BIOMECHANICAL STUDY SUMMARY

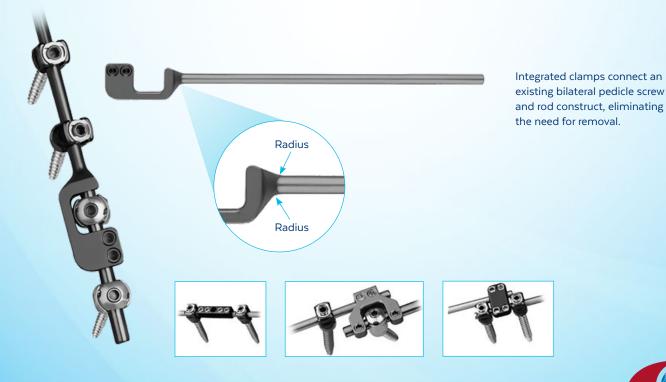
Biomechanical Evaluation of a Novel Posterior Integrated Clamp that Attaches to an Existing Posterior Instrumentation for Use in Thoracolumbar Revision

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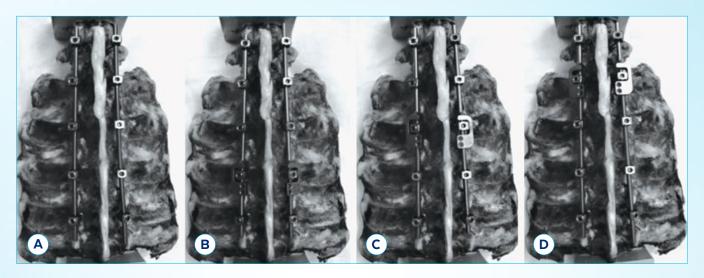
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OBJECTIVE: This study aimed to evaluate the biomechanics of the REVERE[®] ADDITION[®] posterior integrated clamp (IC) that extends on an already implanted construct in comparison to a single long continuous bilateral pedicle screw (BPS) and rod stabilization system.

METHOD: Six osteoligamentous T12-L5 calf spines were tested on a spine motion simulator by varying the ratio between the BPS and IC in the following configurations: intact, four-level constructs (T13-L4), three-level constructs (L1-L4), and two-level constructs (L2-L4). A load control protocol of 8Nm moments was applied at a rate of 1° /sec to establish the range of motion value for each construct in flexion-extension, lateral bending, and axial rotation. Statistical analysis was performed on raw data using repeated measures analysis of variance and significance was set at P < 0.05.



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(A) Bilateral pedicle screw (BPS) T13-L4, (B) BPS L3-L4+integrated clamp (IC) T13-L3,
(C) BPS L2-L4+IC T13-L2, and (D) BPS L1-L4+IC T13-L1.

ROM values (degrees) for different surgical constructs at T13-L4

Loading Condition	Intact	BPS T13-L4	BPS L3-L4+IC T13-L3	BPS L2-L4+IC T13-L2	BPS L1-L4+IC T13-L1
Flexion-extension	100±17	18±9	19±7	27±8	24±4
Lateral bending	100±20	29±6	28±8	36±9	36±8
Axial rotation	100±9	53±6	49±11	58±3	52±7

Values are presented as mean±standard deviation.

ROM, range of motion; BPS, bilateral pedicle screw; IC, integrated clamp.

RESULTS:

- On average, the reduction in motion for the four-level continuous pedicle screw and rod construct (67%) was similar to that for constructs extended with the REVERE[®] ADDITION[®] integrated clamps (64%).
- Furthermore, for three-level and two-level constructs, no significant difference in range of motion was observed between continuous pedicle screw constructs and those revised with the REVERE® ADDITION® integrated clamps (regardless of the ratio between BPS and IC).

CONCLUSION:

In this study, the REVERE[®] ADDITION[®] posterior integrated clamps showed equivalent biomechanical rigidity to continuous pedicle screw rod constructs in revision scenarios.



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