Increased symmetry of lower-limb amputees walking with concurrent bilateral vibrotactile feedback

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***Abstract*— Gait asymmetry in lower-limb amputees can lead to several secondary conditions that can decrease general health and quality of life. Including augmented sensory feedback in rehabilitation programs can effectively mitigate spatiotemporal gait irregularities. Such benefits can be obtained with non-invasive haptic systems representing an advantageous choice for usability in overground training and every-day life. In this study, we tested a wearable tactile feedback device delivering short-lasting (100 ms) vibrations around the waist syncronized to gait events, to improve the temporal gait symmetry of lower-limb amputees. Three above-knee amputees participated in the study. The device provided bilateral stimulations during a training program that involved ground-level gait training. After three training sessions, participants showed higher temporal symmetry when walking with the haptic feedback in comparison to their natural walking (resulting symmetry index increases of +2.8% for Subject IDA, +12.7% for Subject IDB and +2.9% for Subject IDC). One subject retained improved symmetry (Subject IDB, +14.9%) even when walking without the device. Gait analyses revealed that higher temporal symmetry may lead to concurrent compensation strategies in the trunk and pelvis. Overall, the results of this pilot study confirm the potential utility of sensory feedback devices to positively influence gait parameters when used in supervised settings. Future studies shall clarify more precisely the training modalities and the targets of rehabilitation programs with such devices.**

***Index Terms*—Gait symmetry, haptic interfaces, lower-limb amputation, sensory aids.**

I. INTRODUCTION

GAIT asymmetries are common in transfemoral amputees [1]. In these individuals, pain at the stump-socket interface, decreased muscle volume and force [2], [3], and limited confidence in the prosthesis [4] cause them to shift more weight and for a longer period of time on their sound limb compared to the prosthesis. As a result, they face increased energetic costs of ambulation and diminished overall mobility [5]–[9]. Asymmetric gait can also lead to several additional consequences including osteoarthritis of the sound limb, osteoporotic changes in the residual limb, lower-back and joint pain [3].

Augmented sensory feedback systems may present an effective supplement to conventional physiotherapy in the rehabilitation of gait asymmetries [10]. These systems are equipped with sensors measuring spatiotemporal gait parameters such as the stance times and stride periods or biomechanical variables such as ground reaction forces and the position of the center of pressure (CoP) under the foot. Sensor information is then used to provide the user with auditory [11], [12], visual [12], haptic [6], [7] or electrotactile [5], [13] stimuli intended to either inform the user about his/her performance relative to a tolerance interval or a target (*instructive feedback approach*) [6], [11], [12], [14], or to reflect the evolution of specific biomechanical parameters (*concurrent feedback approach*) [6]–[9]. Yang and colleagues [11], for example, developed an instructive system that delivered acoustic cues whenever amputees' symmetry index (SI) exceeded a specific range. In Crea et al. [7], the patients received concurrent discrete vibrotactile feedback at each gait event detected on the prosthesis, while walking on a treadmill. Visual cues on the SI were also provided to train the amputees to the use of the haptic feedback. In both cases, gait symmetry improvements have been achieved by providing audio or visual feedback, restricting the applicability of those feedback devices to laboratory or clinical settings. By contrast, haptic feedback systems provide gait-related information without overloading sensory systems already occupied during locomotion and activities of daily living. Haptic devices for gait rehabilitation typically deliver tactile stimuli unilaterally, to the amputee's impaired side.

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Haptic feedback can be conveyed via pneumatic systems [9], skin-stretch [8], vibrotactile [7] or electrotactile [5], [13] stimuli. Some of the aforementioned solutions have been tested in clinical trials and resulted in improving amputees' spatiotemporal gait parameters. However, these systems have been tested during treadmill walking, and it is unclear whether similar enhancements in gait symmetry can still be achieved overground. The difference between treadmill-based and overground gait training programs has been investigated in several studies which have found gait abnormalities to be less pronounced while walking on the treadmill. As an example, treadmill walking could be characterized by higher symmetry than overground gait [15]–[17] due to involuntary sensorimotor reactions to the moving treadmill belt [18].

Provision of instructive feedback on gait symmetry, i.e. rhythmic cues either utilizing audio metronomes or portable haptic devices, has been shown to facilitate changes in gait symmetry in clinical populations with movement disorders such as Parkinson's disease [19]–[21] and stroke [22], [23]. Despite its potential value for clinical gait rehabilitation, the instructive approach may be more intrusive in unstructured environments, in which forcing users to follow a fixed pre-defined cadence may not be perceived as natural. Based on these considerations, it can be hypothesized that the introduction of bilateral, concurrent feedback providing sensory information from both the intact and the impaired limbs in real-time could foster a more symmetric gait pattern in amputees, without explicitly instructing users to follow pre-defined cadences.

In the present study, time-discrete vibrotactile stimuli were delivered to the waist of three transfemoral amputees, using the wearable haptic feedback device presented in [24]. The feedback was provided synchronously with the occurrence of heel-strike events of both limbs during ground-level walking at self-selected speed. For the first time, the feedback was provided bilaterally to generate a rhythm, with the rationale that the amputees would walk more symmetrically in the attempt to balancing the feedback cadence between the two sides. Such a short-lasting and single event-driven stimulation strategy was chosen to avoid overlap in the stimuli originating from both sides during double-support phases. The goal of the study was to analyze the effectiveness of the feedback device and the bilateral stimulation strategy in improving gait symmetry of transfemoral amputees during ground-level walking, following a short training period.

II. STUDY DESIGN

A. Bidirectional Interface

The wearable feedback device used in this study is the so-called Bidirectional Interface (BI), shown in Fig. 1a and presented in detail in [24]. The BI is composed of: (i) a pair of shoes equipped with pressure-sensitive insoles, each one featuring 16 optoelectronic transducers [25], [26]; (ii) a processing unit for real-time measurement of plantar pressure and encoding gait information into discrete event-driven haptic stimuli (iteration frequency of the real-time routine: 100 Hz); (iii) a waist belt integrating 12 vibrotactile (VT) units made of vibrating motors encapsulated in a Polydimethylsiloxane (PDMS) matrix, to deliver the desired stimulation [24].

B. Sensory Feedback Strategy

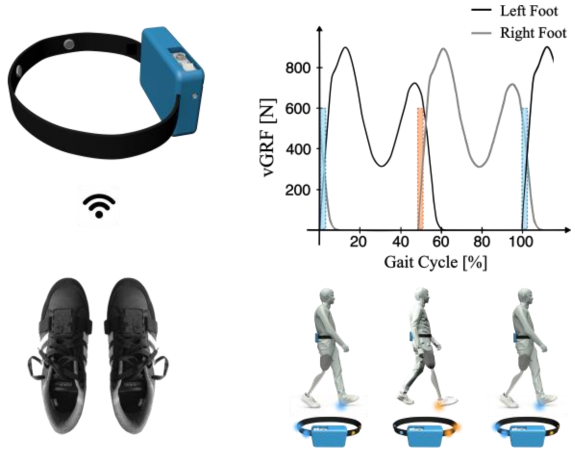
The BI provides bilateral, time-discrete vibrations (100 ms duration each) synchronously with the heel-strike (HS) of each foot. The choice of delivering short-lasting, fixed-duration vibrations was intended to avoid overlap between consecutive stimuli provided bilaterally, possible discomfort, and habituation effects [27], while still ensuring the effective and prompt perception of the vibrations, as demonstrated in a previous study [24]. For each side of the waist, the pair of VT units closest to the spine were activated simultaneously with the HS of the ipsilateral foot (Fig. 1b). In addition to timing information, the stimulation provides a spatial representation of the plantar pressure distribution, associating the rearfoot ground contact with the user's back. Furthermore, compared to the abdominal area, the back is less prone to fat storage, which may affect the perception of the vibrations [28].

For HS recognition, the system computes the real-time vertical ground reaction force (vGRF) and the coordinate of the CoP along the longitudinal foot axis (yCoP) from the insole sensor signals [25]. The vGRF is computed as

$$vGRF\;[N] = \sum_{i=1}^{16} F_i \qquad F_i = \begin{cases} f(V_i) & |V_i| \geq |V_{thresh}| \\ 0 & |V_i| < |V_{thresh}| \end{cases} \tag{1}$$

$F_i = i^{th}\ sensor\ force\ [N]$
$V_i = output\ voltage\ of\ the\ i^{th}\ sensor\ [V]$
$V_{thresh} = noise\ output\ voltage\ threshold\ [V]$

The output voltage of each sensor is preliminarily converted into force using the sensor characteristic equation extracted according to the procedure described in [25]. The yCoP is calculated only during the stance phase, identified through a



(a) (b)

Fig. 1. (a) The Bidirectional Interface (BI), composed of the waist belt equipped with the VT units (only the two VT units for each side used for the adopted feedback strategy are displayed) and the control electronics (blue case) and the instrumented shoes. (b) Schematics of the stimulation strategy implemented in the BI to activate a couple of VT units on each side of the waist, synchronously with the corresponding ipsilateral heel-strike (HS).

threshold-based algorithm on the vGRF: whenever the vGRF exceeds or drops below a pre-set threshold, the HS or the toe-off (TO) events are detected, respectively. The insoles' timely detection of gait events has been characterized in [25]. During the stance phase, the yCoP is computed by weighting the response of each activated sensor by its coordinate and by the sensor spatial density at that coordinate, to account for the clustered sensor distribution over the plantar surface:

$$CoP\ [cm] = \begin{cases} \dfrac{\sum_{i=1}^{16}\left(F_i \cdot w_{y_i} \cdot y_i\right)}{\sum_{i=1}^{16}\left(F_i \cdot w_{y_i}\right)} & vGRF \geq vGRF_{thresh} \\ NaN & vGRF < vGRF_{thresh} \end{cases} \quad (2)$$

$F_i = i^{th}\ sensor\ force\ [N]$

$y_i = coordinate\ of\ the\ i^{th}\ sensor\ [cm]$

$w_{y_i} = weight\ of\ the\ i^{th}\ sensor\ coordinate\ [\#]$

$vGRF_{thresh} = foot-contact\ threshold\ [N]$

The stimulation intensity of the VT units is controlled with 1 kHz PWM of a 5 V source with a 100% duty cycle. These parameters correspond to a peak vibration amplitude of 2.13 g, when the motors are activated for 100 ms [24]. This activation level has been selected according to the findings reported in [24], since it has resulted in effectively perceived vibrations, with no attenuation due to the action of walking. With the selected PWM, the response of the VT units is characterized by rising and settling times of 57 ms and 92 ms, respectively. Considering (i) this performance, (ii) the insoles' delay in detecting gait events [25] and (iii) the dynamics of tactile afferent stimuli [29], the system is expected to elicit a sensation in the user in approximately 250 ms, which would be appropriate to perceive the stimuli as synchronous to the associated gait event [30].

C. Participants

Three trans-femoral amputees (Table I) were enrolled for the study. The subjects were recruited among the patients of the clinical center Fondazione Don Carlo Gnocchi of Florence (Italy) who completed the post-amputation rehabilitation process. The enrolment (1 hour and a half) was carried out to verify patients' satisfaction of inclusion and exclusion criteria, and to evaluate clinical features concerning the amputation (year, cause, side and level of the amputation) and the prosthesis in use. Specifically, the participants were recruited according to the following inclusion criteria: (i) unilateral transfemoral amputation, (ii) age in the range of 30-80 years, (iii) foot size between 40 and 43 (European Union size). Following the initial screening, qualified medical personnel assessed the subjects' ability to walk at different speeds (i.e. Medicare Functional Classification Level ≥ K2) and their psycho-physical status (i.e. absence of sensory deficits, chronic cardiovascular or pulmonary diseases, cognitive impairment, severe anxiety or depression), by means of specific questionnaires (Mini Mental State Examination, State-Trait Anxiety Inventory-Y and Beck Depression Inventory-II [31]).

D. Experimental Protocol

The study was conducted at the premises of Fondazione Don Gnocchi of Florence (Italy), in accordance with the applicable regulations and with approval of the local ethics committee (i.e. Comitato Etico Area Vasta Centro Toscana; approval number: 12739_spe; ClinicalTrials.gov ID: NCT03296904). All participants provided written informed consent before starting the protocol. In addition to the enrolment session, the experiments comprised a pre-training assessment (pre-assessment), three training sessions, and a post-training assessment (post-assessment). The five sessions were performed on separate days, within the span of two weeks.

During the assessment sessions, the patients were asked to wear the BI and perform several ground-level walking trials with and without the feedback, to evaluate the effects of the BI on their gait before and after the training sessions. On the pre- and post-assessment sessions, the gait of the participants was assessed in five different walking conditions, all performed overground: (i) natural walking (NW), i.e. the natural gait of the patient; (ii) symmetrical walking (SW), i.e. walking while trying to spend the same amount of time on the prosthetic and sound limbs; (iii) symmetrical walking with sensory feedback (SF), i.e. symmetrical walking relying on the additional sensory feedback provided by the BI; (iv) symmetrical walking with a concurrent cognitive task (SW+ce), i.e. walking trying to spend the same amount of time on the prosthetic and the sound limbs while performing a concurrent cognitive task; and (v) symmetrical walking with sensory feedback and a cognitive task (SF+ce), i.e. symmetrical walking relying on the additional sensory feedback provided by the BI while performing a concurrent cognitive task.

The cognitive test of SW+ce and SF+ce consisted of backward counting: the participants started walking at their self-selected speed and after 15 s, they were invited to

TABLE I
PARTICIPANTS' CHARACTERISTICS

ID	Sex	Age (years)	Weight (kg)	Height (cm)	Prostehsis side	Knee prosthesis	Ankle prosthesis	Year of amputation	Cause of amputation	Mobility level*
A	F	71	66	176	L	Kenevo 3C60=ST (Ottobock)	SACH (details not avaliable)	2015	Vascular	K3
B	M	53	73	166	L	3R45 (Ottobock)	1C40 C Walk (Ottobock)	1981	Traumatic	K3
C	M	61	92	177	R	Total Knee 1900 (Össur)	Balance Foot J (Össur)	2017	Infectious	K3

*Medicare Functional Classification Level progressively subtract 7 from an initial value. The starting value was computed to include 14 steps before reaching the last positive value and each time the test was repeated, the initial value was slightly varied to avoid learning effects. In case of a wrong answer, participants were invited to try again. During such dual-task trials, the patients were instructed to attempt to achieve a symmetrical gait while primarily focusing on the backward counting, which had to be accomplished as quickly and accurately as they could.

The five walking conditions (NW, SW, SF, SW+ce, and SF+ce) were performed along a 20-m corridor equipped with the Optogait (Microgate S.r.l., Italy) and Witty (Microgate S.r.l., Italy) systems. Optogait is an optical system comprising two parallel arrays, one equipped with light emitters and the other with receivers, able to detect the timing and longitudinal placement of each step. The system is thus able to measure spatiotemporal gait parameters such as the stride/step length and period and the stance/swing duration. The Witty device is made of two photocells, used to measure gait speed. Subjects were required to walk continuously for three minutes for each experimental condition.

At the pre-assessment, a short familiarization with the VT feedback was performed before performing all walking trials. During the familiarization, the subjects were initially allowed to use the device without receiving any details on its functioning principles; then, the experimenters explained the feedback strategy and ascertained the actual perception of the vibrations but they did not provide other indications before the first training session.

In addition to the aforementioned walking trials performed along a corridor, the NW, SW and SF trials were performed also in a room equipped with an 8-camera BTS Smart Motion Tracking system (BTS Bioengineering, Italy), to evaluate the full lower-limb kinematics in different conditions. Before the beginning of the trials, the experimenter placed 22 reflective markers on the trunk and lower-limb landmarks, according to the Davis protocol [32]. In this case, for each trial, the subjects walked along an 8-m corridor for 10 times. It is worth noting that the NW, SW and SF conditions were repeated twice –once to evaluate the temporal gait symmetry walking continuously in the 20-m corridor and the second one to evaluate gait kinematics in the gait laboratory– because walking continuously around the gait laboratory was not possible. Each assessment session had an overall duration of approximately 3 hours, including rests between trials and preparatory operations, necessary to don and doff the BI and place the markers.

During training sessions, the participants walked overground with the device actively providing vibrations and were guided to familiarize themselves with its use. During these sessions, the participants performed an initial NW trial, lasting approximately 3 minutes. Then, they performed several SF trials of variable duration while a physiotherapist provided instructions on how to utilize the rhythmic feedback to improve their temporal symmetry. Instruction from the clinicians was gradually reduced throughout the three sessions. Overall, each training session lasted about 1 hour and a half, during which the participants walked on average 20-30 minutes, taking short trials and frequent rests to avoid physical fatigue.

E. Data Acquisition And Analysis

At pre- and post-assessments, the gait parameters necessary to evaluate the temporal symmetry were measured using the pressure-sensitive insoles of the BI. During the trials performed in the corridor, the commercial devices Optogait (Microgate S.r.l., Italy) and Witty (Microgate S.r.l., Italy) were used to estimate the spatial determinants to extract the spatial symmetry and the gait speed, respectively. The BTS Smart Motion Tracking (BTS Bioengineering, Italy) system was used in the trials performed in the gait analysis room.

All data were processed offline in Matlab (MathWorks, USA) to assess gait performance. The data from the insoles were segmented into single strides, according to the same threshold-based algorithm used online to identify the foot contact with the ground. From the raw stride data of the pressure-sensitive insoles, the temporal symmetry index (SI [#]) and the single-support duration [%GC] were computed. The SI was calculated as the ratio between the stance duration of prosthetic and the sound limb [11], so that an SI of 1 indicates complete symmetry whereas an SI lower/greater than 1 is indicative of longer stance durations on the sound/prosthetic side. Single-support durations corresponded to the time spent solely on the sound limb or on the prosthesis. The data recorded by the Optogait were used to estimate the spatial symmetry index (Spatial SI [#]), i.e. the ratio between the stride lengths of the prosthetic and sound limbs [13].

For all parameters, the median and interquartile range were calculated for each NW, SW and SF trials of the pre- and post-assessment sessions. For the same trials, the gait speed (Speed [m/s]) was extracted from Witty data. For the dual-task trials (SW+ce, SF+ce), only the temporal SI was considered. A non-parametric, independent-samples t-test (Wilcoxon rank sum test) was performed between the pre- and post-assessment medians and across all the investigated conditions to assess the statistical significance ($\alpha=0.05$) of the observed variations. Finally, the kinematics of the lower limbs and of the trunk was extracted from the BTS software, and the reports of the NW, SW and SF trials were inspected by a physiatrist to reveal any clinically-relevant variation across the three conditions at each assessment sessions.

III. RESULTS

All subjects completed the protocol without any difficulties, related adverse events, or symptoms.

In the post-assessment, all subjects achieved increased temporal symmetry when walking with the sensory feedback (SF) compared to their natural walking (NW) (Fig. 2). During NW, the median(IQR) SI was 0.80(0.06) for IDA, 0.78(0.03) for IDB and 0.84(0.06) for IDC, while in the SF condition it was 2.8% higher for IDA, +12.7% for IDB and +2.9% for IDC ($p<0.05$). During the same session, walking with active feedback increased temporal symmetry also compared to walking symmetrically without any cueing (SW) in IDA and

IDC. In fact, during SW they showed essentially the same SI as in NW (unvaried for IDA, +0.7% in SW for IDC). By constrast, IDB had an SI 14.9% higher in SW than in NW and did not further increase the index during SF, which showed a lower SI than SW, although the difference did not register as statistically significant.

At the pre-assessment, the same comparisons yielded different results: both IDA and IDB recorded the highest SI in the SW condition (SI=0.81(0.06), IDA; SI=0.85(0.03), IDB), while IDC had the highest SI in NW (SI=0.84(0.05)). Indeed in SF, an increased SI with respect to NW was recorded only for IDA but to a lesser extent than after the training and still lower than in SW (SI=0.80(0.04), IDA; SI=0.79(0.03), IDB; SI=0.84(0.05), IDC).

Comparing temporal symmetry in the same conditions between pre and post evaluations, the SI during NW was unchanged for IDA and IDC, while it decreased by 2.5% (SI_{NW_pre}=0.80(0.03)) for IDB. After training, the SI changed in the conditions of symmetrical walking (SF, SW), where all subjects presented significant improvements in one or both conditions. Notably, for IDB, the pre-post gain in the SI in those conditions was markedly higher than the negative variation in NW.

Notably, each participant increased temporal symmetry by adjusting different gait parameters (Fig. 2, Appendix: Table II-Table V). For instance, IDA decreased the gait speed from 0.45(0.03) m/s in NW to 0.31(0.04) m/s in SW at the pre-assessment, while the SI increased by 2.5%. At the post-assessment, gait speed variations did not correlate with the SI, and the increased SI under SF was achieved at the same speed as in NW. As for single-support times, at the post-assessment, the increased SI was obtained by decreasing the single stance on the sound limb in favor of longer double-support durations (Appendix: Table III).

For IDB, the most evident change associated with symmetry was in the gait speed: the subject always achieved the highest gains in the temporal symmetry while reducing the gait speed. At the pre-assessment, the speed decreased from 1.02(0.03) m/s during NW to 0.83(0.02) m/s in SW (while SI increased by 6.4%). This trend was more pronounced at the post-assessment, when the gait speed ranged from 1.00(0.03) m/s in NW to 0.48(0.01) m/s in SW and 0.43(0.02) m/s in SF, while the SI improved by 14.9% and 12.7%, respectively. Speed reductions also corresponded to increased double-support phases, mostly related to decreased sound-limb single-stance phases, while the time spent on the sole prosthesis remained approximately unvaried. At the post-assessment, the single-support time on the sound and prosthetic limbs was 48.1(1.1)% and 33.6(1.1)% respectively during NW, and 40.8(2.2)% and 32.6(3.2)% during SF.

For IDC, the gait speed did not show any significant variation, with average values around 0.72(0.03) m/s. Load

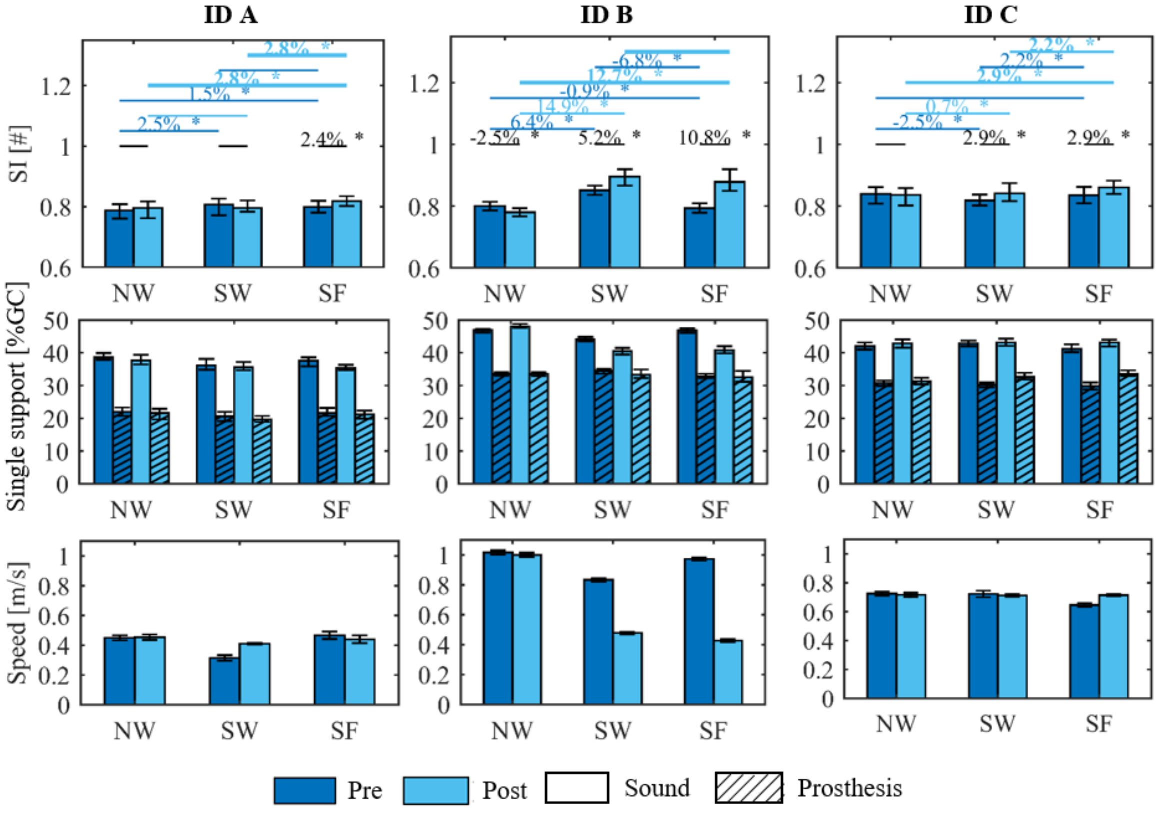


Fig. 2. Results on (i) temporal symmetry index (SI), (ii) percentage of single support duration on each limb and (iii) gait speed for the 3 participants in the 3 experimental conditions (natural walking (NW), symmetrical walking (SW) and symmetrical walking with sensory feedback (SF)), at the pre- and post-assessments. The horizontal lines mark the performed statistical comparisons: black lines are for pre-vs-post; light and dark blue are for comparing different conditions at the pre- and post-assessments, respectively. Bold lines highlight the most relevant comparisons for discussion. Stars mark statistically-significant differences. In that case, also the percentage variation is reported.

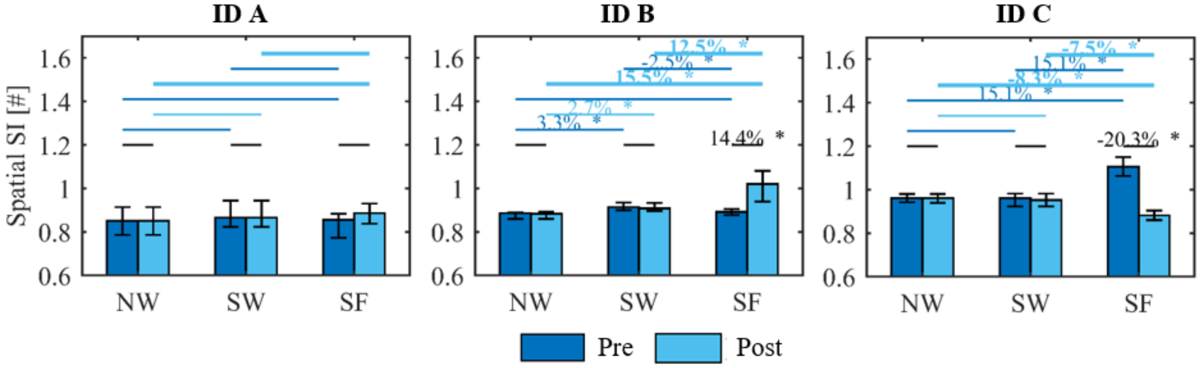


Fig. 3. Results on spatial symmetry of the 3 participants in the 3 experimental conditions (natural walking (NW), symmetrical walking (SW) and symmetrical walking with sensory feedback (SF)), at the pre- and post-assessments. The horizontal lines mark the performed statistical comparisons: black lines are for pre-vs-post; light and dark blue are for comparing different conditions at the pre- and post-assessments, respectively. Bold lines highlight the most relevant comparisons for discussion. Stars mark statistically-significant differences. In that case, also the percentage variation is reported.

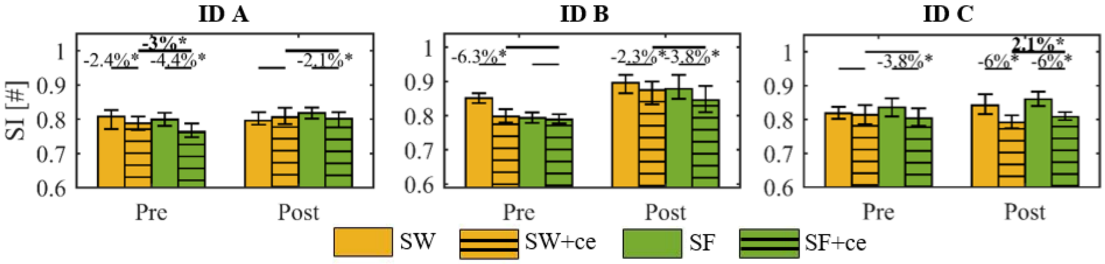


Fig. 4. Results of the temporal symmetry of the 3 participants during symmetrical walking (SW), symmetrical walking during the execution of a cognitive task (SW+ce), symmetrical walking with sensory feedback (SF) and symmetrical walking with sensory feedback during the execution of a cognitive task (SF+ce)), at the pre- and post-assessments. The horizontal lines mark the performed statistical comparisons. Bold lines highlight the most relevant comparisons for discussion. Stars mark statistically-significant differences. In that case, also the percentage variation is reported.

bearing was modulated with both the single-limb support phases, growing from the pre- to the post-assessment. Distinctively from the other participants, when the SI increased, the time spent in double-support decreased, while the time spent exclusively on the prosthesis increased relatively more than on the sound-limb, determining the positive variation of the SI (Appendix: Table III).

The relationship between spatial symmetry and temporal symmetry varied across subjects (Fig. 3, Appendix: Table V). For IDA, who had a spatial symmetry of 0.85(0.13), the relative stride lengths remained substantially unchanged throughout the study. IDB positively varied the spatial symmetry after the training: in SF, the spatial SI was 15.5% higher than in NW. In SW, despite the comparable temporal SI with SF, the gain in the spatial SI with respect to NW was smaller (+2.7%). Finally, for IDC, spatial symmetry changed only with the active sensory feedback and it did not correlate with the variations in the temporal index: after the training, it was 8.3% lower in SF than in NW, while the temporal SI increased by 2.9%, as previously reported.

Fig. 4 shows the additional results related to the mental load related to the utilization of the device. Generally, the addition of a cognitive task lowered temporal symmetry compared to the single-task conditions, regardless of the presence of feedback, i.e. symmetry was generally lower in SW+ce and SF+ce than in SW and SF, respectively. However, there were no evident differences in symmetry performance between SW+ce and SF+ce.

The results of the gait analyses performed before and after the training are useful to complete the description of the overall changes in the gait of the participants associated with the utilization of the BI. Generally, at the pre-assessment, no clinically significant modifications to gait were observed across

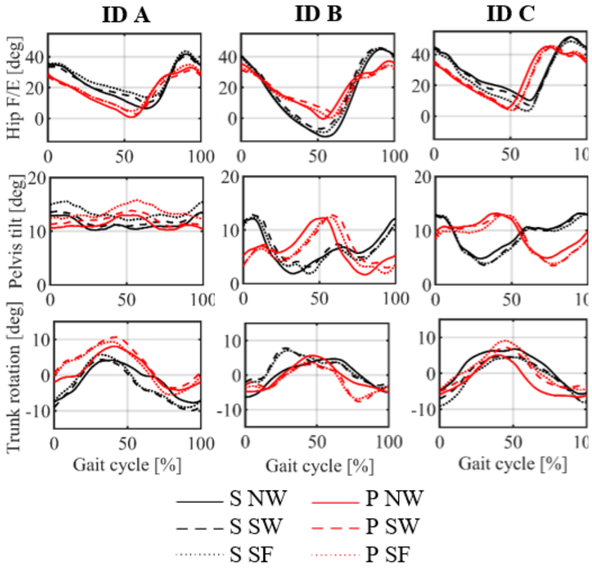


Fig. 5. Results of the gait analyses performed at the post-assessment showing sample kinematic profiles of the sound (black) and prosthetic (red) limbs in the 3 experimental conditions (natural walking (NW), symmetrical walking (SW) and symmetrical walking with sensory feedback (SF)).

the three walking conditions, except for IDB, who exhibited a slight increase of the sound-limb extension and elongated duration of hip flexion on the two sides, in both SF and SW with respect to NW. At the post-assessment, differences were found between NW and both SF and SW (Fig. 5). In these two conditions, at the level of the hip joint, the kinematic data seem to confirm improvements in temporal symmetry: all subjects showed postponed start of flexion on the prosthetic side and earlier or unchanged timing on the sound side, possibly implying longer stance durations on the prosthesis. Also, IDB and IDC showed enhanced hip ranges of motion in the sagittal plane as well, the former reducing hyperextension on the sound limb and the latter increasing its maximum extension. Separately, IDA reduced the angular excursion during the extension of the sound limb. In turn, however, the subjects modified other kinematic profiles, such as trunk and pelvis movements. For example, Fig. 5 shows an increased pelvis tilt for IDA and IDC and trunk rotation for all subjects. Overall, the physiatrist evaluation deemed SF and SW comparable, as more pronounced positive effects in one case were balanced by more appreciable compensations as well.

IV. DISCUSSION

As a main outcome of the study, all subjects were able to use the BI to walk with increased temporal symmetry relative to the natural walking (no feedback) condition after the three training sessions. Even though this improvement was limited in magnitude for two of three subjects, the resulting SI changes in the range of 3-13% were in line with the results observed in similar studies with lower-limb amputees using both *instructive* or *augmented sensory feedback* devices [7], [11], [13]. For example, in [11], two out of three transtibial amputees improved their SI by +3.3% and +26.5% (respectively) during ground-level walking, after using the LEAFS system for six training sessions. Using electrotactile feedback, Pagel et al. observed that two out of three transfemoral amputees reached 5.1% and 6.9% improvements in temporal symmetry during treadmill walking with unilateral feedback in a single session [13]. Finally, the interquartile range of the SI of three trasnfemoral amputees went from [0.82, 0.84] to [0.98, 1.02] during treadmill walking after three training sessions combining visual feedback and haptic cues on the residuum [7].

As in these previous studies, we observed considerable between-subject variability in the results. Given the limited sample size, this variability represents a major limitation to deriving general conclusions concerning the effectiveness of haptic feedback for rehabilitation purposes [33]. Both IDA and IDC demonstrated the ability to walk more symmetrically with the device feedbck (SF) than during their natural walking post-training, yet they did not maintain the same improvement without feedback (i.e. in SW). By contrast, IDB maintained improved symmetry relative to NW both with (SF) and without (SW) feedback, thus suggesting effective motor learning, at least in the short term [34]. The differing extent of positive results across subjects may be related to their different individual ambulatory abilities. Despite belonging to the same Medicare mobility class, the three participants exhibited different clinical and demographic characteristics that likely affected their response to gait training with feedback. For example, IDB was much younger, generally fitter, and had undergone amputation in his youth – and thus had high confidence in the prosthesis and a gait speed nearly comparable to able-bodied subjects [35]. By contrast, IDA and IDC –who displayed overall lower mobility and trust in the prosthesis– managed to improve their gait to a lesser degree. While a higher potential margin of improvement may have been expected with these subjects due to their relatively short time since amputation, their overall lower health and mobility may have diminished their ability to benefit from sensory feedback training. It is possible that with longer or different kinds of training, they could have retained significant progress in symmetry even without concurrent stimuli. Moreover, it is possible that individual differences between users warrant the development and use of novel predictive methodologies to personalize feedback and rehabilitation strategies to the capabilities and learning style of each user.

In [13], Pagel et al. hypothesized that the extent of symmetry improvements might reflect the different levels of asymmetry of the patients at baseline, since the most important improvements in symmetry were achieved by the subject with the most marked asymmetry, while the feedback was not effective for the person with initial symmetry closest to 1. Even though this relationship was also observed (to a lesser extent) in the study of Yang at al. [11] and in ours, this study revealed also that participants with similar initial SI yielded far different results. Therefore, although the margin for potential improvement becomes thinner when the SI approaches 1 – especially considering the impossibility of passive or semi-active prostheses to fully replace the functionality of an intact limb [36], [37]– the observed improvements in symmetry seemed more related to the level of user mobility rather than to their level of initial symmetry.

Further, the tactile feedback strategy is likely a strong contributing factor to variations in symmetry . For symmetry training, several strategies have been proposed, but no approach has been clearly established as superior [38], [39], [13], and the optimal strategy may vary by subject [13], [22]. One of the limitations of the strategies tested so far with vibrotactile feedback may lie in their unilateral application on the impaired side, which does not allow straightforward instructions to the user, whereas a bilateral stimulation may create a rhythm which may facilitate a more symmetric gait. From the results of this study, however, bilateral stimulation did not appear to induce superior changes in symmetry than the other unilateral strategies tested so far [7], [13]. However, since a direct comparison between uni- and bi-lateral feedback was not conducted in this study, the potentially more intuitive nature of bilateral stimulation remains an open point.

In any case, the choice of an appropriate strategy has possibly been decisive to induce the observed changes in the SI. A pilot run of the protocol with an additional amputee (ID0) using a different feedback strategy had not elicited any changes in symmetry. The previous strategy mapped the sagittal progression of the center of pressure (CoP) of each foot into a spatiotemporal series of six discrete vibrations progressing around each side of the waist, from the spine (coinciding with the heel) to the navel (associated to the toe) (Fig. 6a). Despite the subject reporting qualitatively that the feedback was easily perceived, intuitively understood, and highly descriptive of the movement, he exhibited no significant improvement in his gait symmetry (Fig. 6b). Nevertheless, when the same subject was provided with other prescriptive types of feedback during an additional experimental session performed on the treadmill, he was able to improve temporal symmetry even after a short familiarization. This evidence suggested that the simpler feedback strategy conveying only heel strike information was more effective for the given subject and task (Fig. 6c).

Following these early findings, we deemed our initial feedback strategy too rich and complex to be advantageous and designed a simpler one that could still provide bilateral rhythmic information but with higher intuitiveness, an important requirement for the implementation of effective strategies [10], [33], [34]. In particular, we emulated one of the strategies giving promising results on the treadmill, to simply provide heel-strike-driven discrete vibrations, thus pacing subjects' steps at their own cadence without constraining the natural speed variations occurring during overground walking.

Along with the intuitiveness of the feedback strategy, another important element to consider is the mental effort associated with system use. Generally, concurrent feedback, i.e. that provided in real-time during motor tasks, seems to prevent cognitive overload during the initial stages of learning a complex motor task [34] and could thus potentially simplify the learning process. In our case, the absence of clear differences in the symmetry between the execution of the dual-task with and without the feedback suggests that training symmetry with the BI was cognitively comparable to walking while paying attention to spending an equal amount of time on both limbs. At the same time, dual-task trials highlight a low degree of automaticity of symmetrical walking. The execution of a concurrent cognitive task affected symmetry in all cases, i.e. both with and without the feedback, whereas automatized motor skills do not usually require much conscious control and their performance is robust to the execution of concurrent tasks [40]. Assuming that longer training would consolidate the observed improvements in temporal symmetry, it might be hypothesized that the cognitive load associated with symmetrical walking would concurrently decrease as the task gradually becomes automatized. Still, the potential advantages of training with sensory feedback for lowering the cognitive effort required by learning to walk more symmetrically remain to be addressed by future studies.

Extending our analysis to additional spatiotemporal parameters, the overall benefit of walking with increased temporal symmetry is unclear. For example, improved temporal symmetry was achieved by IDB at the cost of decreased walking speed, by approximately half. This result makes it difficult to isolate the gain in symmetry, as amputees' temporal symmetry has been shown to be velocity-dependent. In particular, transfemoral amputees were found to reduce temporal gait asymmetry with increasing walking speeds, while increasing loading asymmetry [3]. Thus, given the existing and insufficiently investigated relation between gait speed and symmetry, future studies should consider maintaining speed constant across trials in order to avoid potential confounds in the results.

Further, the relationship between temporal and spatial symmetry was not clear in the present study. Of the three subjects, only IDB increased spatial symmetry with the BI, whereas IDC lowered it and IDA did not show variations. This result contrasts with [13], where spatial and temporal symmetry followed the same trend.

As for the kinematic gait analyses of SF and SW, the onset of visible compensatory movements at the pelvis and trunk level in conjunction with the improvements in hip timing and range of motion was not desired. According to older literature, increased pelvic movements might lead to muscle and joint overload and to low-back pain as a long term adverse effect [41]. Though more recent findings have not shown a causal link between low-back pain and enhanced pelvic tilt [42], it seems advisable that physiotherapists pay attention to pelvis and trunk biomechanics during therapy, encouraging patients to avoid compensatory movement patterns until future studies clarify the long-term effects of such biomechanical modifications.

These outcomes further underline the difficulty of walking with increased symmetry, which might as well be abandoned after rehabilitation if perceived as too laborious. Thus, adopting appropriate training modalities urges attention not only to avoid jeopardizing the beneficial effects of increased symmetry with the development of potentially-dangerous compensatory

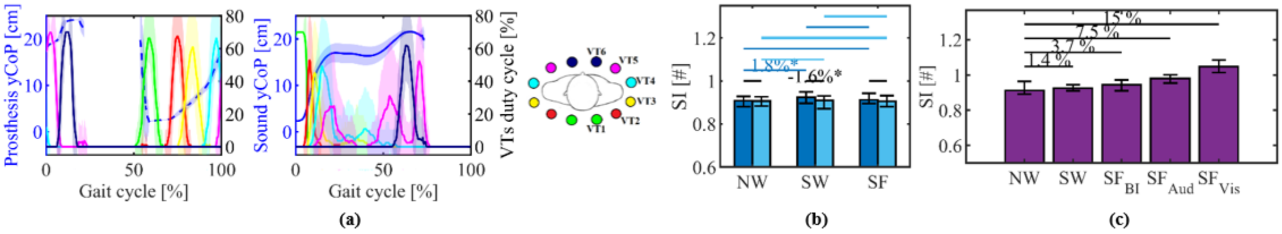


Fig. 6. Summary of preliminary experiments with ID0. (a) Activations of the VT units based on the feedback strategy mapping the evolution of the CoP. (b) Results for temporal symmetry in the 3 experimental conditions (natural walking (NW), symmetrical walking (SW) and symmetrical walking with sensory feedback (SF)), at the pre- and post-assessments. (c) Results for temporal symmetry in the 5 experimental conditions (natural walking (NW), symmetrical walking (SW), symmetrical walking with BI sensory feedback (SF$_{BI}$), symmetrical walking with auditory sensory feedback (SF$_{Aud}$) and symmetrical walking with visual sensory feedback (SF$_{Vis}$)) during the additional session.

movements but also for keeping at a minimum the additional effort of walking symmetrically, which might otherwise concur to restore asymmetric walking schemes in the long term. In our specific case, the supervision of physical therapists was not intended to correct the movements of the subjects but only to maintain the participants' focus on the rhythm of the vibrations. In this way, this study reaffirms the role of sensory feedback devices as complements rather than substitutes to therapists' involvement. This complementary relationship is particularly important for training complex functional movement patterns such as locomotion, that involve multi-joint synergies with multiple degrees of freedom. In such scenarios, the prescription of effective gait modifications should be assessed and provided by the physiotherapist [10].

V. CONCLUSIONS

In this pilot study, vibrotactile feedback intended to improve gait symmetry of transfemoral amputees was provided for the first time during an overground gait training program and implementing a novel, bilateral stimulation strategy.

One subject with good baseline locomotor function was able to substantially and consistently improve his temporal gait asymmetry, both with and without feedback active. On the other hand, the symmetry gains recorded for the other two participants with lower mobility were limited in amplitude and constrained to concurrent feedback application. These results leave open questions as to whether the limited response of these subjects may be attributed to the limited training duration, to the usability of the feedback strategy, and/or to the potential need for additional physiotherapist guidance by subjects with low mobility. Indeed, this study showed that physical therapists' supervision could be fundamental when using such sensory feedback devices for rehabilitation of complex motor tasks involving more degrees of freedom, not only to maximize the beneficial effects for temporal symmetry but also to avoid the onset of compensatory movements.

Unfortunately, the limited sample size represented a main limitation for inferring definite and generalizable conclusions. Indeed the results of this study should serve as meaningful inputs for designing future experimentations rather than representing firm outcomes. In the future, it will be crucial to recruite larger pools of subjects in order to overcome confounding results related to inter-subject variability, and essential for clinicians to provide proactive instruction to subjects so as to avoid foreseeable compensatory movement patterns. Future research should also compare the effectiveness of unilateral and bilateral feedback approaches.

APPENDIX

Table II-Table V show the numeric results of the spatiotemporal gait parameters.

TABLE II
MEDIAN(IQR) OF THE SYMMETRY INDEX (SI)

SI [#]	**NW**		**SW**		**SF**	
	Pre	**Post**	**Pre**	**Post**	**Pre**	**Post**
IDA	0.79(0.05)	0.80(0.10)	0.81(0.06)	0.80(0.04)	0.80(0.04)	0.82(0.03)
IDB	0.80(0.02)	0.78(0.02)	0.85(0.03)	0.90(0.05)	0.79(0.03)	0.88(0.07)
IDC	0.84(0.05)	0.84(0.06)	0.82(0.04)	0.84(0.05)	0.84(0.05)	0.86(0.04)

TABLE III
MEDIAN(IQR) OF THE SINGLE SUPPORT PHASES ON THE SOUND AND PROSTHETIC LIMBS

Single support [%GC]	**NW**				**SW**				**SF**			
	Pre		**Post**		**Pre**		**Post**		**Pre**		**Post**	
	Sound	**Prost**	**Sound**	**Prost**	**Sound**	**Prost**	**Sound**	**Prost**	**Sound**	**Prost**	**Sound**	**Prost**
IDA	38.7 (2.2)	21.9 (2.5)	37.7 (2.9)	21.6 (3.3)	36.2 (3.3)	20.6 (2.8)	35.6 (2.6)	19.7 (1.8)	37.6 (2.7)	21.6 (2.5)	35.3 (1.8)	21.2 (2.5)
IDB	46.9 (1.2)	33.4 (1.2)	48.1 (1.1)	33.6 (1.1)	44.1 (1.4)	34.5 (1.5)	40.6 (2.1)	33.3 (2.7)	46.9 (1.4)	32.8 (1.3)	40.8 (2.2)	32.6 (3.3)
IDC	42.0 (2.2)	30.7 (1.6)	42.9 (2.5)	31.3 (2.0)	42.9 (1.8)	30.2 (0.5)	43.1 (2.2)	32.7 (2.0)	41.2 (2.3)	29.8 (2.2)	43.1 (2.0)	33.6 (1.6)

TABLE IV
MEAN(±STANDARD DEVIATION) OF GAIT SPEED.

Speed [m/s]	**NW**		**SW**		**SF**	
	Pre	**Post**	**Pre**	**Post**	**Pre**	**Post**
IDA	0.45±0.02	0.45±0.02	0.31±0.02	0.41±0.01	0.47±0.02	0.44±0.03
IDB	1.02±0.01	1.00±0.001	0.83±0.01	0.48±0.01	0.97±0.01	0.43±0.01
IDC	0.73±0.01	0.72±0.01	0.72±0.02	0.71±0.01	0.65±0.01	0.72±0.01

TABLE V
MEDIAN(IQR) OF THE SPATIAL SYMMETRY INDEX (SI)

Spatial SI [#]	**NW**		**SW**		**SF**	
	Pre	**Post**	**Pre**	**Post**	**Pre**	**Post**
IDA	0.85(0.12)	0.85(0.12)	0.87(0.12)	0.87(0.12)	0.86(0.11)	0.89(0.09)
IDB	0.89(0.03)	0.88(0.03)	0.91(0.04)	0.91(0.03)	0.89(0.03)	1.02(0.14)
IDC	0.96(0.04)	0.96(0.04)	0.96(0.06)	0.95(0.06)	1.11(0.09)	0.88(0.04)

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