna Ankle offers clearly higher wearing comfort. |
| | The handling of the Dyna Ankle was predominantly assessed as "easy" 8/19 and "learnable" 10/19. The bandage and the stirrup orthoses were most frequently rated as "easy". |
| | Likewise, the result on the feeling of limitation was as expected. The soft orthoses were most frequently rated as "low" and the rigid orthoses as "moderate" to "strong". Within the group of rigid orthoses, the Dyna Ankle also shows clear advantages here. (Matussek et al., 2000) |
| References of summarized studies | Matussek, J.; Bröcker, L.; Mellerowicz, H.; Neff, G. (2000). Sprunggelenksorthesen- prüfung unter Einsatz eines neuen plyometrischen Testverfahrens – Versuchsbe- schreibung und Analyse der Daten. Testing ankle orthoses by means of a new plyometric technique. <i>Medizinisch Orthopädische Technik</i> , 120: 72-81. |
| Other References | Batavia, A. I.; Hammer, G. S. (1990). Toward the development of consumerbased criteria for the evaluation of assistive devices. <i>Journal of rehabilitation research and development</i> , 27(4): 425-436. |
| | Goodacre, L.; Turner, G. (2005). An investigation of the effectiveness of the Quebec user evaluation of satisfaction with assistive technology via a postal survey. <i>British</i> <i>Journal of Occupational Therapy</i> , 68(2): 93-96 |
| | Scherer, M. J. (2002). The change in emphasis from people to person: introduction to the special issue on Assistive Technology. <i>Disability and rehabilitation</i> , 24(13): 1-4. |
| | Wielandt, T.; Strong, J. (2000). Compliance with prescribed adaptive equipment: a literature review. <i>The British Journal of Occupational Therapy</i> , 63(2): 65-75. |

A Back to overview table

3 Summaries of individual studies

On the following pages, you find summaries of studies that researched Dyna Ankle. You find detailed information about the study design, methods applied, results and major findings of the study. At the end of each summary, you also can read the original study authors' conclusions.

| Reference | Matussek, J.; Bröcker, L.; Mellerowicz, H.; Neff, G.; | | | | | | | |
|----------------|---|--|--|--|--|--|--|--|
| | Orthopädische Universitätsklinik und Polyklinik der Freien Universität Berlin. | | | | | | | |
| | Testing ankle orthoses by means of a new plyometric technique | | | | | | | |
| | Sprunggelenksorthesenprüfung unter Einsatz eines neu entwickelten plyometrischen Testverfahrens – Versuchsbeschreibung und Analyse der Daten | | | | | | | |
| | Medizinisch Orthopädische Technik 2000, 120: 72-81 | | | | | | | |
| Products | Dyna Ankle (Ottobock); Caligamed, MalleoLoc (Bauerfeind); mediMAC, Ro- cketSoc (medi); Antiv (Röck); Aircast (Aircast); Micros-OV (Warncke); Tape | | | | | | | |
| Major Findings | With Dyna Ankle: | | | | | | | |

→ highest reduction (6.7° or 60.5%) of supination angle of all competitor orthoses in comparison to barefoot situation

Mean reduction of supination angle in comparison to barefoot situation



ightarrow high sense of security in 15 of 19 subjects

- → good wearing comfort in 16 of 19 subjects
- → easy to learnable handling in 18 of 19 subjects
- \rightarrow low to moderate feeling of restriction in 15 of 19 subjects

Population

Subjects:

19 (14 male, 5 female) 10 healthy, 9 with known supination trauma 29.0 \pm 4.7 years (range 19-40 years)

Mean age:

Study Design

Randomized crossover design with intra-individual control:



Results

| Functions and Activities Pa | | | | | | Participation |
|---|---------------------------------|-------|--|------------------------|------------------|---------------|
| Biomechanics – Static measures | Biomechanics – Gait analysis | X-Ray | EMG | Functional tests | Clinical effects | Satisfaction |
| Category | Outcomes | | Results for Dyn | a Ankle and competitor | products | sig. |
| Functional tests – Supination angle deep jump | | ngle | Reduction of supination angle due to intervention compared to barefoot situation | | | |
| | | | | Reduction (°) | Reduction (%) | |
| | | | Dyna Ankle | 6.7 | 60.5 | _ |
| | | | Caligamed | 5.6 | 53.3 | _ |
| | | | mediMAC | 4.1 | 36.8 | _ |
| | | | MalleoLoc | 4.5 | 42.9 | _ |
| | | | Antiv | 4.3 | 42.5 | _ |
| | | | Aircast | 3.6 | 32.3 | _ |
| | | | Mikros | 4.0 | 36.4 | _ |
| | | | RocketSoc | 2.0 | 17.4 | _ |
| | | | Таре | 1.9 | 17.6 | _ |

| | Biomechanics – X-Ray Gait analysis | EMG | Functional | tests Clinical effects | Satisfaction | n |
|--------------|---------------------------------------|----------------------------------|--|------------------------|--------------|------|
| Category | Outcomes | Results for Dy | na Ankle and comp | petitor products | si | ig.' |
| Satisfaction | Sense of security | | the survey of the sul answers is shown. | pjects regarding the o | orthoses. n. | n.a. |
| | | | high | low | | |
| | | Dyna Ankle | 15 | 4 | | |
| | | Caligamed | 15 | 4 | | |
| | | mediMAC | 16 | 3 | | |
| | | MalleoLoc | 12 | 7 | | |
| | | Antiv | 16 | 3 | | |
| | | Aircast | 14 | 5 | | |
| | | Mikros | 14 | 5 | | |
| | | RocketSoc | 15 | 4 | | |
| | | Таре | 10 | 9 | | |
| | Wearing comfort | | he survey of the subj answers is shown. | ects regarding the ort | hoses. n | ı.a |
| | | | hardly irritating | somewhat irritating | irritating | |
| | | Dyna Ankle | 6 | 10 | 3 | |
| | | Caligamed | 1 | 6 | 12 | |
| | | mediMAC | 12 | 6 | 1 | |
| | | MalleoLoc | 11 | 7 | 1 | |
| | | Antiv | 9 | 9 | 1 | |
| | | Aircast | 15 | 4 | 0 | |
| | | Mikros | 10 | 7 | 2 | |
| | | RocketSoc | 10 | 6 | 3 | |
| | | Таре | 15 | 4 | 0 | |
| | Handling during donning and doff- | Findings from t The number of | hoses. n. | .a. | | |
| | ing | r | easy | learnable | difficult | |
| | | Dyna Ankle | 8 | 10 | 1 | |
| | | Caligamed | 9 | 9 | 1 | |
| | | mediMAC | 8 | 9 | 2 | |
| | | MalleoLoc | 7 | 9 | 3 | |
| | | Antiv | 15 | 4 | 0 | |
| | | Aircast | 16 | 3 | 0 | |
| | | Mikros | 10 | 9 | 0 | |
| | | RocketSoc | 9 | 10 | 0 | |
| | | | 1 | 1 1 | | |

| Functions and Activ | vities | | | | | Participation |
|---------------------|-----------------------------|-----------|-----------------------------------|--|-------------------|---------------|
| | | | | Functional tests | Clinical effects | Satisfaction |
| Category | Outcomes | Res | ults for Dyna | Ankle and competite | or products | sig |
| | Feeling of re- striction | | lings from the s number of ans | survey of the subjects wers is shown. | regarding the ort | hoses. n.a |
| | | | | low | moderate | strong |
| | | Dyn | a Ankle | 7 | 8 | 4 |
| | | Cali | gamed | 1 | 9 | 9 |
| | | mec | liMAC | 9 | 10 | 0 |
| | | Mal | leoLoc | 10 | 9 | 0 |
| | | Anti | v | 7 | 11 | 1 |
| | | Airc | ast | 15 | 4 | 0 |
| | | Miki | ros | 17 | 2 | 0 |
| | | Roc | ketSoc | 16 | 3 | 0 |
| | | Тар | e | 16 | 3 | 0 |
| | Would you v the orthosis | for a The | lings from the s number of ans | urvey of the subjects wers is shown. | regarding the ort | hoses. n.a |
| | longer time? |) | | yes | reluctantly | no |
| | | Dyn | a Ankle | 3 | 7 | 9 |
| | | Cali | gamed | 0 | 6 | 13 |
| | | mec | liMAC | 11 | 8 | 0 |
| | | Mal | leoLoc | 7 | 10 | 2 |
| | | Anti | v | 5 | 12 | 2 |
| | | Airc | ast | 12 | 7 | 0 |
| | | Miki | ros | 10 | 6 | 3 |
| | | Roc | ketSoc | 11 | 7 | 1 |
| | | Тар | , | 11 | 8 | 0 |

Author's Conclusion

"The plyometric (retrograde standing jump) test procedure for determining the protective effect of ankle joint orthoses has the advantage of simulating the supination stress situation as far as possible. Eight commonly available braces and classical taping were analysed in view of observing the supination that occurs during landing. The orthoses of the rigid group effectively have the most favourable absolute protective effect, whereby wearing comfort of the Caligamed has to be significantly reduced compared to the Dyna Ankle." (Matussek et al. 2000)

<u>A Back to overview table</u>

Copyright:

© 2014, Otto Bock HealthCare Products GmbH ("Otto Bock"). All Rights Reserved. This document contains copyrighted material. Wherever possible we give full recognition to the authors. We believe this constitutes a 'fair use' of any such copyrighted material according to Title 17 U.S.C. Section 107 of US Copyright Law. If you wish to use copyrighted material from this site for purposes of your own that go beyond 'fair use', you must obtain permission from the copyright owner. All trademarks, copyrights, or other intellectual property used or referenced herein are the property of their respective owners. The information presented here is in summary form only and intended to provide broad knowledge of products offered. You should consult your physician before purchasing any product(s). Otto Bock disclaims any liability related from medical decisions made based on this document.