

INPLASY PROTOCOL

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All authors declare that they have no conflict of interest.

Zero-profile versus cage-plate interbody fusion system in anterior cervical discectomy and fusion for the treatment of multilevel cervical spondylosis

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Review question / Objective: P: diagnosed as symptomatic cervical spondylosis; I: Zero-profile interbody fusion system in anterior cervical discectomy and fusion; C: control groups were cage-plate interbody fusion system in anterior cervical discectomy and fusion; O: Operative Time, Blood Loss, Clinical Function Outcome, Radiologic Outcomes and Complications were assessed; S: comparative design were included.

Condition being studied: This systematic review was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-analyses statement. Four English electronic databases: CENTRAL, PubMed, EMBASE, Web of Science and four Chinese databases, namely China National Knowledge Infrastructure (CNKI), Wanfang, Chinese Biomedical Literature Database (CBM) and Chinese Science and Technology Journal Database (VIP) were systematically searched from inception to June 2020.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 20 July 2020 and was last updated on 20 July 2020 (registration number INPLASY202070095).

INTRODUCTION

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METHODS

Search strategy: The search was conducted by using the combination of the following terms: “zero-profile” OR “zero profile” OR “zero-p” OR “stand-alone” OR “anchored spacer” OR “anchored.

Participant or population: P: Diagnosed as symptomatic cervical spondylosis.

Intervention: Zero-profile interbody fusion system.

Comparator: Cage-plate interbody fusion system.

Study designs to be included: comparative design.

Eligibility criteria: The inclusion criteria for this study were as follows: 1) All patients with MCSM undergoing ACDF involving 2 or more levels. 2) The study included a comparative design (zero-profile vs. cage-plate). 3) Follow-up of at least 12 months.

Information sources: We will search Pubmed, Cochrane Central Register of Controlled Trials (CENTRAL), Web of Science, Embase as well as four Chinese databases, namely China National Knowledge Infrastructure (CNKI), Wanfang, Chinese Biomedical Literature Database (CBM) and Chinese Science and Technology Journal Database (VIP). All the English and Chinese literature published

from inception to May 31, 2020 will be retrieved. In addition, we will also undertake a targeted gray literature search on Clinical Trials.gov and the Chinese Clinical Trial Registry to gain unpublished or in-progress trials or completed but prepared for publication. Meanwhile, the reference list of previous clinical studies and reviews will be searched as supplementary sources.

Main outcome(s): Operative Time and Blood Loss.

Additional outcome(s): Clinical Function Outcome; Radiologic Outcomes; Complications.

Quality assessment / Risk of bias analysis: The following items will be independently assessed by two authors using the risk of bias assessment tool. (1) Was there adequate sequence generation (selection bias)? (2) Was allocation adequately concealed (selection bias)? (3) Was knowledge of the allocated interventions adequately prevented during the study? (4) Participants and personnel (performance bias) (5) Outcome assessors (detection bias) (6) Were incomplete outcome data adequately addressed (attrition bias)? (7) Are reports of the study free of suggestion of selective outcome reporting (reporting bias)? (8) Was the study apparently free of other problems that could put it at a risk of bias?

Strategy of data synthesis: Data will be pooled using the random-effects model but the fixed effect model will also be used to ensure robustness of the model chosen and susceptibility to outliers.

Subgroup analysis: Based on available data, we will perform the following subgroup analyses: (1) 2 levels; (2) 3 levels; (3) 4 levels.

Sensibility analysis: We will perform sensitivity analyses in order to explore the influence of the following factors on effect size: (1) Repeating the analysis taking account of risk of bias (allocation concealment) (2) Repeating the analysis

excluding any very long or large studies to establish how much they dominate the results.

Country(ies) involved: China.

Keywords: protocol; systematic review; Zero-P profile; ACDF; multilevel cervical spondylosis.

Contributions of each author:

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Author 2 - Rui Wang.

Author 3 - Wei Teng.

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