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The Impact of Postoperative Bracing on Patients Undergoing Anterior Cruciate Ligament Reconstruction: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

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ADMINISTRATIVE INFORMATION

Support - None.

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Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 1 November 2024 and was last updated on 1 November 2024.

INTRODUCTION

Review question / Objective To investigate the effect of postoperative bracing in ACL-reconstructed patients based on the available evidence.

Rationale Anterior cruciate ligament (ACL) injuries are a significant and growing orthopedic concern; however, the effectiveness of postoperative rehabilitation, particularly the use of knee bracing, remains inconclusive. Therefore, we aim to conduct a systematic review and meta-analysis to investigate the effect of bracing after ACL surgery.

Condition being studied The PICO (population, intervention, comparison, outcome) setting of the current meta-analysis included: (1) P: ACL-reconstructed patients; (2) I: post-operative bracing; (3) C: placebo; and (4) O: changes in thigh muscle strength, knee mobility, subjective or objective performance, knee stability, or functional test outcomes.

METHODS

Search strategy Two authors (P.-H.C. and S.-H.-L.T.) made independent electronic searches in the PubMed, Embase, Cochrane CENTRAL, Web of Science and ClinicalTrials.gov with keyword of ('anterior cruciate ligament reconstruction' OR 'acl reconstruction' OR 'acl repair' OR 'acl surgery' OR 'anterior cruciate ligament reconstruction' OR 'anterior cruciate ligament repair' OR 'anterior cruciate ligament surgery') AND ('brace' OR 'bracing' OR 'braces-orthopedic appliances' OR 'orthopedic brace') through the earliest record to Oct 31, 2024.

Participant or population ACL-injured patients who have undergone surgical repair.

Intervention Post-operative knee bracing.

Comparator Placebo.

Study designs to be included Randomized controlled trials.

Eligibility criteria To generate a recruited study list, the following inclusion criteria will be used: (1) Studies involving patients who underwent ACL reconstruction. (2) Studies with two groups: one using a knee brace and the other with no brace. (3) Randomized controlled trials (RCTs) involving human participants, and (4) Studies reporting outcomes such as thigh muscle strength, knee ROM, or assessments using established questionnaires, instrumented testing, or functional evaluations.

Information sources Two authors (P.-H.C. and S.-H.-L.T.) made independent electronic searches in the PubMed, Embase, Cochrane CENTRAL, Web of Science and ClinicalTrials.gov with keyword of ('anterior cruciate ligament reconstruction' OR 'acl reconstruction' OR 'acl repair' OR 'acl surgery' OR 'anterior cruciate ligament reconstruction' OR 'anterior cruciate ligament repair' OR 'anterior cruciate ligament surgery') AND ('brace' OR 'bracing' OR 'braces-orthopedic appliances' OR 'orthopedic brace') through the earliest record to Oct 31, 2024.

Main outcome(s) The primary outcomes were the changes in the thigh muscle strength and knee mobility following knee brace application or placebo.

Additional outcome(s) The secondary outcomes included commonly used questionnaires, instrumented testing, and functional knee assessments.

Data management Two independent authors (P.-H.C. and S.-H.-L.T.) extracted data from the selected studies, including demographic data, study design, details of brace use and placebo interventions, and the values of the primary and secondary outcomes. The evaluators carefully considered the direction of effect of the scales used in each trial to prevent misinterpretation. When data were unavailable in the published articles, we contacted the corresponding authors to acquire the original data.

Quality assessment / Risk of bias analysis We assessed the methodological quality of the included studies using the Cochrane risk-of-bias tool for randomized trials, version 2 (RoB 2), which consists of six key domains: the randomization process, adherence to interventions, missing outcome data, measurement of outcomes, selective reporting, and overall risk of bias. In the

intervention adherence section of RoB 2, there are two options for evaluating studies: intention-to-treat (based on intervention assignment) or per-protocol (based on intervention adherence). For this meta-analysis, we opted for per-protocol evaluation, as it aligned with the design of the studies included.

Strategy of data synthesis Due to the heterogeneity of the target populations across the included studies, we conducted the current meta-analysis using a random-effects model with Comprehensive Meta-Analysis software, version 3 (Biostat, Englewood, NJ). A two-tailed p-value of less than 0.05 was considered statistically significant. To quantify continuous outcomes, we used the standard mean difference (SMD) with 95% confidence intervals (CIs). An SMD of 0.2, 0.5, and 0.8 was interpreted as small, moderate, and large effect sizes, respectively. For discrete outcomes, we employed odds ratios with 95% CIs. The degree of heterogeneity among studies was assessed using the I^2 statistic and Cochran's Q test. I^2 values of 25%, 50%, and 75% were interpreted as indicating low, moderate, and high heterogeneity, respectively.

Subgroup analysis Subgroup analyses were conducted based on the type of surgical graft and type of brace used. Meta-regressions were performed to examine whether the treatment effects of bracing duration were correlated with these parameters.

Sensitivity analysis To confirm the robustness of the meta-analysis, the sensitivity analyses were performed using one-study removal method to see if there was a significant change in the summary effect size after removing a particular trial from the analysis.

Language restriction Articles written in English.

Country(ies) involved Taiwan.

Keywords ACL Reconstruction, Knee Brace, Thigh Muscle Strength, Knee Mobility.

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