International Journal of Physical Medicine & Rehabilitation

OPEN ACCESS Freely available online

Research Article

Novel Bimanual Polyform Device for Hand Neurorehabilitation after Acute Ischemic Stroke

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ABSTRACT

Background: Stroke is a major public health challenge in the United States, with nearly 800,000 strokes occurring per year. Most of these are acute ischemic strokes. There are almost 8 million stroke survivors living in the United States. Approximately 80% of strokes involve the upper extremity and hand, which are vital for maintaining independence. Notably, approximately 50%-80% of these patients do not regain robust hand function.

Purpose: This study aimed to determine whether larger studies should be conducted to assess the usefulness of bimanual neurorehabilitation using a novel polyform device for hand recovery after stroke.

Study Design: Single-center observational cohort study.

Methods: Eight patients with acute ischemic stroke resulting in moderate-to-severe paresis of the hand and upper extremities were enrolled. Patients were monitored and received Occupational Therapy (OT) according to the established protocol. Participants were also provided with a polyform bimanual device and instructed to use it for 5 minutes four times per day, with one of these sessions performed in conjunction with OT. Patients were followed up by telephone at three months to report their recovery level. The recovery rate of the group was calculated from these reports. The expected outcome comparator was set at a 30% recovery rate, and Fisher's exact test was performed to compare the results.

Results: All eight enrolled patients reported normal hand function at the three-month follow-up. This result was considerably higher than that of standard therapy alone. Fisher's exact test, which was used to compare the results with an expected normal or near-normal recovery rate of 30%, yielded a p-value of 0.007.

Conclusion: Incorporating a polyform bimanual device in bimanual neurorehabilitation may improve the recovery rate of hand function after acute ischemic stroke and should be considered. Additional studies with larger cohorts and more robust bimanual outcome measures may prove fruitful.

Keywords: Stroke; Neuroplasticity; Neurorehabilitation; Hand; Bimanual; Rehabilitation

INTRODUCTION

Stroke is a significant public health issue in the United States, with nearly 800,000 strokes occurring annually. Of these, approximately 600,000 are first-time strokes, whereas approximately 190,000 are recurrent. Ischemic strokes account for roughly 85% of all cases [1]. Approximately 20% of stroke victims die [2], and about 8 million Americans are stroke survivors [3]. A major contributor to disability among survivors is impaired hand and upper limb function, which frequently persists to a chronic stage, leading to long-term deficits and reduced independence in activities of daily living [4,5]. About 80% of strokes result in compromise of an upper extremity [6]. Most data suggest that less than 50% (as low as 15%) of survivors of ischemic stroke regain significant hand function at 6 months [7,8]. Notably, hand function has been previously shown to predict arm function [9,10]. Unfortunately, recovery rates have remained stagnant for decades [9], which has prompted a search for innovative rehabilitation tools and methods, as well as the quest for a better understanding of the underlying

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Received: 19-Jun-2025, Manuscript No. JPMR-25-37701; Editor assigned: 23-Jun-2025, PreQC No. JPMR-25-37701 (PQ); Reviewed: 07-Jul-2025, QC No. JPMR-25-37701; Revised: 14-Jul-2025, Manuscript No. JPMR-25-37701 (R); Published: 21-Jul-2025, DOI: 10.35248/2329-9096.25.S31.001.

Citation: Epley R, Barr L (2025). Novel Bimanual Polyform Device for Hand Neurorehabilitation after Acute Ischemic Stroke. Int J Phys Med Rehabil. S31:001.

neurological framework of hand and upper limb function. One of the methodologies being actively studied is bimanual neurorehabilitation [8], which is based on three key premises: 1) the majority of daily hand engagements are bimanual tasks; 2) there are complex, subtle coordination networks linking the two hands, allowing robust, dynamic bimanual hand function; and 3) there is ongoing neuroplastic activity in the adult brain that may be engaged by bimanual activity during recovery [11-13].

Bimanual devices are often complex and costly computerized or robotized devices, and their deployment in the acute setting presents considerable challenges. Despite displaying promising results, simple options, such as mirror therapy, are more commonly used in the chronic phase (or rarely in the subacute phase) [4, 14-16].

Importantly, recovery after stroke exhibits a logarithmic pattern, with more substantial improvements occurring early in the course, and then tapering off [17]. In consideration of this, a novel bimanual device, termed a polyform, was developed to provide a low-cost bimanual neurorehabilitation tool that is rapidly deployable and suitable for use in the acute setting (Figure 1).

METHODS

Patients diagnosed with acute ischemic stroke resulting in moderate-to-severe paresis of the hand and upper limb were instructed by an occupational therapist on how to use a novel polyform device, and instructed to utilize it for 5 minutes, four times per day, as part of their hand therapy. Proper use of the device was demonstrated to the patients. Exercises included coordinated, alternating squeeze/release/turn sequences. The enlarged knob segment of the device was engaged with the more compromised hand in a performing role, and the paddle segment by the less compromised hand in a supporting roll. All participants provided written informed consent, including consent for publication. Additionally, patients performed routine occupational therapy according to the established protocol of the facility. The inclusion criteria were normal cognitive function, acute ischemic stroke with resultant impairment of the hand and upper limb, no previous impairment of the hand or upper limb, and possessing two hands. The exclusion criteria were encephalopathy or other impaired cognition, prior ipsilateral hand impairment excluding arthritis, having only one hand, refusal to provide consent, and plastic allergy. The patients were also provided with standard putty and squeezer-type tools, and therapist-directed rehabilitation. They were followed up by telephone at three months to report their hand function. A presumed 30% of the patients who would report normal or near-normal hand recovery was used as the expected outcome.

Fisher's exact test was used to assess disparities between the expected and observed outcomes.

A null hypothesis of polyform use leading to no statistical difference between the observed and expected outcomes was used, with statistical significance set at $p<0.05$.

Whether bimanual therapy with a novel polyform device affects the clinical outcomes of hand function at 3 months was assessed. The null hypothesis was that use of the polyform device would not lead to a statistically significant difference between the reported hand function and the expected recovery rate of 30% (Figure 2 and 3).

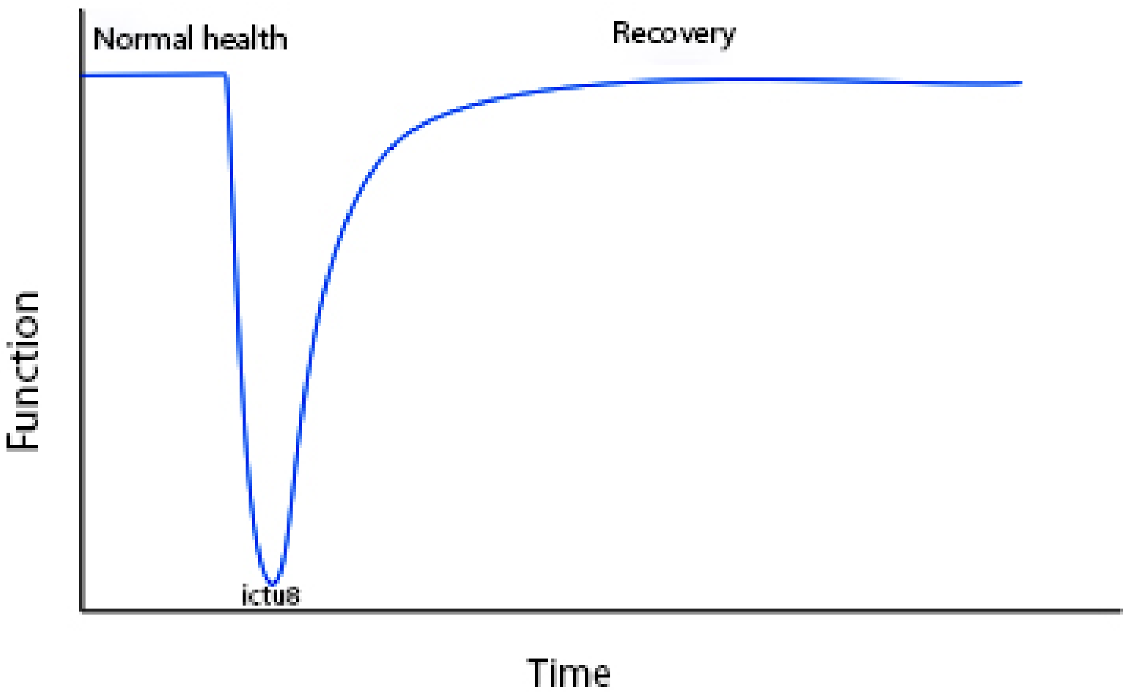

Figure 1: Adapted version of a logarithmic recovery plot.

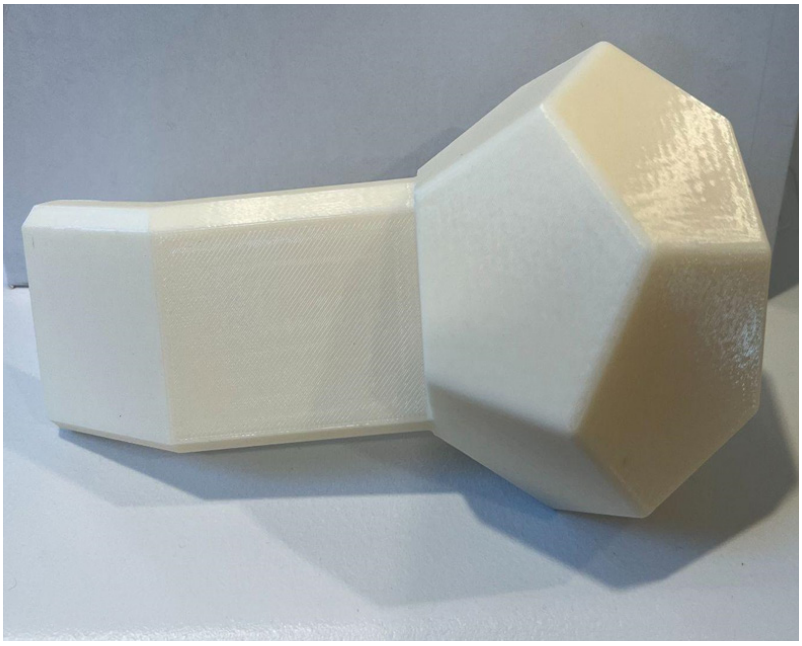

Figure 2: Image of the polyform bimanual neurorehabilitation tool.

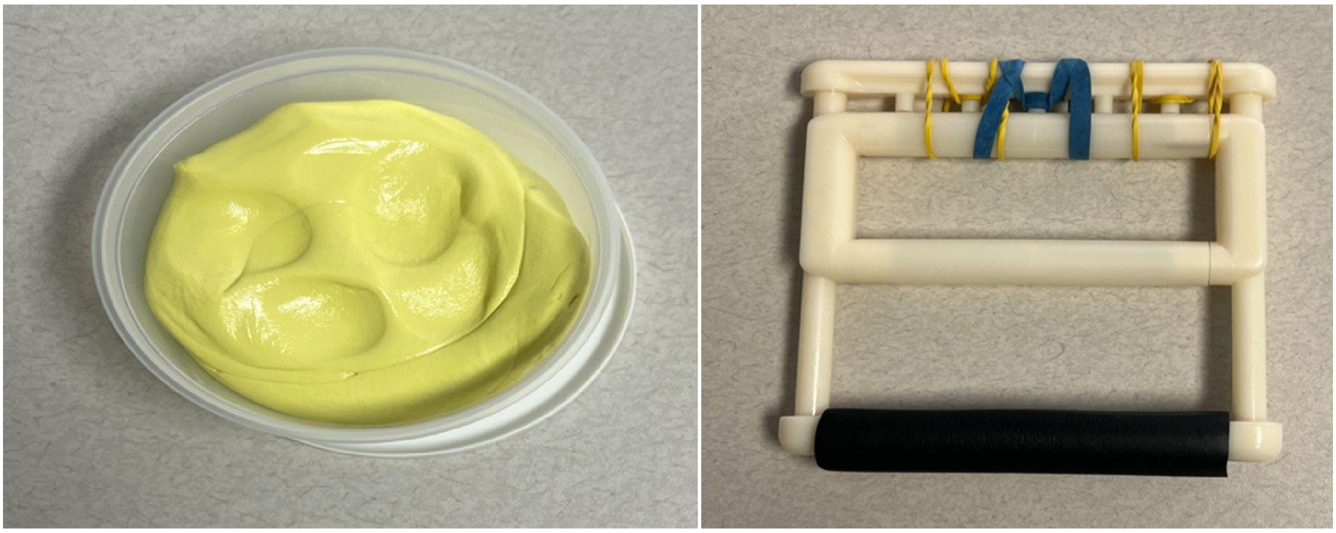

Figure 3: Image of 'legacy "putty" and "squeezer" devices' commonly used for hand rehab in the acute setting.

RESULTS

A total of eight patients were included (women: 5, men: 3; mean age: 67 years; mean National Institutes of Heath Stroke Scale score: 7 [range: 4-11]; Average duration of hospitalization: 6 [range: 3-15] days). All eight patients reported normal or near-normal hand function at three months. Using a 30% cut-off for the report of normal or near-normal recovery as the expected outcome, one would expect 2 out of 8 patients to recover. Fisher's exact test yielded a p-value of 0.007. This was below the cut-off value of $p<0.05$, thereby rejecting the null hypothesis.

DISCUSSION AND LIMITATIONS

The present research examined the impact of a novel polyform device on the mobility and hand function of patients with acute ischemic stroke. Ongoing advancements in hand function devices for patients with stroke, such as bimanual neurorehabilitation modalities, show great potential. Among the eight patients who utilized the polyform device, all reported normal functioning, with no notable hand deficits after three months. It appears that incorporating bimanual therapy devices into rehabilitation programs for patients with stroke significantly enhances recovery. The limitations of this study include the small sample size, lack of a diverse population, and absence of validated outcome measures. Despite these limitations, the study's strong statistical signal, and the excellent outcomes in the user group suggest that bimanual devices, including of the polyform type, merit further investigation with larger randomized cohorts.

Bimanual therapy is an effective means of restoring and creating new neuronal circuits following an ischemic stroke. The use of devices that engage both limbs has been shown to increase motor capabilities in short- and long-term follow-up studies. Previous research has demonstrated the integration between the left and right arms during neural control of symmetrical bimanual motor actions [18]. Additionally, the combination of bimanual therapy and electrical stimulation, has been shown to consistently improve motor function by stimulating neuroplasticity, and optimizing interhemispheric synchronization and disinhibition [19]. In children with hemiplegia, bimanual therapy has been demonstrated to increase neuroplasticity which was quantified by increased white matter integrity in the corpus callosum and corticospinal tract [20]. The benefits of bimanual therapy are not limited to patients with stroke, hemiplegia, or cervical spinal injury, but also extend to children with unilateral cerebral palsy [21]. Typically, as the patient's functionality begins to improve, more challenging tasks are assigned to further stimulate and enhance limb function. In theory, the ultimate goal of regaining normal functioning is achievable, and bimanual rehabilitation devices have been shown to be effective in restoring limb function in a variety of conditions.

Neuroplasticity involves the brain's ability to adapt its function and rewire itself in response to acquired learning experiences. These neuronal pathways enable individuals who have suffered brain damage to retain some of their previous abilities [22]. Motor experiences can influence motor cortex functions through neuroplasticity. Engaging in bilateral movement therapy can increase motor function by increasing the use of undamaged pathways in the damaged hemisphere of the brain, increasing supplementation of the damaged corticospinal pathways, and amplifying premotor neuron commands on spinal neurons [8]. By participating in bimanual exercises, neuroplasticity is stimulated within the brain. The brain region corresponding to the affected limb can be expanded, ultimately enhancing the designated skill [21]. Research indicates that the formation of new pathways can enhance motor function following brain injury. Bimanual rehabilitation therapy has been shown to improve fine motor skills, which is likely a result of the rewiring of synaptic pathways and changes in brain plasticity.

Individuals with brain injuries, such as ischemic stroke, frequently experience bilateral dysfunction, although only unilateral injury is present in the brain. Bimanual neurorehabilitation stimulates neuroplasticity and neural coupling, which aims to improve interhemispheric communication between both limbs, regardless of which half of the brain is damaged. Neuroplasticity is believed to be impacted by interlimb neural coupling, which is indicative of the observation that unilateral stroke affects function bilaterally [19]. It is expected that performing bimanual, coordinated movements will improve both "affected" and "unaffected" sides [12]. Although this has not been extensively studied, the initial evidence is substantial enough to warrant further exploration. Future studies could help elucidate this in the case of polyform devices.

The capacity of bimanual neurorehabilitation devices to facilitate transformative changes in the realm of neurological recovery, with particular focus on their application following ischemic stroke, has demonstrated their ability to restore lost motor capabilities and create new neuronal circuits, thereby leading to enhanced motor function. The vital role of neuroplasticity in the recovery process underscores how bimanual therapy can promote adaptive changes within the brain, ultimately improving recovery and outcomes after ischemic stroke. Although further studies are required to fully explore the potential of bimanual therapy, the current body of evidence is compelling, and suggests that bimanual therapy may be beneficial. Our findings indicate that bimanual neurorehabilitation using the novel polyform device offers a promising new approach for improving hand function in individuals who have experienced acute ischemic stroke.

CONCLUSION

Use of the polyform device for bimanual therapy in an acute setting may aid in improving hand function after ischemic stroke. Larger studies with more robust outcome measures are required. This device could also be useful in recovery from other injuries or procedures that affect upper extremity function. Further testing and evaluation of the polyform may uncover additional scenarios in which its implementation could be useful. Overall, bimanual therapy appears to be a promising modality for recovery from stroke.

CONFLICT OF INTEREST

Dr. Barr is the inventor of the polyform bimanual assisted neurorehabilitation device. A commercially available upper extremity rehabilitation system utilizing a device based on this concept is marketed through his company Plasticity Neurorehabilitation, LLC, under the trade name Polyform-1h. Plasticity Neurorehabilitation paid the processing charges for submission.

ACKNOWLEDGEMENTS

We would like to express our gratitude to all the participants in this study.

FUNDING

Plasticity Neurorehabilitation provided devices, training, and any publishing fees

DECLARATION OF GENERATIVE AI AND AI-ASSISTED TECHNOLOGIES IN THE WRITING PROCESS

During the preparation of this work the authors used commonly available artificial intelligence tools to edit grammar, syntax, and formatting. After using this tool/service, the authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

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