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Original research

Clinical experience with the Bendit steerable microcatheter: a new paradigm for endovascular treatment

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ABSTRACT

Background Vessel tortuosity poses a challenge during endovascular treatment of neurovascular lesions. Bendit Technologies (Petah Tikva, Israel) has developed flexible, steerable microcatheters designed with unique bending and torquing capabilities.

Objective To describe our first-in-human trial of Bendit21.

Methods Bendit21 was used in our exploratory, prospective, multicenter, open-label, single-arm clinical study, and in two compassionate use cases. Procedures were conducted at four centers in Austria, Germany, Israel, and the United States between May 2021 and March 2022, in patients with neurovascular conditions. The primary endpoints were device-related safety events, successful navigation through the neurovasculature, and, when intended, successful delivery of contrast or therapy.

Results Two patients with giant aneurysms were treated successfully under compassionate use approval. The clinical study included 25 patients (mean age: 63.4±11.8 years; 32.0% female). Fourteen patients (56.0%) had aneurysms, two had arteriovenous malformations/fistulas (8.0%), one had a stroke (4.0%), four (16.0%) had intracranial stenosis, and four (16.0%) had other conditions. Bendit21 was used without a guidewire in 12/25 (48.0%) procedures. Bendit21 was successfully navigated through the vasculature without delays or spasms in all cases (100%). Contrast was delivered as intended in 7/7 (100%) cases. Therapeutic devices were delivered successfully with Bendit as intended in 14/18 (77.8%) cases; four deficiencies occurred in three patients with aneurysms, in whom delivery of coils, an intrasaccular device, or a flow diverter was attempted. There were no device-related safety events or mortalities.

Conclusions Our initial clinical experience with the Bendit21 microcatheter demonstrates its usefulness in achieving technical success in patients with challenging neurovascular conditions.

INTRODUCTION

Many types of microcatheters are used for the endovascular treatment of intracranial aneurysms, with no consensus about the ideal shape of a microcatheter for different procedures.^{1–4} Compared with conventional microcatheters with a fixed shape, steerable microcatheters can bend or articulate, allowing fuller control over the placement of endovascular devices.^{5–12} The Bendit steerable

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Challenging vessel anatomy can prevent successful treatment of neurovascular conditions, including intracranial aneurysms, arteriovenous malformations/fistulas, and stroke.

WHAT THIS STUDY ADDS

⇒ Bendit21 is a flexible, steerable microcatheter that was used to treat 25 patients in this prospective, multicenter, first-in-human clinical study. Bendit21 was successfully navigated through the vasculature without any delays, spasms, device-related safety events, or mortalities occurring in any patient.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ This initial experience indicates the utility of this microcatheter for treating challenging neurovascular conditions with technical success.

and bendable microcatheter (Bendit Technologies, Ltd., Petach Tikva, Israel) received Food and Drug Administration (FDA) clearance in 2019. The device possesses three-dimensional controlled bending (articulating) and torquing capabilities and can be used with or without a guidewire. In preclinical investigations,¹³ we demonstrated the Bendit's ability to be maneuvered through tortuous vessels, and its precise ability to deliver and move coils. Contrast material can be injected as the Bendit navigates, and can cross through braided stents and high-grade stenosis. We also demonstrated its ability to treat sidewall aneurysms with intrasaccular devices that were originally developed to treat bifurcation aneurysms.¹³ Based on these experiences, the Bendit has the potential to treat aneurysms for which conventional microcatheters are not suitable, such as sidewall aneurysms requiring directional control and stable tip positioning for the delivery of intrasaccular devices.

Here, we describe compassionate uses of the Bendit21 in two patients (in Israel and the United States) with giant aneurysms that could not be treated with available techniques and could not be accessed with conventional microcatheters. We also describe our clinical experience as part of a

prospective clinical trial assessing the Bendit21 in a series of patients from three centers.

METHODS

Compassionate use cases

Compassionate use approval was sought in Israel and the United States for two patients with giant aneurysms for whom treatment with other conventional methods had failed. The Israeli Ministry of Health granted approval for the first procedure, while the FDA granted approval for the second procedure.

Clinical study design

A prospective, non-randomized, multicenter, open-label, single-arm clinical trial was conducted to assess the use of Bendit21 at three centers in Austria, Germany, and Israel between May 2021 and March 2022. The study was approved by the respective local ethics committees, and all patients provided written consent prior to enrollment. We have previously documented the technical description and benefits of the Bendit steerable microcatheter.¹³

Adult patients aged 18 or older who were candidates for intracranial diagnostic vascular imaging or selective therapeutic treatment and gave informed consent were included in the study. Exclusion criteria consisted of the following: (1) pregnant or lactating patients, (2) disorders of vascular fragility (eg, Ehlers-Danlos syndrome), (3) prior vascular dissection or injury to vessels to be catheterized, (4) myocardial infarction or uncontrolled arrhythmia, (5) uncontrolled serum electrolyte imbalance, (6) severely decreased renal function (estimated glomerular filtration rate <30), (7) fever (>30°C) or ongoing uncontrolled known infection, (8) bleeding disorders, (9) known contraindication to contrast material, (10) hypersensitivity to nickel, and (11) enrollment in another trial that has not reached the primary endpoint or that interferes with the current study endpoints.

The primary effectiveness endpoint was intraprocedural technical success, defined as successful navigation of the device through the neurovasculature and, when intended, the delivery of contrast or therapy (including stents, coils, intrasaccular devices, flow diverter, or other embolic material).

The primary safety endpoint was any intraprocedural major adverse event, including device-related vessel perforation or dissection, device-related vessel thrombosis or occlusion, device-related vasospasm with permanent neurological manifestation, and device malfunction resulting in permanent neurologic injury or death. All subjects were followed until either (a) discharge from the intensive care unit or (b) 48 hours after the operation for assessment of adverse events and an additional follow-up at 7 days (in Germany only).

Angiographic imaging via conventional fluoroscopy, with or without roadmapping, and digital subtraction angiography were performed by the investigators to visualize catheterization and the placement of coils, stents, flow diverters, and intrasaccular devices.

A secondary endpoint involved a 21-question user satisfaction survey administered to the treating physicians at the end of each procedure. A total of 19 questions assessed the difficulty of using the Bendit21 and were scored on a Likert-based scale from 1 to 5. Questions included the ability to deliver guidewires, contrast, and deliverables, and the ability to advance, bend, and steer the device. Two final questions (scored with a dichotomous 'yes' or 'no' response) asked the interventionalist whether they felt the Bendit saved time and whether they would use the Bendit in future procedures.

Statistical analysis

Data are presented as the mean and standard deviation (SD) for continuous variables and frequencies and percentages for categorical variables.

RESULTS

Compassionate use cases

Giant basilar tip aneurysm

Prior to the clinical investigation, the Bendit was used in a patient in their 70s under compassionate use approval for Y-stenting and coiling of a giant wide-necked basilar tip aneurysm (2.3 cm x 2.7 cm) (online supplemental figure 1A) that could not be treated in two previous attempts with different combinations of guidewires, microcatheters, and microcatheter shapes with and without steam. Both posterior cerebral arteries (PCAs) originated from the aneurysmal sac, and previous attempts to place a stent in the tortuous right PCA had failed. The aneurysm was compressing the patient's brainstem and creating a high risk for a brain hemorrhage. Furthermore, the aneurysm neck was deemed to be too large for an intrasaccular device or bifurcation neck bridging. As the patient's clinical state continued to decline, a single compassionate use of Bendit21 was granted by the Israeli Ministry of Health; the patient and their family consented.

On the day of the operation, the Bendit was employed after several other microcatheters had been unable to access the right PCA due to difficult artery anatomy and the steep angle at which the right PCA was projecting out of the aneurysm. The Bendit was used to advance a 0.014" Synchro 2 guidewire into the distal P3 segment (online supplemental figure 1B); it took 12 min to achieve this. This subsequently allowed for the deployment of a Solitaire (5x30mm) stent through the Bendit from the distal basilar artery to the right PCA. Ultimately, Y-stenting was deployed around the aneurysm to protect the bilateral PCAs, and 25 coils were delivered into the aneurysm sac (online supplemental figure 1C). The operation resulted in excellent embolization (Raymond-Roy class II), preserving normal blood flow in the bilateral PCAs and superior cerebral arteries (online supplemental figure 1C). The patient remained neurologically stable following the operation (functional status modified Rankin Scale score 4), although the patient ultimately died from an aggressive primary lung tumor.

Giant internal carotid artery aneurysm

A patient in their 50s had a symptomatic (diplopia, facial paresis, and left orbital pain) unruptured giant left cavernous internal carotid artery aneurysm (27 mm x 29 mm x 26 mm), with a 9 mm distance between the inlet and outlet. Attempted endovascular treatment at an outside institution had failed owing to the inability to place a catheter across the neck of the aneurysm due to its size and morphology. A temporary carotid artery occlusion test was not tolerated by the patient, and it was agreed that flow diverter placement would be preferable to a more invasive surgical bypass procedure. However, a repeat attempted endovascular treatment again failed owing to the inability to place a catheter across the neck of the aneurysm.

Authorization was obtained from the FDA and the institutional review board to use the Bendit21. On the day of the procedure, the treating physician was able to use the Bendit21 over an Aristotle guidewire to rapidly direct a microwire across the aneurysm neck and advance it into the middle cerebral artery (online supplemental figure 2A and B), while access was not achieved with the use of multiple other catheters and wires during previous attempts. A larger lumen catheter was then used

Table 1 Baseline characteristics

Characteristics	Frequency (n=25)
Mean age (years)	63.4±11.8 (37–88)
Female sex	8 (32.0)
Site	
Sheba Medical Center	5 (20.0)
Salzburg University Hospital	16 (64.0)
Alfried Krupp Krankenhaus	4 (16.0)
Medical history	
Coronary artery disease	1 (4.0)
Hypertension	15 (60.0)
Hypercholesterolemia	3 (12.0)
Dyslipidemia	5 (20.0)
Previous stroke or TIA	6 (24.0)
Neurological disease	12 (48.0)
Renal insufficiency	2 (8.0)
Cancer/malignancy	2 (8.0)
Baseline mRS score	
0	21 (84.0)
1	2 (8.0)
3	1 (4.0)
Not assessed	1 (4.0)
Procedure indication	
Aneurysm	14 (56.0)
Small:<10 mm	12 (92.3) (n=13)
Large: 10 to <25 mm	1 (7.7) (n=13)
Giant:≥25 mm	0 (0.0) (n=13)
AVM/fistula	2 (8.0)
Stroke	1 (4.0)
Stenosis	4 (16.0)
Other/diagnostic	4 (16.0)

Data presented as mean±standard deviation (range) or n (%).
AVM, arteriovenous malformation; mRS, modified Rankin Scale; TIA, transient ischemic attack.

to perform stent-assisted coiling, but the stent did not deploy properly after coil placement and was removed with the catheter, losing access. The physician then used the Bendit21 for a second time to rapidly re-access the vessel through the deployed coils and cross the aneurysm neck. Ultimately, a second stent was deployed through a larger lumen catheter, resulting in good flow and significant stasis of the aneurysms. The physician experienced no problems with the Bendit21, and the patient remained at their neurological baseline, with no complications other than a mildly worsened left retro-orbital headache after the procedure. The patient remained stable and was ultimately discharged 2 days after the procedure.

PROSPECTIVE STUDY

Patient and procedural characteristics

As of March 2022, the clinical trial has included 25 patients (mean age: 63.4±11.8 years; 8 (32.0%) female) with a variety of neurovascular conditions. Patient baseline characteristics are presented in [table 1](#). A total of 14 patients (56.0%) had aneurysms, two had arteriovenous malformations/fistulas (8.0%), one had a stroke (4.0%), four (16.0%) had intracranial stenosis, and four (16.0%) had other procedural indications.

Procedural details are reported in online supplemental table 1. The Bendit21 was used without a guidewire in 12/25

Table 2 Primary endpoint analysis

Endpoint	Frequency
Safety endpoints	
Device-related vessel perforation or dissection requiring clinical intervention	0 (0%)
Device-related vessel thrombosis or occlusion	0 (0%)
Device-related vasospasm with permanent neurological manifestation	0 (0%)
Device malfunction resulting in permanent neurologic injury or death	0 (0%)
Effectiveness endpoints	
Navigation through the neurovasculature	25/25 (100%)
Contrast delivered successfully as intended	7/7 (100%)
Intended therapy delivered successfully with Bendit	14/18 (77.8%)

(48.0%) procedures. The mean total procedure time was 83.96±36.28 min (n=24), and the mean time from procedure start to Bendit retraction was 60.9±26.9 min (range, 22–122; n=25).

Most procedures used one Bendit device, except for one procedure (4.2%) in which two Bendit catheters were used (patient 13), due to challenging vessel anatomy involving severely elongated and tortuous access vessels. The first Bendit catheter was removed owing to unsatisfactory positioning. The removed catheter was found to be intact and performed as expected. A second Bendit catheter was used, with similar results—the catheter was difficult to maneuver inside the aortic arch and distal intracranial internal carotid artery and A1 segment due to tortuous vessels and was retrieved. The treating physician then decided to change the treatment strategy, and used a Headway17 to deliver coils inside the aneurysms, as the anatomy only allowed a 17-system.

Primary safety and efficacy endpoints

All procedures (25/25, 100%) met the primary endpoint of successful navigation through the neurovasculature ([table 2](#)). Contrast was successfully delivered as intended in 7/7 (100%) cases. Therapeutic devices were delivered successfully with Bendit as intended in 14/18 (77.8%) cases.

There were procedural deficiencies involving Bendit in three patients with aneurysms. One involved the inability to deliver a Silk flow diverter (patient 2), which did not result in an adverse event. In another procedure (patient 18), the Contour 9 did not pass the Bendit Luer to the shaft. In the third patient (patient 24) high friction was experienced while delivering embolic coils, resulting in replacement with a conventional microcatheter without any clinical manifestations.

There were no device-related safety events or mortalities during the course of the clinical study. A single safety event occurred during the trial, which involved vessel occlusion resulting from delayed heparinization after two aneurysms were treated (patient 17). This was resolved with stenting and medication. The modified Rankin Scale score at discharge was 0 for all patients for whom data were available (n=18), except for two patients with scores that were unchanged from baseline.

Illustrative cases from the prospective study

Catheterization and navigation through a stent and area of stenosis The Bendit21 was used to catheterize the left vertebral artery (online supplemental figure 3A), the right common carotid artery (online supplemental figure 3B), and the left common carotid artery (online supplemental figure 3C) without a guidewire and without vessel spasms. The physician was able to

quickly navigate the Bendit21 around the acute-angled branch in the internal carotid artery to gain access to the anterior cerebral artery (online supplemental figure 3D). The Bendit21 acted as a scaffold to advance 6F Sofia and 8F catheters (online supplemental figure 3E).

The physician was able to navigate the Bendit21 across two LVIS stents (4.5×23 mm) to enter a sidewall petrous carotid aneurysm without a guidewire, with no visible movement of the stent. In one case involving stenosis of the proximal left vertebral artery, after deploying a Wallstent (Boston Scientific) without using the Bendit catheter, the stent was displaced and migrated distally (online supplemental figure 3F). Multiple unsuccessful attempts were made to enter the stent. The Bendit21 was used to engage the stent's inner lumen. Owing to the stability of the Bendit21, recatheterization was easily achieved with the aid of a 0.014" Transcend guidewire, and a second stent was deployed (online supplemental figure 3G).

Contour Neurovascular System deployment

In eight procedures, the Bendit21 was used to deploy the Contour Neurovascular System device successfully without the assistance/use of guidewires. The Bendit21 was used to deploy a 9 mm Contour device in an anterior communicating artery aneurysm (5×7 mm) (online supplemental figure 4A; patient 7). The device remained in a stable position while the 7 mm Contour device was deployed in a basilar tip aneurysm (5×5 mm) with a wide neck (online supplemental figure 4B; patient 8). The Bendit also allowed for the delivery of a 5 mm Contour device in a sidewall aneurysm (3.0×2.9 mm) (online supplemental figure 4C; patient 9). Slight movements of the Bendit (ie, 2° to 3°) within the aneurysm neck allow the user to optimize the position of the device and thus to optimize flow diversion, as demonstrated by the increased stagnation of contrast material in the sac of the aneurysm. Based on these differences, a precise position within the aneurysm can be chosen as the ideal position for the deployment of the intrasaccular device.

Venous navigation

The Bendit21 was successfully used for the transvenous catheterization of a cortical vein in one patient, permitting an exchange maneuver for microcatheter placement (patient 22) (online supplemental figure 5).

Questionnaire results

Treating physicians were administered a survey of 21 questions for each of the 25 procedures (online supplemental table 2). The mean of all responses was 4.6, indicating that Bendit21 use ranges from good (4) to excellent (5). For the crucial question of whether the physician would choose to use the Bendit again, 24/25 (96%) responses were affirmative. For the question of whether time was saved with the Bendit21, 17/25 (68.0%) responses were affirmative. In contrast, 4/25 (16.0%) responses indicated that the question of time could not be evaluated, while 4/25 (16.0%) responses indicated that time was not saved with the Bendit21.

DISCUSSION

We used the Bendit21 to catheterize the distal arterial segments in two giant aneurysms that could not be accessed with conventional microcatheters. In our clinical study, the Bendit21 was able to navigate through the internal carotid and vertebral arteries and maneuver through stents and areas of stenosis without delays, dissections, thrombosis, occlusions, vessel spasms, or device malfunction

resulting in injury. The Bendit remained in a stable position while it was used to deploy stiff intrasaccular devices in three different aneurysms. A particular advantage of the Bendit was the ability to reorient the microcatheter in an aneurysm for optimal angle of coil or intrasaccular device delivery. Our questionnaire indicated that the majority of treating physicians would recommend the use of the Bendit21. Thus, the Bendit may be a good option for procedures involving tortuous vasculature and challenging lesions and/or frequent guidewire and catheter exchanges.

Our early first-in-human results highlight the ability of the Bendit21 to be navigated through complex vasculature without delays or vessel damage. The acute-angle branching in the internal carotid artery has presented a challenge for catheterization with conventional microcatheters.^{11 14 15} Likewise, the extradural (V3) curve of the vertebral artery is difficult to reproduce in microcatheters of a fixed shape.³ However, the Bendit could be navigated through the tortuous internal carotid and vertebral arteries with no delays or navigation failures. It could also be used to easily catheterize the very acute angulation of cortical veins where they reach the superior sagittal sinus. In addition to its navigation capabilities, the Bendit could also be maneuvered through a braided LVIS stent without any movement of the stent, and it catheterized an anchored stent, which was not possible with presently available technology.

Currently available microcatheters/microguidewires may not be able to reach the desired position, which presents a challenge for embolization.^{4 8 14} We were able to coil two giant aneurysms that could not be treated with other microcatheters because it was not possible to gain access to the distal vessels even with a loop in the aneurysm or due to tortuous vessels, or where the carotid artery exiting the aneurysm is in an unfavorable angle, where present catheter/guidewires combination were unable to get access. We also found the Bendit to be useful in deploying the Contour Neurovascular System. Although the Contour and other intrasaccular devices were originally designed to treat terminal, bifurcation aneurysms,¹⁶ the Bendit was able to deliver the Contour device to sidewall aneurysms by providing a stable catheter position and no kick back during device delivery.

The advantage of using the Bendit21 in ischemic stroke thrombectomy is to reduce the exchange maneuvers. Using the Bendit21 as the inner device for navigation, during catheterization of the carotids for example, and coaxially deflecting and bending the intermediate catheter to engage the brachiocephalic vessels, gives support to advance the intermediate catheter and then a triaxial, balloon, or another guiding catheter, avoiding the need for exchange maneuvers. Although the Bendit21 may be more expensive than other microcatheters, the saving in time and potential distal emboli from arch manipulation may be significant.

Because the Bendit can be used without a guidewire, it has the potential to reduce procedural time during aneurysm treatment, and it seems to be much safer to position a larger microcatheter at the base of a 3 mm carotid sidewall aneurysm, which is usually very challenging as the microcatheter does not maintain its shape well and there is a risk of losing position during device delivery. The Bendit21 combines the abilities of a 0.035" guidewire, a 0.014" guidewire, a multishaped guidewire, and a microcatheter into one device. The benefits of not using a guidewire are that the procedure is faster, with a reduced risk of vessel trauma or perforation, and the ability to inject contrast during navigation, especially if the roadmap is affected by motion. Martin *et al*¹⁷ noted that wireless navigation with the SwiftNINJA to treat uterine fibroids reduced procedure times by 60%, which they attributed to fewer wire/catheter exchanges, real-time contrast injection, and the ease of catheter

navigation with a steerable microcatheter. In a similar manner, we felt that Bendit use tended to reduce procedure times due to less wire or microcatheter exchange for reshaping. Procedural time savings could, in turn, decrease anesthesia times and patient exposure to contrast media and radiation; however, further investigation is necessary to examine the extent of time savings when using the Bendit to treat intracranial aneurysms.

It is worth noting that technical problems with coil and flow diverter delivery occurred in 21% of aneurysm cases. The delivery of soft 0.014" coils through a 0.021" inner diameter can compact the coils. The Bendit17 is designed for coil deliveries, and several improvements of the lining are being implemented. Additionally, while the outer diameter is comparable to that of currently available 0.027" microcatheters, the outer diameter is larger due to the assembly of the two hypotubes, which increases the size of the wall. The second marker adds to the outer diameter, as the construction comprises nitinol, as opposed to a polymer that allows incorporation of the marker into the catheter wall. The Bendit21 is best used as a support for access in tortuous anatomy and stability in sidewall aneurysm catheterization because its 0.021" inner diameter is not optimal for coil treatment. However, for intrasaccular devices, its stability prevents the catheter from being expelled out of the aneurysm. Navigation is also safer, as advancement is facilitated with the one-to-one response. In small ruptured aneurysms where introducing the guidewire followed by catheter advancement is probably more dangerous, the Bendit21 in the neutral position has similar stiffness to conventional 0.021" microcatheters. Animal studies including histopathology have shown similar attribute to vessel pathology when deflecting and torquing the Bendit21 in comparison with the control Headway21.¹³

Given the lack of clinically significant events, the results of this study support the safety of the Bendit without a separate guidewire. The lack of evidence for arterial damage in the absence of a guidewire has also been noted in studies using other steerable catheters without a guidewire, including the SwiftNINJA (Merit Medical, Utah, USA) and the Direxion (Boston Scientific, Natick, Massachusetts, USA).^{5 6 12 17–19} Although the Direxion microcatheter showed promising results in vessel catheterization in a porcine model,¹⁸ the device requires preshaped tips. The SwiftNINJA and Enzo are able to bend 180° and 90°, respectively, in both directions. However, the Bendit microcatheters have a unique hypotube structure giving a one-to-one torquing function, and the hand control can be locked to any degree of angulation, maintaining its shape while torquing. These features are not present in the SwiftNINJA and Enzo, which are restricted to two dimensions. In addition to the Bendit's stability in its articulated position, its three-dimensional flexibility permits optimal placement to deliver intrasaccular devices to terminal and sidewall aneurysms.

LIMITATIONS

This study's limitations include the non-blinded study design with no comparator group and the minimal number of procedures performed at four centers, which limits generalizability and statistical inferences on patient outcomes.

CONCLUSIONS

We demonstrate the ability of the Bendit21 microcatheter to reach the intracranial circulation safely and effectively in both arterial and venous systems and deliver endovascular devices to treat a variety of neurovascular conditions. This study suggests that Bendit21 is well-equipped to navigate through tortuous vasculature with or without a guidewire.

Correction notice Since this article was first published, the following sentence 'The Bendit21 was used without a guidewire in 14/25 (56.0%) procedures' has been updated to 'The Bendit21 was used without a guidewire in 12/25 (48.0%) procedures'.

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Competing interests AB is the chief marketing officer, a board member, and a shareholder of Bendit. OC is the inventor, the chief technology officer, a board member, and a shareholder of Bendit. RC is a shareholder of Bendit.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by the respective local ethics committee from each center: (1) Ethikkommission für das Bundesland Salzburg, Austria 1210/2020; (2) Helsinki committee of the Sheba Medical Centre, Tel-Aviv, Israel 7930-20-SMC; (3) Ethikkommission of the Alfried Krupp Krankenhaus Rüttenscheid, Essen, Germany 2021098. For the compassionate use: (1) Helsinki committee of the Sheba Medical Centre, Tel-Aviv, Israel MOH approval: 202018209; (2) UT Southwestern Medical Center Institutional Review Board, Dallas, Texas FDA grant letter: U210529; (3) Baptist Health Institutional Review Board, Jacksonville, Florida FDA grant letter: U210309. Participants gave informed consent to participate in the study before taking part.

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