A Retrospective Comparison of a Self-Administered Assisted Motion Device ("NeeHab") and Manual Physical Therapy after Primary Total Knee Arthroplasty

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Introduction

The goals of total knee arthroplasty (TKA) include pain relief, stability throughout the gait cycle and maximizing range of motion (ROM). Many activities of daily living require at least 90 degrees of flexion such as rising from a chair, getting into a bath tub, or stair climbing.[1–3] To aid in regaining this functional ROM, physical therapy (PT) following a total knee replacement is thought to be a critical part of the overall procedure.[4–6] Although there are several therapeutic modalities administered to patients during their visits to physical therapy, the major focus is on maximizing ROM through active ROM and active-assisted ROM exercises. Gentle manual physical therapy is also routinely performed by the therapist; however, this modality is time consuming for the therapist and sometimes painful for the patient. Furthermore, the pain felt by the patient during manual physical therapy is thought by some surgeons to be counterproductive, producing a vicious cycle of pain that limits ROM often leading to more aggressive manipulations which may cause increased pain that further limits ROM.

The Neehab device, allows a patient to self-administer and regulate their physical therapy (PT) after total knee arthroplasty (TKA). It is possible this device may aid patients in regaining functional range of motion (ROM) after TKA to a similar or greater extent as formal manual PT by a physical therapist.

Device Information

The Neehab device is a Class 1 exempt device and was approved on April 26, 2016. A CMS code was assigned to this device on December 16, 2016 under the common procedure code E1811. This product received its US Patent on December 4, 2018 and is listed under Patent Number US 10,143,611 B2 as a Joint Rehabilitation Apparatus. No known formal clinical studies have been done for the NeeHab device. This is the only known device on the market that is portable and light weight, and is designed for patients to improve flexion and extension rehabilitation post-surgery or injury.

This comparative study is the only known study on this device to date.

Study Purpose

The purpose of this study is to document the results of knee range of motion when using a self-administered assisted motion device, the NeeHab device, compared to manual PT after total knee arthroplasty. The comparison is a retrospective patient series who had unilateral primary total knee arthroplasty by a single surgeon with PT done at a single clinic. The results of this study is to be used for informational purposes only and not representive of a scientific analysis of clinical outcomes.

Study Design

This study is a retrospective primary unilateral TKA series review. The Neehab User group are patients who used the Neehab device in conjunction with manual PT after TKA surgery. The Control group are patients who underwent manual PT after surgery without the use of the Neehab device. All patients underwent a primary unilateral TKA by a single surgeon as well as all PT was completed by the same Physical Therapist at Carolina Orthopaedic and Sports Medicine Center. Patients excluded from this study included those with a BMI >43, bilateral cases and those that did not return for follow-up PT.

This study received IRB approval on May 21, 2024 from WCG. This study met the requirements for waiver of consent under 21 CFR 50.22.

There are 21 patients in each group. The Neehab User group were implanted from May 18, 2021 through November 17, 2021. The Control group were implanted from January 4, 2021 through May 10, 2021. All patients had a pre-operative diagnosis of osteoarthritis.

In both groups, patients <70 years of age were implanted with DePuy Attune™ and patients > 70 years were received the Zimmer Biomet Persona®

PS. The post-operative target ROM was set at 120° at 6 weeks.

Table 1: Device Summary

Group	Device (n)	N = 21 (each group)	Number of Cases	Percentage All Cases per Group
Neehab User	Attune (12)	Male	6	28.6%
		Female	6	28.6%
	Persona (9)	Male	5	23.8%
		Female	4	19.0%
Control	Attune (7)	Male	5	23.8%
		Female	2	9.5%
	Persona (14)	Male	6	28.6%
		Female	8	38.1%

All patients are asked to begin PT at a maximum of 2 weeks post-TKA and to use the same physical therapy office, namely Carolina Orthopaedic and Sports Medicine Center.

The Neehab User group were instructed to use the Neehab device in conjunction with standard physical therapy after surgery. The Neehab device was given to the patient at the preoperative visit and instructed to begin use as soon as they felt comfortable. All patients started using the Neehab device by POD 7. The prescribed use was a 10 - 15 minute session up to a maximum of 3 times a day. Twelve patients (63%) used the Neehab device twice a day for 10 minutes. Seven patients (37%) used it for 15 minutes twice a day. Over half of this group did not require a 12 week physical therapy session. There were no reported complications associated with the use of the Neehab device.

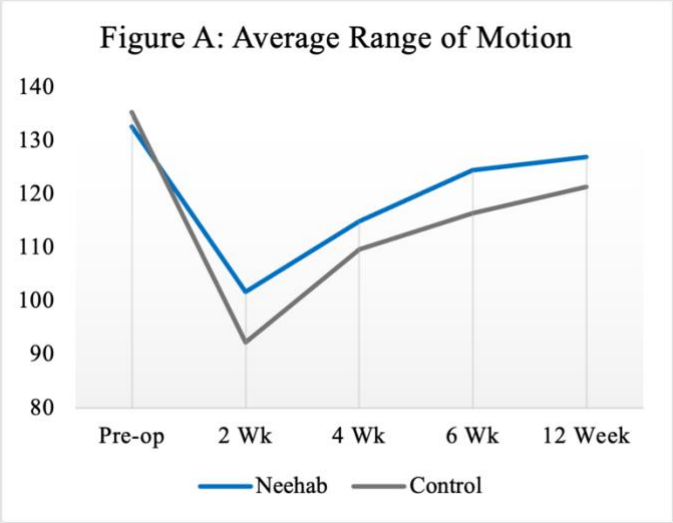
The Control group were prescribed the practice standard physical therapy without the use of the Neehab device.

Range of Motion Results

Range of Motion (ROM) was collected on both groups at Pre-op and 2, 4, 6, and 12 weeks post-operatively. Table 2 and Figure A show the average range of motion over the course of the physical therapy program.

Table 2: Average Range of Motion

Group	Pre-op (n)	2 Wk (n)	4 Wk (n)	6 Wk (n)	12 Wk (n)
Neehab User	130 (21)	101 (21)	116 (19)	124 (19)	127 (10)
Control	135 (21)	90 (21)	109 (21)	116 (21)	121 (19)



Conclusion

Increased range of motion was observed in the Neehab User group at all follow-up time intervals compared to our normally prescribed physical therapy. Our data shows the Neehab User group achieved a greater average range of motion at 6 weeks (124°) compared to the Control group at 12 weeks (121°).

The use of the Neehab device may be beneficial for patients as motivation to a earlier return to their normal daily activities. This is demonstrated by an increase in the post-operative ROM and the need for less physical therapy, resulting in a potential reduction in health care costs.

References

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