Assessing the Effectiveness of Lower Limb Home Exercises with the Use of a Prototype Exercise Robot for Continuous Passive Movement in People with Tetraparesis in the Long-Term Follow-Up: a Preliminary Report

Ocena skuteczności domowych ćwiczeń kończyny dolnej z wykorzystaniem prototypowego robota do ćwiczeń ciągłego ruchu pasywnego u osób z tetraparezą w obserwacji odległej: raport wstępny

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Keywords
home exercises, continuous passive movement, tetraparesis

Abstract
Introduction: Chronic venous insufficiency is the most commonly occurring vascular disease. One of the major risk factors for its development is long-term sitting or standing in prolonged unchanged position and the nature performed work.
Study aim: The aim of this study was to assess the effectiveness of lower limb home exercises limb with the use of the Bella Vena robot following disease onset causing tetraparesis in long-term observation.
Materials and methods: A group of 15 patients (43.80 ± 14.97 years) was enrolled in the study. These patients had experienced whiplash injury causing total or partial inertia, with preserved mobility in the ankle joints. The total duration of the observation lasted 8 months (8 visits), during which the following parameters were assessed at the beginning and end of this period: pain intensity – according to the Visual Analogue Scale (VAS), level of saturation on the toe, pulse rate of the lower limb via Doppler ultrasound evaluation of reflux parameters.
Result: Statistically significant improvement was achieved after home exercises within the following ranges - quality of pain intensity on VAS ($p \leq 0.01$), saturation at the level of the big toe ($p \leq 0.05$), Doppler ultrasound: reflux in the right femoral vein ($p \leq 0.05$), Doppler ultrasound: reflux in the left femoral vein ($p \leq 0.05$)
Conclusion: Home exercises with using a prototype of the Bella Vena device showed a moderate effect on improving calf pump in the group of patients with quadriplegia in long-term observation.

Słowa kluczowe
ćwiczenia domowe, ruch ciągły bierny, tetrapareza

Streszczenie
Wprowadzenie: Przewlekła niewydolność żylna jest najczęstszą chorobą naczyniową. Jednym z głównych czynników ryzyka jego rozwoju jest długotrwałe siedzenie lub stanie w tej samej pozycji oraz charakter wykonywanej pracy.

The individual division of this paper was as follows: A – research work project; B – data collection; C – statistical analysis; D – data interpretation; E – manuscript compilation; F – publication search

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Cel pracy: Celem pracy była ocena skuteczności ćwiczeń domowych kończyny dolnej z użyciem robota „Bella Vena" po wystąpieniu choroby powodującej tetraparezę w obserwacji długoterminowej.
Materiał i metody: Zakwalifikowana do badania grupa 15 pacjentów (43,80 ± 14,97 lat) doznała uszkodzenia urazowego kręgosłupa szyjnego powodujący całkowitą lub częściową bezwładność, z zachowaną ruchomością w stawach skokowych. Całkowity czas obserwacji trwał osiem miesięcy (osiem wizyt), podczas których na początku i na końcu tego okresu oceniano następujące parametry: ocena natężenia bólu – według skali VAS, poziom saturacji na palcu, częstość tętna kończyn dolnych ultrasonograficzna ocena parametrów refluksu Dopplerowskiego.
Wyniki: Istotną statystycznie poprawę uzyskano po ćwiczeniach domowych w następujących zakresach - jakość natężenia bólu VAS ($p \leq 0{,}01$), saturacja na poziomie palucha ($p \leq 0{,}05$), USG Doppler: refluks w żyle udowej prawej, ($p \leq 0{,}05$), USG dopplerowskie: refluks w żyle udowej lewej, ($p \leq 0{,}05$)
Wnioski: Ćwiczenia domowe z wykorzystaniem prototypu urządzenia „Bella Vena" miały umiarkowany wpływ na poprawę pompy łydkowej w grupie pacjentów z tetraplegią w obserwacji długoterminowej.

INTRODUCTION

Earlier physiotherapy for individuals with neurological damage, such as spinal cord injury (SCI), has been focused on learning compensatory movements to regain function from the past. At present, the focus of physiotherapy has shifted to functional neurorecovery or function restoration through repetitive movement training of the affected limbs, especially the ankle. Technologies, such as robotic devices and electrical stimulation, are being developed to facilitate repetitive motor training; however, their implementation into mainstream clinical practice has not been realised[1,2].

Home-based physical therapy (PT) is a promising alternative to outpatient care or hospital-based physiotherapy programmes due to its favourable family atmosphere. There is a lack of literature in which the impact of home rehabilitation programmes would be described, specifically designed for people with various types of physical disabilities[3].

It is well-documented that people with SCI engage in lower levels of physical activity compared to groups without disabilities. Other benefits of home-based programmes include their low cost (compared to onsite programmes), the elimination of travel time as well as the ability for individuals to work at a self-selected pace and in a comfortable environment[4].

Chronic venous insufficiency is the most commonly occurring vascular disease. One of the major risk factors for its development is long-term sitting or standing in unchanged position and the nature of performed work. All symptoms of chronic venous insufficiency develop in patients immobilised in a wheelchair, in a seated position and having a forced position of the lower limbs[5].

The venous system of the lower limbs includes the superficial, deep and perforating veins. The antegrade flow of blood within these veins is ensured by a system of muscular venous pumps and bicuspid valves. Dysfunction of the system may result from degeneration of the vein wall, post-thrombotic valvular damage, chronic venous obstruction or dysfunction of muscular pumps. Venous return from the lower extremities is vitally dependent on the action of the foot, calf and thigh muscle pumps, with approximately 90% of venous return attributed to these muscle structures during ambulation. For these reasons, any form of forced movement in the ankle joint, shin or thigh muscles is an element improving quality of life[6,7].

STUDY AIM

The aim of this study was to assess the effectiveness of lower limb home exercises with the use of the Bella Vena robot following the onset of diseases causing tetraparesis in long-term observation and, above all, to answer the following research questions:

1. What is the impact of lower limb home exercises with the use of the Bella Vena robot on the improvement of calf pump functioning in a group of patients with quadriplegia in long-term observation?
2. What is the impact of lower limb home exercises with the use of the Bella Vena robot to reduce adverse symptoms directly related to immobilisation in a wheelchair?

Based on such research questions, the following research hypotheses have been presented:

1. Home exercises with the use of automatic exercise rehabilitation devices improve blood flow by activating the calf pump in a group of patients with quadriplegia
2. Home exercises with the use of an automatic exercise rehabilitation device reduce adverse symptoms directly related to adoption of a forced sitting position and immobilisation in a wheelchair.

MATERIALS AND METHODS

Materials

All the results of this study have been presented in the format: measurement value ± standard deviation. This study received funding for the development and manufacturing of the "Rehabilitation Robot – Bella Vena" medical device from the National Centre for Research and Development – NCBiR. The conducted clinical trial was carried out in accordance with the guidelines proposed by the institution supervising the trial, which approved the clinical trial protocol, and the institution intermediating in the trial of the National Centre for Research and Development. Permission to initiate clinical trials was obtained from the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products on November 19, 2018, No. U.D.WM. DNB.83.2018.

This study has been approved by the Bioethics Committee of the Medical University of Silesia in Katowice – Research No.: MIDMED/BV/2017,

Table 1

Characteristics of included patients				
Study group				
Variables	$\bar{x} \pm SD$	median	max	min
Age [years]	43.80±14.97	39	92	25
Body mass [kg]	77.93±11.94	80	100	55
Body height [cm]	174.73±11.23	176	187	140
BMI/females [kg/m^2]	30.61	30.61	30.61	30.61
BMI/males [kg/m^2]	25.24±3.58	25.49	33.41	18.38
BMI [kg/m^2]	25.59±3.72	25.74	33.41	18.38

BMI – body mass index; $\bar{x}$ – arithmetic mean; *SD* – standard deviation

and each participant signed a written, informed consent form to participate in the trial. The study comprised 15 individuals (14 men and 1 woman) from a group of 110 men and women who met the adopted inclusion criteria. The selection of the study group was deliberate. Members of the group were recruited via correspondence in response to a written invitation. The average age of groups participants was 43,80 ± 14.97, the mean body mass totalled 77.93 ± 11.94, while body mass index (BMI)[8] equalled 25.59 ± 3.72 (Table 1). The group of patients enrolled in the study had previously experienced whiplash injury causing total or partial inertia, with preserved mobility in the ankle joints – G82 – the inclusion criteria. The exclusion criteria for the study were: recent deep vein thrombosis of the lower extremities, fresh thrombosis of the superficial vein system of the lower limbs, acute inflammation in the venous system of the lower extremities without thrombosis, inflammation of all joints of the lower limbs, especially in situations where immobilisation of the limb is recommended, pregnancy and breastfeeding, plaster of casts preventing movement in the ankle, knee and hip joints, inability to adopt appropriate body position for using the device (contractures in the joints, lack of mobility of the joints), cardiovascular diseases, on recommendation of the attending physician not to use this type of device, other diseases preventing the use of the device in accordance with the instructions for use, severe general condition of the patient, insufficient physical and mental fitness of the patient to independently operate the product (unless under the constant supervision of the caregiver).

Parameter measurements

The total duration of the observation lasted 8 months (8 visits), during which the following parameters were assessed at the beginning and end of this period: assessment of pain intensity – according to the VAS, the level of saturation on the toe, the pulse rate of the lower limb via Doppler ultrasound evaluation of reflux (right popliteal vein, left popliteal vein, right small saphenous vein outlet, left small saphenous vein outlet, right great saphenous vein outlet, left great saphenous vein outlet, right femoral vein, left femoral vein), measurement of the right and left shin circumference using a measuring tape, subjective patient assessment according to the degree of reflux (on a 0-4 scale). Doppler ultrasound examination with colour flow imaging was performed after 15 'adaptation of the patient with the Sono Scape S 8 apparatus, linear probe (frequency: 5-7.5 MHz). The examination was performed in a seated position.

The assessment of reflux on the popliteal vein was performed at the exit of the small sagittal vein by pressing the calf muscle. All ultrasound examinations were carried out by 1 physician who was authorised to conduct this type of examination and to correctly interpret the results of examination[9,10].

The case report form (CRF) contained data on the occurrence of: oedema of the legs, skin cyanosis, muscle cramps – involuntary tension, leg heaviness, patients with immobilised residual movements in the shoulder girdle, as well as other symptoms. Subsequent visits, except for the first one, contained the same questions and analogous physical and imaging examinations were performed. Visits took place every 4 to 5 weeks.

Intervention

In order to improve the quality of life among patients from the study group (all immobilised in a seated position in a wheelchair), the Bella Vena device forcing movement in the ankle joint was used to activate the calf pump. The Bella Vena device is an automated platform for exercising the lower limbs by forcing the heel – toe – heel movement of the foot at a properly selected foot inclination angle and speed of movement. The user places both feet on the exercising platform and then activates the device using the IR remote control. Thanks to the properly designed movement of the platform stimulating gait, the Bella Vena device provides a possibility for training in the form of foot movement activating the calf muscles. The so-called calf pump improves blood outflow from the lower limbs. During the operation of the device, movement is forced in the ankle joints by appropriate tilting of the training platform on which the feet are located. The DC motor installed in the Bella Vena device performs work in accordance with the values programmed in the microcomputer's memory – the number of repetitions, speed of movement and the angle of the platform. The mechani-

cal structure of the device is responsible for the platform's inclination angle. The pendulum movement of the platform is possible due to a specially-designed drive transmission system from the engine to the movable part of the platform. The operation of the device is selected in such a way as not to exceed the limit values for the ankle joint, including ankle flexion angle, as excessive movement can damage the joint. The device is powered by 230-V mains through the AC/DC adapter that reduces the voltage supplying the device to a value safe for humans – 24V DC. The Bella Vena device allows to exercise 2 feet at the same time or only 1 – left or right, depending on the user's needs. The casing of the Bella Vena device is made entirely of aluminum, while inside there is a DC motor with electronics controlling the motor operation and a drive transmission system. The exercisers used the device once a day for 30 minutes, the frequency of the platform swing is 1 time/sec. The swing angle is 23 degrees. During the 8-month period of physical therapy at home, patients also had the opportunity for telephone consultation with the physical therapist supervising this form of treatment. The device, before transferred to testing with the participation of patients, was subjected to a safety test for selected points of the PN-EN 60601 standard for medical devices by the Institute of Medical Technology and Apparatus in Zabrze and KOMAG in Gliwice, where tests were carried out to obtain the International Protection (IP) degree. The physical parameters of the device were selected in such a way that the device is suitable for 90% of society. The device is intended for people with a maximum weight of 120 kg. The components of the device in the form of electronics, motor, power supply and construction were selected for this scale. For people over 120 kg, a modified, so-called heavy-duty version of the device was used. In this type, the appropriate design and electronics can cope with the increased weight of the lower limbs (Figures 1, 2).

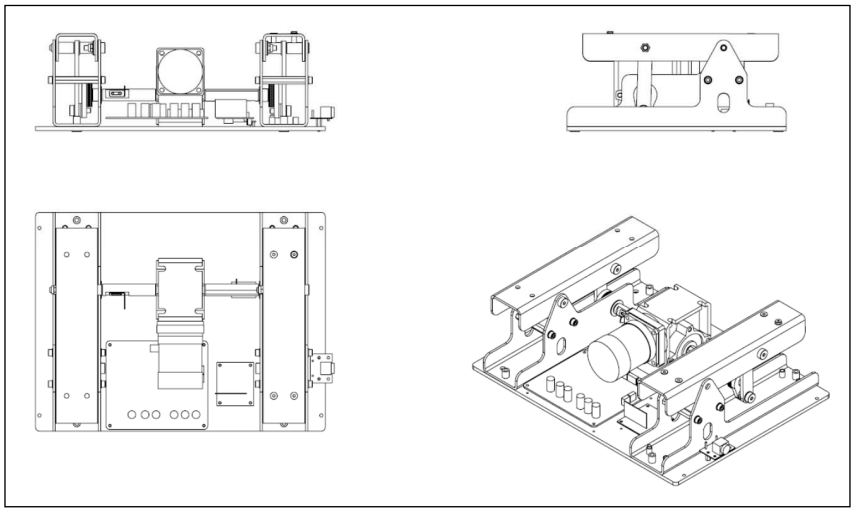

Figure 1

Diagram of the Belle Vena device

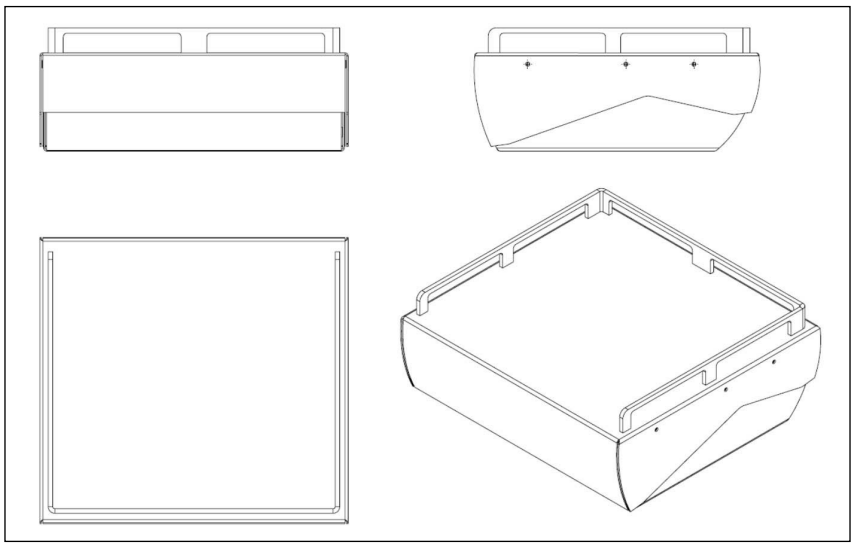

Figure 2

Diagram of the Belle Vena device

Statistical analysis

In order to select an adequate statistical test to compare the studied dependent groups, the Shapiro-Wilk's test for normality of distribution was performed, then, the non-parametric Wilcoxon test (continuous variables) and the McNemar test (nominal variables) were applied.

Moreover, the basic descriptive statistics were calculated: arithmetic mean, standard deviation (continuous variables) and the percentage frequency of occurrence (nominal variables). The results at $p \leq 0.05$ were considered statistically significant, and the results at $p \leq 0.01$ as highly significant. In order to establish potential correlations between variables, statistical analysis was conducted using a contingency table via the use of Pearson's χ^2 test. In addition, the correlation coefficient was calculated using Yule's Φ. Statistical analysis was performed with the STATISTICA 12 software by StatSoft.

RESULTS

Lower limb oedema persisted in 11 patients at the first and last visits. One person improved – no symptoms at the last visit. The correlation coefficient ($\Phi = 0.83$) indicates a very high relationship between the variables. Skin cyanosis only occurred in 1 person.

The correlation coefficient ($\Phi = 0.87$) indicates a very high relationship between variables. Symptoms of

muscle cramps appeared in 7 patients during the first visit, and after 8 visits, they did not occur in 3. In 5 subjects, this symptom was not visible throughout the entire study period. The correlation coefficient (Φ = 0.66) indicates a high relationship between variables. Heaviness of the limbs did not appear in 13 people throughout the entire study period. This symptom was recorded at all visits for 1 person. The correlation coefficient (Φ = 0.68) indicates a high relationship between variables. In other cases, no statistical significance is reached; thus, the occurrence of other symptoms (p = 0.7565) during the first-V1 and the last-V8 does not differ from one another (Table 2). In the study group, statistically significant improvement was noted after home exercises between tests V1 and V8 within the following ranges – the quality of pain intensity on the VAS, ($p \leq 0.01$), saturation at the level of the big toe ($p \leq 0.05$), Doppler ultrasound: reflux in the right femoral vein ($p \leq 0.05$), doppler ultrasound: reflux in the left femoral vein ($p \leq 0.05$) (Table 3).

When assessing venous reflux using Doppler ultrasound at the level

Table 2

Values of study variables – symptoms

V1. Occurrence of symptoms		V8. Group G 82 - paralysis of the lower limbs and quadriplegia						
		yes		no				
		N	%	N	%	χ^2	p	Φ
Oedema of the legs	yes	11	91.67%	1	8.33%			
	no	0	0.00%	3	100.00%	10.31	0.0013	0.83
Skin cyanosis	yes	9	100.00%	0	0.00%			
	no	1	16.67%	5	83.33%	11.25	0.0008	0.87
Muscle cramps	yes	7	70.00%	3	30.00%			
	no	0	0.00%	5	100.00%	6.56	0.0104	0.66
Leg heaviness	yes	1	100.00%	0	0.00%			
	no	1	7.14%	13	92.86%	6.96	0.0083	0.68
Patient immobilised	yes	12	100.00%	0	0.00%			
	no	3	100.00%	0	0.00%	-	-	-
Other Sx	yes	1	16.67%	5	83.33%	0.10	0.7565	0.08

V1 – 1st visit; V8 – 8th visit; Sx (abbreviation) – symptoms

Table 3

Values of study variables

	Study group	
	Pre- intervention (V1)	Post- intervention (V8)
Parameters	$\bar{x} \pm SD$	$\bar{x} \pm SD$
VAS Scale [cm]	5.67±0.55	3.47±1.48**
Saturation on the toe [%]	97.07±1.22	98.07±0.70*
Measuring the pulse rate of the lower limb [number per minute]	64.40±12.21	65.47±3.36^{-}
Doppler ultrasound evaluation of reflux: [velocity-cm/s]		
Right popliteal vein	0.08±0.12	0.07±0.09^{-}
Left popliteal vein	0.07±0.12	0.06±0.09^{-}
Right small saphenous vein outlet	0.00±0.00	0.00±0.00
Left small saphenous vein outlet	0.00±0.00	0.00±0.00
Right great sahpenous vein outlet	0.00±0.00	0.00±0.00
Left great sahpenous vein outlet	0.00±0.00	0.00±0.00
Right femoral vein	0.17±0.21	0.01±0.04*
Left femoral vein	0.13±0.15	0.01±0.03*
Right shin circumference [cm]	35.73±3.58	35.67±3.75^{-}
The left shin Circumference [cm]	35.73±3.61	35.73±3.71
Subjective patient assessment according to degree of reflux [scale 0-4]	0.13±0.35	0.07±0.26

**$p \leq 0.01$; *$p \leq 0.05$; $^{-}p > 0.05$ Wilcoxon signed rank test; V1- 1st visit; V8 – 8th visit

of the right and left popliteal veins, no statistically significant changes were found. Similarly, when assessing measurements of lower limb circumference, no significant differences in circumference were obtained in the whole study group ($p>0.05$) (Table 3).

DISCUSSION

Analysis of the results regarding the assessment of subjective symptoms among patients during the study period shows significant improvement in only one of them – the level of lower limb pain. The remaining variables of subjective assessment, such as limb oedema, skin cyanosis, symptoms of muscle cramps and the feeling of heaviness in the lower limbs did not change. The varying degree of occurrence concerning these symptoms in the studied group indicates the adverse effects of maintaining a seated position for a prolonged period of time on the work of the lower extremity venous system. Analysis of the results regarding saturation assessment at the toe level and reflux in the right and left femoral veins shows a favourable changes in vascular and venous flow. This may be the result of the calf pump being forced by the operation of the Bella Vena device.

A significant change in the value of only 3 parameters indicates a moderate effect of these exercises on the venous system in the studied group.

Patients with spinal cord injury are at risk of deep vein thrombosis (DVT) and pulmonary embolus due to immobility, alterations in fibrinolytic activity and platelet function, as well as impaired circadian variations of fibrinolytic and haemostatic activity. Prophylaxis in DVT is mandatory and should be initiated no later than 72 h after injury. Non-pharmacological treatments include mobilisation of the patient, compression stockings, physical therapy and pneumatic compression boots[11,12]. Chronic pain after SCI is reported to be as high as 94%. It affects patients emotionally and interferes with activities of daily living[13].

The Consortium for Spinal Cord Medicine (CSCM) recommends that spinal cord injury survivors perform at least 150 minutes of exercise per week. This may be achieved by completing 30-60-minute sessions once a day or 10-minute session 3 times a day, 3-5 days per week. People who are not able to meet these guidelines should avoid inactivity by engaging in regular physical activity according to their abilities[14].

Patients with spinal cord injuries often do not have the opportunity to perform supervised exercises with a physiotherapist, which is important in the prevention of thrombosis and chronic pain in the lower extremities. The developed Bella Vena device significantly reduced the subjectively perceived pain and improved venous outflow. In previous studies in this group of patients, their authors have only assessed the effect of electrical stimulation on inadequate muscles of the lower limbs, without evaluating venous outflow[15,16]. The positive effects of lower limb exercises in the prevention and treatment of venous disease are well-documented. Improvement in venous flow can be observed after exercising with the use of continuous passive movements. Such studies have not been conducted in a group of patients with spinal cord injuries[17,18].

The innovation of the Bella Vena device is its availability and ease of use at home. The intention of the authors was that anyone in need could use this device at home and exercise even several times a day. This device aims at activation by imitating physiological movement in the ankle joints. It can be compared to passive exercises performed by a physiotherapist, which results in the stimulation of venous blood flow.

The objective of the designers was to create a device available to everyone. The Bella Vena device should not be compared to highly technologically-advanced robots. It should be treated as a supplement to daily physiotherapy.

In the conducted research, the regularity of training was supervised by monthly visits and telephone consultations with physical therapists. This supervision ensured control of training and provided an opportunity to submit comments on the prototype of the device during its operation. The device itself is easy to use and enables the performance of home exercises according to the patient's physical state.

Nonetheless, there are some limitations such as the lack of a control group, small group size and no statistical analysis of differences between sexes. The available literature lacks data on the assessment of symptoms that might suggest chronic venous insufficiency in people with tetraplegia prior to trauma, such as: assessment of lower limb oedema, bruising of the integuments, night involuntary tension (cramps), heavy leg symptoms and problems with displacement. For these reasons, the authors could not compare their results with the data obtained by other authors.

CONCLUSION

1. Home exercises using a prototype of the Bella Vena device for exercising the lower limb with paresis had a moderate effect on improving the calf pump in a group of patients with quadriplegia in long-term observation.
2. Home exercises with the use of an automatic exercise rehabilitation device reduced symptoms directly related to immobilisation in a wheelchair, but only in terms of pain.
3. Further research must be focused on expanding the technological capabilities of the device, which will allow the patient to fully engage in exercises based on biofeedback.

Conflict of interest
The authors of work are not bound by a conflict of interest

Approval of the Research Ethics Committee
This study has been approved by the Bioethics Committee of the Medical University of Silesia in Katowice – Research No.: MIDMED/BV/2017.

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