

# The use of medical devices in people with hemiparesis of the upper limb and the presentation of the competence of the master and specialist of physiotherapy in the prescription of orthopedic supplies

Bernadeta Faustyna Piwowar-Kuczyńska<sup>1</sup>, Michał Zabojszcz<sup>2</sup>, Monika Urbaniak<sup>3</sup>, Rafał Trąbka<sup>4</sup>, Mateusz Curyło<sup>5,6</sup>

<sup>1</sup> Medical Center VADIMED Ltd., Poland

<sup>2</sup> Department of Internal Medicine and Family Medicine, Jan Kochanowski University in Kielce, Kielce, Poland

<sup>3</sup> Chair and Department of Facility Management Organizations in Health Care, Department of Medical Law, Faculty of Health Sciences, Poznan University of Medical Sciences, Poznan, Poland

<sup>4</sup> Department of Rehabilitation, Faculty of Health Sciences, Jagiellonian University Medical College, Krakow, Poland

<sup>5</sup> Department of Internal Medicine, Rehabilitation and Physical Medicine, Medical University of Lodz, Lodz, Poland

<sup>6</sup> Medical Rehabilitation Department, The Ministry of the Interior and Administration Hospital, Krakow, Poland

**Correspondence to:** Mateusz Curyło, email: mateusz\_curylo@o2.pl

**DOI:** <https://doi.org/10.5114/phr.2023.133718>

**Received:** 12.06.2023 **Reviewed:** 12.07.2023 **Accepted:** 13.07.2023

## Abstract

**Background:** Medical devices are special-purpose articles used, among other things, to prevent or compensate for motor dysfunctions caused by neurological disorders. Being authorized in this regard indicates the obligation of a physiotherapist to have the appropriate knowledge and competence to prescribe the devices and also to train the patient for their use.

**Aims:** The purpose of this study was to present the possibility and evaluate the effectiveness of using upper limb orthoses in hemiparesis and present the authority of the master and specialist of physiotherapy to prescribe medical devices.

**Material and methods:** The available literature was analyzed based on English-language databases PubMed, Scopus, ScienceDirect, Medline, and others, using the Google Scholar search engine. Twenty articles were analyzed out of 75 retrieved by the above method. Publications no older than 14 years were used as search criteria using the following keywords: hemiparesis, upper limb orthosis, and medical device prescribing.

## Key words

hemiparesis, medical device prescription, upper limb orthosis, literature review.

**Results:** Many types of orthoses for the upper limb are used to treat hemiparesis. Most have been shown to improve motor function, reduce muscle tension, and positively affect upper limb function. They can be prescribed by a master and specialist of physiotherapy.

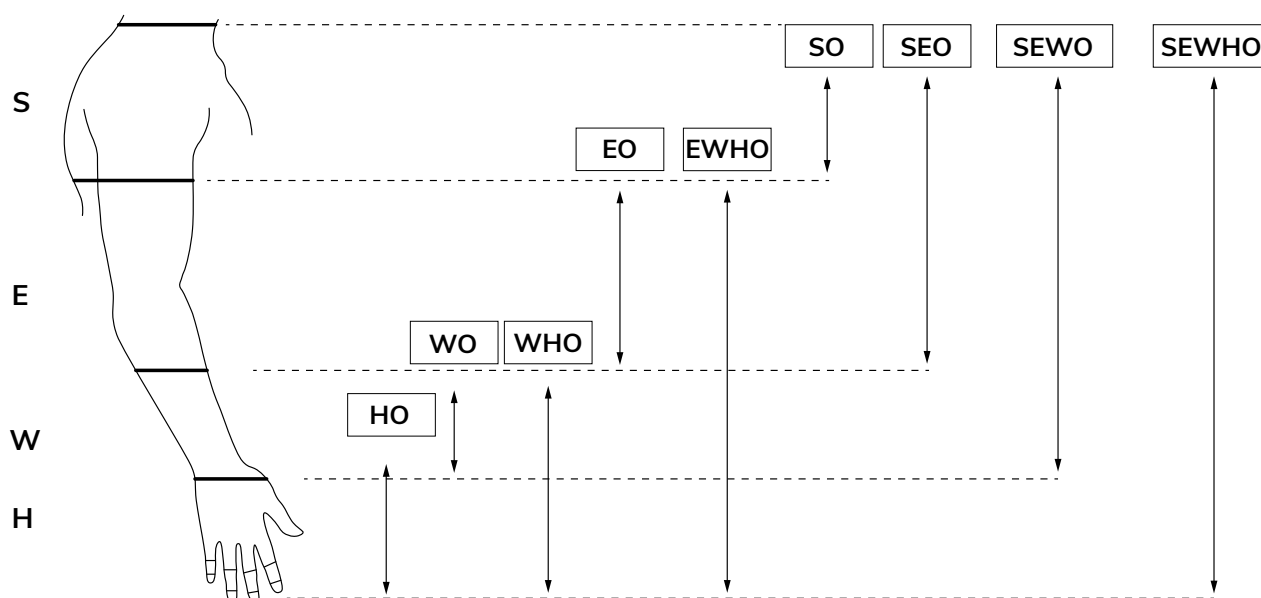
**Conclusions:** Modern research indicates that properly selected and used upper limb orthoses can be a good form of support for the treatment and rehabilitation of people with hemiparesis. A physiotherapist has the knowledge and competence to prescribe medical devices.

## Introduction

Medical devices are specialized or universal products developed using rehabilitation engineering technology. Their function is to prevent or compensate for motor dysfunctions caused by neurological disorders. They can reduce motor dysfunctions and support the rehabilitation process to improve movement and participation [1]. They can correct limb deformities and avoid secondary damage when used early enough, along with rehabilitation. By improving motor function

and compensatory abilities, patients' ability to perform activities of daily living and self-care can be improved. This will reduce the burden on the family and society [2,3].

The International Classification of Orthoses is used to determine the location of the segment (major joint) to be affected by the orthosis (**Fig. 1**). The first letters from the English of the joints involved, e.g., WHO (wrist-hand orthosis), are used to designate this [4].



**Figure 1.** International Classification of Orthoses.

**Notes:** S – shoulder, E – elbow, W – wrist, H – hand.

International nomenclature of upper limb orthoses:

- wrist hand orthosis (WHO)
- wrist hand finger orthosis (WHFO)
- elbow orthosis (EO)
- elbow wrist orthosis (EWO)
- elbow wrist hand orthosis (EWHO)
- shoulder elbow orthosis (SEO)
- shoulder elbow wrist orthosis (SEWO)
- shoulder elbow wrist hand orthosis (SEWHO) [4].

Depending on the disorder, WHO orthoses can take on different functions, such as wrist stabilization, wrist-hand stabilization, or wrist and finger stabilization. The biomechanical principle is to promote uprightness within the joints [5]. WHO orthoses help stabilize joints in a functional position and can be considered an effective method of passive stretching to reduce wrist flexor spasticity. WHO orthoses prevent contractures in the wrist and hand joints in people with hemiplegia, but their effectiveness is unclear [6].

Conventional wrist and hand orthoses have some disadvantages. Some of these orthoses are bulky and time-consuming to adjust. With the development of technology, new custom-made orthoses with three-dimensional (3D) printing are appearing on the market. With this technology, they can be accurately designed and made using computer graphics software. This can be an alternative to conventional orthoses, which are more complex to manufacture and involve more difficult fitting and time [7].

In turn, dynamic orthoses are used for patients with spastic paresis of the upper limb. They are designed to help the spastic muscles antagonists move actively with the help of various rubber bands, springs, etc. Mostly, the idea is to help the extensor muscle groups of the fingers, wrist, and possibly the elbow [8].

SaeboFlex is a dynamic, custom-made wrist and hand-finger orthosis (WHFO). It is dedicated to people with a limited range of motion, mainly extension. It allows patients with limited wrist,

hand, and finger function to participate actively in rehabilitation as well as daily activities. It is often used for people after stroke, spinal cord injury, and acquired brain injury [9]. The SaeboStretch is also a dynamic orthosis consisting of interchangeable toe support parts. They are selected according to the hand pick-up pellet, the degree of spasticity, and the hand stabilization bands (it is possible to separate fingers II-IV and V). This allows for adequate stabilization of the little finger. In addition, they have an outer material that is removable and washable. It is also possible to adjust the angle of flexion and extension at the wrist, as well as adduction and abduction of the thumb [10].

SEWHO and EWHO are aimed at static, progressive stretching and maintaining a maximum range of motion in the antispastic pattern of the shoulder and elbow joint. EWHOs can contribute to stretching of the forearm. EWHO is used to increase elbow joint extension [8].

#### **Competences of physiotherapists to prescribe medical devices**

Physiotherapist, as of the date of pronouncement of the Polish Act on the Profession of Physiotherapist, September 25, 2015 (Journal of Laws of 2018, item 505) and with the amendments that were introduced on April 12, 2019, became an independent medical profession. Autonomy means independence in decision-making, i.e., the right to decide on the choice of a patient's therapy while meeting certain guidelines normalized by the Act above. The scope of health services that a physiotherapist can provide is detailed in ten subsections. Three of the ten principles outlined principles directly and indirectly to medical devices and the ability to use them in the physiotherapy treatment process.

- No. 5 – prescribing medical devices by regulations issued pursuant to Article 38 (4) of the Act of May 12, 2011, on reimbursement of drugs, foodstuffs for particular nutritional purposes, and medical devices (Journal of Laws of 2017, item 1844, as amended).

- No. 6 – selecting medical devices to suit the patient's needs,
- No. 7 – teaching the patient to use medical devices.

Having authority in this area indicates the obligation of the physiotherapist to have the appropriate knowledge and competence to prescribe devices and train the patient to use them [11,12].

## Aims

This paper aimed to present the possibility and evaluate the effectiveness of using upper limb orthoses in hemiparesis and to present the authority of a master and specialist of physiotherapy to prescribe medical devices.

## Material and methods

The available literature was analyzed based on English-language databases PubMed, Scopus, ScienceDirect, Medline, and others, using the Google Scholar search engine. Twenty articles were analyzed out of 75 retrieved by the above method. Publications no older than 14 years were used as search criteria using the following keywords: hemiparesis, upper limb orthosis, and medical device prescription.

## Results

After reviewing the articles, many orthoses are designed to assist in treating hemiparesis. The orthoses are dedicated to individual joints, taking into account the area of greatest dysfunction. Most have been shown to positively affect motor function and muscle tone in people with hemiparesis. Serial medical devices are ordered by a master of physiotherapy who, after completing specialty training, is given greater authority to prescribe individual medical devices.

## Discussion

A study by Moskiewicz et al. [13] showed that combined treatment based on botulinum toxin and the SaeboFlex dynamic orthosis in a patient

with chronic spastic hemiparesis improved quality of life and reduced disability. The case report study was conducted on a 43-year-old woman who was evaluated before the study and after 6, 12, and 16 weeks. The program consisted of three 50-minute daily sessions focused on grasping and releasing objects with and without the orthosis.

Lannin et al. [14], in their study on upper limb motor training using the Saebo orthosis to increase task-specific exercise in hospitalized stroke patients, concluded that the use of the Saebo-Flex device produced mixed results, with some positive trends in hand function, especially dexterity.

In a study conducted by Andring et al. [5] on the tolerance and effectiveness of a dynamic hand and wrist orthosis in chronic stroke patients, it is noted that the majority of patients who were included in the study tolerated the new dynamic orthosis for at least 6 hours a day. Its use significantly reduced wrist contractures over a 6-month follow-up period. The study included six patients with upper limb spasticity who did not tolerate the static orthosis; the dynamic orthosis was individually selected and made for each patient.

A study by Khallaf et al. [15] on the effect of task training and an upright orthosis on a range of motion and joint function in the hand area indicates that in post-stroke patients, task training along with an orthosis is effective and improves finger dexterity, upper limb function and range of motion of the wrist or hand.

However, another study by Wong et al. [16] indicates that task training combined with a dynamic hand orthosis did not significantly improve motor function, compared to task-oriented training alone, in subacute stroke survivors. Therefore, further studies are needed to determine whether orthoses combined with task-oriented training positively affect post-stroke patients.

Zheng et al. [17] compared two types of wrist orthoses, 3D-printed and low-temperature thermoplastic plates. Their results were as follows: they found that 3D-printed orthoses were better

at reducing spasticity in post-stroke patients. In addition, they significantly reduced swelling, improved motor function of the wrist joint, and passive range of motion in the wrist dorsal flexion.

A study by Hoppe-Ludwig et al. [18] evaluated the usability, functionality, and effectiveness of a myoelectric elbow-wrist-hand orthosis. The orthosis was shown to improve the range of motion during use and was effective in managing upper limb disability after stroke.

Dunaway et al. [19] also reached similar conclusions in their case report of a veteran diagnosed with chronic stroke. After using the orthosis, the active range of motion and strength of the upper limb affected by hemiparesis increased significantly (both with and without the orthosis), as well as the spastic paresis decreased. The participant showed an improved ability to engage the affected limb in a wide range of bilateral global motor activities of daily living, such as lifting a chair, preparing meals, opening doors, etc.

A study by Sharma et al. [20] on the use of a shoulder elbow wrist hand orthosis (SEWHO) in the treatment of shoulder subluxation in post-stroke patients with hemiplegia deduced that the orthosis as an adjunct to a routine rehabilitation program could effectively reduce shoulder instability in post-stroke patients with hemiplegia.

#### **Authorization of master and specialist of physiotherapy to prescribe medical devices**

A master of physiotherapy with the right to provide physiotherapy services independently obtains the right to issue orders for medical devices defined in the Annex to the Regulation as:

- Group J, ordinal no. 36-44
- Group L, ordinal no. 47-53
- Group M, ordinal no. 57-63
- Group O, ordinal no. 69 and 70

Physiotherapists who hold the title of specialist have additionally been authorized to order medical devices from groups of:

- Group A, ordinal no. 1-3
- Group B, ordinal no. 4-11
- Group C, ordinal no. 12-17
- Group D, ordinal no. 8-20
- Group E, ordinal no. 21
- Group F, ordinal no. 22 and 23
- Group G, ordinal no. 24-27
- Group H, ordinal no. 28-33
- Group I, ordinal no. 34, 35
- Group K, ordinal no. 45, 46
- Group L, ordinal no. 54-56
- Group N, ordinal no. 64-68
- Group O, ordinal no. 69 and 70
- Group P, ordinal no. 92 and 93 and 124-133

A physiotherapist with a master's degree and a specialist with a master's degree can prescribe medical devices covered by reimbursement in both commercial practices reported to the National Health Service (in pol. Narodowy Fundusz Zdrowia, NFZ) and facilities with a contract with the NFZ.

With respect to the article, orthopedic supplies for the upper limb can be ordered by a master of physiotherapy from Group L, ordinal no. 47-53:

- Orthosis for stabilizing or correcting hand (excluding Stack and Capener braces)
- Hand and forearm orthoses
- Elbow orthosis with flexion angle adjustment with or without hand inclusion,
- Elbow joint orthosis with or without arm inclusion,
- Shoulder and arm orthoses (excluding slings and Dessault orthoses)

- Shoulder and arm orthosis of the type Dessault
- Shoulder abduction orthosis with adjustable angle of abduction

The specialist in physiotherapy has been given additional authority to prescribe medical devices from the:

- Groups E, ordinal no. 21:
  - Cosmetic prosthesis within the hand
- Groups F, ordinal no. 22 and 23:
  - Cosmetic prosthesis within the forearm
  - Preparatory prosthesis with a preparatory tip within the forearm
- Groups G, ordinal no. 24-27:
  - Cosmetic prosthesis within the shoulder
  - Preparatory prosthesis with a preparatory tip within the shoulder
  - Upper limb cosmetic prosthesis after shoulder debridement
  - Preparatory upper limb prosthesis with preparatory tip after shoulder debridement [11,12].

## Conclusions

Contemporary research indicates that properly selected and used upper limb orthoses mostly bring improvements in motor function and reduce muscle tension in people with hemiparesis and can be prescribed by the master and specialist of physiotherapy.

## References

1. Nikamp CD, Buurke JH, van der Palen J, Hermens HJ, Rietman JS. Early or delayed provision of an ankle-foot orthosis in patients with acute and subacute stroke: a randomized controlled trial. *Clin Rehabil.* 2017; 31 (6): 798–808.
2. Nadler M, Pauls M. Shoulder orthoses for the prevention and reduction of hemiplegic shoulder pain and subluxation: systematic review. *Clin Rehabil.* 2017; 31 (4): 444–453.
3. Yeung LF, Ockenfeld C, Pang MK, Wai HW, Soo OY, Li SW, et al. Randomized controlled trial of robot-assisted gait training with dorsiflexion assistance on chronic stroke patients wearing ankle-foot-orthosis. *J Neuroengineering Rehabil.* 2018; 15 (1) :51.
4. Kolář P. Rehabilitace v klinické praxi [Rehabilitation in clinical practice]. Galén; 2009. pp. 516–520.
5. Andringa AS, Van de Port IGL, Meijer JWG. Tolerance and effectiveness of a new dynamic hand-wrist orthosis in chronic stroke patients. *NeuroRehabilitation.* 2013; 33 (2): 225–231.
6. Winstein CJ, Stein J, Arena R, Bates B, Cherney LR, Cramer SC, et al. Guidelines for Adult Stroke Rehabilitation and Recovery: A Guideline for Healthcare Professionals from the American Heart Association/American Stroke Association. *Stroke.* 2016; 47 (6): e98–169.

7. Meng X, Ren M, Zhuang Y, Qu Y, Jiang L, Li Z. Application Experience and Patient Feedback Analysis of 3D Printed AFO with Different Materials: A Random Crossover Study. *BioMed Res Int.* 2021; 2021: 8493505.
8. Fuksová B. Možnosti ortézování paretických končetin u pacientů po CMP [Options for parietic limb bracing in patients after stroke]. 2017. Available at: <https://dspace.cuni.cz/handle/20.500.11956/85015>
9. Andriske L, Verikios D, Hitch D. Patient and Therapist Experiences of the SaeboFlex: A Pilot Study. *Occup Ther Int.* 2017: e5462078.
10. Hoffman J, Hoffman A, Ozdarska K, Sochanek M. Rehabilitacja kończyny górnej po udarze mózgu [Rehabilitation of the upper limb after stroke]. In: *Choroby XXI wieku – wyzwania w pracy fizjoterapeuty [Diseases of the 21st century – challenges in the work of a physiotherapist]*, Ed. Podgórska M Wydawnictwo Wyższej Szkoły Zarządzania, Gdańsk 2017. Available at: <https://depot.ceon.pl/bitstream/handle/123456789/14520/Rehabilitacja%20kończyny%20górnej%20po%20udarze%20mózgu.pdf?sequence=1>
11. Śliwiński Z, Sieroń A, Szczegieliński J. Wielka fizjoterapia [The great physiotherapy]. Ed. I Polish. Edra Urban & Partner 2017, Wrocław 2014. p. 467.
12. Curyło M, Rynkiewicz-Andryśkiewicz M, Mikos M, Kiljański M, Śliwiński Z, Raczkowski J.W. Wyroby medyczne wydawane na zlecenie w praktyce fizjoterapeuty [Prescription medical devices in the practice of a physiotherapist]. *Fizjoter Pol.* 2020; 20 (3): 180–183.
13. Moskiewicz D, Mraz M, Chamela-Bilińska D. Botulinum Toxin and Dynamic Splint Restore Grasping Function after Stroke: A Case Report. *Int J Environ Res Public Health.* 2023; 20 (6): 4873.
14. Lannin NA, Cusick A, Hills C, Kinnear B, Vogel K, Matthews K, et al. Upper limb motor training using a Saebo orthosis is feasible for increasing task-specific practice in hospital after stroke. *Aust Occup Ther J.* 2016; 63 (6): 364–372.
15. Khallaf ME, Ameer MA, Fayed EE. Effect of task specific training and wrist-fingers extension splint on hand joints range of motion and function after stroke. *NeuroRehabilitation.* 2017; 41 (2): 437–444.
16. Wong Y, Li CJZ, Ada L, Zhang T, Månnum G, Langhammer B. Upper Limb Training with a Dynamic Hand Orthosis in Early Subacute Stroke: A Pilot Randomized Trial. *J Rehabil Med.* 2022; 54.
17. Zheng Y, Liu G, Yu L, Wang Y, Fang Y, Shen Y, et al. Effects of a 3D-printed orthosis compared to a low-temperature thermoplastic plate orthosis on wrist flexor spasticity in chronic hemiparetic stroke patients: a randomized controlled trial. *Clin Rehabil.* 2020; 34 (2): 194–204.
18. Hoppe-Ludwig S, Armitage J, Turner KL, O'Brien MK, Mummidisetty CK, Koch LM, et al. Usability, functionality, and efficacy of a custom myoelectric elbow-wrist-hand orthosis to assist elbow function in individuals with stroke. *J Rehabil Assist Technol Eng.* 2021; 8.
19. Dunaway S, Dezsi DB, Perkins J, Tran D, Naft J. Case Report on the Use of a Custom Myoelectric Elbow-Wrist-Hand Orthosis for the Remediation of Upper Extremity Paresis and Loss of Function in Chronic Stroke. *Mil Med.* 2017; 182 (7): e1963–8.
20. Sharma GS, Singh YN, Joy A, Singh B, Touthang AT, Devi T. Study of Effectiveness of Shoulder Elbow Wrist Hand Orthosis in the Management of Glenohumeral Subluxation in Post-stroke Hemiplegic Patients. *Indian J Phys Med Rehabil.* 2016; 27 (3): 78–86.