INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Three-dimensional printing for total joint replacement: a protocol for a systematic review and meta-analysis of clinical trials

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Review question / Objective: **This study was designed to provide a comprehensive and objective evaluation basis for the use of 3DP technology in joint replacement surgery. To this end, the proposed systematic review will address the following question: Whether the 3DP is benefited for the joint replacement surgery.**
Condition being studied: **It was reported that the global population over 60 has exceeded 650 million and is expected to increase to 2 billion by 2050. With the progress of aging, the health care system is facing the challenge of managing the burden of chronic diseases caused by aging. Severe osteoarthritis is a common disease in the elderly. It can cause pain and ultimately disability, loss of function, and severe impairment of quality of life which has greatly increased the personal and social burden. Total joint replacement (TJR) is an effective surgical intervention for osteoarthritis by reconstructing the surface of the bone with prosthetic components, which has been reported to have a positive effect on pain reduction, mobility, and health-related quality of life. It enables the patient to maintain an independent lifestyle and contributes to social interaction and mental health. These benefits can be seen early after surgery and can last for decades. Therefore, the demand for joint replacement surgery is increasing. According to reported that there are more than one million patients undergo total knee replacement (TKR) or total hip replacement (THR) each year, and the number is expected to grow to nearly four million by 2030 in the United States.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 January 2022 and was last updated on 09 January 2022 (registration number INPLASY202210039).

INTRODUCTION

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METHODS

Participant or population: All patients over 60 years of age undergoing total joint replacement for osteoarthritis will be included in this study. There is no restriction on source, gender, race, site of disease, etc.

Intervention: All clinical studies using 3DP to prepare and perform total joint replacement as intervention for experimental group will be included.

Comparator: Traditional total joint replacement surgery using X-ray fluoroscopy or CT-based computer-assisted guide system without 3DP was defined as intervention for control group.

Study designs to be included: All clinical studies which using 3DP in total joint replacement surgery including case control studies, cohort studies and randomized controlled trials (RCTs) will be included in this review.

Eligibility criteria: Eligibility criteria was defined according to the PICOS(participant, intervention, comparator, study design). The details reported in item 12 to 15.

Information sources: Four English online databases (Medline, EMBASE, CENTRAL, Cochrane) will be searched from inception until December 31, 2021.

Main outcome(s): Accuracy of component placement, precision, perioperative blood-loss volume, improvement of pain and range of motion were defined as the primary outcomes.

Data management: Data extraction will be completed by two authors independently using a data extraction MS Excel sheet. For included studies, following information will be extracted: general information, study population, intervention characteristics and outcomes. The conversion of the data will be done through EXCEL for data analysis. For the multiple-arm studies, the two sets of data that best meet the inclusion criteria will be extracted. Inconsistencies will be discussed and resolved through discussions with a third reviewer. Data synthesis and management will be done using Cochrance Review Writting Soft (RevMan5.3).

Quality assessment / Risk of bias analysis: The quality of included studies will be evaluated using methodological index for non-randomized studies (MINORST) item or “Risk of bias” (ROB) table based on the type of studies [30]. Methodological quality assessment will be carried out by two authors independently. Inconsistencies will be discussed and resolved through discussions with a third reviewer.

Strategy of data synthesis: In this study, the continuity data such as perioperative blood-loss volume, range of motion, cost, and hospitalization length will be reported using mean differences (MDs) or standard

MDs with 95% CIs. The dichotomous data such as accuracy of component placement, precision, and complications will be reported using risk ratios (RRs) with 95% CIs. The data analysis method will be determined based on the data collected and the results of the heterogeneity. If the data meets the conditions of quantitative analysis, Cochrane Review Manager (Revman5.3) will be used to synthetic data for the overall effect. For different outcomes, the random-effect or the fixed-effect method will be selected according to the results of the heterogeneity. If the collected data cannot be performed quantitative analyses, then only qualitative analysis will be performed.

Subgroup analysis: If the results of the heterogeneity indicate there are heterogeneity between studies included, the subgroup analysis will be carried out for each outcomes. The subgroups will be set according to different intervention methods, different surgical sites, or different assessment tools.

Sensitivity analysis: The stability of research results will be assessed via the sensitivity analysis. Subgroup analysis is mainly to compare whether there is a difference between the original effect size and the effect size after removing the poor quality studies. If there is no significant change between the two effect sizes, the results is stable. If the two effect sizes are very different or even opposite, it means that the reliability of the result is poor, and we need to be cautious when interpreting the results and drawing conclusions.

Language: The language will be limited to English without any restrictions on publication type.

Country(ies) involved: China.

Keywords: three-dimensional printing, total joint replacement, review, protocol.

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