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ORIGINAL ARTICLE

Movement therapy in advanced heart failure assisted by a lightweight wearable robot: a feasibility pilot study

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Abstract

Aims The aim of this pilot study was to investigate the safety, feasibility, tolerability, and acceptability of an assisted mobilization of advanced heart failure patients, using a lightweight, exoskeleton-type robot (Myosuit, MyoSwiss AG, Zurich, Switzerland).

Methods and results Twenty patients in functional NYHA class III performed activities of daily life (ADL, *n* = 10) or participated in a single, standardized, 60 min rehabilitation exercise unit (REU, *n* = 10) with and without the Myosuit. The outcome assessment included the evaluation of vital signs, adverse events, rates of perceived exertion and dyspnoea (RPE, RPD), the ability to perform ADL or REU, and the individual acceptability. The mean age of the subjects was 49.4 (±11.0) years; 80% were male. The mean left ventricular ejection fraction was 22.1% (±7.4%) and the median NT-proBNP 2054 pg/mL (IQR 677, 3270 pg/mL). In all patients, mobilization with the Myosuit was feasible independently or with minor support. The mean individual difference in the total walking distance of the patients without and with robotic assistance was −26.5 m (95% confidence interval (CI) −142 to 78 m, *P* = 0.241). No adverse events occurred. RPE and RPD showed no significant difference with or without the device (ADL: RPE −0.1 m, 95% CI −1.42 to 1.62, *P* = 0.932 and RPD −0.95 m, 95% CI −0.38 to 2.28, *P* = 0.141; REU: RPE 1.1 m, 95% CI −2.90 to 0.70, *P* = 0.201 and RPD 0.5 m, 95% CI −2.02 to 1.02, *P* = 0.435). All median responses in the acceptability questionnaire were positive. The patients felt safe and enjoyed the experience; 85% would be interested in participating in robot-assisted training on a regular basis.

Conclusion This feasibility pilot trial provides first indications that a robotic exoskeleton-assisted mobilization of patients with advanced heart failure is safe, feasible, well-tolerated, and well-accepted. The results are highly encouraging to further pursue this innovative approach in rehabilitation programmes. This trial was registered at ClinicalTrials.gov: NCT04839133.

Keywords Heart failure; Exoskeleton; Robotic-assisted; Rehabilitation; Exercise training; Myosuit

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Introduction

Patients with chronic heart failure frequently suffer from skeletal muscle wasting and the symptoms of heart failure force to physical inactivity. This fatally aggravates deconditioning and exercise intolerance, leading to an increased risk of hospitalization and a loss of independence and quality of life.[1,2] To interrupt this vicious cycle, physical activity must be restored, as exercise intolerance can be successfully improved by physical training.[3]

Regular physical activity is an evidence-based adjuvant therapy of chronic heart failure.[4] Structured exercise training

is safe, increases exercise capacity, relieves symptoms, and can reduce the rate of rehospitalization. A trend towards reduction of mortality with structured training has been reported.[1,2]

Robotic devices have been investigated as an effective adjunct to conventional exercise training in rehabilitation from neurological disorders (e.g. spinal cord injury and stroke).[5,6] Robotic assistance can augment the effect of physical training by facilitating motor recovery, supporting balance and stability and thus improving exercise capacity to a greater degree than conventional, non-assisted training. As a result, longer duration of the exercise sessions and a higher training intensity can be achieved.[7–11]

To date, this innovative approach has not been applied in cardiovascular rehabilitation training, despite its great potential to counteract the deconditioning experienced by patients with symptomatic chronic heart failure. The aim of this pilot study was to investigate the safety, feasibility, and tolerability of exoskeleton-type robotic-assisted mobilization protocols in patients with severe heart failure.

Methods

The Myosuit

The Myosuit (MyoSwiss AG, Zurich, Switzerland) is a soft, wearable, exoskeleton-type robot that supports the synergistic extension of the hip and knee joints during various activities of daily life, such as walking, standing, sitting transfer, and stair climbing (*Figure 1*). The support is achieved by two ultra-high-molecular-weight polyethylene cables, which are routed in textile guides across the dorsal lower back and legs and which are proximally connected to electric motors that are housed inside a backpack-like driver unit. Movement sensors on the patient's trunk, thighs, and lower legs ('inertial measurement units') allow an internal control of the Myosuit to estimate the patient's state of movement and to provide assistive forces that are appropriate according to the individual needs. In addition to this active support, flexion of the hip and knee joints is supported by passive adjustable polymer spring elements. The structure and function of the Myosuit and its precursor models have been described in-depth previously.[12–14] The Myosuit is CE marked and is available in the European market. To date, it is exclusively used for neurological and orthopaedic indications.

Study design

From March to July 2021, 20 patients from the institutional outpatient clinic for advanced heart failure were recruited for this pilot study. The study design and protocol were approved by the local ethics committee (EA2/011/20) and registered at ClinicalTrials.gov (NCT04839133). The investigation conforms to the principles outlined in the Declaration of Helsinki. Written informed consent was obtained from all participants.

Patients with functional New York Heart Association (NYHA) class III heart failure, who met the inclusion criteria, were informed about the trial. Inclusion criteria included the ability to stand up from a chair and walk more than 10 meters (with or without traditional assistive devices, e.g. walking stick). Patients with signs of acute cardiac decompensation or mechanical circulatory support devices were

Figure 1 The Myosuit—an exoskeleton-type robotic device.

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excluded from the study. Further exclusion criteria were defined according to the requirements for an optimal fit of the device: The adjustable size of the textile upper body vest and the waist belt as well as the knee orthoses of the Myosuit is approved for patients with a body height between 150 and 195 cm, a body weight between 45 and 110 kg, a body mass index ≤35 kg/m^2, and waist size ≤135 cm (Supporting Information, *Table S1*).

The first 10 patients included in this trial were in group 1 (G1) and performed activities of daily life (ADL). The second 10 patients were in group 2 (G2) and participated in a standardized rehabilitation exercise unit (REU). All patients in each group performed the mobilization protocols in a cross-over design both with and without the Myosuit (*Figure 2*). All participants were inexperienced, first time users of the Myosuit and received a standardized oral introduction as well as a 2 min practical briefing. A specially trained medical doctor who supervised the study made donning of the device and the choice of its technical settings (i.e. mode and level of support).

Interventions

Patients of G1 performed ADL, which included a single session of timed walking for 6 min, standing, sitting down on a chair, standing up from a chair, and climbing stairs. For standing, a static mode of the Myosuit, supporting isometric balance by keeping a constant tension to extend hip and knee joints, was chosen.

Patients of G2 performed a single, standardized, 60 min REU in our institutional cardiac rehabilitation centre guided by a professional training therapist. Exercises included a dynamic walking training combined with resistance exercise of the upper body as well as dynamic and static balance training. The static or dynamic mode of the Myosuit was chosen according to the exercises performed.

Within both groups, patients started the mobilization protocols alternately with or without the robotic device. Participants were seated comfortably for rest during an at least 15 min break between the sessions.

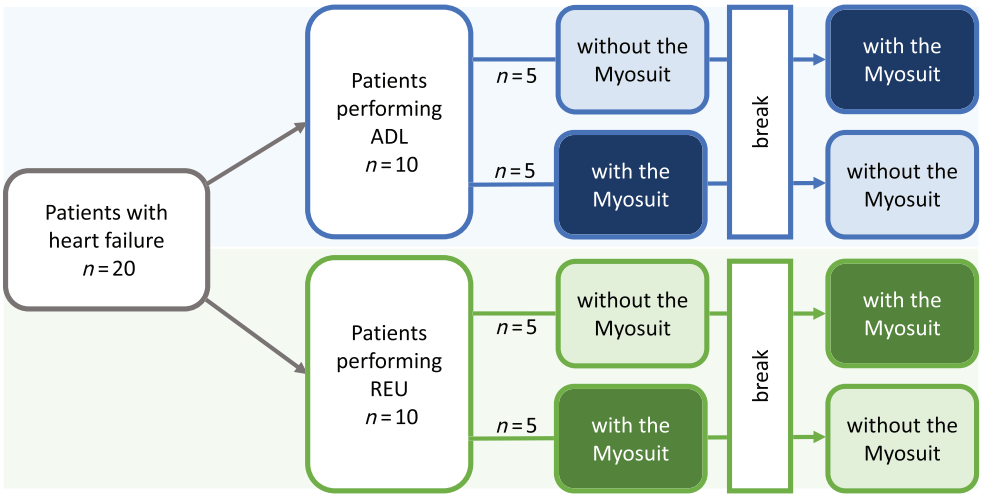
Outcome measurements

The ability to complete the mobilization protocols as well as the need for support was documented using a numerical scale from 1 to 4 (1 = unable to perform; 2 = with major support; 3 = with minor support; 4 = independently). Vital parameters (blood pressure, heart rate, respiratory rate, and peripheral oxygen saturation) were closely monitored and rates of perceived exertion (RPE, scale 6–20) and dyspnoea (RPD, scale 0–10) were investigated by numerical and visual analogous scales as described previously.[15,16] All patients were monitored for adverse events being defined as musculoskeletal or neurological injuries, vertigo, syncope, arrhythmias, hypertension, or hypotension. The individual acceptability was examined by a feedback questionnaire developed by Birch.[17] The distances during timed walking were measured by an investigator who followed the participant with a measuring wheel.

Statistical analysis

Continuous data are summarized as mean and standard deviation (SD) or, in the case of skewed data, as median and interquartile range (IQR). Frequencies and percentages

Figure 2 Study design of the Myosuit Feasibility Trial. ADL activities of daily life (including walking, standing, sitting-standing-transfer, and stairclimbing). REU, rehabilitation exercise unit.



are reported for categorical data. Wilcoxon tests were performed to analyse 6 min walk distances (6MWDs), RPE, and PRD. SPSS 25 was used for statistical analysis.

Results

Patient characteristics

Twenty patients with advanced heart failure in functional NYHA class III performed standardized mobilization protocols ADL (G1) or a REU (G2) both with and without robotic assistance. The mean age was 49.4 (±11.0) years; 16 (80%) were male. Most of the patients (70%) had dilated cardiomyopathy, and all patients were in evaluation for or on heart transplantation waiting list of Eurotransplant. *Table 1* presents the baseline characteristics of the patient cohort.

Feasibility

The ADL were successfully completed independently or with minor support both with and without wearing the Myosuit (*Figure 3A*). Minor support was defined as the use of a walking stick, placing the hands on the chair or thighs for sitting transfer or using the handrail when climbing stairs. One of the patients in G1 had a concomitant muscular dystrophy and was unable to climb up stairs with or without robotic assistance. All patients in G2 successfully completed the REU independently; no participant terminated the training early. The mean total walk distance of all patients without and with robotic assistance was 364.0 m (±111.7 m) and 325.2 m (±157.6 m), respectively, with a median difference of −26.5 m (95% CI −142 to 78 m, $P = 0.241$) (*Figure 3B*).

Table 1 Baseline characteristics

	All patients, $n = 20$	Group 1, $n = 10$	Group 2, $n = 10$
Age in years	49.4 (±11.0)	51.9 (±9.8)	46.8 (±12.0)
Male	16/20	8/10	8/10
BMI in kg/m^2	25.8 (±4.3)	24.78 (±4.5)	26.9 (±4.0)
Diagnosis			
DCM	14/20	7/10	7/10
HCM	1/20	1/10	0/10
IHD	5/20	2/10	3/10
LV-EF in %	22.1 (±7.4)	23.0 (±7.5)	21.2 (±7.1)
NT-proBNP in pg/mL	2054 (677, 3270)	2247 (1324, 3627)	990 (557, 2440)

BMI, body mass index; DCM, dilated cardiomyopathy; HCM, hypertrophic cardiomyopathy, IHD, ischaemic heart disease; LVEF, left ventricular ejection fraction; NTproBNP, N-terminal prohormone of brain natriuretic peptide.

Safety

No adverse events occurred during the trial. The vital parameters pre, during and post intervention are presented in *Table 2*. None of the patients received or required supplemental oxygen.

Tolerance and acceptability

As measures of tolerance, the mean RPE without and with the Myosuit was 10.6 (±3.1) and 10.5 (±3.3), respectively, with a mean difference of −0.1 (95% CI −1.42 to 1.62; $P = 0.932$); and the mean RPD without and with the Myosuit was 2.8 (±2.5) and 1.8 (±2.0), respectively, with a mean difference of −0.95 (95% CI −0.38 to 2.28; $P = 0.141$) during ADL in G1.

In group 2, the mean RPE without and with the Myosuit was 12.0 (±3.5) and 12.6 (±2.9) (mean difference 0.6; 95% CI −3.92 to 2.72; $P = 0.404$) after 15 min and 12.9 (±3.5) and 14.0 (±2.7) (mean difference of 1.1; 95% CI −2.90 to 0.70; $P = 0.201$) after 30 min, respectively. The mean RPD without and with the Myosuit was 3.0 (±2.9) and 3.5 (±2.3) (mean difference 0.5; 95% CI −2.02 to 1.02; $P = 0.435$) after 15 min and 2.9 (±2.7) and 3.8 (±2.7) (mean difference 0.5; 95% CI −2.02 to 1.02; $P = 0.435$) after 30 min, respectively (*Figure 4*).

Participants of G1 and G2 completed a questionnaire about the Myosuit acceptability (*Table 3*); 75% of Myosuit-related statements and all median ratings were positive after a single exercise session. Most patients felt safe (80%; 25% strongly agreed, 40% moderately agreed, 15% slightly agreed) and experienced the mobilization with the Myosuit and its control as easy (75% and 80%, respectively). Most patients (56%) experienced stairclimbing easier with the device, but 44% of patients disagreed; 25% reported the Myosuit as too heavy and 46% of participants with positive statements concerning the weight of the device only slightly agreed; 95% of patients enjoyed the experience; and 17 of 20 (85%) would be interested in a robotic-assisted exercise training on a regular basis. A comparison between G1 and G2 found no differences in the rate of positive and negative responses.

Discussion

The aim of this pilot trial was to investigate the safety, feasibility and tolerability of an exoskeleton-assisted mobilization of patients with advanced heart failure. No adverse events occurred and despite an additional weight of 5.5 kg, the participants were able to complete ADL and a REU successfully. The Myosuit was well-tolerated by all patients.

Figure 3 (A) Ability to perform ADL with and without wearing the Myosuit. The evaluation was performed using a numerical scale from 1–4 (1 = unable, 2 = with major support, 3 = with minor support, 4 = independently). Data presented as mean ± standard deviation. (B) Walked distances of patients in G1 with and without robotic assistance.

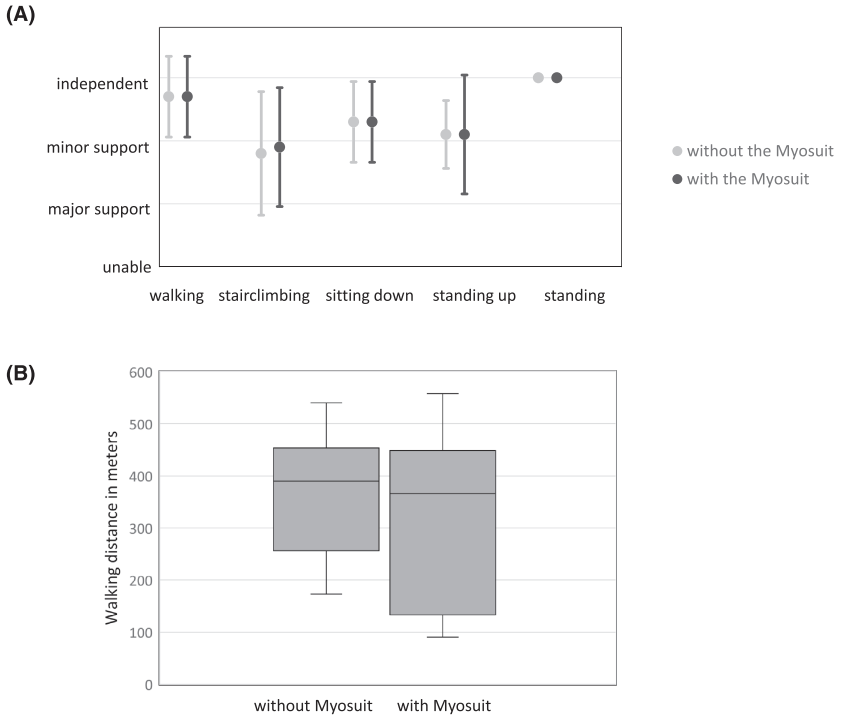


Table 2 Vital parameters pre, during and post mobilization

	Group 1 without myosuit			Group 1 with myosuit		
	Pre	Intervention	Post	Pre	Intervention	Post
SBP in mmHg	105.3 (±18.7)	108.2 (±18.0)	106.4 (±22.1)	106.2 (±18.9)	111.4 (±18.4)	110.5 (±19.6)
DBP in mmHg	67.1 (±14.0)	70.0 (±16.7)	66.7 (±15.2)	70.2 (±11.6)	71.7 (±12.2)	69.2 (±11.8)
HR in min^{-1}	76.9 (±15.0)	76.2 (±31.4)	80.0 (±14.5)	72.8 (±24.2)	86.2 (±12.7)	81.0 (±13.5)
RR in min^{-1}	17.5 (±2.6)	22.3 (±3.3)	18.1 (±3.0)	16.3 (±2.0)	19.8 (±3.2)	17.8 (±2.0)
SpO_2 in %	97.6 (±1.9)	97.1 (±2.2)	98.1 (±0.9)	97.1 (±1.9)	98.4 (±1.3)	97.8 (±1.9)
	Group 2 without Myosuit			Group 2 with Myosuit		
	pre	intervention	post	pre	intervention	post
SBP in mmHg	107.3 (±16.9)	108.2 (±15.6)	106.4 (±8.0)	106.0 (±9.9)	109.3 (±9.2)	104.9 (±11.3)
DBP in mmHg	69.9 (±11.9)	68.2 (±12.1)	66.4 (±10.1)	69.9 (±11.2)	69.0 (±7.5)	68.0 (±12.2)
HR in min^{-1}	75.1 (±13.1)	90.2 (±31.0)	83.0 (±27.1)	79.4 (±19.4)	89.6 (±21.5)	96.2 (±31.4)
RR in min^{-1}	17.8 (±2.7)	24.4 (±4.0)	24.8 (±3.1)	19.7 (±2.6)	21.7 (±2.7)	23.1 (±4.4)
SpO_2 in %	97.9 (±1.5)	97.8 (±1.9)	97.2 (±2.3)	98.0 (±1.4)	97.7 (±1.5)	97.8 (±1.4)

DBP, diastolic blood pressure; HR, heart rate; RR, respiratory rate; SBP, systolic blood pressure; SpO_2, peripheral oxygen saturation.

None of the participants terminated the mobilization protocols early, which we interpreted as an additional evidence for the safety and acceptability of the Myosuit. However, the walked distances did not increase when comparing intraindividual assisted and non-assisted walks. This might be due to a lack of adaption or familiarization to the device. Haufe *et al*. even described an initial decrease in walking speed and distance in the first session of gait training with the Myosuit in patients with motor disorders. However, in the following sessions an increase of speed and distance was reported for most patients.[18]

Robotic-assisted training represents a new, innovative approach in the treatment of heart failure related deconditioning. Previously, the Lokomat® system was tested for gait

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Figure 4 RPE and RPD in G1 performing the 6MWT and ADL (A) and G2 performing a REU (B). Data are presented as mean and SD.

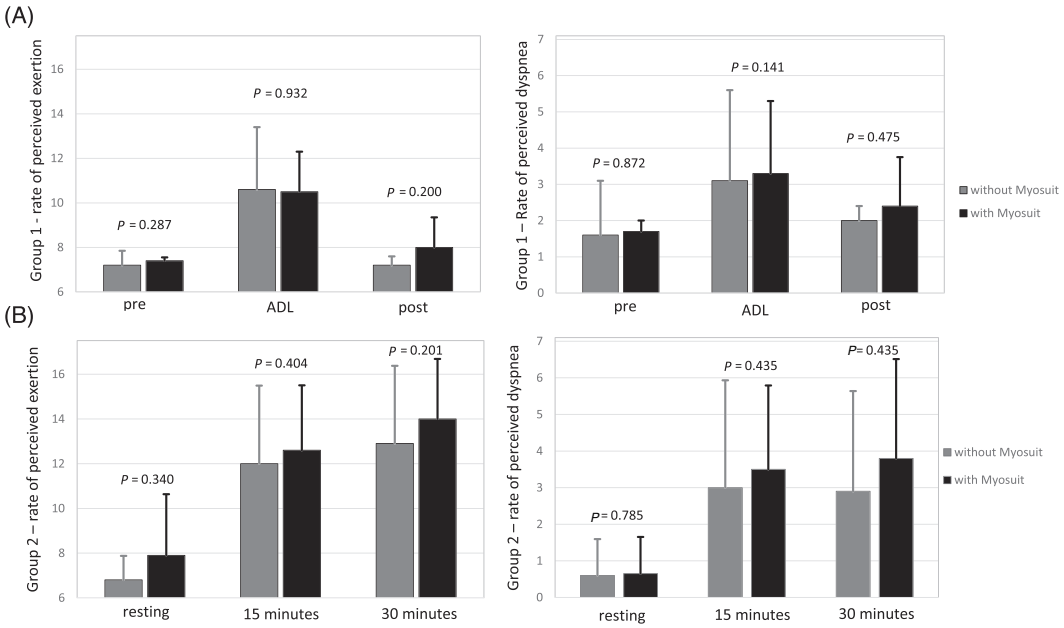

Table 3 Acceptability questionnaire

	Strongly disagree	Moderately disagree	Slightly disagree	Neutral	Slightly agree	Moderately agree	Strongly agree	Median rating
I felt safe using the MS	0	3	0	1	3	8	5	Moderately agree
The MS provided stability	1	1	1	4	4	2	7	Slightly agree
I found the MS comfortable	2	1	0	5	4	6	2	Slightly agree
The weight of the MS did not bother me	0	3	2	2	6	3	4	Slightly agree
Mobilization with the MS was easy for me	1	0	1	3	3	8	4	Moderately agree
The MS made climbing up stairs easier for me[a]	0	2	1	0	0	3	2	Moderately agree
The MS was easy to control	1	1	0	2	1	10	5	Moderately agree
I enjoyed my experience with the MS	1	0	0	0	3	5	11	Strongly agree
I would like to exercise with the MS regularly	2	0	0	1	3	4	10	Moderately to strongly agree

MS, myosuit.
[a]Only applicable in G1; one patient was unable to climb stairs.

training in a pilot trial including five participants with advanced heart failure. In line with our results using the Myosuit, the Lokomat® training was safe. Furthermore, it was associated with a trend towards an increase in exercise capacity, muscle strength, quality of life as well as a decrease in cardiac and inflammatory biomarkers.[11] Compared with the Myosuit, the Lokomat® system requires more adjustments and is locally bound due to its immobilizing size; whereas the Myosuit allows exercise training at various localizations and during daily-life activities. Group training is possible and would allow patients to benefit from group dynamic effects in a cost-effective way.[19] By the choice of mode (dynamic or static) a great variety of exercises is supported by the Myosuit.

An advanced decrease of skeletal muscle mass and tone causes a functional instability of joints. The Myosuit might be used for self-training at home or, as indicated by one of our participants, as an 'ADL assistive device' in everyday life, providing safety and stability, for example, 'during standing while preparing meals'. This application mode may have

the potential to improve the quality of life of heart failure patients.

Heart failure therapy currently addresses two main pathophysiological concepts: (i) an increase of oxygen supply (by improving cardiac function) and (ii) an increase of oxygen uptake (by exercise training). Robotic-assistance might complement the conventional concepts by addressing a third approach—the reduction of muscular oxygen requirement, allowing a longer duration and higher intensity of aerobic exercise training that would potentially facilitate cardiopulmonary reconditioning. This hypothesis needs to be verified in further research.

In conclusion, the results of our single centre pilot study strongly indicate that Myosuit-assisted mobilization is safe, feasible and well-accepted by patients with advanced heart failure. Based on these promising findings, we are currently initiating a randomized, controlled, clinical trial to investigate specific training effects in an eight-week Myosuit-assisted exercise programme.

Limitations

The study was performed in a single centre including a limited number of patients; only 20% of participants were female. Despite the break between robotic supported and non-supported mobilization, patients might have been more exhausted or less motivated performing the second part of the study on the same day. Due to the single-session design, the study was not aiming to analyse an advantage or disadvantage of the robotic support.

Conflict of interest

V.F. has relevant (institutional) financial activities outside the submitted work with following commercial entities: Medtronic GmbH, Biotronik SE & Co., Abbott GmbH & Co. KG, Boston Scientific, Abiomed, Edwards Lifesciences, Berlin Heart, Novartis Pharma GmbH, JOTEC/CryoLife GmbH, Zurich Heart. N.C. reports consulting fees from Abbott Cardiovascular, DiNAQOR. F.E. reports grants from German Research Foundation (DFG), grants from German Ministry of Education and Research, during the conduct of the study; personal fees and non-financial support from Novartis, grants and personal fees from Boehringer Ingelheim, personal fees from CVRx, Pfizer, Medtronic, grants and personal fees from Servier, personal fees from MSD/Bayer, personal fees from Bayer, personal fees from Resmed, personal fees from Berlin Chemie, grants from Thermo Fischer, personal fees from Vifor Pharma, personal fees from PharmaCosmos, personal fees from Merck, outside the submitted work. R.R. holds a shared patent together with MyoSwiss staff (soft wearable muscle assisting device), is member of the scientific advisory board of MyoSwiss AG and owes a small amount of MyoSwiss AG stocks. F.S. reports institutional grants from Novartis, Abbott, non-financial support from Medtronic, institutional fees (speaker honoraria) from Orion Pharma and Astra Zeneca outside the submitted work. The other authors declare that there is no conflict of interests.

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Supporting information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Table S1 Inclusion and exclusion criteria.

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