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Omo Neurexa

Quality for life

Clinical Study Summaries

This document summarizes clinical studies conducted with the Omo Neurexa. The included studies were identified by a literature search made on PubMed and within the journals NeuroRehabilitation, Orthopädie-Technik and Neurologie & Rehabilitation.

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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).

Reference		Category						
		Functions and Activities						Participation
Author	Year	Biomechanics – Static measures	Biomechanics – Gait analysis	X-Ray	EMG	Functional tests	Clinical effects	Satisfaction
Hesse	2013		x	x	x	x	x	x
Hesse	2009		x	x	x	x	x	x
Hesse	2008			x			x	x
Total number: 3		0	2	3	2	2	3	3

2 Summaries of categories

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

Biomechanics – Gait analysis

Major Findings

With Omo Neurexa compared to no orthotic treatment:

→ Significantly more symmetric gait

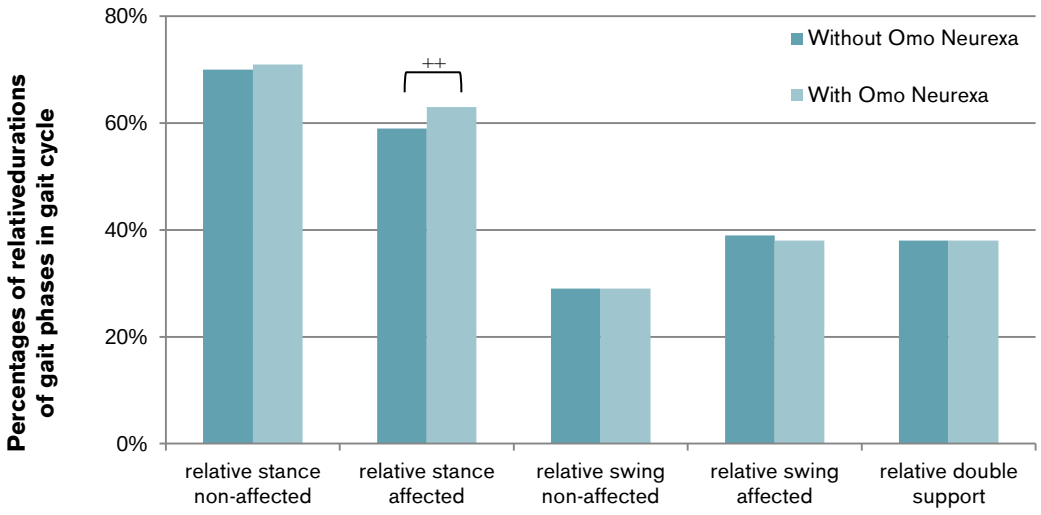
- 7.5% prolonged hemiparetic side stance phase (Hesse et al. 2013)
- 6.9% increased stance symmetry ratio (Hesse et al. 2013)
-
- 17% reduction in relative double support phase (Hesse et al. 2009)

→ Tendency towards a greater stride length and towards a lower cadence (Hesse et al. 2009)

→ Other gait relating aspects:

- 70% of patients reported that they felt more secure during transfer tasks and mobility (Hesse et al. 2009)
- Protection of the paretic arm leads to a better concentration on gait rehabilitation (Hesse et al. 2008)
- Improved patient- and therapist-reported activity level and performance in mobility related activities of daily living (Hesse et al. 2013)

The instrumented gait analysis showed that the patients walked more symmetrically while wearing the Omo Neurexa



(Hesse et al. 2013; *Asterisks* indicate significant group differences with ++= p< 0.05)

Clinical Relevance

Faster and more efficient gait is an important goal of rehabilitation after stroke, especially for the chronic stroke patient who often continues to be limited in daily activities by slow, insecure gait. (Jonsdottir et al. 2007)

For lower extremities, the most important function is ambulation. It influences the mobility grade of the subject, participation and, therefore, general quality of life. Furthermore, a natural gait pattern is favorable as it prevents the sound side from higher or inappropriate loading due to compensatory movements. Gait asymmetries can contribute to secondary diseases such as osteoarthritis.

Safety aspects while walking are highly relevant to the patients. Since the fear of falling can have a negative impact on activities of daily living as well as on participation, perceived safety is regarded as an important factor for quality of life.

Cognitive demand of walking is investigated to determine how much attention has to be paid to walking. This is important because many activities in daily life are performed simultaneously (e.g. walking and talking on the phone).

The Omo Neurexa aims to repositioning the subluxated shoulder joint in the right position and thus reducing pain and improving gait.

Summary

Three studies evaluated the effectiveness of the Omo Neurexa:

Instrumented gait analysis was performed with and without the Omo Neurexa by Hesse et al. (2009 and 2013). Initially, patients performed the 10-m test twice without any instrumentation, in order to determine their self-selected walking velocity. During the subsequent instrumented gait analysis with and without the orthosis, the patients were instructed to walk at their self-selected speed, cued by a metronome. Gait analysis was performed on a floor 100-m long walk way. Limb-dependent cycle parameters were averaged over 30s, and normalized with respect to the gait cycle (= 100%). Symmetry ratios were calculated for stance and swing durations (duration of the left-side divided by that of the right if the duration of the left was shorter, or vice versa).

During the instrumented gait analysis a more symmetric and dynamic gait pattern could be observed when walking with the Omo Neurexa (Hesse et al. 2009, Hesse et al. 2013) and an improvement in activity level and performance during mobility-related activities of daily living (Hesse et al. 2013). Improved gait quality may help re-learn walking and performing mobility-related activities (Hesse et al. 2013). Furthermore, it promotes restoration of activity. The results of the gait analysis are consistent with a more secure and dynamic gait; there was also facilitation of the knee extensor on the affected side in some selected patients. (Hesse et al. 2009)

References of summarized studies

Hesse, S., Bardeleben, A., Rembitzki, I., Werner, C. (2009). Klinische und ganganalytische Befunde zur Schulterorthese Omo Neurexa. Clinical and Gait Analysis Data on Shoulder Orthosis Omo Neurexa. *Orthopädie-Technik*, 3: 177–181.

Hesse, S., Herrmann, C., Bardeleben, A., Holzgraefe, M., Werner, C., Wingendorf, I., Kirker, S. (2013). A new orthosis for subluxed, flaccid shoulder after stroke facilitates gait symmetry: A preliminary study. *Journal of Rehabilitation Medicine*, 45 (7): 623–629. DOI: 10.2340/16501977-1172

Other References

Jonsdottir, J., Cattaneo, D., Regola, A., Crippa, A., Recalcati, M., Rabuffetti, M., ... & Casiraghi, A. (2007). Concepts of motor learning applied to a rehabilitation protocol using biofeedback to improve gait in a chronic stroke patient: an AB system study with multiple gait analyses. *Neurorehabilitation and neural repair*, 21(2):190-194.

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X-Ray

Major Findings

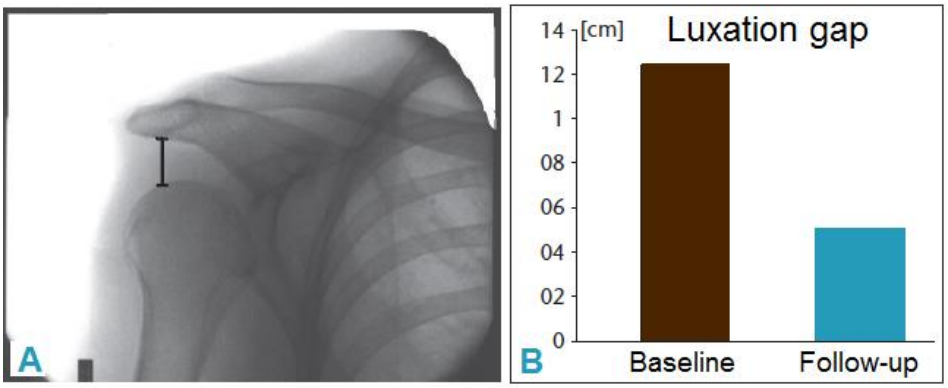
With Omo Neurexa compared to no orthotic treatment:

→ **The distance between the point of the acromion and a perpendicular vertical line through the central point of the humeral head decreased by a mean of 0.8 ± 0.6 cm (in 83% of radiographed patients (10 out of 12) = significant repositioning of the humeral head** (Hesse et al. 2013)

→ **In 70% of patients the shoulder joint space was reduced by an average of 2.5cm after the 4-week intervention** (Hesse et al. 2009)

→ **42% of patients wore the orthosis because of a shoulder subluxation: in 60% of those, the gap between the acromion and humeral head was closed and in 40% the gap was reduced after the 4-week intervention** (Hesse et al. 2008)

Omo Neurexa improved the position of the humeral head



A) X-ray image of subluxated shoulder: Distance = gap between the point of the acromion and a perpendicular vertical line through the central point of the humeral head (Hesse et al. 2013); B) After 4-week intervention with Omo Neurexa the position of the humeral head could be improved, shown is the average subluxation gap (Hesse et al. 2009).

Clinical Relevance

"Stroke is the most frequent cause of permanent impairment in the industrialized world (Hesse et al. 2009)." In Germany approximately 180 persons per 100,000 suffer from stroke annually (Kolominsky-Rabas et al. 2006). A significant proportion of stroke survivors will experience neurologic squeal and pain, with the hemiplegic shoulder pain being most common with 15-84% of patients (Andersen et al. 1995, Barlak et al. 2009, Bowsher 1995, Kong et al. 2004, Leijon et al. 1998, Ratnasabapathy et al. 2003, Van Ouwenaller et al. 1986, Zorowitz et al. 1996). In the later phases of rehabilitation, a shoulder-hand syndrome may develop which is characterized by pain, edema and a restricted flexibility of shoulder and hand (Hesse et al. 2008).

The etiology of the painful shoulder syndrome (PSS) has been ascribed to the biomechanical compromise of the post-stroke glenohumeral joint, subluxation due to paresis of the shoulder girdle, shoulder spasticity, rotator cuff tears, and a limited range of motion (ROM) of the shoulder (Davies 1990, Paci et al. 2007, Vuagnat & Chantraine 2003). In early rehabilitation, a flaccid, rather than a spastic, type of PSS predominates, mainly characterized by paresis of the shoulder girdle, with shoulder subluxation, shoulder micro trauma and soft tissue inflammation (Braus et al. 1994, Hesse et al. 1992). When the patient raises the arm, the humeral head bumps against the acromion and causes micro trauma and soft tissue inflammation. It is the current understanding that this is an essential factor in the pathogenesis of the flaccid form of the painful shoulder. (Braus et al. 1994)

The Omo Neurexa aims at repositioning the subluxated shoulder joint in the right position and thus reducing pain and improving gait.

Summary

Three studies evaluated the effectiveness of the Omo Neurexa:

A conventional anterior-posterior X-ray of the affected shoulder with and without the Omo Neurexa was carried out, while the patient was standing. Two experienced radiologists independently measured to what extent the orthosis repositioned the shoulder head vertically. Two reference points were identified: the most inferolateral point of the acromion and the apex of the humeral head. A line was drawn between these two points, and the distance was measured.

This X-ray examination revealed that the orthosis repositioned the humeral head in the vertical direction to a relevant extent. A repositioning effect was reported in 83.3% of patients (Hesse et al. 2013). A closing of the subluxation gap was also observed in 60% of patients in the study of Hesse et al. (2008). In the remaining 40% of patients included in this study, a reduction of the subluxation gap was observed. Hesse et al. (2009) reported a mean reduction in joint space of 2.5cm.

Furthermore 45-86% of patients reported a reduction of shoulder pain due to wearing the Omo Neurexa (Hesse et al. 2008, Hesse et al. 2009, Hesse et al. 2013).

References of summarized studies

Hesse, S., Bardeleben, A., Grunden, J., Rembitzki, I., Werner, C. (2008). Vorstellung einer neuen Schulterorthese zur Behandlung der schmerzhaften Schulter von hochparetischen Patienten in der Frührehabilitation. *Neurologie & Rehabilitation*, 14 (2): 91–94.

Hesse, S., Bardeleben, A., Rembitzki, I., Werner, C. (2009). Klinische und ganganalytische Befunde zur Schulterorthese Omo Neurexa. Clinical and Gait Analysis Data on Shoulder Orthosis Omo Neurexa. *Orthopädie-Technik*, 3: 177–181.

Hesse, S., Herrmann, C., Bardeleben, A., Holzgraefe, M., Werner, C., Wingendorf, I., Kirker, S. (2013). A new orthosis for subluxed, flaccid shoulder after stroke facilitates gait symmetry: A preliminary study. *Journal of Rehabilitation Medicine*, 45 (7): 623–629. DOI: 10.2340/16501977-1172

Other References

Andersen, G., Vestergaard, K., Ingeman-Nielsen, M., Jensen, T. S. (1995). Incidence of central post-stroke pain. *Pain*, 61:177-86.

Barlak, A., Unsal, S., Kaya, K., Sahin-Onat, S., & Ozel, S. (2009). Poststroke shoulder pain in Turkish stroke patients: relationship with clinical factors and functional outcomes. *International Journal of Rehabilitation Research*, *32*(4):309-315.

Bowsher, D. (1995). The management of central post-stroke pain. *Postgraduate Medical Journal*, 71:598-604

Braus, D.F., Krauss, J.K., Strobel, J. (1994). The shoulder-hand syndrome after stroke: a prospective clinical trial. *Annals of Neurology*, 36:728–733.

Davies, P.M. (1990). Right in the middle, selective trunk activity in the treatment of adult hemiplegia. Berlin: Springer-Verlag.

Hesse, S., Friedrich, H., Domasch, C., Mauritz, K. H. (1992). Botulinum toxin therapy for upper limb flexor spasticity: preliminary results. *J Rehab Sci*, 5:98–101.

Kolominsky-Rabas, P. L., Heuschmann, P. U., Marschall, D., Emmert, M., Baltzer, N., Neundörfer, B., Schöffski, O., Krobot, K. J. (2006). Lifetime cost of ischaemic stroke in Germany: results and national projections from a population-based stroke registry: the Erlangen Stroke Project. *Stroke*, 37:1179-1183.

Kong, K. H., Woon, V. C., & Yang, S. Y. (2004). Prevalence of chronic pain and its impact on health-related quality of life in stroke survivors. *Archives of physical medicine and rehabilitation*, 85(1):35-40.

Leijon, G., Boivie, J., Johannson, I. (1989). Central post-stroke pain - neurological symptoms and pain characteristics. *Pain*, 36:13-25.

Paci, M., Nannetti, L., Taiti, P., Baccini, M., Rinaldi, L. (2007). Shoulder subluxation after stroke: relationships with pain and motor recovery. *Physiotherapy Research International*, 12:95–104.

Ratnasabapathy, Y., Broad, J., Baskett, J., Pledger, M., Marshall, J., Bonita, R.(2003). Shoulder pain in people with a stroke: a population-based study. *Clinical Rehabilitation*, 17(3):304-311.

Van Ouwenaller, C., Laplace, P. M. & Chantraine, A. (1986). Painful shoulder in hemiplegia. *Archives of physical medicine and rehabilitation,* 67:23–26.

Vuagnat, H. & Chantraine, A. (2003). Shoulder pain in hemiplegia revisited: contribution of functional electrical stimulation and other therapies. *Journal of Rehabilitation Medicine*, 35:49-54.

Zorowitz, R. D., Hughes, M. B., Idank, D., Ikai, T., & Johnston, M. V. (1996). Shoulder pain and subluxation after stroke: correlation or coincidence?. *American Journal of Occupational Therapy*, 50(3):194-201.

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EMG (Electromyographic) examination

Major Findings

With Omo Neurexa compared to no orthotic treatment:

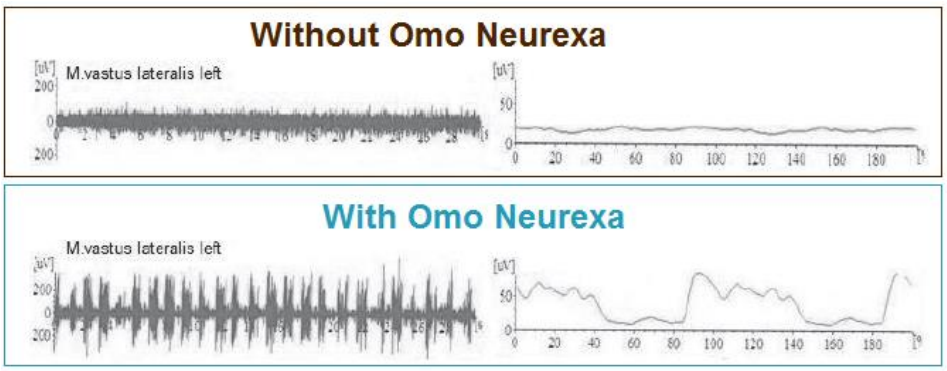
→ **Significantly more symmetric gait** (Hesse et al. 2013)

- Prolonged hemiparetic side stance phase

→ **Higher and more appropriately timed muscle activity of the paretic quadriceps muscle**

- Vastus lateralis muscle:
  67% of patients had a more normal phasic pattern of activation in early stance phase (Hesse et al. 2013)
- Vastus medialis and biceps femoris muscles:
  75% of patients had a more normal phasic pattern of activation in early stance phase (Hesse et al. 2013)
- Gluteus medialis muscle:
  42% of patients showed more muscle activity during the early stance phase (Hesse et al. 2013)
- Quadriceps femoris muscle:
  40% of patients showed a more pronounced activity and showed an earlier onset of activity during the stance phase (Hesse et al. 2009)

There is more pronounced and more appropriately timed muscle activation when walking with Omo Neurexa



Raw and averaged and normalized activity of the affected Vastus lateralis muscle of a hemiparetic patient when walking without (top figure) and with Omo Neurexa (lower figure). (Hesse et al. 2013)

Clinical Relevance

A myoelectric signal, or electromyogram (EMG), is the electrical manifestation of a muscle contraction. EMG is used as a diagnostic tool for identifying neuromuscular diseases, or as a research tool for studying kinesiology and disorders of motor control. It is recorded to detect and analyze the voluntary muscle activation in functional movements. With this method, the following questions can be answered: Is the muscle active? Is the muscle more / less active? When is the muscle active? Furthermore, the question of muscle coordination can be answered (symmetrical innervation of synergists, appropriate co-innervation of antagonists). (Konrad 2005)

At rest, muscle tissue is normally electrically inactive. After the electrical activity, the electromyograph should not detect any abnormal spontaneous activity. When the muscle contracts voluntarily, action potentials begin to appear. As the force of the

muscle contraction increases, more and more muscle fibers produce action potentials. EMG findings vary with the type of disorder. Interpreting EMG findings is usually best done in a context of physical examination of the patient, and in conjunction with the results of other relevant diagnostic procedures. (Konrad 2005)

EMG provides easy access to physiological processes that cause the muscle to generate force, produce movement, and accomplish the countless functions that allow us to interact with the world around us (de Luca 1997).

Summary

Two studies evaluated the effectiveness of the Omo Neurexa:

Electromyographic activity was detected by self-adhesive surface electrodes, which were attached 2 cm apart on the muscle bellies. On each subject's affected side, recordings were obtained for the following muscles: tibialis anterior, medial head of the gastrocnemius, vastus lateralis, vastus medialis, rectus femoris, biceps femoris, gluteus medius and erector spinae.

The qualitative analysis of the dynamic EMG revealed a more normal phasic pattern of activation of the vastus lateralis muscle in the early stance phase. For the vastus medialis and biceps femoris, the same pattern change was seen. The gluteus medius muscle became more active in the early stance phase. The shank muscles and the erector spinae revealed no discernible alterations of their muscle activation patterns. (Hesse et al. 2013)

One aspect observed when walking with the Omo Neurexa was a more symmetric and dynamic gait pattern (Hesse et al. 2009, Hesse et al. 2013) and an improvement in activity level and performance during mobility related activities of daily living (Hesse et al. 2013).

This improved gait quality may help in re-learn walking and performing mobility-related activities (Hesse et al. 2013).

Furthermore, it promotes restoration of activity. The results of the gait analysis are consistent with a more secure and dynamic gait; there was also facilitation of the knee extensor on the affected side in some selected patients. (Hesse et al. 2009)

References of summarized studies

Hesse, S., Bardeleben, A., Rembitzki, I., Werner, C. (2009). Klinische und ganganalytische Befunde zur Schulterorthese Omo Neurexa. Clinical and Gait Analysis Data on Shoulder Orthosis Omo Neurexa. *Orthopädie-Technik*, 3: 177–181.

Hesse, S., Herrmann, C., Bardeleben, A., Holzgraefe, M., Werner, C., Wingendorf, I., Kirker, S. (2013). A new orthosis for subluxed, flaccid shoulder after stroke facilitates gait symmetry: A preliminary study. *Journal of Rehabilitation Medicine*, 45 (7): 623–629. DOI: 10.2340/16501977-1172

Other References

De Luca, C. J. (1997). The use of surface electromyography in biomechanics. *Journal of applied biomechanics*, 13:135-163.

Konrad, P. (2005). EMG-Fibel. ABC of EMG. A Practical Introduction to Kinesiological Electromyography. Noraxon Inc. USA.

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Functional tests

Major Findings

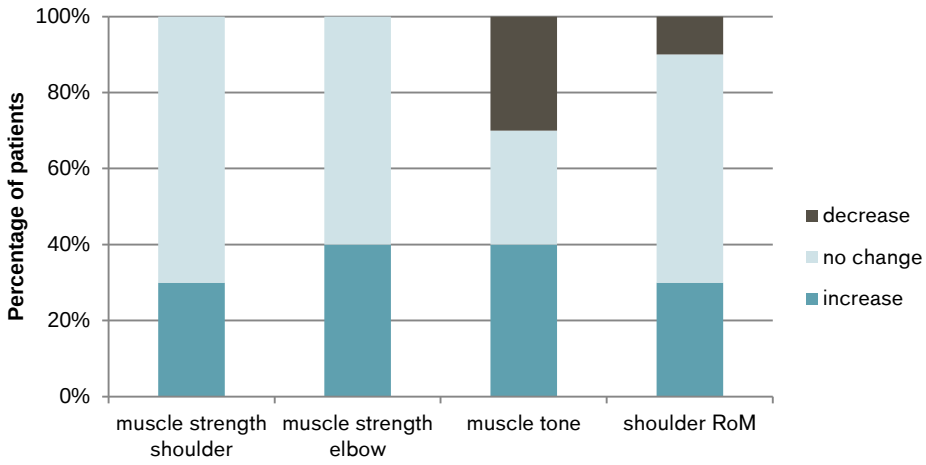
With Omo Neurexa compared to no orthotic treatment:

→ **The muscle strength (MRC score) increased significantly** (Hesse et al. 2013)
- 30% of patients showed an increase in shoulder strength (Hesse et al. 2009)
- 40% of patients showed an increase in elbow strength (Hesse et al. 2009)

→ **Minor changes in muscle tone assessed on Ashworth scale**
- 30% of patients showed a decreased Ashworth score (reduction of spasticity) (Hesse et al. 2009)
- 40% of patients showed an increase in the Ashworth score (development of flexor spasticity) (Hesse et al. 2009)
- The muscle tone on Ashworth scale remains constant (Hesse et al. 2013)

→ **Tendency towards an increased shoulder Range of Motion (RoM)** (Hesse et al. 2013)
- 30% of patients showed an improvement in passive RoM (Hesse et al. 2009)
- 10% of patients showed a deterioration in passive RoM (Hesse et al. 2009)

With Omo Neurexa improvements in functional tests was observed



(Hesse et al. 2009)

Clinical Relevance

"Stroke is the most frequent cause of permanent impairment in the industrialized world (Hesse et al. 2009)." Fifteen million people suffer from stroke every year worldwide, five million die and another five million are left with permanent disability (WHO report 2009). An ischemic stroke may lead to a hemiparesis, accompanied by abnormalities of muscle tone (identified as spastic hypertonia or spasticity), muscle weakness and impaired muscular coordination (movement dysfunction) (Dewald et al. 2001, Sabut et al. 2011).

Muscle weakness is a significant consequence of stroke. Reduction of muscle strength is due to the combined effects of the upper motor neuron lesion and secondary adaptations due to denervation, disuse and inactivity and, in some individuals, the effects of aging. Muscle strength is directly related to functional performance. (Ng & Shepherd 2013)

The major clinical problems related to spasticity after stroke are mobility decrease and hypertonus, resulting in a range of motion (RoM) restriction, abnormal postures, pain and fixed contractures, with poor response to physiotherapy (Reiter et al. 1998).

The recovery of upper limb function is of great importance in improving the patients' quality of life and helping them maximize their independence (Kwakkel et al. 2003). Rehabilitation can help to ease symptoms, and restore upper limb function. Assessment of recovery is an important aspect of any rehabilitation program. (Bai et al. 2014)

The Ashworth scale is the most popular clinical measure of muscle spasticity and resistance to passive movement (Ansari et al. 2009).

The Medical Research Council (MRC) Scale for muscle strength grades the muscle strength from 0= "no movement is observed" to 5= "muscle contract normally against full resistance". (Paternostro-Sluga et al. 2008)

Summary

Two studies evaluated the effectiveness of the Omo Neurexa:

The muscle strength evaluated with the MRC score could be increased in the shoulder and elbow muscles in 30-40% of patients as well as the range of motion in the shoulder joint. Accordingly, the muscle tone, assessed with the Ashworth scale remains constant (Hesse et al. 2009, Hesse et al. 2013).

References of summarized studies

Hesse, S., Bardeleben, A., Rembitzki, I., Werner, C. (2009). Klinische und ganganalytische Befunde zur Schulterorthese Omo Neurexa. Clinical and Gait Analysis Data on Shoulder Orthosis Omo Neurexa. *Orthopädie-Technik*, 3: 177–181.

Hesse, S., Herrmann, C., Bardeleben, A., Holzgraefe, M., Werner, C., Wingendorf, I., Kirker, S. (2013). A new orthosis for subluxed, flaccid shoulder after stroke facilitates gait symmetry: A preliminary study. *Journal of Rehabilitation Medicine*, 45 (7): 623–629. DOI: 10.2340/16501977-1172

Other References

Ansari, N. N., Naghdi, S., Arab, T. K., & Jalaie, S. (2008). The interrater and intrarater reliability of the Modified Ashworth Scale in the assessment of muscle spasticity: limb and muscle group effect. *NeuroRehabilitation*, 23(3):231-237.

Bai, L., Pepper, M.G., Yan, Y., Spurgeon, S.K., Sakel, M., Phillips, M., (2014). Quantitative Assessment of Upper Limb Motion in Neurorehabilitation Utilizing Inertial Sensors. TNSRE-2013-00273.R2. https://kar.kent.ac.uk/47726/1/TNSRE-2013-00273%20R2-Final_Version.pdf

Dewald, J. P., Sheshadri, V., Dawson, M. L., & Beer, R. F. (2001). Upper-limb discoordination in hemiparetic stroke: implications for neurorehabilitation. *Topics in stroke rehabilitation*, 8(1):1-12.

Kwakkel, G., Kollen, B. J., van der Grond, J., & Prevo, A. J. (2003). Probability of regaining dexterity in the flaccid upper limb impact of severity of paresis and time since onset in acute stroke. *Stroke*, 34(9):2181-2186.

Ng, S. S., & Shepherd, R. B. (2013). Weakness in patients with stroke: implications for strength training in neurorehabilitation. *Physical Therapy Reviews*.

Paternostro-Sluga, T., Grim-Stieger, M., Posch, M., Schuhfried, O., Vacariu, G., Mittermaier, C., ... & Fialka-Moser, V. (2008). Reliability and validity of the Medical Research Council (MRC) scale and a modified scale for testing muscle strength in patients with radial palsy. *Journal of rehabilitation medicine*, 40(8):665-671.

Reiter, F., Danni, M., Lagalla, G., Ceravolo, G., & Provinciali, L. (1998). Low-dose botulinum toxin with ankle taping for the treatment of spastic equinovarus foot after stroke. *Archives of physical medicine and rehabilitation*, 79(5):532-535.

Sabut, S. K., Sikdar, C., Kumar, R., & Mahadevappa, M. (2011). Functional electrical stimulation of dorsiflexor muscle: effects on dorsiflexor strength, plantarflexor spasticity, and motor recovery in stroke patients. *NeuroRehabilitation*, 29(4):393-400.

WHO report. Cardiovascular diseases: Facts about cardio- vascular diseases, 2009. [Online] http://www.who.int/mediacentre/factsheets/fs317/en/index.html.

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Clinical effects

Major Findings

With Omo Neurexa compared to no orthotic treatment:

Patient-reported

→ **Patients reported a positive effect of Omo Neurexa in terms of pain reduction (45%), activity level (55%) and performance of mobility related ADL's (58%)** (Hesse et al. 2013)

→ **50% of patients reported a reduction of shoulder pain and another 50% reported on no change in the pain situation** (Hesse et al. 2009)

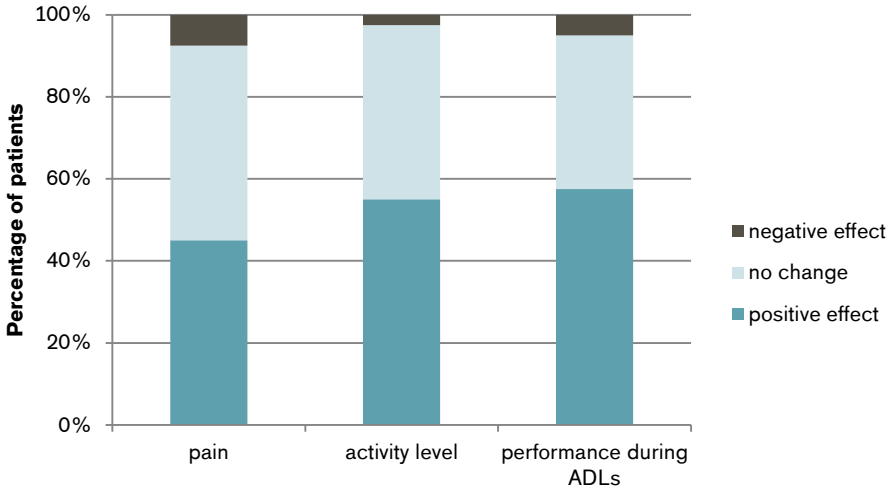
→ **58% of patients reported shoulder pain at the beginning of the intervention phase: 86% of those patients reported a relevant reduction of shoulder pain due to wearing the orthosis** (Hesse et al. 2008)

→ **Protection of the paretic arm leads to a better concentration on gait rehabilitation** (Hesse et al. 2008)

Therapist-reported

→ **Therapists reported a positive effect of Omo Neurexa in terms of activity level (70%) and performance of mobility-related ADL's (55%)** (Hesse et al. 2013)

Omo Neurexa improved the ability of the patients to participate in daily activities



(Hesse et al. 2013)

Clinical Relevance

The annual incidence of stroke in the industrialized world is approximately 180 per 100,000 inhabitants, and it is the most common cause of permanent disability (Hesse et al. 1995, Kolominsky-Rabas et al. 2006). A significant proportion of stroke survivors will experience neurologic squeal and complications. Pain is a common complication after a stroke. The most frequent pain condition is the hemiplegic shoulder pain. (Kong et al. 2004)

The painful shoulder syndrome (PSS) occurs in 15–84% of subacute stroke survivors, and it is associated with an extended length of stay and a poorer rehabilitation outcome (Andersen et al. 1995, Barlak et al. 2009, Bowsher 1995, Leijon et al. 1998, Ratnasabapathy et al. 2003, Van Ouwenaller et al. 1986, Zorowitz et al. 1996). It leads to a limitation in performing ADLs, participation and rehabilitation activities. All this leads to a poor functionality. (Lindgren 2013, Murie-Fernández et al. 2012)

Activity and mobility are assessed to get an insight into general independence of the patient. An increased grade of mobility is crucial to reach a satisfying quality of life. Activities of daily living (ADLs) include self-care activities as functional mobility, dressing, eating and personal hygiene as well as activities to live independently in a community.

Summary

Three studies evaluated the effectiveness of the Omo Neurexa:

A reduction in shoulder pain due to wearing the Omo Neurexa was reported by 45%-86% of patients in all three studies that evaluated the Omo Neurexa (Hesse et al. 2008, Hesse et al. 2009, Hesse et al. 2013).

Another aspect observed when wearing the Omo Neurexa was an improvement in activity level and performance during mobility related activities of daily living (Hesse et al. 2013).

This might be due to the finding that the subluxation gap could be reduced or even closed with Omo Neurexa in the majority of patients in all three studies (Hesse et al. 2008, Hesse et al. 2009, Hesse et al. 2013).

References of summarized studies

Hesse, S., Bardeleben, A., Grunden, J., Rembitzki, I., Werner, C. (2008). Vorstellung einer neuen Schulterorthese zur Behandlung der schmerzhaften Schulter von hochparetischen Patienten in der Frührehabilitation. *Neurologie & Rehabilitation*, 14 (2): 91–94.

Hesse, S., Bardeleben, A., Rembitzki, I., Werner, C. (2009). Klinische und ganganalytische Befunde zur Schulterorthese Omo Neurexa. Clinical and Gait Analysis Data on Shoulder Orthosis Omo Neurexa. *Orthopädie-Technik*, 3: 177–181.

Hesse, S., Herrmann, C., Bardeleben, A., Holzgraefe, M., Werner, C., Wingendorf, I., Kirker, S. (2013). A new orthosis for subluxed, flaccid shoulder after stroke facilitates gait symmetry: A preliminary study. *Journal of Rehabilitation Medicine*, 45 (7): 623–629. DOI: 10.2340/16501977-1172

Other References

Andersen, G., Vestergaard, K., Ingeman-Nielsen, M., Jensen, T. S. (1995). Incidence of central post-stroke pain. *Pain*, 61:177-86.

Barlak, A., Unsal, S., Kaya, K., Sahin-Onat, S., & Ozel, S. (2009). Poststroke shoulder pain in Turkish stroke patients: relationship with clinical factors and functional outcomes. *International Journal of Rehabilitation Research*, 32(4):309-315.

Bowsher, D. (1995). The management of central post-stroke pain. *Postgraduate Medical Journal*, 71:598-604

Hesse, S., Jahnke, M. T., Ehret, R., Mauritz, K. H. (1995). Shoulder-hand syndrome in hemiplegic patients: temperature, sympathic skin responses and nerve conduction velocities. *J Neurol Rehab*, 9:229-233

Kolominsky-Rabas, P. L., Heuschmann, P. U., Marschall, D., Emmert, M., Baltzer, N., Neundörfer, B., Schöffski, O., Krobot, K. J. (2006). Lifetime cost of ischaemic stroke in Germany: results and national projections from a population-based stroke registry: the Erlangen Stroke Project. *Stroke*, 37:1179-1183.

Kong, K. H., Woon, V. C., & Yang, S. Y. (2004). Prevalence of chronic pain and its impact on health-related quality of life in stroke survivors. *Archives of physical medicine and rehabilitation*, 85(1):35-40.

Murie-Fernández, M., Iragui, M. C., Gnanakumar, V., Meyer, M., Foley, N., & Teasell, R. (2012). Painful hemiplegic shoulder in stroke patients: causes and management. *Neurología (English Edition)*, 27(4):234-244.

Leijon, G., Boivie, J., Johannson, I. (1989). Central post-stroke pain - neurological symptoms and pain characteristics. *Pain*, 36:13-25.

Lindgren, I. (2013). Shoulder pain after stroke - Prevalence, contributing factors and consequences in daily life *Doctoral Dissertation*, Lund University.

Ratnasabapathy, Y., Broad, J., Baskett, J., Pledger, M., Marshall, J., Bonita, R. (2003). Shoulder pain in people with a stroke: a population-based study. *Clinical Rehabilitation*, 17(3):304-311.

Van Ouwenaller, C., Laplace, P. M. & Chantraine, A. (1986). Painful shoulder in hemiplegia. *Archives of Physical Medicine and Rehabilitation*; 67:23–26.

Vuagnat, H. & Chantraine, A. (2003). Shoulder pain in hemiplegia revisited: contribution of functional electrical stimulation and other therapies. *Journal of Rehabilitation Medicine*, 35:49-54.

Zorowitz, R. D., Hughes, M. B., Idank, D., Ikai, T., & Johnston, M. V. (1996). Shoulder pain and subluxation after stroke: correlation or coincidence?. *American Journal of Occupational Therapy*, 50(3):194-201.

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Satisfaction

Major Findings

With Omo Neurexa compared to no orthotic treatment:

Wearing comfort: Patient-reported

→ **Patients perceived the material of the orthosis as comfortable on the skin** Furthermore, no pressure sores, chafe marks or other adverse reactions (especially no relevant increase in spasticity at the upper extremity, no stiffening of the shoulder, no excessive swelling of the hand, no skin irritations or redness) were seen (Hesse et al. 2008)

→ **76.9% of patients reported good wearing comfort** (Hesse et al. 2009)

→ **80% of patients had a score ≥ 7 on VAS (visual analog scale; 0= very bad, … 10= excellent), indicating good wearing comfort** (Hesse et al. 2013)

Wearing Comfort: Therapist-reported

→ **73% of the therapists rated wearing comfort with a VAS score ≥ 7, indicating good wearing comfort** (Hesse et al. 2013)

Odour nuisance: Patient-reported

→ **Minimal odour nuisance due to transpiration** (Hesse et al. 2008)

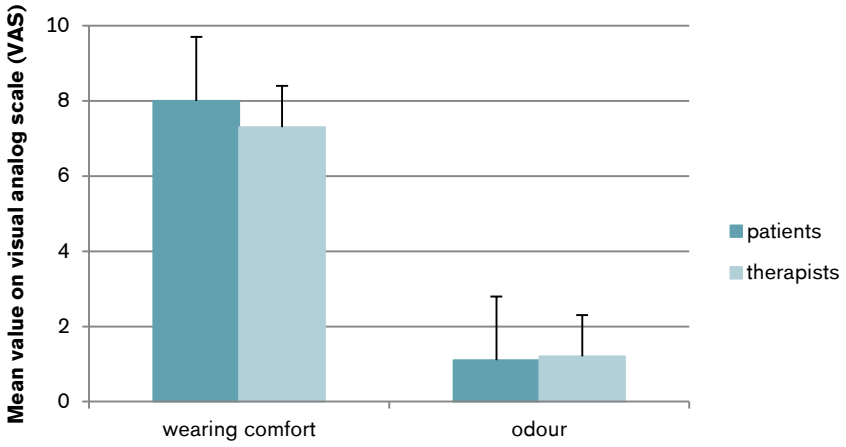
→ **76.9% of patients had only minimal odour build-up** (Hesse et al. 2009)

→ **85% of patients had a score ≤ 3 on VAS (0= absent, … 10= intolerable), indicating tolerable odour nuisance** (Hesse et al. 2013)

Odour nuisance: Therapist-reported

→ **83% of the therapists rated odour with a VAS score ≤ 3, indicating tolerable odour nuisance** (Hesse et al. 2013)

Omo Neurexa showed good wearing comfort and minimal odour nuisance



(Hesse et al. 2013)

Clinical Relevance

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

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). Reasons for non-use involve lack of consumer involvement, inadequate performance of the product, failure of the product to improve function, and difficulty in operating the product (Batavia & Hammer 1990, Wielandt & Strong 2000). Obtaining user perspectives and satisfaction is therefore fundamental.

Summary

The satisfaction with the Omo Neurexa was assessed in all three studies:

At the end of the intervention, the patients (Hesse et al. 2008, Hesse et al. 2009, Hesse et al. 2013) and the attending physiotherapists (Hesse et al. 2013) rated the wearing comfort and the odour nuisance using a visual analog scale (0-10). The physiotherapists based their assessment on the observation of patients during treatment.

The majority of patients tolerated the orthosis well. In all referenced studies, patients reported a good wearing comfort of the orthoses and only minimal odour nuisance (Hesse et al. 2008, Hesse et al. 2009, Hesse et al. 2013). The physiotherapists reported that the orthosis helped improve walking performance and other mobility-related tasks (Hesse et al. 2013). Furthermore 45-86% of patients reported a reduction of shoulder pain due to wearing the Omo Neurexa (Hesse et al. 2008, Hesse et al. 2009, Hesse et al. 2013).

“The well-tolerated shoulder orthosis … offered a good fit, and ease of performing activities” (Hesse et al. 2013)

References of summarized studies

Hesse, S., Bardeleben, A., Grunden, J., Rembitzki, I., Werner, C. (2008). Vorstellung einer neuen Schulterorthese zur Behandlung der schmerzhaften Schulter von hochparetischen Patienten in der Frührehabilitation. *Neurologie & Rehabilitation*, 14 (2): 91–94.

Hesse, S., Bardeleben, A., Rembitzki, I., Werner, C. (2009). Klinische und ganganalytische Befunde zur Schulterorthese Omo Neurexa. Clinical and Gait Analysis Data on Shoulder Orthosis Omo Neurexa. *Orthopädie-Technik*, 3: 177–181.

Hesse, S., Herrmann, C., Bardeleben, A., Holzgraefe, M., Werner, C., Wingendorf, I., Kirker, S. (2013). A new orthosis for subluxed, flaccid shoulder after stroke facilitates gait symmetry: A preliminary study. *Journal of Rehabilitation Medicine*, 45 (7): 623–629. DOI: 10.2340/16501977-1172

Other References

Batavia, A. I., & Hammer, G. S. (1990). Toward the development of consumer-based criteria for the evaluation of assistive devices. *Journal of rehabilitation research and development*, 27(4):425-436.

Scherer, M. J. (2002). The change in emphasis from people to person: introduction to the special issue on Assistive Technology. *Disability and rehabilitation*, 24(1-3):1-4.

Wielandt, T., & Strong, J. (2000). Compliance with prescribed adaptive equipment: a literature review. *The British Journal of Occupational Therapy*, 63(2):65-75.

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3 Summaries of individual studies

On the following pages you find summaries of studies that researched Omo Neurexa. 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

Hesse, S., Herrmann, C., Bardeleben, A., Holzgraefe, M., Werner, C., Wingendorf, I., & Kirker, S. G. B.

Medical Park Berlin Humboldtmühle, Neurological Rehabilitation, Charité - University Medicine Berlin, Germany.

A new orthosis for subluxed, flaccid shoulder after stroke facilitates gait symmetry: a preliminary study.

Journal of Rehabilitation Medicine 2013; 45 (7): 623-629.

DOI: 10.2340/16501977-1172.

Products

Omo Neurexa

Major Findings

With Omo Neurexa compared to no orthotic treatment:

→ In 83.3% of radiographed patients: repositioning of the humeral head

→ 45% of patients reported a reduction of pain

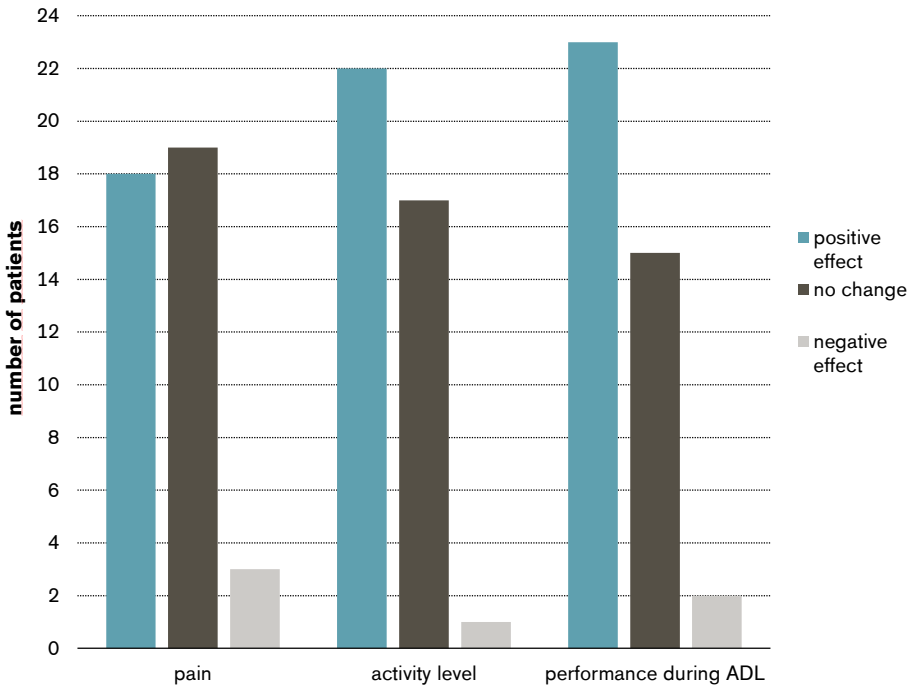
→ Improved patient- and therapist-reported activity level and performance in mobility related activities of daily living

→ Significantly more symmetric gait

- Prolonged hemiparetic side stance phase
- Higher and more appropriately timed muscle activity of the paretic quadriceps muscle

→ Very good wearing comfort and minimal odour nuisance

Omo Neurexa improved the ability of the patient to participate in daily activities



Population

Subjects:	40 patients (27 men, 13 women)
Mean age:	60.3 ± 16.7 years
Time since stroke:	6.3 ± 3.3 weeks
Inclusion criteria:	- first-ever supratentorial stroke - hemiparesis - participation in a comprehensive in-patient rehabilitation programme - non-functional upper extremity - subluxated shoulder - pain in the effected shoulder, reported by the patient and/or therapist - ability to walk at least 20 m - no relevant impairment of pain sensation in the arm

Study Design

Before-and-after study with 4-week follow-up (with Omo Neurexa compared to no orthotic treatment):

Radiography of the shoulder and instrumented gait analysis with dynamic EMG recording with and without the orthosis was performed in 12 of the 40 patients in one trial site after at least one week of wearing the orthosis.

Results

Functions and Activities						Participation
Biomechanics – Static measures	Biomechanics – Gait analysis	X-Ray	EMG	Functional tests	Clinical effects	Satisfaction

Category	Outcomes	Results for Omo Neurexa	Sig.*
Biomechanics – Gait analysis	Relative stance phase duration (affected leg)	**Significant increase by 7.5% (from 58.8% to 63.2%)**	++
	Stance symmetry ratio	**Significant increase by 6.9% (from 0.87 to 0.93)**	++
	Walking velocity	No significant differences	0
	Stride length	No significant differences	0
	Cadence	No significant differences	0
	Relative double support ratio	No significant differences	0
	Swing symmetry ratio	No significant differences	0

Functions and Activities						Participation
Biomechanics – Static measures	Biomechanics – Gait analysis	X-Ray	EMG	Functional tests	Clinical effects	Satisfaction

Category	Outcomes	Results for Omo Neurexa	Sig.*
X-Ray	Distance between the point of the acromion and a perpendicular vertical line through the central point of the humeral head	**Distance decreased by a mean of 0.8 ± 0.6 cm (in 83% of radiographed patients (10 out of 12)** **→ repositioning of the humeral head**	**++**
EMG	Lateral vastus muscle	67% of patients had a more normal phasic pattern of activation in early stance phase (8 out of 12 patients)	n.a.
	Medial vastus muscle / biceps femoris muscle	75% of patients had a more normal phasic pattern of activation in early stance phase (6 out of above mentioned 8 patients)	n.a.
	Medial gluteus muscle	42% of patients showed more muscle activity during the early stance phase (5 out of 12 patients)	n.a.
	Shank muscles / erector spinae muscle	No changes in muscle activation pattern	n.a.
Functional tests	Shoulder ROM [Fugl-Meyer-score]	Mean increase: 2.2 ± 3.2 Tendency towards an increased shoulder ROM	+
	Muscle strength sum score [Medical Research Council (MRC) grades]	**Mean increase: 6.2 ± 6.0**	**++**
	Muscle tone	Remained constant	0
Clinical effects	Patient: results for the assessment of pain, activity level and performance of mobility-related activities of daily living		

	Positive effect	No change	Negative effect
Pain	45%	47.5%	7.5%
Activity level	55%	42.5%	2.5%
Performance of mobility related ADL	57.5%	37.5%	5%

Therapist: results for the assessment of activity level and performance of mobility-related activities of daily living for the patients

	Positive effect	No change	Negative effect
Activity level	70%	27.5%	2.5%
Performance of mobility related ADL	55%	32.5%	12.5%

Satisfaction	Wearing comfort 0 = very bad 10 = excellent	Patients: 80% of patients had a score >7, indicating a good wearing comfort
		Therapists: in 73% of patients the therapists rated wearing comfort with a score >7, indicating a good wearing comfort

Functions and Activities						Participation
Biomechanics – Static measures	Biomechanics – Gait analysis	X-Ray	EMG	Functional tests	Clinical effects	Satisfaction

Category	Outcomes	Results for Omo Neurexa		Sig.*
	Odour 0 = absent 10 = intolerable	Patients:	85% of patients had a score <3, indicating a tolerable odour nuisance	
		Therapists:	in 83% of patients the therapists rated odour with a score <3, indicating a tolerable odour nuisance	
	Wearing time per day	Mean: 6.8 ± 1.8 hours		

* no difference (0), positive trend (+), negative trend (–), significant (**++/––**), not applicable (n.a.)

Author's Conclusion

"In conclusion, the well-tolerated shoulder orthosis improved gait quality and repositioned the subluxated humeral head, offered a good fit, eased performing activities, but did not help reduce pain. The orthosis may be a clinical option for wheelchair-bound stroke subjects with PSS when re-learning walking and performing mobility-related activities. This preliminary study does not warrant any definite conclusions on the effectiveness of the orthosis; further studies are needed to compare its effect with other models." (Hesse et al. 2013)

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Reference

Hesse, S., Bardeleben, A., Rembitzki, I., & Werner, C.

Medical Park Berlin Humboldtmühle, Neurological Rehabilitation, Charité - University Medicine Berlin, Germany.

Clinical and Gait Analysis Data on the Shoulder Orthosis Omo Neurexa

Klinische und ganganalytische Befunde zur Schulterorthese Omo Neurexa

Orthopädie-Technik 2009; 3: 177-181.

Products

Omo Neurexa

Major Findings

With Omo Neurexa compared to no orthotic treatment:

→ 50% of patients reported a relevant pain reduction

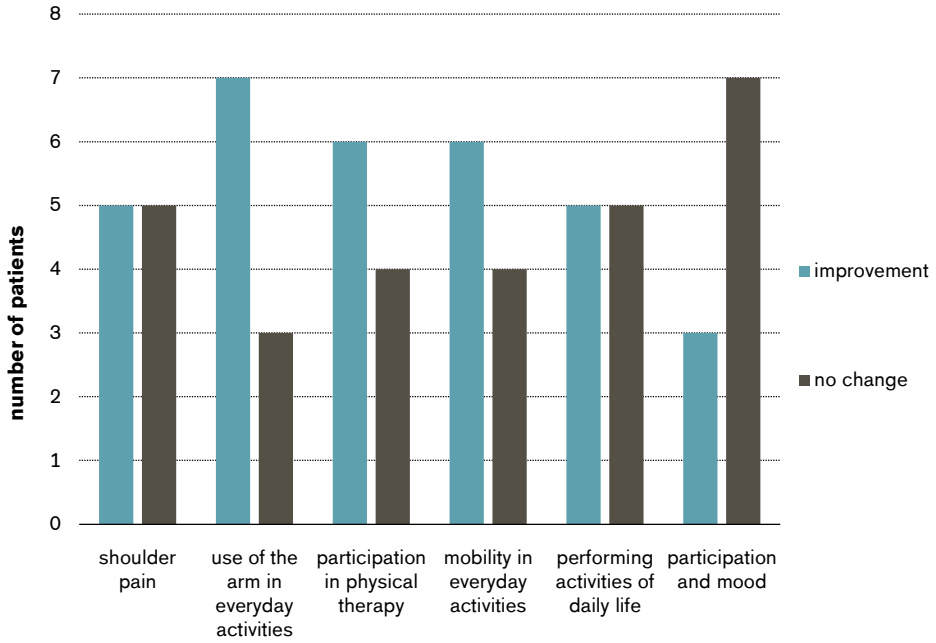
→ Decrease of the shoulder subluxation was observed

→ 70% of patients reported that they felt more secure during transfer tasks and mobility

→ More dynamic gait pattern

→ Good wearing comfort, minimal transpiration

Omo Neurexa showed improvements in majority of categories assessed

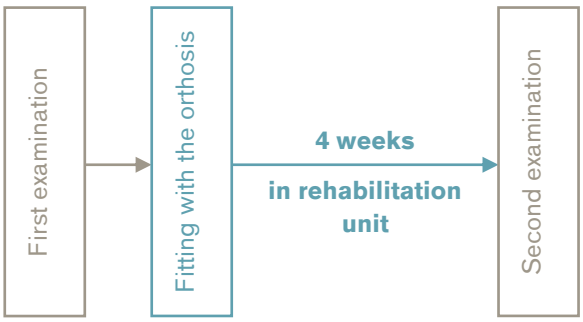


Population

Subjects:	13 patients** (10 men, 3 women) ** 3 patients stopped using the orthosis prematurely
Mean age:	61.7 ± 12 years
Mean interval since stroke (before the orthosis was prescribed):	8.3 ± 3.8 weeks
Inclusion criteria:	- shoulder pain or clinical signs of subluxation - first-ever stroke with treatment in inpatient early rehabilitation - non-functioning paretic upper extremity

Study Design

Pilot Study with a four-week-intervention



Gait analysis and measurement of EMG was performed with 10 patients with and without the orthosis.

Results

Functions and Activities						Participation
Biomechanics – Static measures	Biomechanics – Gait analysis	X-Ray	EMG	Functional tests	Clinical effects	Satisfaction

Category	Outcomes	Results for Omo Neurexa**	Sig.*
Biomechanics – Gait analysis	Relative double support phase	**Mean reduction: 17%**	**++**
	Stride length	Tendency towards a greater stride length	+
	Cadence	Tendency towards a lower cadence	+
	Gait speed	No significant differences	0
	Relative stance and swing periods	No significant differences	0
	Symmetry quotients	No significant differences	0
X-Ray	Distance between the point of the acromion and a perpendicular vertical line through the central point of the humeral head	Mean reduction of 2.5cm due to the orthosis (in 70% of patients)	n.a.

Functions and Activities						Participation
Biomechanics – Static measures	Biomechanics – Gait analysis	X-Ray	EMG	Functional tests	Clinical effects	Satisfaction

Category	Outcomes	Results for Omo Neurexa**	Sig.*
EMG	Dynamic EMG	40% of patients showed a more pronounced activity of the quadriceps femoris muscle	n.a.
		40% of patients showed an earlier onset of activity of the quadriceps femoris muscle during the stance phase	n.a.
Functional tests	Passive shoulder ROM	30% of patients showed an improvement	n.a.
		10% of patients showed a deterioration	n.a.
	MRC strength grade	30% of patients showed an increase in shoulder strength	n.a.
		40% of patients showed an increase in elbow strength	n.a.
	Ashworth score	30% of patients showed a decreased Ashworth score (reduction of spasticity)	n.a.
		40% of patients showed an increase in the Ashworth score (development of flexor spasticity)	n.a.
Clinical effects	Pain	50% of patients reported a reduction of shoulder pain	n.a.
		50% of patients reported shoulder pain as unchanged	n.a.

* no difference (0), positive trend (+), negative trend (–), significant (**++/––**), not applicable (n.a.)
** results are valid for those 10 patients who finished the study

Category	Outcomes	Results for Omo Neurexa***	Sig.*
Satisfaction	Wearing comfort	76.9% of patients: good wearing comfort with only minimal odour build-up	n.a.
		23.1% of patients stopped wearing the orthosis prematurely	n.a.

* no difference (0), positive trend (+), negative trend (–), significant (**++/––**), not applicable (n.a.)
*** results are valid for all 13 patients who were included in the study

Author's Conclusion

"In summary, the newly developed shoulder orthosis is an interesting component in the prevention and therapy of painful shoulder in severely paretic patients in multiprofessional early rehabilitation. Provided that the nursing staff is given extensive training, good fit, a high level of wearing comfort, and minimal amount of unpleasant odour can be ensured. The open study indicates that the orthosis reduces subluxation and promotes restoration of activity. The results of the gait analysis are consistent with a more secure and dynamic gait; there was also facilitation of the knee extensor on the affected side in some selected patients. A controlled study is indicated." (Hesse et al. 2009)

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Reference

Hesse, S., Bardeleben, A., Grunden, J., Rembitzki, I., & Werner, C.

Medical Park Berlin Humboldtmühle, Neurological Rehabilitation, Charité - University Medicine Berlin, Germany.

Presentation of a new shoulder orthosis for the treatment of a painful shoulder in highly paretic patients in the early phase of rehabilitation

(Vorstellung einer neuen Schulterorthese zur Behandlung der schmerzhaften Schulter von hochparetischen Patienten in der Frührehabilitation)

Neurologie & Rehabilitation 2008; 14 (2): 89-92.

Products

Omo Neurexa

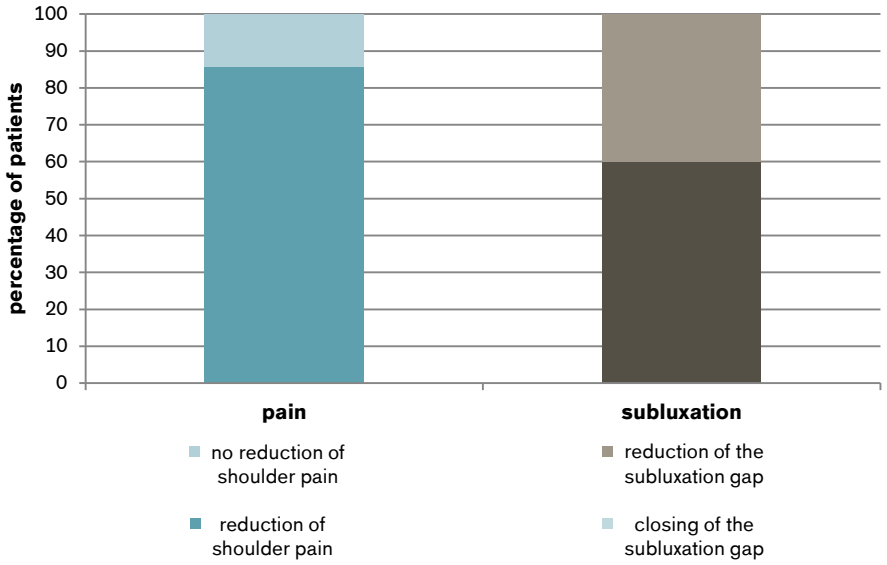
Major Findings

With Omo Neurexa compared to no orthotic treatment:

58% of patients reported shoulder pain at the beginning of the intervention phase:
→ 86% of those patients reported a relevant reduction of shoulder pain due to wearing the orthosis

42% of patients showed a subluxation of the shoulder at the beginning of the intervention phase:
→ In 40% of patients a reduction of the subluxation gap was observed after the time of intervention
→ In 60% of patients, the gap was closed after the time of intervention
→ 20% of patients developed a painful shoulder (PS) during the intervention period

Patients treated with Omo Neurexa suffer less pain



Population	Subjects:	12 patients (1 patient did not wear the orthosis for the whole 4 weeks because of missing efficiency)
	Mean age:	n.a.
	Indication:	hemiparetic patients in the early stages of rehabilitation: Patients did suffer from a subluxation of the shoulder or a painful shoulder

Study Design

Clinical experience

Results

Functions and Activities						Participation
Biomechanics – Static measures	Biomechanics – Gait analysis	X-Ray	EMG	Functional tests	Clinical effects	Satisfaction

Category	Outcomes	Results for Omo Neurexa	Sig.*
X-Ray	Shoulder subluxation	42% of patients wore the orthosis because of a shoulder subluxation	n.a.
		60% of patients: closing of the gap	n.a.
		40% of patients: reduction of the gap	n.a.
		20% of patients: development of shoulder pain	n.a.
Clinical effects	Shoulder Pain	59% of patients suffered from a painful shoulder	n.a.
		86% of patients reported a reduction of shoulder pain	n.a.
	Concentration	Protection of the paretic arm leads to a better concentration on gait rehabilitation	n.a.
Satisfaction	Wearing comfort	Patients perceived the material of the orthosis as comfortable on the skin. → no pressure scores, chafe marks or other adverse reactions (especially no relevant increase of spasticity within the upper extremity, no stiffening of the shoulder, no excessive swelling of the hand, no skin irritations or redness)	n.a.
	Odour nuisance	Minimal odour nuisance due to transpiration	n.a.

* no difference (0), positive trend (+), negative trend (–), significant (**++/––**), not applicable (n.a.)

Author's Conclusion

"In conclusion the orthosis is an interesting option in the treatment and prevention of shoulder pain of the severely affected arm after stroke. Further studies are needed." (Hesse et al. 2008)

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