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The Range of motion Outcome After Hybrid Assisted Limbs (HAL) Rehabilitation on End-stage osteoarthritis patients undergoing Total Knee Arthroplasty: A Systematic Review and Meta Analysis

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ABSTRACT

Background: Total knee arthroplasty (TKA) effectively treats advanced knee osteoarthritis by reducing pain and restoring function, though limited postoperative range of motion (ROM) remains a challenge. Innovations like the Hybrid Assistive Limb (HAL) offer robotic support to enhance neuromuscular activation and movement precision during recovery.**Objective:** The objective of this research was to carefully assess and quantitatively aggregate the current data about the impact of HAL rehabilitation on knee flexion range of motion (both active and passive) in patients receiving total knee arthroplasty for end-stage osteoarthritis.**Methods:** A systematic review and meta-analysis were performed in accordance with PRISMA recommendations. A thorough literature search was conducted using PubMed, Cochrane Library, and ScienceDirect. Studies were included if they involved TKA patients undergoing HAL rehabilitation with reported outcomes in active or passive knee flexion. Mean differences with 95% confidence intervals (CI) were aggregated using a random-effects model, and I^2 assessed heterogeneity.**Results:** Eight studies with 306 participants met the criteria. A meta-analysis showed a significant mean difference of 13.01° in active ROM during flexion, favoring the HAL group (95% CI: 10.26–15.77; $p < 0.00001$; $I^2 = 0\%$). In passive ROM during flexion, five investigations indicated a mean difference of 5.51° in favor of HAL (95% CI: 2.75–8.26; $p < 0.0001$; $I^2 = 0\%$). Both results showed low heterogeneity, indicating consistent results across studies. **Conclusion:** HAL rehabilitation significantly enhances both active and passive ROM following TKA. Future research should explore long-term outcomes, economic feasibility, and applicability across broader patient populations.

Keywords: Hybrid Assisted Limbs, Meta-analysis , Osteoarthritis, Total Knee Arthroplasty

1. BACKGROUND

Osteoarthritis (OA) is a multifactorial, degenerative condition characterized by the deterioration of hyaline cartilage and adjacent tissues in the joint.[1,2] Knee osteoarthritis is a frequent musculoskeletal disorder, impacting around 22.9% of adults aged 40 and above.[3] Knee osteoarthritis, with hip osteoarthritis, ranks as the 11th leading cause of worldwide disability among the aged.[4] Knee osteoarthritis results in functional restrictions, chronic discomfort, and diminished quality of life.[5,6]

In cases of severe end-stage knee osteoarthritis, when conservative treatments are ineffective in alleviating pain and enhancing patient functionality, total knee arthroplasty (TKA) is the preferred intervention. In the United States, this procedure was performed on 4.55% of individuals aged 50 and older, with an anticipated yearly incidence of primary total knee arthroplasty reaching 3.5 million by 2030.[7,8] Patients with end-stage knee osteoarthritis may have delays of several months prior to undergoing total knee arthroplasty for different reasons. The waiting period for total knee arthroplasty (TKA) may exacerbate the patient's condition regarding pain, physical function, and health-related quality of life.[9]

The most common treatment for advanced knee osteoarthritis (OA) is total knee arthroplasty (TKA), which is also useful for inflammatory arthritis, fractures (post-traumatic osteoarthritis and/or deformity), dysplasia, and cancer.[10,11] Modern total knee arthroplasty has progressed over the last 50 years since its inception at the Hospital for Special Surgery in the early 1970s.[12] The worldwide demand for total knee arthroplasty is escalating significantly due to the rising incidence of knee arthritis. The quantity of primary TKA operations is anticipated to increase by 85% (1.26 million procedures) by 2030.[13]

In recent years, TKA has shown remarkable advancement. The partnership between surgeons and engineers led to several advancements in prosthesis design, ranging from conventional resurfacing prostheses to restricted and meniscal bearing prostheses.[14] In addition, computer-assisted navigation systems, preoperative software, patient-specific cutting guides, and robots were introduced into orthopedic surgery a few years ago; these innovations greatly improved the consistency and accuracy of bone resection as well as the preservation of ligament balance.[15]

Total knee arthroplasty (TKA) is a surgical intervention aimed at relieving pain and enhancing knee joint functionality. The damaged knee parts are removed and replaced with prosthetic implants during this surgical procedure. Studies have demonstrated that total knee arthroplasty (TKA) successfully reduces pain, increases mobility, and restores knee function. However, a lengthy recovery time is required after major surgical procedures. A smooth and effective recovery following total knee arthroplasty (TKA) depends on prompt rehabilitation.[16,17]

Furthermore, early rehabilitation is crucial since it reduces the likelihood of problems and facilitates recovery. Prompt initiation of rehabilitation post-surgery enables patients to use the joint and restore strength, flexibility, and mobility. This may aid in averting joint stiffness, muscular atrophy, and other issues subsequent to TKA.[18]

Recent technological breakthroughs have resulted in the creation of exoskeletons, wearable devices designed to aid mobility and support the knee joint. Facilitating recovery, improving mobility, and reducing the risk of future harm, these devices may greatly aid in the rehabilitation process following TKA.[19] Supporting and stabilizing the leg in addition to enhancing the knee's natural motion, exoskeletons are a great invention. These leg-specific devices are often made of lightweight materials like carbon fiber or aluminum. The exoskeleton's ability to move is controlled by a combination of sensors and motors.[20]

One of the primary benefits of exoskeletons is their capacity to provide precise and regulated support to the knee joint, therefore alleviating stress on the joint and facilitating smoother, more natural mobility. This is particularly beneficial for those who have had total knee arthroplasty, since the knee joint is still recuperating and may not be capable of bearing full body weight.[21] Utilizing an exoskeleton enables patients to begin ambulation and mobility sooner post-surgery, hence potentially expediting their recovery period (**Figure 1**).[22]

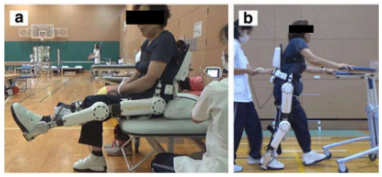


Figure 1. Training for the Hybrid Assistive Limb (HAL). Sitting with the head in a neutral position and the knees bent and extended is an excellent workout (a). Training for gait while utilizing the sagittal plane and HAL (b)

The concept of robot-assisted training (RAT) emerged in the early part of the millennium. There is a lot of evidence from studies on patients with neurological illnesses, such as cerebral palsy, spinal cord damage, and stroke, that RAT improves their ability to walk.[23–26] Nevertheless, there are few publications that validate the impact of RAT in postoperative rehabilitation after TKA.[27]

The Hybrid Assistive Limb is a device designed for supported training. HAL is a wearable robot that dynamically responds to the wearer's voluntary movements. Preliminary investigations have disclosed details of the HAL system.[28,29] Both single-leg and dual-leg variants of the HAL are offered, with the selection contingent upon the user's needs. The HAL can detect bioelectrical impulses generated by the user's muscles, floor response force signals caused by changes in the user's weight, or even both. By integrating the advantages of voluntary control and ambulation performance, HAL makes it easier to train the lower limbs and improve gait through voluntary drive. The majority of existing exoskeleton systems rely on predefined motions that are generated autonomously. On the flip side, HAL responds to the wearer's deliberate effort by delivering movement. By adjusting their muscle contractions, the user can command HAL. Researchers have shown that HAL is safe to use in clinical trials with individuals suffering from

neurological disorders, cerebral palsy, spinal cord injuries, and stroke.[30–34].

Although total knee arthroplasty (TKA) is widely used for advanced osteoarthritis, limited postoperative range of motion (ROM) remains a key issue affecting recovery and patient satisfaction. Standard rehabilitation often falls short, especially in older or severely ill patients. As TKA rates rise globally, more effective ROM-focused rehabilitation is needed. HAL rehabilitation, using robotic exoskeletons and bioelectric signals, offers a novel approach to improving joint mobility and neuromuscular function. While early results are promising, evidence on HAL's impact on ROM after TKA is limited and inconsistent. A thorough review and meta-analysis are needed to evaluate its effectiveness and inform clinical use

2. METHODS

2.1 Search strategy

We followed the guidelines laid out by PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) when conducting and documenting this meta-analysis. By utilizing ScienceDirect, the Cochrane Library, and PubMed up until October 18, 2025, a thorough literature review was performed. This literature review uses the following terms: "(total knee arthroplasty OR Total Knee Replacement) AND (Hybrid Assistive Limb OR HAL) AND Rehabilitation AND Osteoarthritis." Articles with pertinent titles and abstracts will be incorporated into this procedure to enable a comprehensive examination and subsequent quantitative and qualitative analysis.

2.2 Inclusion and exclusion criteria

The studies were evaluated based on the following inclusion criteria: (1) Studies involving patients with end-stage osteoarthritis undergoing total knee arthroplasty; (2) Studies comparing outcomes of active and passive knee flexion between HAL and conventional rehabilitation. Consequently, the following exclusion criteria were defined: (1) Full-text articles that are inaccessible and (2) studies deemed unsuitable regarding their design, intervention, or outcome. **Figure 2** depicts the details of the study search strategy.

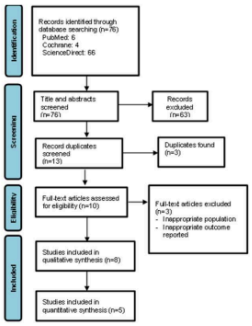


Figure 2. Diagram flow of literature search strategy for this meta-analysis

2.3 Data extraction and risk of bias assessment

Afterwards, we retrieved information from the articles that were chosen. Using the RoB-2 Tool, which is given by Cochrane, the articles were also evaluated for their quality. All reviewers worked together to assess the quality of the work until they reached an agreement.

2.4 Statistical Analysis

The tool used to perform the meta-analysis was Review Manager version 5.1, developed and maintained in Copenhagen by the Nordic Cochrane Centre and The Cochrane Collaboration. Common measures included the Mean Difference (MD) and the 95% CI around it. The effect values were consolidated using random-effects models to account for clinical variability. A p-value < 0.05 indicates statistical significance in the analysis. In order to examine heterogeneity, the Higgins I-squared (I^2) statistical model was employed. Results were classified as low (25–25%), moderate (50–75%), or high (>75%) based on the heterogeneity test.

Author, year	Intervention	Control	Intervention (n)	Control (n)	Passive extension				Active Extension				Passive flexion				Active flexion				Extension lag			
					Intervention	SD	Control	SD	Intervention	SD	Control	SD	Intervention	SD	Control	SD	Intervention	SD	Control	SD	Intervention	SD	Control	SD
Yoshikawa, 2018	Hybrid Assisted Limbs (HAL)	Conventional rehabilitation	9	10	-0.8	2	-4.2	3.8	-2.5	2.7	-5.8	3.8	122.5	11.7	117.8	11.4	115.8	13.6	109.2	11.6				
Kotani, 2019	Hybrid Assisted Limbs (HAL)	Conventional rehabilitation	12	10									109.6	12	100.5	13.2	102.5	12.9	86.5	11.8				
Yoshioka, 2021	Hybrid Assisted Limbs (HAL)	Conventional rehabilitation	12	12																	6.3	4	5.2	5
Mrozek, 2022	Hybrid Assisted Limbs (HAL)	Continous passive motion	16	15									105.33	13.43	102.81	12.11								
Waraho, 2024	Hybrid Assisted Limbs (HAL)	Conventional rehabilitation	14	16									115.3	9.7	111.8	8.7								
Maeda, 2024	Hybrid Assisted Limbs (HAL)	Conventional rehabilitation	41	37	-7.1	4.9	-6.1	3.9	-13.5	5.7	-12.7	4.7												
Goto, 2016	Hybrid Assisted Limbs (HAL)	Conventional rehabilitation	10	10																	4.5	7.98	14	8.76
Cai, 2022	Hybrid Assisted Limbs (HAL)	Conventional rehabilitation	40	42	C								104.75	8.35	98.5	8.13	103.53	5.76	90.33	7.8				

Table 1. Characteristics and result of the included studies

3. RESULT

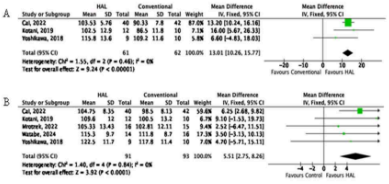


Figure 3. Pooled results of HAL for (A) active ROM and (B) passive ROM

A total of 306 patients were included in the studies selected for meta-analysis, evaluating the impact of Hybrid Assistive Limb (HAL) rehabilitation versus conventional therapy on postoperative range of motion (ROM) in patients undergoing total knee arthroplasty (TKA) due to end-stage osteoarthritis **(Table 1)**. The results were classified into two primary parameters: active range of motion (ROM) in flexion and passive ROM in flexion, each evaluated via pooled mean differences along with associated confidence intervals and evaluations of heterogeneity **(Figure 3)**.

Three studies supplied sufficient data for a meta-analysis of active range of motion in flexion. The aggregated mean difference favored the HAL group, demonstrating a statistically significant enhancement of 13.01 degrees relative to traditional rehabilitation (95% CI: 10.26 to 15.77; $p < 0.00001$). The analysis revealed no heterogeneity ($I^2 = 0\%$), suggesting a high degree of consistency across the studies considered. This study shows a consistent and significant advantage of HAL therapy in enhancing voluntary knee flexion post-TKA.

Likewise, passive range of motion in flexion was evaluated according to five research. The meta-analysis demonstrated a statistically significant mean difference of 5.51 degrees favoring the HAL group (95% CI: 2.75 to 8.26; $p < 0.0001$), with no detected heterogeneity ($I^2 = 0\%$). Although the extent of improvement was less significant than that of active range of motion, the outcome still demonstrates a distinct benefit of HAL-assisted treatment in augmenting joint flexibility via externally facilitated movement.

The lack of variation in results indicates that HAL rehabilitation's impact on ROM is uniform across various research groups and contexts. This uniformity enhances the dependability of the aggregated estimates and diminishes the probability that the observed effects arise from study-level variability or methodological discrepancies. The tight confidence intervals reinforce the accuracy of the predicted treatment effects.

The quantitative synthesis demonstrates that HAL rehabilitation produces better results in both active and passive knee flexion range of motion compared to traditional rehabilitation procedures after total knee arthroplasty. These results provide substantial evidence for the therapeutic efficacy of HAL in enhancing postoperative functional recovery, especially for joint mobility. Additional research and discourse are necessary to investigate the underlying processes, patient groupings that may get the most benefit, and implications for rehabilitation treatment.

4. DISCUSSION

This systematic review and meta-analysis aimed to assess the impact of Hybrid Assistive Limb (HAL) rehabilitation on postoperative range of motion (ROM) outcomes in patients with end-stage osteoarthritis after total knee arthroplasty (TKA). Total knee arthroplasty (TKA) is a highly recognized and efficacious surgical procedure for severe knee osteoarthritis, mainly designed to alleviate pain and restore mobility. Nonetheless, despite successful surgery, some patients encounter inadequate recovery of range of motion, a crucial factor influencing functional independence and overall quality of life. In this scenario, rehabilitation measures are essential for optimizing postoperative results. Conventional rehabilitation techniques,

although often advantageous, may inadequately address the particular neuromuscular deficiencies and joint rigidity linked to chronic osteoarthritis. The advent of robotic rehabilitation systems, exemplified by HAL, has created novel opportunities for improving postoperative recovery by using real-time feedback and mobility assistance to facilitate neuromuscular training. This research thoroughly synthesizes current information to determine whether HAL significantly enhances ROM improvements after TKA.

This meta-analysis includes 306 participants from various trials, concentrating on two primary outcomes: active range of motion in flexion and passive range of motion in flexion. These measurements were selected since they embody critical aspects of knee functionality that directly influence a patient's capacity to engage in activities of daily living, including ambulation, squatting, and stair navigation. Active range of motion indicates the patient's voluntary movement control, while passive range of motion demonstrates the joint's intrinsic mechanical flexibility when manipulated by an external force. Both are essential in the postoperative context, when joint rigidity, edema, and muscle atrophy often hinder healing. This study aimed to ascertain whether robotic-assisted rehabilitation provides a significant benefit over conventional therapy in restoring essential knee function.

The meta-analysis demonstrated a statistically and clinically significant enhancement in active range of motion flexion in patients who received HAL rehabilitation. The aggregated mean difference was 13.01 degrees favoring the HAL group (95% confidence interval: 10.26 to 15.77; $p < 0.00001$), with no heterogeneity ($I^2 = 0\%$), indicating exceptional consistency across the three trials examined. This degree of enhancement is significant in the realm of post-TKA rehabilitation, as even little increases in active ROM may result in substantial functional advantages. A flexion angle of at least 110–120 degrees is often necessary for most everyday tasks, and attaining this might be difficult, especially for elderly persons or those with prolonged joint immobility. The significant enhancement seen indicates that HAL may expedite the restoration of voluntary motor control, perhaps decreasing the duration of functional recovery and discharge.

For passive ROM in flexion, five trials supplied data to the study, and the pooled findings similarly revealed a statistically significant advantage of HAL rehabilitation. The mean difference was 5.51 degrees (95% CI: 2.75 to 8.26; $p < 0.0001$), again with no heterogeneity ($I^2 = 0\%$). The extent of improvement was less significant than that seen in active range of motion; nonetheless, this result is still clinically relevant. Passive range of motion is often the first focus of mobility rehabilitation in the early postoperative phase, establishing a basis for subsequent active movement. Enhancements in passive range of motion suggest that HAL may also promote soft tissue flexibility, joint capsule mobility, and decreased periarticular stiffness. These are essential first objectives in rehabilitation and may profoundly affect the course of recovery in the weeks subsequent to surgery.

The absence of heterogeneity in both outcome domains enhances the validity of the results. In meta-analytic terminology, heterogeneity denotes the extent of diversity in outcomes across studies. When $I^2 = 0\%$, it indicates that the impact of HAL on ROM was uniform across various patient demographics, clinical environments, and rehabilitation strategies. This is especially significant since rehabilitation results are often affected by several confounding variables, including age, sex, comorbidities, preoperative mobility status, and therapist expertise. The consistency in the direction and amount of impact indicates that the advantages of HAL are substantial and likely replicable in larger clinical contexts, bolstering its potential for widespread use.

These results include significant consequences for clinical practice. Functional range of motion is a principal objective in post-total knee arthroplasty rehabilitation, and the inability to attain sufficient knee flexion correlates with diminished patient satisfaction, delayed resumption of daily activities, and, in some instances, the need for manipulation under anesthesia. Standard rehabilitation procedures often include a mix of physical therapy techniques, such as passive stretching, active-assistive exercises, and strength training. Although they are crucial, using HAL may mitigate some restrictions. HAL offers robotic-assisted motion activated by the patient's bioelectrical impulses, facilitating voluntary participation and neuromuscular reeducation. This real-time feedback mechanism may expedite the recovery of motor patterns and improve the coordination required for effective knee function.

The observed improvements in active range of motion are particularly encouraging from a neurorehabilitative perspective. HAL's capacity to identify and enhance feeble bioelectric signals enables patients—especially those with muscular inhibition or impaired proprioception—to execute motions they may otherwise struggle to do efficiently. This facilitates brain activation and neuroplasticity, which are crucial for regaining

coordinated movement after significant joint surgery. Conversely, traditional passive modalities provide restricted sensory feedback and voluntary regulation, which may result in prolonged neuromuscular recovery. The supplementary neurofeedback offered by HAL may explain the greater improvements shown in active range of motion relative to passive range of motion.

Nonetheless, it is crucial to acknowledge the limitations of the existing evidence base. Despite the usually excellent methodological quality of the studies included in this meta-analysis, the overall number of studies was limited, especially with active range of motion outcomes. Moreover, the sample sizes in individual investigations were limited, potentially diminishing the statistical ability to identify lower effect sizes or examine subgroup differences. Although the absence of heterogeneity is reassuring, it is conceivable that discrepancies in patient demographics, HAL device types, treatment durations, or postoperative timeframes were inadequately recorded or not comprehensively documented in the study.

A further drawback is the short follow-up period in the majority of the research examined. Although rapid and short-term improvements in range of motion are crucial for early recovery, the persistence of HAL's advantages over the medium to long term remains uncertain. HAL may expedite initial advantages; but, these disparities might lessen over time as traditional rehabilitation progresses. Longitudinal trials with follow-up durations of six months or longer are required to ascertain if the initial benefits in range of motion result in enhanced long-term functional outcomes, including improved gait mechanics, decreased fall risk, or increased independence in community mobility.

Economic factors must be evaluated prior to the widespread use of HAL. The implementation of robotic exoskeletons such as HAL entails considerable initial expenses, including equipment acquisition, personnel training, and upkeep. No research in this study performed formal cost-effectiveness assessments, resulting in a lack of insight into the economic viability of incorporating HAL into standard rehabilitation programs. Subsequent study should assess if the functional advantages of HAL—such as abbreviated hospitalizations, expedited return to employment, or less need for supplementary interventions—justify the initial expenditure.

Notwithstanding these constraints, the results of this meta-analysis provide persuasive data advocating for the incorporation of HAL rehabilitation into postoperative treatment protocols for certain TKA patients. HAL may be especially advantageous for patients predisposed to inadequate functional recovery, including those with restricted preoperative mobility, muscle atrophy, or neuromuscular dysfunction. Its use may also be broadened to include patients with bilateral conditions or those undergoing revision total knee arthroplasty, who often have heightened rehabilitation difficulties. Tailored patient selection based on clinical, functional, and psychological aspects will be essential for maximizing the use of this technology in practice.

This comprehensive review and meta-analysis conclusively shows that HAL rehabilitation significantly improves both active and passive range of motion in patients receiving TKA for end-stage osteoarthritis. The enhancements are uniform, statistically significant, and clinically relevant, with no detected heterogeneity across the investigations. These results indicate that HAL is a viable complement to traditional therapy, providing improved recovery of joint mobility via real-time voluntary movement assistance and neuromuscular feedback. Future research in robotic rehabilitation should prioritize long-term results, cost-effectiveness, and integration techniques to enhance its efficacy in orthopedic healing. The use of these novel treatments might revolutionize postoperative rehabilitation and enhance the quality of life for an increasing number of TKA patients.

5. CONCLUSION

This systematic review and meta-analysis indicates that Hybrid Assistive Limb (HAL) rehabilitation significantly improves both active and passive range of motion (ROM) in patients with end-stage osteoarthritis receiving total knee arthroplasty (TKA). The results demonstrate a significant mean difference of 13.01° in active flexion and 5.51° in passive flexion relative to traditional therapy, with little heterogeneity a cross trials, suggesting uniform outcomes. These enhancements are clinically significant, indicating that HAL may facilitate neuromuscular recovery and joint mobility more efficiently than conventional treatment alone. Although further study is necessary to evaluate long-term functional results, cost-effectiveness, and wider patient applicability, the existing data endorses HAL as a viable supplement in post-TKA rehabilitation procedures to enhance and expedite recovery.

Ethical Approval

There is no ethical approval.

Conflicts of Interest

The authors declare no conflict of interest.

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Author Contributions

The authors confirm contribution to the article as follows: Conceptualization, RH, TAK, PDS; methodology, RH, TAK, PDS; software, PDS; validation, PDS; formal analysis, PDS; investigation, PDS; resources, PDS; data curation, PDS; writing—original draft preparation, PDS; writing— review and editing, PDS; visualization, PDS; supervision, RH and TAK.

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