CME

Hand Robotic Therapy in Children with Hemiparesis

A Pilot Study

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Objective: The aim of this study was to understand the impact of training with a hand robotic device on hand paresis and function in a population of children with hemiparesis.

Methods: Twelve children with hemiparesis (mean age, 9 [SD, 3.64] years) completed participation in this prospective, experimental, pilot study. Participants underwent clinical assessments at baseline and again 6 weeks later with instructions to not initiate new therapies. After these assessments, participants received 6 weeks of training with a hand robotic device, consisting of 1-hour sessions, 3 times weekly. Assessments were repeated on completion of training.

Results: Results showed significant improvements after training on the Assisting Hand Assessment (mean difference, 2.0 Assisting Hand Assessment units; P = 0.011) and on the upper-extremity component of the Fugl-Meyer scale (raw score mean difference, 4.334; P = 0.001). No significant improvements between pretest and posttest were noted on the Jebsen-Taylor Test of Hand Function, the Quality of Upper Extremity Skills Test, or the Pediatric Evaluation of Disability Inventory after intervention. Total active mobility of digits and grip strength also failed to demonstrate significant changes after training.

Interpretation: Participants tolerated training with the hand robotic device, and significant improvements in bimanual hand use, as well as impairment-based scales, were noted. Improvements were carried over into bimanual skills during play.

Key Words: Hemiparesis, Robotics, Children

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CME Objectives: Upon completion of this article, the reader should be able to: (1) Understand key components of neuroplasticity; (2) Discuss the benefits of robotic therapy in the recovery of hand function in pediatric patients with hemiplegia; and (3) Appropriately incorporate robotic therapy into the treatment plan of pediatric patients with hemiplegia.

Level: Advanced

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emiparesis in children is most commonly the result of unilateral spastic cerebral palsy occurring at an average frequency of 0.7 to 0.9 cases per 1000 in the United States.¹ Other causes of hemiparesis include pediatric stroke, traumatic brain injury, or tumor.^{2,3} Traditional therapy has focused on an exercised-based approach to introduce more typical movement patterns and facilitate motor development for children with hemiparesis. The efficacy of recent techniques, such as constraint-induced movement therapy and bimanual training, demonstrate the importance of active practice with high intensity of treatment.^{4–8} Active practice, with sufficient repetitions

and skill progression, is essential to induce neuroplastic changes within the motor system and improve performance in motor tasks.

The residual motor impairments of the upper extremity common in pediatric hemiparesis are similar to those in adult individuals who have survived stroke. 10 The use of robotics for hemiparesis after stroke is becoming more common with promising results.¹¹ The use of robotic devices to augment traditional therapy can provide highly reliable, reproducible exercise at a higher intensity or dose (as defined by the number of repetitions) than traditional approaches. 12 While in motor learning theory the focus is largely on the execution of functional motor tasks, a key tenet, which is shared between motor learning and robotics, is the importance of practice.¹³ The amount and type of practice a learner receives, how practice relates to the acquisition of a novel task or skill, and the improvement of skilled performance with continued practice are key elements of any exercise therapy.¹⁴

Robotic therapies are often combined with video gaming and primarily focus on learning at the impairment level. However, within a pediatric population, the use of these robotic technologies may improve motor acquisition because of an

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increased salience for the user. In essence, the use of robotics and video gaming within a pediatric population can improve motivation and attention while focusing on the practice of specifically difficult motor tasks. 13 Robotic therapy allows users to provide increased control and an increased dose of exercise for a given training session or over a given time. This ability to control practice and increase the intensity of practice during therapy could facilitate optimizing overall performance in pediatric populations with hemiparesis.

While the robotic literature in the adult stroke population has surged in the past 5 to 10 years, there remain few robotaided exercise training studies in pediatric populations. 15,16 Furthermore, in pediatrics, studies have primarily been limited to virtual reality training and telerehabilitation. While there are a number of devices that are used in adult stroke populations for retraining of the upper extremity, there has been limited focus on functional retraining of the hand. 11,17,18 This is even more apparent in the pediatric literature, as there has been very limited robotic therapy specifically for the wrist-hand to date. 19,20

The Amadeo Hand Robot System (Tyromotion GmbH, Graz, Austria) is designed to provide hand retraining and rangeof-motion exercises for patients with neurological or orthopedic conditions. Although designed for an adult population, the components of the device are easily adjustable to fit smaller/ larger hands, making it feasible for use in a pediatric population. The device has been tested in a population of adult stroke survivors, who have been able to effectively interact with it, but definitive efficacy data are not yet available. 18 The device has not previously been studied in a population of children with hemiparesis.

The purpose of this study was to determine the feasibility of using this device for retraining motor function, specifically grasping and opening of the hand, in children with hemiparesis and obtain preliminary evidence regarding efficacy.

METHODS

Participants

From 2011 to 2013, 14 subjects were recruited from an outpatient pediatric practice. Of these, 2 failed to complete study treatment, and their data were omitted from all analyses. A total of 12 subjects (7 female and 5 male subjects) aged 6 to 17 years (mean age, 9 [SD, 3.64] years) completed the study: 6 subjects with right-sided and 6 subjects with left-sided hemiparesis. The patients included in the study exhibited a range of medical diagnoses (e.g., hemiplegic cerebral palsy, tumor resection at birth, traumatic cerebral hemorrhage at 3 years); however, all participants demonstrated hemiparetic impairments of the upper limb, and all impairments were present prior to the age in which hand dominance is clearly established. Inclusion criteria required the child be at least 6 years of age for participation and have hemiparesis, limiting the function of the upper limb; at least trace (defined as 1/5 on the Medical Research Council scale) strength in at least 3 digits of the involved hand in both flexion and extension; and the child be fully integrated in a mainstream school program. All participants were required to follow multistep commands to participate. Children were excluded if they had received botulinum toxin injections to the affected limb within a 12-week period prior to study entry; had a history of another neurologic or genetic disorder; had previous hand or wrist surgeries; severe spasticity (defined as a Modified Ashworth >3); had contractures of the affected upper extremity that would interfere with the positioning or operation of the device; or had impaired sensation to light touch throughout the affected limb. All subjects were required to defer any further botulinum toxin treatments until after completion of study participation. Parents provided written consent, and children assented to participation. All study procedures were reviewed and approved by the institutional review boards from Columbia University Medical Center and Teachers College, Columbia University.

Device

The Amadeo Hand Robot System (Tyromotion GmbH) is designed to assist movement in finger flexion and extension and provide robotic-assisted exercise in conjunction with virtual gaming modes. Fingers are attached to the device via magnetic finger plates secured to the fingers with adhesives and connected via magnetic tabs to the finger slides on the device (Fig. 1). These finger slides can operate together (gross grasp/ release) or individually (finger individuation) based on settings, which are easily manipulated by the supervising therapist. Each finger slide also contains a force sensor, which by algorithms in the software determines magnitude and directionality of the force applied by the user. The force sensors collate the magnitude and direction of the forces applied to each of the slides. As a result, a vector is created that directly correlates with the summated forces of the finger slides in both magnitude and direction. This collated force vector is used to control





FIGURE 1. Photographs of the Amadeo hand robot device with and without fingers attached.

the gaming software. A computer monitor provides real-time feedback of flexion/extension movements of the digits and allows for real-time patient control of gaming modes.

Various safety features have been incorporated into the device design and software systems. Furthermore, the system is easily adjustable to hand size, which allows the device to easily adapt to use with a pediatric patient population.

Study Design

In this prospective, experimental, pilot study all participants underwent a series of 3 functional outcome testing sessions. Each participant completed initial pretest testing followed by a 6-week latency period and then a second pretest to control for the benefit/improvement of ongoing therapies in which the child was already involved. On completion of the 6-week latency period, subjects were reassessed and began treatment with the Amadeo hand robot device. All participants were seen 3 days per week in 1-hour treatment session blocks. Participants engaged in treatments for a total of 6 weeks after which a final posttest was given. For the duration of the trial, participants were allowed to continue in current therapies but were asked to not initiate any new treatments or therapies for the affected upper limb.

Intervention

Participants sat in a standard height (18-inch seat height) chair, and a cushion was placed behind the back and under the feet (if patient could not reach the floor) for maximum support. The affected upper limb was placed in the arm support, and fingers connected via the magnetic plates to the robot as described previously (Fig. 1). At onset of the first treatment session, the supervising therapist set device parameters to limit range of motion of the participants' hand to the available passive range. The values of the limits of range of motion were stored and used for all subsequent sessions.

The training paradigm was designed to allow the user to achieve a maximum amount of movement repetitions in hand/ finger flexion and extension during the course of a single session. Each session participants underwent a total of 6 minutes of range-of-motion activities with robotic assistance for which visual feedback was provided in the form of interactive smiley faces in each the flexion and extension moment. The robot assisted the participant to complete the entire range of motion in both flexion and extension directions previously set in passive range, and the participant was asked to assist the robot to complete the full range of motion. The size of the smile increased as participants increased the sum of the applied forces in the indicated direction (Fig. 2A). Participants then completed an additional 3 minutes of self-initiated active movement of the digits. In this mode, the robot allowed the participant to initiate the movement in the indicated direction (flexion/extension), and as the participant reached the limits of his/her available active range, the robot assisted him/her to achieve the full passive range. Following the completion of the range-of-motion exercises, participants then completed 6 minutes of participation in gaming modes (Fig. 2B). The gaming modes are controlled isometrically by the summation of magnitude and directionality finger forces applied by the user. The goal of the gaming modes was for the participant to move the indicator on the

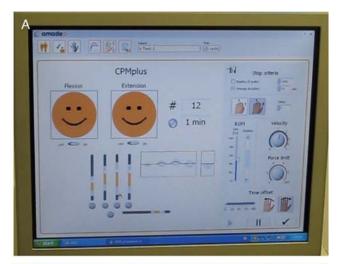




FIGURE 2. A, Photograph of the robot-assisted range-of-motion training mode with smile feedback. B, Photograph of one of the gaming modes in which the patient is required to move the water over the target to extinguish the fire.

screen (controlled by the user's finger forces) to reach a specific target. On gaming modes, there were 3 primary difficulty levels (easy, medium, hard) and 10 sublevels (1-10) within each primary level. Participants were progressed to the next difficulty sublevel by reaching 70% or more of the indicated targets. On successful completion of sublevel 10, participants were advanced to the next primary difficulty level. This series of activities (robot-assisted range of motion, patient-initiated range of motion, and gaming mode) was completed 3 times, successively, within 1 session for a total of 45 minutes of active therapy with the device per session. Participants were engaged in the entire session without breaks except for the time needed to switch to the next subsequent activity mode (maximum 30 seconds).

Outcome Measures

The Assisting Hand Assessment (AHA) was chosen as the primary outcome measure because of its ability to measure the integration and usefulness of the affected limb during typical play tasks. Specifically, this assessment examines the quality of use of the affected hand during bimanual tasks. It is a

video-taped assessment in which the administrator attempts to facilitate bimanual tasks of the child during reaching and grasping in a functional context of play. Reliability and validity have been established within hemiplegic children younger than 12 years. 21,22 As a secondary functional outcome, we included the Jebsen-Taylor Test of Hand Function (JTTHF), a timed assessment composed of 7 subtests including such tasks as manipulation of small objects (e.g., checkers, paper clips), picking up weighted and unweighted can goods, and simulated feeding tasks. ^{23,24} The upper-extremity portion of the Fugl-Meyer (UEFM) scale was also used as a secondary impairment-based measure and is a scale in which the patient is asked to perform movements considered to reflect the sequential stages of motor recovery and the ability to perform selective movements. It consists of 32 items, rated on a 3-point ordinal scale. It is included here because of its common use in the adult stroke patient population^{25,26} and has recently been used in the pediatric population, but reliability and validity have not yet been established for this patient group. 27–30 Further secondary measures of the quality of hand and upper-limb functional movement included the Quality of Upper Extremity Skills Test (QUEST). The test is composed of 4 subscales including dissociated movements, grasps, weight bearing, and protective extension, scored by an observing therapist on a 2-point ordinal scale.³¹ The Pediatric Evaluation of Disability Inventory (PEDI) was also used as an observational assessment of functional skills in the areas of self-care, mobility, and social function. ^{32,33} Other, secondary outcome measures included Total Active Mobility (TAM), a measure of net range of motion of each of the digits of the hand 18 and grip strength as measured by hand dynamometry, as these impairments were the specific target of the training.

Statistical Analysis

Results of primary and secondary outcomes were recorded during the 3 testing periods, and these results were statistically analyzed using descriptive statistics and a repeatedmeasures, 1-way analysis of variance with the use of IBM SPSS Statistics for Mac, Version 21.0 (IBM Corp, Armonk, NY). Sphericity was evaluated with Mauchly test, and was violated only within the measures of the QUEST outcomes. In this instance, the Greenhouse-Geisser coefficient was used to correct the degrees of freedom. A significance criterion of P < 0.05 was set to determine if significance was achieved. The least significant difference (LSD) was used for post hoc analysis.

RESULTS

Of the 12 participants who completed study requirements, no complications or complaints occurred. Performance during training was recorded by advancement on the gaming modes. All subjects initiated gaming activities on "Easy," sublevel 1. All subjects were successfully able to reach the "Hard" primary level, with a final mean sublevel of 7.46 (SD, 3.50) of the "Hard" primary level. Range-of-motion activities were performed to the preset passive range of motion and remained consistent throughout the training. The 2 subjects who were older than 12 years were not included in the analysis of the AHA data.

Results of the AHA demonstrated a significant overall main effect, P = 0.011 (Table 1). Post hoc analysis of the LSD revealed nonsignificant changes between the 2 pretest measures. However, significant improvements were noted between the pretests and posttest measures (mean improvement of 2 AHA units, P = 0.03) (Fig. 3).

The JTTHF also showed a significant main effect of testing session, P = 0.011 (Table 1). On further post hoc analysis of the LSD, there was no significant difference noted between the 2 pretest measures; however, the change between the second pretest and the posttest (mean decrease in time, 41.310 seconds) approached significance (P = 0.055) (Fig. 4).

There was an overall significant main effect noted in the UEFM as well, P = 0.001 (Table 1). Least significant difference post hoc analysis revealed a nonsignificant change between the 2 pretests; however, a highly significant improvement between the second pretest and the posttest was observed (P < 0.05), during which the mean value of the raw score improved 4.33 points (Fig. 5). In addition, the UEFM was broken down into proximal (shoulder/elbow) and distal (wrist/hand) components. Analysis-of-variance results revealed no significant changes within the proximal upper limb; however, a significant main effect was noted within the distal upper limb (P = 0.003), and

TABLE 1. Mean scores (SD) with corresponding F values, degrees of freedom (df), significance, and η^2 (effect size) values for all outcome measures

Measure	Pretest 1 Mean (SD)	Pretest 2 Mean (SD)	Posttest Mean (SD)	F	df, Error	P	Partial η^2
AHA units ^a	55.50 (11.65)	57.40 (12.92)	59.40 (12.55)	5.905	2, 18	0.011	0.396
$JTTHF^a$	781.2 (383.9)	741.6 (386.5)	700.3 (389.4)	5.571	2, 22	0.011	0.336
$UEFM^a$	34.75 (10.24)	34.08 (10.11)	38.42 (11.50)	9.136	2, 22	0.001	0.454
Proximal UEFM	25.25 (3.93)	24.92 (4.78)	26.50 (4.64)	2.227	2, 22	0.132	0.168
Distal UEFM ^a	8.00 (6.31)	7.25 (5.93)	9.25 (6.80)	7.592	2, 22	0.003	0.408
Grip strength	4.04 (3.12)	4.40 (3.00)	3.97 (2.81)	1.017	2, 22	0.378	0.085
TAM	795.50 (207.59)	791.92 (270.16)	815.42 (257.29)	0.316	2, 22	0.733	0.028
QUEST	55.45 (17.06)	55.78 (17.31)	60.18 (18.12)	4.066	1.307, 14.374	0.054	0.27
QUEST part A	71.62 (13.00)	69.27 (15.30)	71.09 (15.27)	1.465	2, 22	0.253	0.118
QUEST part B ^a	39.51 (22.96)	42.28 (21.04)	49.99 (24.08)	5.278	1,366, 15.023	0.028	0.324
PEDI Functional Skills ^a	12.973 (5.99)	15.10 (5.60)	18.064 (8.07)	6.137	1.147, 11.471	0.027	0.38
PEDI Caregiver Assist	39.05 (6.36)	39.73 (10.09)	42.75 (8.90)	1.305	2, 20	0.293	0.115

^aDenotes main effect statistical significance.

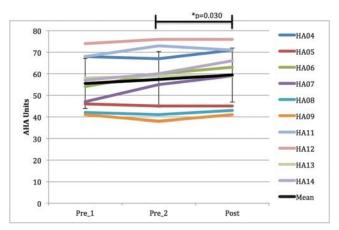


FIGURE 3. The AHA plot by individual subject over the 3 testing sessions. Group mean illustrated by black line with error bars indicating SD. A higher score indicates more integration of the affected limb into bimanual movements.

further LSD post hoc analysis did show significant improvement (Table 1) between the pretest and posttest (P = 0.001).

Results of the QUEST approached, but failed to reach, an overall significant main effect (Table 1) of testing session; however, examination of the individual components of the QUEST showed a significant main effect for grasp (part B) with a mean score improvement of 7.712 (P = 0.028) (Table 1). Yet, changes between pretest and posttest did not reach significance on LSD post hoc analysis. No significant changes were noted in dissociated movements (part A).

The Functional Skills portion of the PEDI demonstrated an overall main effect (mean score improvement, 2.964; P =0.027) (Table 1), which, on LSD post hoc analysis, failed to reach statistical significance from pretest to posttest time points. There was no statistical improvement noted on the Caregiver Assist portion of the PEDI or on TAM or grip strength with training (Table 1).

DISCUSSION

This pilot study found that pediatric individuals with hemiparesis were able to successfully tolerate training with

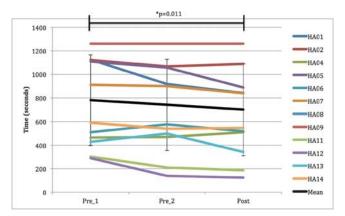


FIGURE 4. The JTTHF plot by individual subject over the 3 testing sessions. Group mean illustrated by black line with error bars indicating SD. A decline in time (faster) indicates better performance.

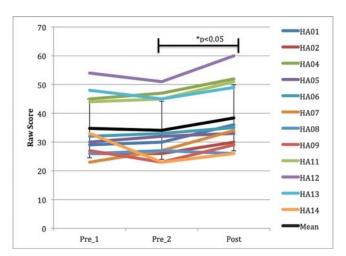


FIGURE 5. The UEFM plot by individual subject over the 3 testing sessions. Group mean illustrated by black line with error bars indicating SD. A higher score indicates better performance.

the Amadeo hand robot device and demonstrated decreased limitations in impairment-based hand measures with carryover to improvements in their ability to perform bimanual skills tasks during play activity.

Based on the results of the study, it appears that for the JTTHF the grasp (part B) component of the QUEST and the Functional Skills component of the PEDI the results individuals received from training with the device were comparable to that which they were already receiving through more conventional means, although trends in the JTTHF suggest possible improvements, although underpowered to reach full significance. This is an interesting finding, however, as impairment-based measures (the UEFM) and bimanual activity-based measures (the AHA) did demonstrate significant improvements over that of which they were already receiving. Considering the overall gradual gains in performance on both the AHA and the JTTHF, it is plausible that the results reflect the gradual improvement seen with more traditional approaches and only modest true gains when robotic training was added. Another possible interpretation of the results of the AHA as compared with JTTHF could be held in understanding of the nuances of each of these measures, respectively. It is conceivable that gains were indeed made and able to be translated into play tasks; however, the JTTHF is a measure of unilateral dexterity evaluated by time of task performance, and although the participants may have been performing tasks more proficiently, without the aid of the unaffected limb, it may have taken them longer to complete the given activity. In a setting wherein skill performance is not restricted to only the affected limb, the participants were more apt to integrate the affected limb into bilateral play and potentially perform tasks more proficiently.

Gains noted on the UEFM from this study are comparable with other upper-limb robotic studies previously performed in populations of adult stroke survivors^{11,18,34,35} and do reach clinically meaningful values.³⁶ On examination in more detail, gains in this study were noted wholly within the distal component of the upper limb. Consistent with these findings, the robotic training that participants underwent was limited to training primarily at the level of the hand. This suggests that the improvements noted were directly related to the components trained.

Furthermore, impairment-based improvements (as measured by the UEFM) could possibly carry over into functionality of the affected limb (as seen by improvements on the AHA) when subjects are required to use their affected limb to complete a bimanual motor task. However, these results should be interpreted with caution, as the gains on the AHA do not reach the clinically meaningful threshold.³

Unfortunately, although overall gains were seen on the JTTHF, grasp (part B) of the QUEST, and the Functional Skills scale of the PEDI, these gains were not meaningfully significant over the period in which the intervention was given. This is an interesting finding considering the significant gains noted on both the UEFM, an impairment-based measure, and the AHA, a bimanual skills-based measure. From an International Classification of Functioning, Disability, and Healthy model, the results on the AHA lead one to believe that some functionality of the hand has been restored, enough to improve engagement in bimanual activity. However, contradicting these findings is the lack of significant evidence in other skills-based tests (JTTHF, QUEST, PEDI). Whereas the UEFM showed gains centered in impairment, no direct gains were seen in range of motion or grip strength, posing a question as to where exactly these impairment gains were made.

In addition, increased tone, or spasticity, is often seen concomitantly with hemiparesis and typically affects flexor more than extensor musculature; thus, individuals with hemiparesis often have more dysfunction in opening their hand than in closing it. While a measure of spasticity was used as part of the exclusion criteria, the amount of muscle tonus was not measured at each of the individual testing periods, and thus it is unclear as to the effect this training possibly had on muscle tone. This is acknowledged as a limitation of the current study. Clinically, botulinum toxin is commonly used to manage spasticity in patients and decrease these contributing limitations to function. 38-40 The participants in this study had not received dosing of botulinum toxin 12 weeks prior to study participation and deferred additional dosage until after completion. While the device paradigm used in this study specifically focused training on strength, particularly on gross extension of the digits, maximizing the use of the full range of finger motion, in both flexion and extension, and coordination of the digits during flexion and extension tasks, it is plausible that the lack of medical management to spasticity throughout the study could have prevented further potential gains. Furthermore, the measurement of grip strength in particular is taken in a flexion moment, and any improvements in extension would not be reflected in these results.

The gains seen in the UEFM and the AHA may have improved some impairment level skills in grasp, but not have contributed to improve overall dysfunction in performing personal tasks, particularly not affecting the amount of assist caregivers are required to provide. Furthermore, the mean age of participants in this study is 9 (SD 3.64) years, which is well after the primary developmental period. Also, all participants were fully integrated into mainstream school programs, suggesting this population was relatively high functioning prior to participation. These factors could contribute to a possible ceiling effect for gains in disability scales.

Moreover, the Amadeo hand robotic device focuses training only on the distal component of the affected upper limb. It is plausible that because no robotic or other training was given to more proximal components of the upper limb the lack of proximal training limited the individual's ability to fully integrate the use of the hand into daily tasks. This would clarify why improvements were noted at the level of the hand on the UEFM and the AHA, and no gains were noted on other scales, such as the JTTHF, the QUEST, and the level of caregiver involvement of the PEDI.

Limitations of this study include the small number of study participants, the absence of a control group, the heterogeneity of the pathological diagnosis leading to hemiparesis, the lack of integration of a home exercise program that would allow participants to incorporate impairment-based gains into functional tasks with the affected upper limb, and the training constraint solely to the affected distal extremity as compared with whole-limb training or bilateral limb training that would more likely yield changes functional-based daily tasks. These limitations impede the participant's ability to transfer impairmentbased and skill-based gains into overall improvement of disability, thus questioning the overall efficacy of this training approach as a standalone therapy alternative. Further limitations include the lack of additional follow-up assessments to determine if the gains these participants did make were maintained over time.

Future studies should be undertaken examining the use of novel robotic therapies within the pediatric hemiparetic population with a larger number of subjects and either in conjunction with home based therapies or in conjunction with other therapies to the entire affected extremity, instead of restricting therapies to only 1 limb segment. The results of this study can be used for power analyses for future controlled trials. Further considerations should be made to better integrate impairmentand skills-based training into daily functional tasks to improve carryover and allow for more meaningful changes to individuals with hemiparesis.

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