ELSEVIER

The Journal of Heart and Lung Transplantation

http://www.jhltonline.org

ORIGINAL CLINICAL SCIENCE

It's not only the pump: Assessment of human factors of wearable components and user experience of patients with left ventricular assist devices

Thomas Schlöglhofer, MSc,[a,b,c] Anna-Sophie Grausenburger, MD,[a] Gregor Widhalm, BSc,[a] Lisa Haberl,[a] Wolfgang Suda,[a] Harald Schwingenschlögl,[a] Julia Riebandt, MD, PhD,[a] Günther Laufer, MD,[a] Dominik Wiedemann, MD,[a] Francesco Moscato, PhD,[b,c,d] Daniel Zimpfer, MD, MBA,[a] and Heinrich Schima, PhD[a,b,c]

From the [a]Department of Cardiac Surgery, Medical University of Vienna, Vienna, Austria; [b]Ludwig Boltzmann Institute for Cardiovascular Research, Vienna, Austria; [c]Center for Medical Physics and Biomedical Engineering, Medical University of Vienna, Vienna, Austria; and the [d]Austrian Cluster for Tissue Regeneration, Vienna, Austria.

KEYWORDS:
left ventricular assist device;
mechanical circulatory support;
human factors engineering;
human factors;
usability;
design;
wearables

BACKGROUND: Despite design improvements in left ventricular assist devices (LVADs) over the past decade, limitations of external, wearable VAD components affect patient quality of life and safety. The aim of this study was to describe both user experience and human factor issues of 2 contemporary LVADs.

METHODS: This single-center, cross-sectional study included LVAD outpatients who were at least 3 months after implantation. Before developing the 16-item survey, a systematic literature review and 2-round Delphi method involving 9 VAD clinicians were used to select items in 6 domains: power supply, emergency situations, wearability, mobility, and freedom to travel, user modifications, lifestyle, and home adaptations.

RESULTS: Fifty-eight patients (61.6 ± 11.6 years, 13.8% female, HeartMate 3 (HM3)/HVAD: n = 39/19) completed the one-time survey after median of 853 days on device: 10.3% reported problems changing power supply, 12.7% unintentional driveline disconnection (HM3: 5.6% vs HVAD: 26.3%, $p = 0.041$). Against the recommendation 74.1% sleep with battery-support (HM3: 88.9% vs HVAD: 44.4%, $p = 0.001$). About 65.3% criticized the carry bag weight/size (HM3: 71.4% vs HVAD: 50.0%, $p = 0.035$), thus 24.1% wear an own carrying-system, 42.1% modified their wearables, 38.9% their clothing, and 65.3% their home to cope with life on LVAD support. Mobility is reduced due to limited wearability: 18.9% went abroad (only 3.7% by plane) and 40.0% use less public transport than before implantation (the older the less: $r = -0.37$, $p = 0.013$).

CONCLUSIONS: HVAD and HM3 wearables still show a variety of human factors issues and potential for improved user experience. User-centered design and incorporation of patient feedback may increase user satisfaction, and patient safety.

J Heart Lung Transplant 000;000:1−12

Reprint requests: Thomas Schlöglhofer, MSc, Department of Cardiac Surgery, Center for Medical Physics and Biomedical Engineering, Medical University of Vienna, Waehringer Guertel 18-20, 1090 Vienna, Austria.

Telephone: +43-1-40400-27280. Fax: +43-1-40400-39880.
E-mail address: thomas.schloeglhofer@meduniwien.ac.at

https://doi.org/10.1016/j.healun.2022.12.015

Left ventricular assist device (LVAD) therapy has emerged as a treatment option for end-stage heart failure, either as a bridge to transplantation or as a destination therapy.[1,2] Despite an older and sicker population,[1] mechanical circulatory support (MCS) has continued to improve patient survival rates and quality of life due to improvements in pump design[3] and implantation technique.[4]

In addition to the implantable components, external wearable components (LVAD peripherals) are connected to the blood pump via the percutaneous driveline to provide power supply and monitor the operation of the LVAD.[5] Following hospital discharge, the extracorporeal LVAD components are operated by patients and caregivers, resulting in a change in daily routine and a limitation of their activities.[6,7] Since LVADs are critical life support systems, devices should be self-explanatory, and usability optimization is necessary to improve safety as well as user experience.[8] Therefore, human factors engineering (HFE) is an integral part of the development process to reduce application errors, and increase user satisfaction. Human factors describe the interaction between the patient, the environment and the device, while the device-user interface is the only means of communication between the device and the patient.[9] Of particular interest are handling errors that can lead either to a hazardous situation due to inappropriate device response, incorrect user action, or to a lack of action when errors occur because of perceptual or cognitive misinterpretations of users.[10]

However, in MCS research, primarily adverse events and clinical outcomes of LVADs are studied, whereas less attention is paid to human factors and so-called nonpump malfunctions of LVAD wearables. As several studies showed,[8,11,12] connectors, visual displays, alarms, and carry systems are of particular importance to LVAD design and thus have enormous potential for improved, human-centered design.[5]

Therefore, the aim of this study was to describe both user experience and human factors, and to compare the HeartMate 3 LVAD (Abbott, Chicago, IL) HeartMate 3 (HM3) and HeartWare HVAD (Medtronic, Dublin, Ireland) wearables to assess user modifications, lifestyle and home adaptations by patients to understand the limitations of LVAD peripherals and identify necessary improvements to future products.

Methods

Study design

This single-center, cross-sectional study of LVAD outpatients at least 3 months after LVAD implantation and successful equipment training, was conducted from July to October 2020. Before developing the 16-item survey (multiple-choice and 4-point Likert scale), a systematic literature review and 2-round Delphi method involving 9 VAD clinicians were used to generate and select items. The study protocol was approved by the Institutional Review Board (identification number: EK1667/2020) and is in compliance with the ISHLT Ethics Statement, and all participants provided written informed consent.

Systematic literature review

A systematic literature review (Figure 1) was conducted by 2 independent reviewers using the PubMed database and a combination of the search term "heart-assist devices" with the keywords "human factors," "usability," "user experience," "daily," "lifestyle," "daily experience," and "quality of life" in June 2020. Inclusion criteria were peer reviewed full text journal articles, including at least one user (patient) experience issue with LVAD wearables and were written in English language. Exclusion criteria were non−LVAD-related literature, and pediatric patients.

Expert interviews

A 2-round Delphi method was used to create and select questionnaire items, involving 9 clinicians with experience in MCS and VAD coordination. The Delphi method[13] is a systematic, multistage method for obtaining expert opinion through a series of iterative interviews with the aim of achieving group consensus. In the first Delphi survey, the levels of importance, and clarity of items in the questionnaire were evaluated. The identified topics were ranked, and questions for the second Delphi round were derived from the first-round responses, if more than 70% of the VAD experts agreed to retain, delete, or add a topic in the second survey.

The second Delphi survey aimed to reach consensus on the final selection of questions. If the content validity ratio was equal or greater than the critical value of 0.78 (for N = 9 expert panelists)[14] the question was included. The readability of the original (German language) survey was evaluated with the readability index (LIX).[15]

Study population

Following the systematic literature review and expert interviews, the clinical records of 89 outpatients who received an LVAD between January 2011 and April 2020, and were on support at the time of the study, were reviewed to determine whether they were eligible. Patients aged <18 and >80 years, with primary devices other than LVAD (isolated right ventricular assist devices, biventricular assist devices, total artificial hearts), devices other than HM3 or HVAD, <3 months of LVAD support, patients who had not successfully completed their device training, and patients with language barriers were excluded.

Statistical analysis

Statistical analyses were performed with SPSS for Windows Release 26.0.0 (IBM, New York, NY). Descriptive statistics are presented as mean ± standard deviation (SD) for normally

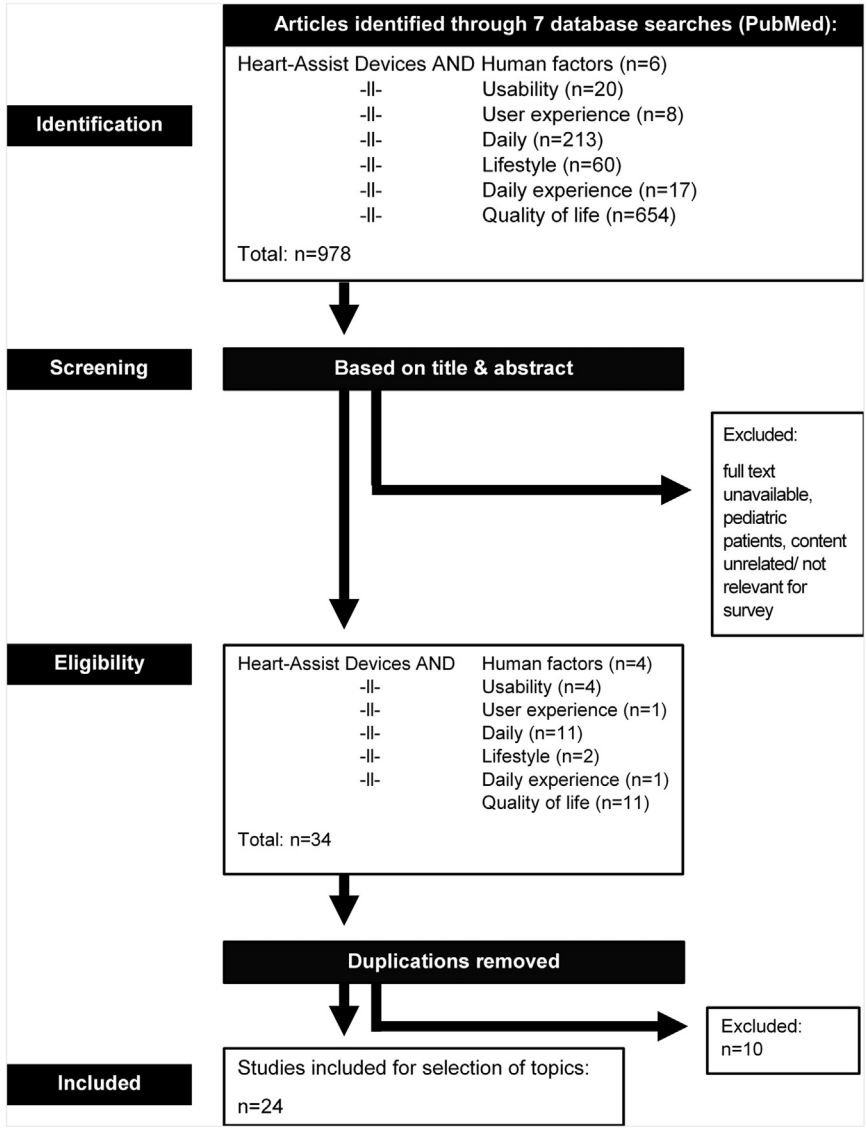

Figure 1 Framework for the systematic literature review.

distributed continuous variables and number (percentage) for categorical variables. For non-normally distributed continuous variables, data are presented as median and interquartile range. Normal distribution was determined using the Shapiro-Wilk test. Baseline characteristics and survey results were compared by device type (HM3 vs HVAD) and gender using the fisher's exact test for categorical variables and, depending on the normal distribution, Student *t*-test or Mann-Whitney U test for independent continuous variables. Pearson and Spearman correlations were applied to examine the relationship between user experience and age, days on LVAD support, highest completed education, and history of stroke. Statistical significance was set at $p < 0.05$.

Results

Systematic literature review

The initial literature search revealed 978 studies. All studies with potentially relevant content and which did not meet any exclusion criteria were included into further analysis, resulting in a total of 24 studies (Supplementary File 1).

Expert interviews

Based on the topics identified in the systematic literature review, a preliminary 20-item version of the HFE-survey was created. In the first Delphi round, 16 items were judged as relevant, taking out 4 items due to inaccurate wording and redundancy. The final 16-item version (Supplementary File 2) achieved consensus by all VAD experts (content validity index[14] = 0.9, Supplementary File 3) and included 6 domains: power supply, emergency or challenging situations, wearability, mobility, and freedom to travel, user modifications, lifestyle, and home adaptations.

Patient characteristics

Of 89 long-term MCS patients, 10 patients were excluded because of devices other than LVAD, HM3, or HVAD (n = 10). Language barriers (n = 5), <3 months on support (n = 5), or no regular outpatient follow-up (n = 11) during the study period resulted in further 31 excluded patients.

Table 1 Baseline Demographics, Comorbidities, and Socio-Economic Status for the Overall Study Population, Additionally Stratified by Device Type

n (%) or mean ± SD	Total cohort (n = 58)	HeartMate 3 (n = 39)	HVAD (n = 19)	*p*-value[a]
Patient characteristics				
Sex (female)	8 (13.8%)	2 (5.1%)	6 (31.6%)	0.01
Age at implant (years)	61.6 ± 11.6	60.6 ± 9.9	55.3 ± 12.9	0.10
BMI (kg/m^2)	28.9 ± 4.2	28.7 ± 4.0	29.4 ± 4.7	0.50
INTERMACS level				0.30
1	16 (27.6%)	9 (23.1%)	7 (36.8%)	
2	11 (19.0%)	6 (15.4%)	5 (26.3%)	
3	17 (29.3%)	13 (33.3%)	4 (21.1%)	
4-7	14 (24.1%)	11 (28.2%)	3 (15.8%)	
Cardiomyopathy				0.50
Ischemic	33 (56.9%)	24 (61.5%)	9 (47.4%)	
Dilated	22 (37.9%)	13 (33.3%)	9 (47.4%)	
Other	5 (8.6%)	3 (7.7%)	2 (10.5%)	
Strategy				0.70
Destination therapy	21 (36.2%)	15 (38.4%)	6 (31.6%)	
Bridge to transplantation	10 (17.2%)	7 (17.9%)	3 (15.8%)	
Bridge to candidacy	27 (46.6%)	17 (43.6%)	10 (52.6%)	
Stroke history	4 (6.9%)	4 (10.3%)	0 (0.0%)	0.30
Tobacco use (prior LVAD)	42 (72.4%)	28 (71.8%)	14 (73.7%)	1.00
Socio-economic status				
Highest completed education				0.70
Compulsory school	6 (10.3%)	4 (10.3%)	2 (10.5%)	
Secondary school	44 (75.9%)	28 (71.8%)	16 (84.2%)	
A-levels	4 (6.9%)	3 (7.7%)	1 (5.3%)	
University degree	4 (6.9%)	4 (10.3%)	0 (0.0%)	
Living situation				0.20
Alone	13 (22.4%)	9 (23.1%)	4 (21.1%)	
In partnership	39 (67.2%)	28 (71.8%)	11 (57.9%)	
Share accommodation	6 (10.3%)	2 (5.1%)	4 (21.1%)	
Caregiver support	18 (31.0%)	14 (35.9%)	4 (21.1%)	0.40

Abbreviations: BMI, body mass index; INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support; LVAD, left ventricular assist device.

[a]*p*-value comparing HeartMate 3 vs HVAD cohort.

The study cohort (100% response rate) consisted of 58 patients (age: 61.6 ± 11.6 years, body mass index: 28.9 ± 4.2 kg/m^2, female: 13.8%, HM3/HVAD: 67.2%/32.8%) who completed the one-time survey after a median of 853 (997) days on support between July and October 2020. Baseline demographics and comorbidities for the overall study population and stratified by device type are shown in Table 1, and by gender in Supplementary File 4.

Survey

The survey results of the overall population and stratified by device type (HM3 vs HVAD) are summarized in Table 2. Twenty-three patients (39.7%) answered all questions, and 17 (29.3%) omitted one or 2 questions, resulting in a mean of 13.8% missing responses per question. The LIX[15] of 44.5 indicated low reading complexity of the survey.

In the domain power supply, 11.8% of patients reported problems changing power supply (HM3: 12.1% vs HVAD: 11.1%, $p = 0.90$). As possible reasons, 10.3% mentioned their dexterity, 11.4% the visibility of markings indicating the correct connection point of the power source. Contrary to the manufacturers' recommendation, 74.1% of all participants sleep with battery power supply (HM3: 88.9% vs HVAD: 44.4%, $p = 0.001$), and of these, 77.1% HM3 and 41.2% HVAD users every night ($p = 0.004$).

Overall, 13.7% of the patients felt unprepared for possible technical emergency situations (e.g., controller exchange), consequently 84.6% stated that equipment retraining is not necessary. In total, 12.7% unintentionally disconnected the driveline at least once, with significant differences between the 2 devices (HM3: 5.6% vs HVAD: 26.3%, $p = 0.041$).

The carry bag was the most frequently defective wearable in both systems (HM3: 82.1% vs HVAD: 84.6%), followed by batteries (HM3: 21.4% vs HVAD: 61.5%) and the driveline (HM3: 21.4% vs HVAD: 30.8%), without significant differences between the devices ($p = 0.06$).

Weight and size of the carry bag was criticized by 65.3% (HM3: 71.4% vs HVAD: 50.0%, $p = 0.035$), thus 24.1% wear an own carrying system, 38.9% adapted their clothing and 42.1% modified parts of their wearables. Additionally, 56.4% adjusted their home to cope with daily life on LVAD

Table 2 Survey Results of the Overall Population and Stratified by Device Type

n (%), median (IQR) or mean ± SD	Total cohort (n = 58)		HeartMate 3 (n = 39)		HVAD (n = 19)		*p*-value[c]
1. Power supply							
I have problems changing the power supply	n = 51		n = 33		n = 18		0.90
never	45	(88.2%)	29	(87.8%)	16	(88.9%)	
rarely (≤3x/month)	4	(7.8%)	2	(6.0%)	2	(11.1%)	
sometimes (1x/week)	1	(2.0%)	1	(3.0%)	0	(0.0%)	
often (several times a week)	0	(0.0%)	0	(0.0%)	0	(0.0%)	
always (daily)	1	(2.0%)	1	(3.0%)	0	(0.0%)	
My dexterity makes changing power supply difficult[b]	n = 29		n = 18		n = 11		0.20
I completely agree	0	(0.0%)	0	(0.0%)	0	(0.0%)	
I rather agree	3	(10.3%)	3	(16.7%)	0	(0.0%)	
I rather disagree	4	(13.8%)	3	(16.7%)	1	(9.1%)	
I completely disagree	22	(75.9%)	12	(66.7%)	10	(90.9%)	
The right sequence of steps can cause problems[b] (when changing power supply)	n = 33		n = 19		n = 14		0.20
I completely agree	0	(0.0%)	0	(0.0%)	0	(0.0%)	
I rather agree	0	(0.0%)	0	(0.0%)	0	(0.0%)	
I rather disagree	6	(18.2%)	2	(10.5%)	4	(28.6%)	
I completely disagree	27	(81.8%)	17	(89.5%)	10	(71.4%)	
Sometimes I disconnect the wrong (fully charged) battery[b] (when changing power supply)	n = 32		n = 18		n = 14		0.70
I completely agree	0	(0.0%)	0	(0.0%)	0	(0.0%)	
I rather agree	0	(0.0%)	0	(0.0%)	0	(0.0%)	
I rather disagree	6	(18.8%)	3	(16.7%)	3	(21.4%)	
I completely disagree	26	(81.3%)	15	(83.3%)	11	(78.6%)	
When I'm tired, it is more likely that errors occur[b] (when changing power supply)	n = 35		n = 21		n = 14		0.90
I completely agree	1	(2.9%)	1	(4.8%)	0	(0.0%)	
I rather agree	1	(2.9%)	1	(4.8%)	0	(0.0%)	
I rather disagree	7	(20.0%)	3	(14.3%)	4	(28.6%)	
I completely disagree	26	(74.3%)	16	(76.2%)	10	(71.4%)	
The markers which indicate the connectors are not good to see[b] (when changing power supply)	n = 35		n = 21		n = 14		0.40
I completely agree	2	(5.7%)	1	(4.8%)	1	(7.1%)	
I rather agree	2	(5.7%)	1	(4.8%)	1	(7.1%)	
I rather disagree	7	(20.0%)	6	(28.6%)	1	(7.1%)	
I completely disagree	24	(68.6%)	13	(61.9%)	11	(78.6%)	
I use batteries as a power source during sleep	n = 54		n = 36		n = 18		0.001
Yes	40	(74.1%)	32	(88.9%)	8	(44.4%)	
No	14	(25.9%)	4	(11.1%)	10	(55.6%)	
How often patients use batteries during sleep		n = 52		n = 35		n = 17	0.004
Never	11	(21.2%)	3	(8.6%)	8	(47.1%)	
Up to 3x/month	4	(7.7%)	3	(8.6%)	1	(5.9%)	
1-3x/week	1	(1.9%)	1	(2.9%)	0	(0.0%)	
3-6x/week	2	(3.8%)	1	(2.9%)	1	(5.9%)	
Every night	34	(65.4%)	27	(77.1%)	7	(41.2%)	
2. Emergency or challenging situations							
I do not feel prepared for possible technical emergency situations[b]	n = 51		n = 34		n = 17		0.60
I completely agree	7	(13.7%)	5	(14.7%)	2	(11.8%)	
I rather agree	10	(19.6%)	9	(26.5%)	1	(5.9%)	
I rather disagree	12	(23.5%)	5	(14.7%)	7	(41.2%)	
I completely disagree	22	(43.1%)	15	(44.1%)	7	(41.2%)	

(*continued on next page*)

Table 2 (*Continued*)

n (%), median (IQR) or mean ± SD	Total cohort (n = 58)		HeartMate 3 (n = 39)		HVAD (n = 19)		*p*-value[c]
Reasons for not feeling prepared[a]	n = 23		n = 14		n = 9		0.10
Too much time elapsed since initial training	12	(52.2%)	10	(71.4%)	2	(22.2%)	
Meaning of alarms unclear	1	(4.3%)	0	(0.0%)	1	(11.1%)	
The situation itself is stressful	18	(78.3%)	11	(78.6%)	7	(77.8%)	
Others	2	(8.7%)	1	(7.1%)	1	(11.1%)	
I would like equipment retraining to feel more secure during emergency situations[b]	n = 52		n = 36		n = 16		0.70
I completely agree	2	(3.8%)	1	(2.8%)	1	(6.3%)	
I rather agree	6	(11.5%)	6	(16.7%)	0	(0.0%)	
I rather disagree	8	(15.4%)	3	(8.3%)	5	(31.3%)	
I completely disagree	36	(69.2%)	26	(72.2%)	10	(62.5%)	
If retraining is desired, when to retrain?	n = 14		n = 10		n = 4		0.12
6 months	3	(21.4%)	3	(30.0%)	0	(0.0%)	
12 months	6	(42.9%)	5	(50.0%)	1	(25.0%)	
24 months	5	(35.7%)	2	(20.0%)	3	(75.0%)	
Number of unintentional driveline disconnections	n = 55		n = 36		n = 19		0.04
0	48	(87.3%)	34	(94.4%)	14	(73.7%)	
1	5	(9.1%)	1	(2.8%)	4	(21.1%)	
3	1	(1.8%)	0	(0.0%)	1	(5.3%)	
4	1	(1.8%)	1	(2.8%)	0	(0.0%)	
Patients who unintentionally disconnected the driveline	n = 55		n =36		n = 19		0.04
Yes	7	(12.7%)	2	(5.6%)	5	(26.3%)	
No	48	(87.3%)	34	(94.4%)	14	(73.7%)	
3. Wearability							
Most frequent defective peripheral component[a]	n = 41		n = 28		n = 13		0.06
Driveline	10	(24.4%)	6	(21.4%)	4	(30.8%)	
Battery	14	(34.1%)	6	(21.4%)	8	(61.5%)	
Battery cable	3	(7.3%)	2	(7.1%)	1	(7.7%)	
Battery charger	1	(2.4%)	0	(0.0%)	1	(7.7%)	
Power supply to AC	1	(2.4%)	1	(3.6%)	0	(0.0%)	
Carry bag	34	(82.9%)	23	(82.1%)	11	(84.6%)	
Controller	5	(12.2%)	2	(7.1%)	3	(23.1%)	
Monitor	2	(4.9%)	0	(0.0%)	2	(15.4%)	
Others	2	(4.9%)	1	(3.6%)	1	(7.7%)	
Obstructive peripheral components[a]	n = 49		n = 33		n = 16		0.90
Driveline	18	(36.7%)	11	(33.3%)	7	(43.8%)	
Power supply to AC	1	(2.0%)	1	(3.0%)	0	(0.0%)	
Bag	38	(77.6%)	26	(78.8%)	12	(75.0%)	
Controller	5	(10.2%)	4	(12.2%)	1	(6.3%)	
Battery	13	(26.5%)	10	(30.3%)	3	(18.8%)	
Monitor	3	(6.1%)	2	(6.1%)	1	(6.3%)	
Others	2	(4.1%)	1	(3.0%)	1	(6.3%)	
Challenging situations in daily life as LVAD patient (because of the peripherals)[a]	n = 55		n = 37		n = 18		0.40
None	9	(16.4%)	6	(16.2%)	3	(16.7%)	
Going to the toilet	6	(10.9%)	3	(8.1%)	3	(16.7%)	
Housekeeping	8	(14.5%)	4	(10.8%)	4	(22.2%)	
Activity/Movement	35	(63.6%)	25	(67.6%)	10	(55.6%)	
Sleeping	15	(27.3%)	13	(35.1%)	2	(11.1%)	
Personal hygiene	28	(50.9%)	20	(54.1%)	8	(44.4%)	
Leaving home	4	(7.3%)	3	(8.1%)	1	(5.6%)	
It is difficult to keep the carry bag tidy[b]	n = 54		n = 35		n = 19		0.80
I completely agree	4	(7.4%)	3	(8.6%)	1	(5.3%)	
I rather agree	10	(18.5%)	8	(22.9%)	2	(10.5%)	
I rather disagree	12	(22.2%)	4	(11.4%)	8	(42.1%)	
I completely disagree	28	(51.9%)	20	(57.1%)	8	(42.1%)	

(*continued on next page*)

Table 2 (*Continued*)

n (%), median (IQR) or mean ± SD	Total cohort (n = 58)		HeartMate 3 (n = 39)		HVAD (n = 19)		*p*-value[c]
A second carry bag would be helpful[b]	n = 52		n = 34		n = 18		0.50
I completely agree	32	(61.5%)	22	(64.7%)	10	(55.6%)	
I rather agree	8	(15.4%)	5	(14.7%)	3	(16.7%)	
I rather disagree	4	(7.7%)	2	(5.9%)	2	(11.1%)	
I completely disagree	8	(15.4%)	5	(14.7%)	3	(16.7%)	
Desired improvements for the carry bag[a]	n = 49		n = 35		n = 14		0.04
Weight + size	32	(65.3%)	25	(71.4%)	7	(50.0%)	
Wearing comfort	27	(55.1%)	22	(62.9%)	5	(35.7%)	
Additional pockets	11	(22.4%)	10	(28.6%)	1	(7.1%)	
Material	10	(20.4%)	5	(14.3%)	5	(35.7%)	
4. Mobility and freedom to travel							
Patients still driving themselves	n = 57		n = 39		n = 18		0.02
Yes	38	(66.7%)	22	(56.4%)	16	(88.9%)	
No	19	(33.3%)	17	(43.6%)	2	(11.1%)	
Reasons for not driving themselves	n = 18		n = 15		n = 3		0.70
No driving license	5	(27.8%)	5	(33.3%)	0	(0.0%)	
No desire	4	(22.2%)	3	(20.0%)	1	(33.3%)	
Age	2	(11.1%)	2	(13.3%)	0	(0.0%)	
Safety concerns	5	(27.8%)	4	(26.7%)	1	(33.3%)	
Fear of alarms	6	(33.3%)	4	(26.7%)	2	(66.7%)	
Medical reasons	1	(5.6%)	1	(6.7%)	0	(0.0%)	
I use public transportation as often as before the LVAD implantation[b]	n = 45		n = 31		n = 14		0.10
I completely agree	17	(37.8%)	14	(45.2%)	3	(21.4%)	
I rather agree	10	(22.2%)	7	(22.6%)	3	(21.4%)	
I rather disagree	4	(8.9%)	2	(6.5%)	2	(14.3%)	
I completely disagree	14	(31.1%)	8	(25.8%)	6	(42.9%)	
Problems with public transportation as an LVAD patient[a]	n = 38		n = 26		n = 12		0.046
Equipment impractical	8	(21.1%)	4	(15.4%)	4	(33.3%)	
Looks from other passengers	2	(5.3%)	0	(0.0%)	2	(16.7%)	
Risk of driveline getting stuck	14	(36.8%)	9	(34.6%)	5	(41.7%)	
Fear of theft of carry bag	2	(5.3%)	0	(0.0%)	2	(16.7%)	
None	21	(55.3%)	16	(61.5%)	5	(41.7%)	
My travel habits are the same as before the LVAD implantation[b]	n = 49		n = 34		n = 15		0.80
I completely agree	16	(32.7%)	12	(35.3%)	4	(26.7%)	
I rather agree	6	(12.2%)	4	(11.8%)	2	(13.3%)	
I rather disagree	10	(20.4%)	7	(20.6%)	3	(20.0%)	
I completely disagree	17	(34.7%)	11	(32.3%)	6	(40.0%)	
I have already traveled as an LVAD patient	n = 53		n = 36		n = 17		1.00
Yes	10	(18.9%)	7	(19.4%)	3	(17.6%)	
No	43	(81.1%)	29	(80.6%)	14	(82.4%)	
I have already traveled by plane as an LVAD patient	n = 54		n = 37		n = 17		1.00
Yes	2	(3.7%)	2	(5.4%)	0	(0.0%)	
No	52	(96.3%)	35	(94.6%)	17	(100%)	
Problems when travelling as an LVAD patient[a]	n = 38		n = 26		n = 12		0.70
Flights	18	(47.4%)	11	(42.3%)	7	(58.3%)	
Insecurity	25	(65.8%)	16	(61.5%)	9	(75.0%)	
Battery life	6	(15.8%)	3	(11.5%)	3	(25.0%)	
Forgetting things	18	(47.4%)	11	(42.3%)	7	(58.3%)	
Organizational effort	19	(50.0%)	13	(50.0%)	6	(50.0%)	
None	5	(13.2%)	3	(11.5%)	2	(16.7%)	
5. User modifications							
Patients modified their equipment/peripherals	n = 57		n = 38		n = 19		0.40
Yes	24	(42.1%)	18	(47.4%)	6	(31.6%)	
No	33	(57.9%)	20	(52.6%)	13	(68.4%)	

(*continued on next page*)

Table 2 (*Continued*)

n (%), median (IQR) or mean ± SD	Total cohort (n = 58)		HeartMate 3 (n = 39)		HVAD (n = 19)		*p*-value[c]
Types of user modifications[a]	n = 23		n = 18		n = 5		0.50
Use own carrying system	14	(60.9%)	12	(66.7%)	2	(40.0%)	
Adaptation to official transp. system	5	(21.7%)	4	(22.2%)	1	(20.0%)	
Repairs	4	(17.4%)	2	(11.1%)	2	(40.0%)	
Fixating peripherals	3	(13.0%)	3	(16.7%)	0	(0.0%)	
Labelling	4	(17.4%)	3	(16.7%)	1	(20.0%)	
These modifications made my life easier[b]	n = 17		n = 13		n = 4		1.00
I completely agree	8	(47.1%)	6	(46.2%)	2	(50.0%)	
I rather agree	4	(23.5%)	3	(23.1%)	1	(25.0%)	
I rather disagree	3	(17.6%)	3	(23.1%)	0	(0.0%)	
I completely disagree	2	(11.8%)	1	(7.7%)	1	(25.0%)	
6. Lifestyle and home adaptations							
Patients had to adapt their home	n = 55		n = 37		n = 18		1.00
Yes	31	(56.4%)	21	(56.8%)	10	(55.6%)	
No	24	(43.6%)	16	(43.2%)	8	(44.4%)	
Examples for home adaptations[a]	n = 29		n = 20		n = 9		0.30
Moving furniture in the bedroom	9	(31.0%)	6	(30.0%)	3	(33.3%)	
Relocating power plugs	5	(17.2%)	3	(15.0%)	2	(22.3%)	
Adapting shower	22	(75.9%)	17	(85.0%)	5	(55.6%)	
Adapting bed	9	(31.0%)	8	(40.0%)	1	(11.1%)	
Buying emergency generator	2	(6.9%)	2	(10.0%)	0	(0.0%)	
Adaptations for walking frames	2	(6.9%)	1	(5.0%)	1	(11.1%)	
I had to change/adapt my clothing[b]	n = 54		n = 36		n = 18		0.70
I completely agree	8	(14.8%)	5	(13.9%)	3	(16.7%)	
I rather agree	13	(24.1%)	9	(25.0%)	4	(22.2%)	
I rather disagree	6	(11.1%)	3	(8.3%)	3	(16.7%)	
I completely disagree	27	(50.0%)	19	(52.8%)	8	(44.4%)	
Examples for adaptations of clothing[a]	n = 9		n = 7		n = 2		0.90
Sewing in a slit	3	(33.3%)	2	(28.6%)	1	(50.0%)	
Additional pocket	1	(11.1%)	1	(14.3%)	0	(0.0%)	
Use own vest	5	(55.6%)	4	(57.1%)	1	(50.0%)	
Others	1	(11.1%)	1	(14.3%)	0	(0.0%)	
Patients who are employed	n = 57		n = 38		n = 19		0.30
Yes	5	(8.8%)	2	(5.3%)	3	(15.8%)	
No	52	(91.2%)	36	(94.7%)	16	(84.2%)	
Reasons for unemployment	n = 50		n = 35		n = 15		0.70
Retirement	18	(36.0%)	12	(34.3%)	6	(40.0%)	
Early retirement	30	(60.0%)	22	(62.9%)	8	(53.5%)	
Other reasons	2	(4.0%)	1	(2.9%)	1	(6.7%)	
Reasons for early retirement[a]	n = 29		n = 15		n = 8		0.30
Heart disease	21	(91.3%)	13	(86.7%)	8	(100%)	
Handling of LVAD at work	7	(30.4%)	6	(40.0%)	1	(12.5%)	
Others	1	(4.3%)	1	(6.7%)	0	(0.0%)	
Working is more difficult with an LVAD[b]		n = 28	n = 19			n = 9	0.05
I completely agree	14	(50.0%)	12	(63.2%)	2	(22.2%)	
I rather agree	11	(39.3%)	6	(31.6%)	5	(55.6%)	
I rather disagree	2	(7.1%)	1	(5.3%)	1	(11.1%)	
I completely disagree	1	(3.6%)	0	(0.0%)	1	(11.1%)	
I have safety concerns (at work)[b]	n = 23		n = 16		n = 7		0.10
I completely agree	5	(21.7%)	4	(25.0%)	1	(14.3%)	
I rather agree	9	(39.1%)	8	(50.0%)	1	(14.3%)	
I rather disagree	4	(17.4%)	2	(12.5%)	2	(28.6%)	
I completely disagree	5	(21.7%)	2	(12.5%)	3	(42.9%)	
My employer has safety concerns based on my LVAD[b]	n = 11		n = 6		n = 5		0.50
I completely agree	3	(27.3%)	2	(33.3%)	1	(20.0%)	
I rather agree	3	(27.3%)	2	(33.3%)	1	(20.0%)	
I rather disagree	0	(0.0%)	0	(0.0%)	0	(0.0%)	
I completely disagree	5	(45.5%)	2	(33.3%)	3	(60.0%)	

(*continued on next page*)

Table 2 (*Continued*)

n (%), median (IQR) or mean ± SD	Total cohort (n = 58)		HeartMate 3 (n = 39)		HVAD (n = 19)		*p*-value[c]
Additional equipment would be necessary[b] (at work)	n = 13		n = 7		n = 6		0.10
I completely agree	2	(15.4%)	1	(14.3%)	1	(16.7%)	
I rather agree	3	(23.1%)	3	(42.9%)	0	(0.0%)	
I rather disagree	5	(38.5%)	3	(42.9%)	2	(33.3%)	
I completely disagree	3	(23.1%)	0	(0.0%)	3	(50.0%)	
Remote monitoring would be useful[b]	n = 51		n = 34		n = 17		0.50
I completely agree	27	(52.9%)	17	(50.0%)	10	(58.8%)	
I rather agree	13	(25.5%)	9	(26.5%)	4	(23.5%)	
I rather disagree	7	(13.7%)	5	(14.7%)	2	(11.8%)	
I completely disagree	4	(7.8%)	3	(8.8%)	1	(5.9%)	

Abbreviations: IQR, interquartile range; LVAD, left ventricular assist device.
n = indication of the number of patients who answered the question in the corresponding table row.
[a]Multiple answers possible.
[b]Likert scale: 1 = I completely agree, 2 = I rather agree, 3 = I rather disagree, 4 = I completely disagree.
[c]*p*-value comparing HeartMate 3 vs HVAD cohort.

support, including the shower (75.9%), bed (31.0%), rearranging furniture in the bedroom (31.0%), installing additional or relocating electrical outlets (17.2%), purchasing an emergency generator, and adapting the home to live with a walking frame (6.9% respectively). Overall, 21.7% (without device-specific differences, $p = 0.50$) have adapted the manufacturer provided bag, and 70.6% agreed that these modifications have made their lives easier. Additionally, 78.4% of responders agreed on the usefulness of remote monitoring (HM3: 76.5% vs HVAD: 82.4%, $p = 0.50$).

Although 66.7% of LVAD patients reported still driving themselves (HM3: 56.4% vs HVAD: 88.9%, $p = 0.018$), mobility is limited due to the limited wearability of the peripheral components. Reasons for stopping driving were fear of alarms (33.3%) and general safety concerns (27.8%), without significant differences between devices ($p = 0.70$) or gender ($p = 0.34$). Although 44.9% disagreed on changed travel habits (HM3: 47.1% vs HVAD: 40.0%, $p = 0.80$), only 18.9% traveled abroad (3.7% by plane). The main reasons for not traveling were insecurity (HM3: 61.5% vs HVAD 75.0%), organizational burden (HM3: 50.0% vs HVAD 50.0%), and fear of forgetting components (HM3: 42.3% vs HVAD 58.3%), without significant differences between devices ($p = 0.70$). Additionally, 40.0% used less public transport than before implantation (the older, the less: $r = -0.37$, $p = 0.013$), with the most cited concern (36.8%) of getting stuck with the driveline and injuring themselves. No further statistically significant correlations between age, days on LVAD support, highest completed education, history of stroke and the questionnaire items could be found. Survey results disaggregated by gender (Supplementary File 4) showed significant differences ($p = 0.02$) only for problems while traveling.

In general, 89.3% of respondents completely or rather agreed that working with an LVAD is more difficult than prior to the implantation (HM3: 94.8% vs HVAD: 77.8%, $p = 0.05$). Moreover, 91.2% of the responders were unemployed. In addition to 36.0% who retired at adequate retirement age, 60.0% had to retire earlier, primarily because of the severity of the underlying heart disease or difficulties handling the LVAD at work.

Discussion

Recently, LVAD research has mainly focused on hemocompatibility-related adverse events, pump malfunction, or patient survival[1]. However, LVADs consist not only of the pump but also of the peripherals, mainly operated by patients and their relatives, implicating a potential for human factors issues. Nonpump malfunctions occur more frequently[16] and can be as life-threatening as pump malfunctions, emphasizing the necessity for HFE, improved design of LVAD wearables and consideration of human factors evaluation in future clinical trials.

This has been the first study comparing human factors issues of HM3 and HVAD patients in 6 predefined domains. Although several studies have addressed the user experience of LVAD patients,[6,8,11,12,17-25] this study added information on coping mechanisms, user modifications and employment issues to the MCS field.

Applying a systematic approach using the Delphi method[13] to generate a questionnaire based on consensus of LVAD experts before study enrollment provided a novel insight into patients' coping mechanisms in dealing with limitations of LVAD peripherals design. This technique is particularly useful when there is no true or predictable answer and reliance on a single expert would lead to bias. Nine VAD-Coordinators[26] were recruited as human factors experts on LVAD wearables. With a content validity index close to 1 (Supplementary File 3), they rated the survey content as very valid[14] to measure what it was designed for.

Except for gender, baseline demographics and socioeconomic factors were evenly distributed among devices: significantly more women received an HVAD (31.6%) than HM3 (5.1%, $p = 0.01$). Prior to the market withdrawal of the HVAD system, we preferably implanted this pump in smaller chest cavities due to its smaller pump size. As

previously reported[12], female LVAD patients desire a reduction in size and weight of the carry bag. This study revealed that 50.0% of HVAD and 71.4% of HM3 patients desired an improvement in size and weight, although the proportion of females was higher in the HVAD group, further emphasizing that not only gender but also device design is critical for user satisfaction. Further results stratified by gender were summarized in Supplementary File 4.

Another important finding was that despite the manufacturer's recommendation, nearly 75% left their controllers on battery power during sleep, and with almost 90% of the HM3 cohort, there was a significant difference ($p = 0.001$) compared to the proportion of HVAD patients (44.4%), highlighting the complexity of HM3 peripherals to switch from battery to AC power and vice versa. Furthermore, this could be a consequence of the additional feeling of safety thanks to the controller internal backup battery and the longer discharge time per battery of the HM3 compared to the HVAD.[27] Consequently, patients reported minor issues when changing power supply, but all patients completely or rather disagreed that the sequence of steps could cause problems which could be attributed to the established patient routines[28] and the fact that patients have to perform a power supply change several times per day.

Although 33% felt unprepared or rather unprepared for emergencies, only 15% of participants desired retraining. As reported[5] there is a need for user-center design of VAD peripherals, focusing the intuitive handling by involving user interface designers earlier in the product development process, since technical emergencies are infrequent and equipment training is often a long time ago. Depending on the manufacturer, and different driveline connector safety concepts, unintentional disconnections were significantly different (HM3: 5.6% vs HVAD 26.3%, $p = 0.041$). While the HM3 controller-driveline connection is based on a lock-and-release connector reducing unintentional disconnection at the expense of possible injury at the percutaneous exit-site, the HVAD connector had an unlocked concept that decoupled at a force[27] of >25N. Therefore, from a clinical perspective and given the associated risks, we recommend mandatory refresher training for all LVAD patients every 12 months (indicated by 42.9% of respondents with a desire for retraining, Table 2).

Recent studies have shown that LVAD patients are limited in their mobility and freedom to travel.[6,25] This study has confirmed these findings, with 40% having reduced their use of public transportation compared to before LVAD implantation. The limited travel capabilities were illustrated by the fact that 18.9% of subjects had already traveled abroad after implantation and only 3.7% had traveled by plane, because they felt insecure and anxious during the trip and were afraid of the additional organizational effort (Table 2), which is also supported by Hanke et al[25] in which 35% of all patients had problems at the security check. Further, older patients used less public transportation than before LVAD implantation ($r = -0.37$, $p = 0.013$)—due to the LVAD wearables many patients were afraid of getting stuck with the driveline and injuring themselves.

Many patients developed creative coping mechanisms to deal with the limitations of LVAD peripheral design, as 42.1% have modified their equipment or peripherals, and 60.9% reported using their own carry systems to better fit their desired lifestyle. As 56.4% had to adapt their home furnishing, it can be concluded that LVAD implantation has a major impact not only on the patient, but also on the patients' environment. Another factor that impacts lifestyle and body image is clothing, with 38.8% of patients reported that clothing modifications were required. Alterations of this nature can draw attention and lead to additional challenges to being "normal" in public.[29,30] The design process of next-generation LVAD systems should focus not only on pump performance and survival but also on discretion, prioritized outside use,[5] and quality of life of LVAD patients and their caregivers. Based on this and previous studies[31–40], first, it is recommended that backup batteries and remote monitoring be incorporated into LVAD controllers to increase patient safety. Second, focus on developing a compact and lightweight, travel-optimized, battery charger and power supply unit that allows patients to regain their ability to travel. Third, minimizing the weight and size of the peripherals should make patients' daily lives easier in terms of additional stress. Fourth, alternative, easily modifiable wearable systems or modular components should be offered to overcome unpredictable changes by the user.

Our study has limitations, including the cross-sectional design that did not include a defined survey time point after LVAD implantation. Nevertheless, no correlation was found between days with LVAD support at the time of the survey and the responses given. Although the HVAD system was withdrawn from the market, the results of this study remain highly relevant, as some design features of the HVAD peripherals appear to be advantageous compared to the HM3, thus highlighting a specific scope for improvements of future LVAD peripheral designs. Due to the single center characteristic of this study, potential influences due to cultural habits, socioeconomic, and center-specific best practices in VAD equipment training need to be identified through the use of the 16-item survey as part of a large-scale multicenter study. Not all datasets were complete, either because questions depended on previous questions that were not answered, or because they were omitted. In addition, women were underrepresented (13.8%), limiting the statistical power of the gender-stratified results. Involving patient representatives in the survey development process could have influenced the comprehensibility and/or topics of individual questions; however, the focus of this study was on exploratory identification of patient-perceived human factors rather than the creation of a validated instrument. Therefore, simulation studies including the HM3 are desirable to objectively quantify human factors and user experience to improve the understanding of the intuitive handling of LVAD peripherals.

Conclusion

To conclude, patients are developing creative ways to deal with the limitations of the LVAD peripheral design by

modifying the wearables, clothes or adapting their home, as the HM3 and HVAD peripherals still show a variety of human factors issues and potential for improved user experience. A user-centered design process and incorporating patients' feedback on LVAD peripherals may enhance user satisfaction, quality of life, patient safety, and thus lead to improved LVAD therapy acceptance.

Author contributions

TS: Conceptualization; Data curation; Formal analysis; Investigation; Methodology; Software; Visualization; Writing-original draft. AG: Data curation; Formal analysis; Investigation; Writing-review & editing; Writing-original draft. GW: Methodology; Writing-original draft; Writing-review & editing. LH: Data curation; Writing-review & editing. HAS: Data curation; Writing-review & editing. WS: Data curation; Writing-review & editing. JH: Data curation; Writing-review & editing. GL: Resources; Supervision; Writing-review & editing. DW: Investigation; Methodology; Writing-review & editing. FM: Methodology; Writing-review & editing. DZ: Conceptualization; Supervision; Writing-review & editing. HS: Conceptualization; Methodology; Resources; Supervision; Writing-review & editing.

Disclosure statement

T.S. is a consultant and advisor at Medtronic Inc., Abbott Inc., and CorWave SA, and has received research grants from Medtronic Inc., Abbott Inc., and CorWave SA. D.W. is a proctor and consultant at Abbott Inc., and advisor at Xenios/Fresenius Medical Care. F.M. has received research grant from Medtronic Inc. D.Z. is a proctor, advisor, and speaker at Medtronic Inc., Abbott Inc., Berlin Heart, Edwards, Abiomed, and has received research and travel grants from Medtronic Inc. and Abbott Inc. H.S. is an advisor at Medtronic Inc., and has received research grants from Medtronic Inc. The remaining authors have nothing to disclose.

This study is not supported by any funding.

Parts of this work were presented at the ASAIO 2021 Annual Meeting.

Acknowledgments

The authors thank all VAD Coordinators at the Medical University of Vienna for their support in conducting this study.

Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.healun.2022.12.015.

References

1. Shah P, Yuzefpolskaya M, Hickey GW, et al. Twelfth interagency registry for mechanically assisted circulatory support report: readmissions after left ventricular assist device. Ann Thorac Surg 2022;113:722-37. https://doi.org/10.1016/j.athoracsur.2021.12.011.
2. Bhat P, Starling RC. Patient population and selection criteria for mechanical circulatory support. In: Karimov JH, Fukamachi K, Starling RC, eds. Mechanical support for heart failure, Basel, Switzerland: Springer International Publishing; 2020:131-9.
3. Mehra MR, Uriel N, Naka Y, et al. A fully magnetically levitated left ventricular assist device—final report. N Engl J Med 2019;380:1618-27. https://doi.org/10.1056/NEJMoa1900486.
4. McGee E, Danter M, Strueber M, et al. Evaluation of a lateral thoracotomy implant approach for a centrifugal-flow left ventricular assist device: the LATERAL clinical trial. J Heart Lung Transplant 2019;38:344-51. https://doi.org/10.1016/j.healun.2019.02.002.
5. Dunn JL, Nusem E, Straker K, Gregory S, Wrigley C. Human factors and user experience issues with ventricular assist device wearable components: a systematic review. Ann Biomed Eng 2019;47:2431-88. https://doi.org/10.1007/s10439-019-02303-3.
6. Hanke JS, Riebandt J, Wahabzada M, et al. Driving after left ventricular assist device implantation. Artif Organs 2018;42:695-9. https://doi.org/10.1111/aor.13130.
7. Standing HC, Rapley T, MacGowan GA, Exley C. 'Being' a ventricular assist device recipient: a liminal existence. Soc Sci Med 2017;190:141-8. https://doi.org/10.1016/j.socscimed.2017.08.016.
8. Geidl L, Deckert Z, Zrunek P, et al. Intuitive use and usability of ventricular assist device peripheral components in simulated emergency conditions. Artif Organs 2011;35:773-80. https://doi.org/10.1111/j.1525-1594.2011.01330.x.
9. Food and Drug Administration Center for Devices and Radiological Health. Human factors and medical devices. 2022. Available at: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/human-factors-and-medical-devices Accessed July 21, 2022.
10. Standard. European, *EN 62366-1:2015—Application of usability engineering to medical devices.* 2020. Available at: https://www.en-standard.eu/bs-en-62366-1-2015-a1-2020-medical-devices-application-of-usability-engineering-to-medical-devices/.
11. Geidl L, Zrunek P, Deckert Z, et al. Usability and safety of ventricular assist devices: human factors and design aspects. Artif Organs 2009;33:691-5. https://doi.org/10.1111/j.1525-1594.2009.00844.x.
12. Schima H, Schlöglhofer T, zu Dohna R, et al. Usability of ventricular assist devices in daily experience: a multicenter study. Artif Organs 2014;38:751-60. https://doi.org/10.1111/aor.12394.
13. Cantrill JA, Sibbald B, Buetow S. The Delphi and nominal group techniques in health services research. Int J Pharm Pract 2011;4:67-74. https://doi.org/10.1111/j.2042-7174.1996.tb00844.x.
14. Lawshe CH. A quantitative approach to content validity. Pers Psychol 1975;28:563-75.
15. W Lenhard and A. Lenhard, Calculation of the readability index LIX according to Björnson, *Dettelbach: Psychometrica*. 2011. Available at: http://www.psychometrica.de/lix.html.
16. Kormos RL, McCall M, Althouse A, et al. Left ventricular assist device malfunctions. Circulation 2017;136:1714-25. https://doi.org/10.1161/CIRCULATIONAHA.117.027360.
17. Dew MA, Kormos RL, Winowich S, et al. Human factors issues in ventricular assist device recipients and their family caregivers. ASAIO J 2000;46:367-73. https://doi.org/10.1097/00002480-200005000-00025.
18. Kirkpatrick JN, Kellom K, Hull SC, et al. Caregivers and left ventricular assist devices as a destination, not a journey. J Card Fail 2015;21:806-15. https://doi.org/10.1016/j.cardfail.2015.05.016.
19. Casida JM, Marcuccilli L, Peters RM, Wright S. Lifestyle adjustments of adults with long-term implantable left ventricular assist devices: a phenomenologic inquiry. Heart Lung 2011;40:511-20. https://doi.org/10.1016/j.hrtlng.2011.05.002.

20. Casida JM, Brewer RJ, Smith C, Davis JE. An exploratory study of sleep quality, daytime function, and quality of life in patients with mechanical circulatory support. Int J Artif Organs 2012;35:531-7. https://doi.org/10.5301/ijao.5000109.
21. Kugler C, Meng M, Rehn E, Morshuis M, Gummert JF, Tigges-Limmer K. Sexual activity in patients with left ventricular assist devices and their partners: impact of the device on quality of life, anxiety and depression. Eur J Cardiothorac Surg 2018;53:799-806. https://doi.org/10.1093/ejcts/ezx426.
22. Merle P, Maxhera B, Albert A, et al. Sexual concerns of patients with implantable left ventricular assist devices. Artif Organs 2015;39:664-9. https://doi.org/10.1111/aor.12535.
23. Modica M, Ferratini M, Torri A, et al. Quality of life and emotional distress early after left ventricular assist device implant: a mixed-method study. Artif Organs 2015;39:220-7. https://doi.org/10.1111/aor.12362.
24. D'Aoust RF, Antonsdottir I, Budhathoki C, Casida J. Sleep quality and depression in adults with durable left-ventricular assist devices. Int J Artif Organs 2021;44:574-9. https://doi.org/10.1177/0391398820982622.
25. Hanke JS, Schmack B, Merzah AS, et al. Flying after left ventricular assist device implantation. Artif Organs 2021;45:230-5. https://doi.org/10.1111/aor.13815.
26. Schroeder SE, Boschi S, Schlöglhofer T. The role of the ventricular assist device coordinator: quo vadis?, *Ann Cardiothorac Surg*. 2021;10:386-388. https://doi.org/10.21037/acs-2020-cfmcs-17.
27. Schlöglhofer T, Schima H. Wearable systems. Mechanical circulatory and respiratory support. London, United Kingdom: Elsevier; 2018:691-721.
28. Weiss KE, Hoermandinger C, Mueller M, et al. Eye tracking supported human factors testing improving patient training. J Med Syst 2021;45:55. https://doi.org/10.1007/s10916-021-01729-4.
29. Abshire M, Prichard R, Cajita M, DiGiacomo M, Dennison Himmelfarb C. Adaptation and coping in patients living with an LVAD: a metasynthesis. Heart Lung 2016;45:397-405. https://doi.org/10.1016/j.hrtlng.2016.05.035.
30. Marcuccilli L, Casida J, Peters RM. Modification of self-concept in patients with a left-ventricular assist device: an initial exploration. J Clin Nurs 2013;22:2456-64. https://doi.org/10.1111/j.1365-2702.2012.04332.x.
31. Throckmorton AL, Patel-Raman SM, Fox CS, Bass EJ. Beyond the VAD: human factors engineering for mechanically assisted circulation in the 21st century. Artif Organs 2016;40:539-48. https://doi.org/10.1111/aor.12600.
32. Morales DL, Catanese KA, Helman DN, et al. Six-year experience of caring for forty-four patients with a left ventricular assist device at home: safe, economical, necessary. J Thorac Cardiovasc Surg 2000;119:251-9. https://doi.org/10.1016/S0022-5223(00)70180-2.
33. Schima H, Schlöglhofer T, Hartner Z, Horvat J, Zimpfer D. Importance of linguistic details in alarm messages of ventricular assist devices. Int J Artif Organs 2013;36:406-9. https://doi.org/10.5301/ijao.5000205.
34. Marcuccilli L, Casida JJ. Overcoming alterations in body image imposed by the left ventricular assist device: a case report. Prog Transplant 2012;22(2):212-6. https://doi.org/10.7182/pit2012579.
35. Adams EE, Wrightson ML. Quality of life with an LVAD: a misunderstood concept. Heart Lung 2018;47:177-83. https://doi.org/10.1016/j.hrtlng.2018.02.003.
36. MacIver J, Rao V, Ross HJ. Quality of life for patients supported on a left ventricular assist device. Expert Rev Med Dev 2011;8:325-37. https://doi.org/10.1586/erd.11.9.
37. Ko KHK, Straker K, Dunn JL, Wrigley C. What really matters? Understanding quality of life determinants impacting ventricular assist device stakeholders. ASAIO J 2020;66:626-36. https://doi.org/10.1097/MAT.0000000000001175.
38. Weerahandi H, Goldstein N, Gelfman LP, et al. Pain and functional status in patients with ventricular assist devices. J Pain Symptom Manage 2016;52:483-490.e1. https://doi.org/10.1016/j.jpainsymman.2016.05.016.
39. Aggarwal A, Kurien S, Coyle L, et al. Evaluation and management of emergencies in patients with mechanical circulatory support devices. Prog Transplant 2013;23:119-26. https://doi.org/10.7182/pit2013848. quiz 127.
40. Najjar E, Hallberg Kristensen A, Thorvaldsen T, et al. Controller and battery changes due to technical problems related to the HVAD® left ventricular assist device—a single center experience. J Cardiothorac Surg 2018;13:74. https://doi.org/10.1186/s13019-018-0759-9.