

ARTICLE



Retrospective safety evaluation of the atalante exoskeleton in a clinical setting in patients with tetraplegia and high paraplegia

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STUDY DESIGN: Retrospective study.

OBJECTIVES: To evaluate the safety of the Atalante exoskeleton in patients with tetraplegia and high paraplegia.

SETTING: Three inpatient rehabilitation centers in France.

METHODS: Data from thirty-three inpatients with tetraplegia (12 motor complete (American Spinal Injury Association Impairment Scale (AIS) grade A or B), 10 motor incomplete (AIS C or D)) and high paraplegia (at or above T4 level; 10 motor complete and 1 motor incomplete) and an average time since Spinal Cord Injury (SCI) of 2.6 years (19 individuals < 12 months after injury), who completed at least one session of training with the Atalante exoskeleton, were analyzed. The primary outcome was the safety assessment through reported device-related adverse effects (AE). Secondary outcomes included pain (Numeric Pain Rating Scale), spasticity (Ashworth scale), walking ability (WISCI-II), and exoskeleton session data.

RESULTS: Participants underwent a median of 7.5 (IQR: 3–22.8) exoskeleton training sessions, with a median verticalization duration of 22.4 min (IQR: 18–26.9) and 583.0 steps (IQR: 347.0–854.0) performed. The estimated rate of AEs per session across all sessions was 0.63%, with a 95% confidence interval ranging from –0.56 to 1.81%. One minor AE occurred in one patient, involving hypotension, fatigue and dizziness, leading to session discontinuation. No therapy-related pain or fracture was reported. Regarding secondary outcomes, spasticity remained unchanged while positive changes were observed in WISCI-II scores in 11 patients with incomplete SCI.

CONCLUSIONS: After individual benefit-risk assessment, the Atalante exoskeleton can be safely used in a clinical setting for high SCI patients.

SPONSORSHIP: Wandercraft

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INTRODUCTION

The use of robotic-assisted gait training has grown over the last decade. One of the advantages of robotic devices is that they can be beneficial in patients with spinal cord injury (SCI) typically considered sedentary and unable to stand and walk [1, 2] by enabling them to perform regular activity at light to-moderate intensity.

Gait training with exoskeletons is more commonly implemented for patients with mid-to-low paraplegia (below T4) than to those with tetraplegia, as gait rehabilitation in tetraplegia and high paraplegia presents greater challenges. One consideration in robotic-assisted gait training for individuals with high SCI is upper limb dysfunction, as many exoskeletons require some degree of upper limb involvement. Furthermore, individuals with complete lesions above T6 are more likely to have more severe cardiovascular autonomic dysfunction, with resting bradycardia, hypotension or orthostatic hypotension [3]. Absence of trunk control increases the energy expenditure during standing and increases the risk of skin issues [4, 5].

Studies published in this SCI population report infrequent adverse effects (AE) consisting mainly of skin lesions [6] and

fractures (with an incidence rate of 3.4%) [7]. In a recent review on wearable powered exoskeletons for gait training in patients with tetraplegia, Rodriguez Tapia et al. identified 166 tetraplegic patients out of 41 studies, including only 26 patients with complete motor lesions (ASIA Impairment Scale (AIS) A or B) [8]. Minor AE were reported in 16 tetraplegic patients, concerning cardiovascular ($n = 8$), pressure sores ($n = 5$), or musculoskeletal ($n = 3$) systems, significantly less than patients with paraplegia. Only one serious AE (stress fracture of tibia) was reported [9]. They concluded that gait training using wearable powered exoskeletons is a feasible and safe intervention after tetraplegia, provided patients' selection is conducted according to safety recommendations. Some evidence suggests that gait training using exoskeletons could lead to improvements in walking parameters, reduce spasticity and constitute a way to perform physical activity after tetraplegia, as has been demonstrated after paraplegia [10–13].

In this paper, we report the 5-year experience of the off-label clinical use of the Atalante exoskeleton (Wandercraft, Paris, France) in 3 French rehabilitation centers from gait trainings in patients with tetraplegia and high paraplegia.

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MATERIAL AND METHODS

In this retrospective study, the data collected from patients aged at least 18 years with tetraplegia or high paraplegia (neurological level of injury at or above T4) and varying etiology and severity were analyzed, who underwent at least one session with the Atalante exoskeleton in a clinical setting between February 2019 and July 2024. Gait rehabilitation using the exoskeleton was an optional component of the rehabilitation program in the three participating French centers—Fondation Hopale, La Musse Hospital, and the CMPR of Pionsat. It was offered to hospitalized patients (inpatients or outpatients) meeting the following criteria: no contraindications per manufacturer guidelines (Annex 1), clinical stability, and experience with vertical or standing position before using the Atalante device. Skin checks were conducted by nurses in the clinic.

Data were retrospectively collected from routine clinical records, measurements, and examinations performed as close as possible to the first exoskeleton session (for baseline data) and before the first and after the last session (for secondary outcomes). A non-opposition form was distributed to all patients, and no objections were reported.

The trial was declared to the CNIL on May 16, 2024 (ref. 2234433 v0), filed under the MR004 reference methodology on the Health Data Hub on May 17, 2024 (file 17911496), and publicly registered on ClinicalTrials.gov (NCT06939634).

Primary outcome

The primary goal of the study was to evaluate the safety of the off-label use of the Atalante exoskeleton in patients with tetraplegia and high paraplegia. All reported AEs directly linked to the use of the exoskeleton were collected and categorized into the following categories: musculoskeletal, cutaneous (skin abrasion), cardiovascular (orthostatic hypotension), pain, and fractures. These events were further characterized as minor or serious based on the nature and the severity.

Descriptive data

To characterize the population, the following data were obtained for all patient:

- Age, gender, cause of injury or pathology, time since injury.
- Urinary and bowel status.
- Severity of the lesion using the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) [14].
- Pain assessment using the subjective Numeric Pain Rating Scale (NPRS)
- Cardiorespiratory status and history of orthostatic hypotension.

And the bone mineral density (BMD) reported in grams per square centimeter (g/cm^2) when available.

Secondary outcomes

This included:

- Spasticity: Modified Ashworth Scale (mean values for lower limb muscles on both sides) [15].
- Dependency on walking aids: Walking Index for Spinal Cord Injury, version II (WISCI II) [16].
- Independence in Activities of Daily Living: Spinal Cord Independence Measure (SCIM III) [17].

Training features

The overall number of sessions and the content of each session was collected, including duration, number of steps, and specifics for each training mode.

The reason(s) for discontinuing sessions (if any) were collected, that might include AE or patient's decision.

Atalante device description

The Atalante exoskeleton is an 80 kg powered, motorized external orthosis designed to assist individuals with paralyzed limbs in achieving self-ambulation without the use of crutches or other technical aids (Fig. 1). It offers multiple gait training options, such as forward, lateral and backwards walking, as well as U-turn and direction changes. The



Fig. 1 Atalante exoskeleton.

exoskeleton is operated using a keyboard for the operator and a remote control, accessible to both the operator and the participant. Movement is initiated by the participant through trunk flexion or by sideways leaning and detected by inertial sensor (IMU) on the vest. This device operates in two independent modes: *EarlyGait* (short steps) and *RealGait*, the latter mimicking a physiological gait pattern with heel-to-toe movement. This is achieved through the use of twelve actuators - 3 in each hip, 1 in each knee, and 2 in each ankle. In *ActiveGait* mode, the operator can customize the level of robotic assistance during walking, adjusting how the effort is shared between the patient and the device ranging from fully passive (100% device assistance) through assisted and active gait (between 0 and 100% assistance) to resistance mode (negative assistance between 0% and -25%). The *Exercise mode* allows the performance of weight-shifting exercises as well as squat movements, which are triggered and controlled by the patient's movements detected through the IMU. Atalante is designed to be used in combination with a safety rail. Trunk support is ensured by a plastic shell back, with the subject's trunk secured to the exoskeleton using a vest. The back support is linked to the exoskeleton's lower limbs, which feature adjustable straps at the thighs, knees, and ankles, to securely fasten the patient's lower limbs.

Statistical analysis

Safety outcomes were computed as the proportion of AE per patient, in respect to number of sessions performed in the study. The overall AE rate was determined by averaging the observed AE rates across all patients, with a 95% confidence interval (CI95%) [18, 19]. Descriptive data are presented as median and interquartile range (IQR).

Changes in the secondary outcome measures before (Baseline) and post-training sessions (Post-training) were assessed using the non-parametric Wilcoxon tests or sign test. All statistical analyses were performed using the XLSTAT (version 2022.1), and R statistical software (version R 4.1.2, R-studio Inc., R Core Development Team).

Table 1. Description of the population.

	All	Tetraplegia	High Paraplegia
Patients	33	22	11
Sex (Female /Male)	8 / 25	5 / 17	3 / 8
Age (years)	38 (IQR: 25–52)	36.5 (IQR: 24.3–45.3)	52 (IQR: 26.5–54)
Time since injury (years)	0.8 (IQR: 0.4–1.8)	1.1 (IQR: 0.5–2.4)	0.4 (IQR: 0.4–0.8)
Levels of Injury	C4–T4	C4–5: 13 C6–7: 9	T1–4: 11
Severity (AIS)	A-B: 22 C-D: 11	A-B: 12 C-D: 10	A-B: 10 C-D: 1
Micturition mode			
Intermittent catheter	20	11	9
Spontaneous micturition	6	5	1
Indwelling catheter	7	6	1
Bowel program			
Manual removal	18	10	8
Suppository alone	6	6	-
Transanal irrigation	1	-	1
Normal	8	6	2
Spasticity (Ashworth Scale) (n = 29)	0–1: 24 2–3: 5	0–1: 16 2–3: 3	0–1: 8 2–3: 2
Pain (NPRS) (n = 32)	2.5 (IQR: 0–5)	0 (IQR: 0–4)	4 (IQR: 0–5)
N patients with no pain (NPRS = 0)	15	11	4
Bone mineral density	n = 17	n = 10	n = 7
Spine T-Score (min / max)	−1.9 / 1.9	−0.7 / 1.9	−1.9 / 1.8
Hip T-Score (min / max)	−2.9 / 0.7	−2.9 / 0.7	−2.0 / −0.1
Knee density (g/cm ²) (min / max)	0.6 / 1.2	0.6 / 1.2	0.6 / 1.1
Ability to walk			
No (WISCI = 0)	26	16	10
Yes (WISCI = 1–19)	7	6	1

Data are presented as median (IQR), along with counts, where applicable.
 AIS American spinal injury association impairment scale grade, NPRS numeric pain rating scale, WISCI walking index for spinal cord injury, version II.

Table 2. Level of injury and severity of the lesions.

	A	B	C	D	Total
C4	2	2	3	2	9
C5		1	2	1	4
C6	1	1	1	1	4
C7	1	4			5
T1		1			1
T2	2	1			3
T3	1		1		2
T4	3	2			5
Total	10	14	6	3	33

participants were treated as inpatients and four as outpatients. With the exception of one patient who left the clinic immediately after his only first exoskeleton session, all participants remained hospitalized for at least two days following their final session (2–7 days: $n = 8$; 8 days or more: $n = 24$). Additional descriptive characteristics are provided in Tables 1 and 2.

Most patients were on intermittent catheterization ($n = 20$), performed manual evacuation of stools ($n = 18$), exhibited slight or no spasticity ($n = 24$), and reported no pain ($n = 15$).

Regarding Bone Mineral Density, knee density was ≥ 0.6 g/cm², while spine and hip T-scores were all ≥ -3.5 for all patients ($n = 17$).

Before the first session, 7 patients (all with motor incomplete lesions) were able to walk.

All 33 patients had experience with vertical or standing position before using the Atalante device. Six patients had a recent history of orthostatic hypotension and were prescribed Midodrine. Twenty-three patients were wearing compressive devices including elastic stockings and/or abdominal bindings; this information was not available for 9 patients.

Training features

In total, 546 rehabilitation sessions were performed. The overall median count of performed sessions was of 7.5 (IQR: 3–22.5), ranging from 1 to 79. The median session duration (including transfer, and effective training) was 30.5 min (IQR: 25.6–36.9). The median duration of verticalization was 22.4 min (IQR: 18.0–26.9). Patients took a median of 583.0 steps per session (IQR: 347.0–854.0). Exercise mode represented only a minor proportion of total session verticality time, with median usage of 0% and usage reaching up to 10% in the upper quartile.

Patients with motor incomplete SCI ($n = 8$) having used Active mode performed a median of 689.0 steps (IQR: 269.5–1039.5) with a median device assistance of 71.4% (IQR: 62.6–79.7). When the exoskeleton was used in Active mode, this mode accounted for a median of 82.6% of the total session verticality duration (IQR: 61.8–88.3%).

Discontinuation of sessions

Two patients discontinued the sessions:

The first patient, a 41-year-old male with a traumatic C5 (AIS D) SCI sustained 2 months earlier, discontinued after the second session. He expressed apprehension about using the exoskeleton and had difficulty with body representation. Despite introducing co-therapy with another healthcare professional, he ultimately requested to discontinue the sessions.

The second patient withdrew after 15 sessions due to the adverse event described below.

The remaining 31 patients completed their rehabilitation without prematurely discontinuing the exoskeleton sessions.

RESULTS

Descriptive data

The data from thirty-three patients with SCI were retrospectively analyzed; 8 women and 25 men, with a median age of 38 years (IQR: 25–52) and a median time since of injury of 0.8 years (IQR: 0.4–1.8) post-injury. Of these, 32 patients had a traumatic SCI, 1 had a non-traumatic SCI secondary to transverse myelitis, 22 presented with tetraplegia (as defined by the ISNCSCI [14]), and 22 had a motor complete (AIS A or B) lesion. All participants completed at least one training session, with a median number of sessions of 7.5 (IQR: 3–22.8) (range: 1–79). Twenty-nine

Primary outcome measures

One minor device-related AE was reported in one patient, a 52-year-old man who sustained a traumatic SCI resulting in high paraplegia (T1 AIS A) and had a history of orthostatic hypotension and neuropathic pain, that started the training with the exoskeleton one year post-injury. One month later, he complained of increased pain and fatigue. His treatment included midodrine (5 milligrams in the morning), Gabapentine (300 milligrams thrice a day) and duloxetine (30 milligrams a day) and was not changed.

One month later (and a total of 12 sessions of exoskeleton training), he complained of more pronounced fatigue with dizziness and hypotension (systolic blood pressure ≤ 90 mmHg), after each of the 3 next training sessions, which led to the discontinuation of the training after the 15th session. The AE was classified as cardiovascular.

No other musculoskeletal or cutaneous issues, pain increase or fractures occurred.

For each patient, the proportion of AE was as follows:

- 0% for 32 patients who performed between 1 and 79 sessions,
- 20% for the patient who performed 15 sessions in total and experienced cardiovascular AE during his last 3 sessions.

Additionally, this indicates that 1 out of 33 patients experienced a device-related AE. For all sessions, the estimation of the rate of AE per-session was 0.63% (CI95% = -0.56%; 1.81%).

Secondary outcome measures

The WISCI II score remained unchanged for the 22 patients with motor complete lesions. Out of the 11 patients with motor incomplete (AIS C or D) lesions, 9 improved their score (Fig. 2). There were 8 patients with tetraplegia and 1 with paraplegia, 5 of them were within 6 months after their SCI. Those patients with positive changes completed a median of 6.0 sessions (IQR: 6–16) that spanned over 6 weeks.

Spasticity ($n = 23$) was unchanged in 13 patients, worsened in 6 (from 0 to 1 or 1 + on the modified Ashworth scale) and improved in 4.

The global SCIM score improved by a median of 2.5 points (IQR: 0–7) (from 34 to 47, Wilcoxon test, $p = 0.028$) in the 10 patients for whom data were available, including 8 with motor complete lesions and 2 with motor incomplete lesions. The improvement

was found in each subscale, significantly for the self-care (from 8.5 to 13.0, $p = 0.042$) and the mobility (from 10.0 to 12.0, $p = 0.038$) subscales, but not for the respiration and the sphincter management subscale (from 16.5 to 22.0, $p = 0.109$).

DISCUSSION

In this retrospective study, the data from 33 patients with high SCI across 3 rehabilitation centers were analyzed and demonstrates that gait training with the Atalante exoskeleton is feasible for patients with tetraplegia and high paraplegia, regardless of neurological level of injury and severity of lesion.

Only one non serious cardiovascular AE was observed in a patient with motor complete high paraplegia, likely resulting from hypotension and fatigue.

Hypotension, defined as a systolic blood pressure ≤ 90 mmHg and/or a diastolic blood pressure ≤ 60 mmHg, is common in patients with SCI and high level of lesion [3, 20]. Chronic low blood pressure can result in fatigue, dizziness, and cognitive impairments [21]. This condition can be exacerbated by medications for neuropathic pain or depression [22]. Oral midodrine helps stabilize blood pressure and may also have long-term benefits on cognitive function in the long term [23]. Fatigue is another frequent symptom in individuals with SCI, and is influenced by factors such as anxiety, stress, depression, pain, analgesic use, lesion level, and medication [24]. Moreover, walking in an exoskeleton is physically demanding, particularly for patients with motor complete high SCI, as it requires some effort to maintain trunk balance within the device. In this patient, fatigue, hypotension and pain management medications likely interacted leading to poor tolerance of physical exercise.

Orthostatic hypotension is a common condition in patients with high SCI that can significantly impact their daily living activities [3, 22] and has also been observed during exoskeleton rehabilitation [25]. Preventive measures such as pressure garments including abdominal binders and compression stockings are widely used and were employed by nearly all patients with available information in this study. Additionally, 6 patients with clinical history of orthostatic hypotension were on Midodrine, a commonly prescribed drug for this condition. While patients with high SCI are more prone to experiencing orthostatic hypotension, our observations suggest that blood pressure stabilizes or even

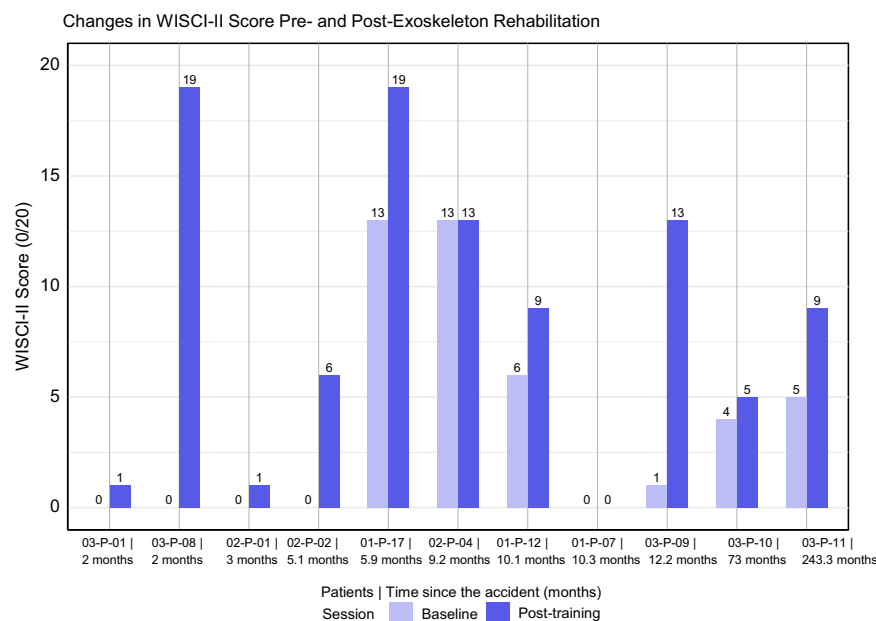


Fig. 2 Changes in WISCI II Score Pre- and Post-Exoskeleton Rehabilitation for patients with motor incomplete lesions.

increases once walking begins, likely to the effects of physical exercise (unpublished data). Intensive locomotor training can also trigger improvements in resting arterial blood pressure and responses to orthostatic stress in individuals with clinically complete cervical SCI [26]. This could explain why orthostatic hypotension did not present a significant issue in the present study.

Clinical studies of comparable devices have reported skin breakdowns [6, 8, 27–29] found at every skin-device contact point. The absence of AEs related to skin issues observed in this study may be attributed to the careful selection and preparation of patients prior to gait training, adherence to the manufacturer's recommendations (height and weight, correct donning and alignment) [30], or to the design of the Atalante exoskeleton itself [31]. Recent research of hazardous situations during exoskeletons use highlights that misalignments account for 60% of skin damages, while mechanical issues contribute to 73.8% of observed injuries [32].

None of the patients in this study experienced bone fracture or musculoskeletal injuries. Notably, the Bone Mineral Density obtained in 17 patients were all within the exclusion criterion specific to the use of the Atalante exoskeleton in the United States (T-Scores ≥ -3.5).

None of the patients reported any significant increase in pain. Spasticity showed variations, slightly improved or worsened, that were not clinically relevant. Our study shows favourable changes in the SCIM score, which align with findings from other studies [33]. However, SCIM data were available for only a limited number of patients and should therefore be interpreted with caution.

The WSCI II improvement observed in nine patients with incomplete SCI is coherent with the available data in the literature, suggesting that exoskeleton rehabilitation could enhance functional gait [8, 33–35]. The clinical outcomes evolution observed in this retrospective study could motivate a future clinical efficacy trial.

Two out of the 33 patients discontinued the sessions: one due to a non-serious cardiovascular AE, and another due to apprehension. Patients with SCI often experience anxiety, depression, and changes in body representation, which are well-documented factors affecting their engagement and adherence to the rehabilitation, including robotic-assisted gait training [36, 37].

The median duration of verticalization was 22.4 min (IQR: 18.0–26.9). This duration aligns with recommendations for individuals with SCI, which suggest the use of a standing device for 30 min 5 times a week for positive impact on outcomes such as self-care and standing balance, range of motion, cardio-respiratory, strength, spasticity, pain [38]. Recent recommendations regarding exoskeleton rehabilitation in patients with SCI propose specific protocols for functional restoration (8 weeks/24 sessions) and cardiorespiratory rehabilitation (12 weeks/36 sessions), both following the same format of 60-min, 3 times a week [34].

As highlighted by Lapidou et al. (2021), the main motivation for suggesting the use of robotic devices/interventions was the therapist's belief that involving patients in such tasks would free clinician time and promote patient compliance by motivating them to engage in other functional tasks they might otherwise avoid [39]. In most cases, training sessions required one to two therapists for both donning/doffing and gait training, depending on the patient's neurological level of lesion, whether the lesion was motor complete or incomplete, and the type of lift used.

This study had several limitations. Being a retrospective study, the amount of data for each outcome varied based on the clinical routines of individual centers and the availability of healthcare professionals. Consequently, some statistical analyses were either not possible or performed on a relatively small patient sample, limiting the ability to generalize the findings to a broader population. The data were collected two times and with variable

numbers of sessions. Therefore, it may be difficult to attribute the observed changes directly to the Atalante exoskeleton sessions. The absence of a control group does not allow to judge the effectiveness of the exoskeleton rehabilitation interventions.

In conclusion, the retrospective analysis of AE data from patients with tetraplegia and high paraplegia who participated after risk-benefit assessment in at least one training session with the Atalante exoskeleton, shows that the device can be safely used in a clinical setting. The functional improvements detected in a subsample of patients are in the range of other forms of intense locomotor trainings.

New prospective studies, using standardized outcome measures, are needed to better define the place of exoskeleton in the rehabilitation of those patients with tetraplegia and high paraplegia.

DATA AVAILABILITY

All relevant data are within the article. The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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AUTHOR CONTRIBUTIONS

JGP, BH, JFB, VP and CC all conceived the work, conceived and the work that led to the submission, acquired data, Drafted or revised the manuscript, approved the final version and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. VP provided additional statistical assistance.

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COMPETING INTERESTS

The authors declare no competing interests.

ETHICAL APPROVAL AND CONSENT TO PARTICIPATE

All methods were carried out in accordance with relevant guidelines and regulations. The trial was registered under the reference methodology MR004 on May 17, 2024, on the Health Data Hub platform (file number 17911496) and was declared to the CNIL (reference 2234433 v 0) on May 16, 2024. A non-opposition form was distributed to all patients, and no objections were reported. In addition, written informed consent was obtained from the patient for the publication of accompanying image.

ADDITIONAL INFORMATION

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