The title of the paper: Motor skills improvement evaluation of cerebral palsy child with lower limbs spasticity by application of variable abduction hip orthosis

Type of work: original paper/clinical observation

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The abbreviated title of the paper: Motor skills improvement in CP child applying VAHO

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A structured Abstract:

Variable abduction Hip Orthosis (VAHO) has been in application for more than 20 years. The manufacturer recommends its application for motor skills improvement in children with spastic palsy of lower limbs of any etiology and prevention of hip displacement in cerebral palsy (CP) children; however, there are no published clinical studies that confirm this statement.

Study objectives: Efficiency evaluation of orthotic fitting in CP children with lower limb spasticity by VAHO application, using clinical assessment parameters witch describe motor skills; objectively determining the difference in manifestation of motor disorder without VAHO, after application of VAHO and after 6 months of VAHO usage.

Methods: Clinical examination and filling up questionnaire to evaluate motor skills using VAHO (the questionnaire is a part of instructions for VAHO application), obtained data analysis. In 10 children (6 boys and 4 girls, age of 4 to 12) we observed parameters: improvement of child's sitting, posture, walking, scissoring gait and walking distance in meters without orthosis, after VAHO application, and after 6 months of VAHO usage. Statistical analysis was made by Wilcoxon test of matched pairs.

Results: in 80% of children studied, indication for VAHO application has been justified because it led to motor skills improvement. In 20% of the cases, application was

discarded. We found statistically significant difference in motor skills improvement of children using VAHO comparing to their motor skills without VAHO, which was evident also after 6 months of application. Walking distance after 6 months using VAHO is even better.

<u>Conclusion</u>: the study confirmed the efficacy of VAHO application and improvement of motor skills in CP children with lower limbs spasticity. There is no significant number of published papers with assessment of the effectiveness in VAHO application and this study can help clinicians deciding about orthotic solution in children with lower limbs spasticity. Longer monitoring needs to be conducted by more users in order to examine the effect of VAHO more closely.

Abbreviations:

VAHO – variable abduction hip orthosis
GMFCS - Gross Motor Function Classification System
ADL – daily life activities
CP – cerebral palsy
SWASH – dinamic "sitting,walking and standing hip orthosis"
HZZO – Croatian Institute for Health Insurance
HKAFO – Hip, Knee, Ankle and Foot orthosis

Background:

Orthosis is the Orthotic Device - an external exoskeletal device that is designed to support, stabilize and/or reposition parts of the body, to prevent and/or correct bone skeletal deformities and to improve weakened or lost functions of the parts of the musculoskeletal system caused by various structural or neuromuscular impairments (1,2). In CP children depending on the present motor deficit have been applied many types of Orthotics with varying success (3, 4, 5, 6,7). VAHO is a semi-finished Orthosis, which according to the needs of users has to be adapted by certified orthotist and has been in application for more than 20 years. It is made from a combination of textile, plastic and metal parts that form the pelvic band, 2 uprights and thigh cuffs. The indication for the application is spastic palsy in lower limbs of any etiology classified by Gross Motor Function Classification System (GMFCS) from II to V level (8,9). By ambulatory and semi-ambulatory children VAHO significantly improves gait, reduces scissoring gait, improves stability of the trunk during walking and sitting, enables hands-free sitting and reduces the risk of hip displacement. In non-ambulatory children VAHO improves stability while sitting, frees the hands for the participation in the activities of daily life (ADL), reduces the risk of the hip displacement, however, its application does not enable non-ambulatory children to walk. VAHO hasn't been often used in Croatia because of the high prices.

In June 2016. Croatian Institute for Health insurance (HZZO) placed VAHO (company manufacturer Allard Int. from Sweden, protected name orthosis is SWASH - dynamic

Standing, Walking and Sitting Hip orthosis) in the reimbursement list - with indication "to walk ", which means that the cost of the orthosis is reimbursed by insurance.

MD Orthopaedics' and physiatrists are authorized to prescribe VAHO. Prior to prescribing it is necessary to check the functionality of orthosis on examinated child. In practice, it means VAHO should be prescribed by a team consisting of a specialist MD physician who has experience with VAHO orthosis, an orthotist specially educated for application of VAHO, and, if possible, a physiotherapist educated for work with neurological patients. Immediately after applying the orthosis, it is expected improving the child's posture, more stable sitting and standing, less scissoring gait in ambulatory children and longer walking distance. "Immediately" is considered a period within 2 hours of the first application of VAHO where there is/or isn't noticeable motor skills improvement, because some children are at first afraid to use the orthosis and need a short adaptation period to relax and try out their possibilities in orthosis. If there are no motor skills improvement within the first 2 hours of using VAHO, it is not expected to occur later, and application is not indicated. In a child with noticeable motor skills improvement within that time, application of VAHO is indicated and in the up-coming months, it is possible to further improve motor skills. VAHO is indicated for persons under 18 years of age and weighing up to 60 kg because of size and technical characteristics of orthosis, and fixed changes of the locomotor system in older persons with the specified diagnosis that could not be corrected by VAHO. Due to the necessity of previous orthosis-functionality verification (which is requested from HZZO) it is clear for practical reasons that very few authorized physicians' specialists are able to prescribe VAHO on that way because they are rarely positioned at the same location with the orthotists and physical therapists. One of such Institution is the Poliklinika OTOS Vita. Health institution for physical medicine and rehabilitation, which is located in the same building as the company OTOS orthopaedic technique in Osijek, and it is possible to conduct pre-fitting functionality assessment of VAHO by the team (doctor, physical therapist, orthotist) before a final decision on prescribing.

Picture number 1 – VAHO (protected name S.W.A.S.H. low profile manufacturer Allard.Int, Malmo Sweden) downloaded from https://www.allardint.com/childrens-hip-orthosis 06.1.2019.



Subjects and methods

Protocol of the study was made in accordance with the principles of the Helsinki Declaration and with children there were always present a parent/guardian. There is a small group of children for whom application of VAHO is indicated, with spastic palsy in lower limbs and under 18 years of age without contraindications listed in the manual about the use of VAHO.

In the period from June 2016. until June 2018. general distributor of VAHO for Croatia delivered 23 VAHOs. 10 Orthoses or 43% were indicated after the previous evaluation of the functionality in the Poliklinika OTOS Vita. The subjects were children with cerebral palsy and spasticity of lower limbs examined at Poliklinika OTOS Vita by doctor

MD specialist for physical medicine and rehabilitation, instructed from other doctors – paediatricians, neurologists, physiatrists and orthopaedics which recommended to do the previous evaluation functionality and to prescribe VAHO if indicated. We have included in the study children in whom VAHO immediately after application improved motor skills, and without contraindications listed in manual: dislocated hips, fixed hip flexion contracture $> 20^\circ$, too strong or too long muscle adductors, dyskinesia.

There were 10 studied children: 6 boys / 60% and 4 girls / 40% aged 4 to 12, average age 8.5 years, of which 9 have had spastic tetraparesis and 1 spastic paraparesis. After GMFCS there were 1 child II level, 5 children III level and 4 children IV level. Mental retardation was very pronounced in 4 children, mildly expressed in 2 children, and in 4 children it was not expressed. 1 girl had an unfixed displacement of the right hip. The methods of research were clinical examination of children and the evaluation of parameters without VAHO, after application of VAHO and after 6 months VAHO usage, and also the completion of the questionnaire for assessing the parameters, which is an integral part of the orthotic handbook, to help clinicians evaluate the effectiveness of orthosis in the user. The motor / parameters evaluation was performed independently by a physician, a orthotist, a physiotherapist and a child's parent / guardian. The questionnaire included a common estimate of all evaluators which was equal for a certain child.

The observed parameters were:

- sitting: very bent, slightly bent, upright
- standing: with assistance, with support of an orthopaedic device or leaning to the wall, independently
- walking: with assistance, with support of an orthopaedic device, independently without support
- scissoring gait: yes / no
- walking distance in meters

After six months the child's parents / guardians were requested to rate VAHO orthosis in ratio from 1 to 5 (where 1 represented the worst and 5 best grades), and to give their opinion about new VAHO application when the child grows up. Because of small number of studied children, statistical analysis was made by Wilcoxon test of matched pairs.

Results Table No 1: Clinical parameters without orthosis, in VAHO orthosis and after 6 months

	sitting			standing			walking			Scissoring gait			Walking distance		
Examinee: Serial number, gender, age, GMFCS	Without VAHO	after application of VAHO	after 6m. of VAHO usage	Without VAHO	after application of VAHO	after 6m. of VAHO usage									
1. m, 7 y.,	3	2	/	2	2	/	3	2	/	da	ne	/	8	12	/
2. m, 7 y.,	2	1	/	2	2	/	3	2	/	da	ne	/	10	20	/
3. f,4 y., IV	3	2	1	3	3	3	3	3	3	da	ne	ne	2	3	3
4. m,12 y., IV	3	2	2	3	2	2	3	2	2	da	ne	ne	2	6	30
5.m,11 y., IV	3	2	2	3	2	2	3	2	2	da	ne	ne	3	6	15
6.m,7 y., II	2	1	1	2	1	1	1	1	1	da	ne	ne	300	400	500
7.f,8 y., IV	3	2	1	3	2	1	3	2	2	da	ne	ne	4	12	20
8.f,11 y.,III	2	1	1	2	1	1	2	1	1	da	ne	ne	4	8	10
9.f,11 y., III	2	1	1	2	1	1	2	1	1	da	ne	ne	10	15	20
10.m,7 y.,	2	1	1	2	1	1	2	1	1	da	ne	ne	10	15	25

Legend: Sitting – posture: upright 1, slightly hunched 2, heavily hunched 3
Standing: independently 1, with support from the environment or an aid 2, with another person 3
Walking: independently without support 1, with support from the environment 2, with another person 3

In all 10 children studied, team-checked previous evaluation has confirmed the functionality of VAHO an immediate improvement of motor skills in the observed parameters, and all the parents/guardians have agreed with the use of orthoses by their child. The manufacturer's recommendation is to use VAHO for at least 6 hours a day, and our children studied have used it daily from 2 to 6 hours, in an average of 4 hours. At 1 girl with nonfixed hip displacement, in the observed period of 6 months, there hasn't been progression of displacement nor changes from the conservative to the operative treatment of the hip.

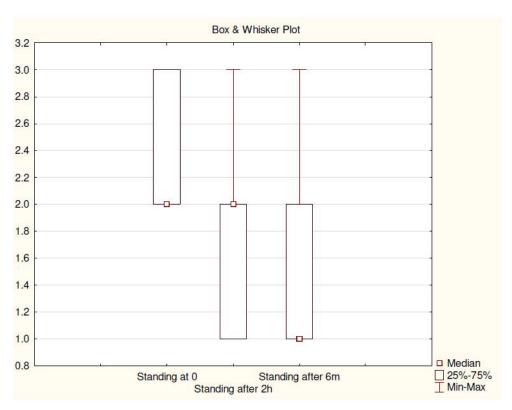
Immediately after the application of VAHO, all children had improvement in posture while sitting (p = 0.005), reduced scissoring gait (p = 0.005) and increase of walking distance in meters (p = 0.005)-statistically very significant differences. In all children there was an improvement of independent standing (p = of 0.018) and walking (p = of 0.018)-statistically moderately significant differences. 20% of children studied - 2 boys aged 7 years GMFCS III, 1 with a mild and 1 with significant mental retardation gave up using VAHO: one refused using VAHO for walking, while second complained because of ache and for those 2 boys there was no evaluation after 6 months.

Comparing the examined parameters in 8 subjects in VAHO immediately after fitting and after 6 months of usage, it was still present only the same improvement comparing with status without orthosis, while in the walking distance in meters after 6 months there has been an further increase – statistically moderately significant differences (p = 0.018). Parents of 8 children rated orthosis, after 6 months of use, with average grade of 4.6 (almost great) and all of them decided positive regarding application of VAHO brace again after child outgrows it.

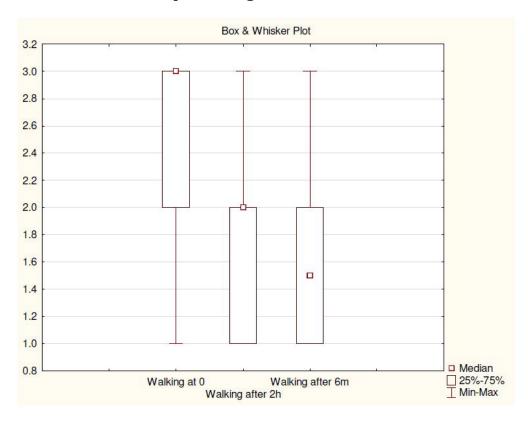
Parents/guardians said additionally:

- the use of orthosis is simpler in smaller and slimmer children
- orthosis is very efficient in improvement of sitting-stability
- it is more uncomfortable for children to use VAHO when it is hot during summer
- After comorbidity complications leading to deterioration of locomotor status (e.g. epileptic status), it may be necessary to re-adapt the child to orthosis usage.

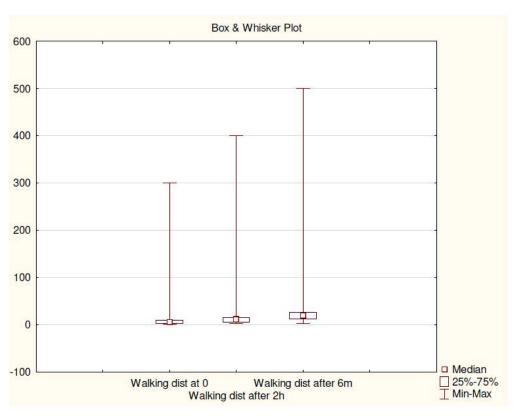
Picture number 2 Graph standing



Picture number 3 Graph walking



Picture number 4 Graph walking distance



Discussion and conclusions

VAHO is intended for relatively small group of users with specific orthotic needs. When assessing the indication for use, experience of medical team is essential, as well as parent / guardian co-operation in order to avoid unsuccessful orthotic fitting and unnecessary costs for insurers. The possibility of supplying VAHO as a product reimbursed by health insurance is important for that group of users because of the availability / high cost of device and variety in choice options for orthotic devices (7,11,12,13). Besides VAHO, children with spastic palsy in Croatia, as a reimbursed product can only receive just another type of devices to walk - the orthosis for the hip, knee, ankle and foot (HKAFO). Although all parents / guardians initially agreed with VAHO application, as well as children – according to their understanding possibilities, 2 or 20% of children still decided against application, suggesting the need to inform the guardians/parents and users better about the possibilities and limitations of VAHO.

Children used VAHO less than the recommended hourly rate, which is consistent with the literature data of very rare use in the full recommended hour (16,17) and points to the need for ongoing support from the medical team to parents/guardians and users in order to achieve better co-operation and thus better performance of VAHO.

In the literature is found the use of VAHO in combination with the use of Botox (18), as well as the presentation to few professional medical conferences on the possibility of using VAHO to improve CP's child motor skills (10,15) but without published clinical studies to confirm the manufacturer's comments on the improvement after the use of the orthosis.

Our study confirmed the manufacturer's recommendation that VAHO used in CP's children with spastic lower limbs can improve posture, stability in sitting and standing, walking and to increase walking distance, thereby improving the ADL. Although it is a very small target group of users of VAHO, in this study, data was analysed for 43% of VAHO delivered in Croatia and we consider them to be relevant. It is necessary to perform wider standardized examination in several institutions over a longer period of time and with a large number of subjects conducted by educated and experienced examiners in the application of VAHO to expand and improve knowledge of the effects of orthosis.

Conclusion:

This study in a small group of respondents confirmed the effect of VAHO on the improvement of CP children's motor skills through the examined parameters, immediately after fitting and after 6 months of application. In order to make a proper decision on the use of the orthosis, a team evaluation of the functionality / indication is necessary by an experienced and educated medical team as a continuous support for the user and family in continuous application. For more credible conclusions about the

usefulness of VAHO, it is necessary to conduct a long-term examination in several institutions on a large number of subjects.

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