Semi-Rigid Rod Fracture of Wave Flex

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INTRODUCTION

Wave Flex is a semi-rigid rod system, which was originally developed to prevent adjacent segmental disease next to the spinal fusion area. We experienced a rare complication of rod fracture of the wavy portion next to a two-level fusion after about one year of surgery.

CASE REPORT

Patient introduction
A 60-year-old female patient presented with acute lower back pain and severe radiating pain in both lower extremities. She had already undergone a posterior fusion from L3 to L5 three years prior at another university hospital (Fig. 1). After the operation, her lower back and leg pain gradually became more aggravated, and other conservative treatments, including nerve block, physical therapy, and medication, all failed. Her past medical history revealed a long history of rheumatoid arthritis, hypertension, and diabetes mellitus. A physical examination showed mild numbness between the left second and third toe. Preoperative computed tomography showed a solid posterior fusion mass between L3 and L4, and an interbody fusion between L4 and L5 (Fig. 2). Magnetic resonance images showed severe disc degeneration, severe paracentral disc herniation, and bilateral foraminal stenosis at L5-S1 level, which was thought to be the main pathological lesion (Fig. 3).

Diagnosis
Posterior fusion surgery from L3 to L5 level with adjacent segmental disease at L5-S1 level.

Surgical plan
1) Anterior lumbar interbody cage insertion at L5-S1 level
2) Open discectomy L5-S1
3) Wave Flex fixation (rigid rod for L4-5 and L5-S1 levels, and semi-rigid rod between L3 and L4)

Procedure
An anterior lumbar interbody fusion at L5-S1 level was done using a horseshoe cage. Posteriorly, the L5-S1 herniated disc was removed. Wave Flex rods and screws were fixed from L3 to S1. The posterior fusion mass between L3 and L4 looked relatively solid and firm. The wavy portion of the rod was located between L3 and L4. Postoperatively, the patient’s preoperative severe leg pain disappeared and she was discharged 10 days after surgery.
RESULTS

Result of operation

One year after surgery, she revisited our hospital having suddenly developed right-side hip area pain. The pain was aggravated with back motion. Simple radiographs were checked and a right-side mid-portion wavy rod fracture was found (Fig. 4). A relationship between the development of the symptom and the rod fracture was not exactly established. Painkillers were prescribed, and she was recommended for regular follow-up and close observation.

Pitfalls & complications

Preoperatively, the interbody fusion was present only at L4-5. At L3-4 level, the posterior fusion mass was definite on the right side, but no secure posterior fusion mass was found on the left side. To get more secure fusion mass, an interbody cage insertion between L3 and L4 should have been done during the operation. The wavy portion of the Wave Flex rod should have not been placed at L3-4 level.

DISCUSSION

The Wave Flex spinal system (Medyssey spine, Skokie, IL, USA) was first developed to prevent adjacent segment disease at fusion level. It is made of Ti6Al4V ELI alloy. According to the manufacturing company’s data, it passed mechanical tests for axial compression, axial tension, torsion, axial pull-out, and fatigue compression. This instru-
ment is a newly developed pedicle screw-based semi-rigid metallic device and is now in use. But instrument-related complications have not been officially reported to date. There is a domestic report of 3% of hard failure, such as screw and rod fracture, similar to those of the BioFlex system (Bio-Spine®, Seoul, Korea). The Dynesys system (Zimmer Spine, Minneapolis, MN, USA) has shown implant failure rates as high as 17%. The AccuFlex rod system (Globus Medical, Inc., Audubon, PA, USA) has been approved by the Food and Drug Administration for single-level fusion when used in conjunction with an interbody graft. There is one report about AccuFlex in which relatively high hardware failure was observed (22.22%), when it was used as a stand-alone device for posterior dynamic stabilization without fusion.

We have performed 12 cases of wavy rods application next to single fusion level, and two cases of wavy rod application next to two-level fusions (follow-ups range from 3 to 17 months). In our series, wavy rod fracture has occurred in just this one case until now (7%). A direct comparison with other implants for dynamic stabilization, like AccuFlex or BioFlex, is not plausible because of the differences in indication for each implant, and the differences between the structural and/or material features.

The possible cause of metal failure is thought to be repetitive accumulated stress next to the two-level fusion. Adjacent segmental degeneration is more likely in longer fusion levels. A greater number of cases and longer follow-up periods are needed to conclude the high risk status of semi-rigid metal failure next to two or more fusion levels.

CONCLUSIONS

The metal failure of semi-rigid portions of Wave Flex next to a two-level fusion was observed. To date, there has not been a semi-rigid rod fracture next to a single-level fusion in any of our cases. Semi-rigid rod fixation, in order to prevent adjacent segmental degeneration next to two or more fusion levels, should be undertaken with caution because of the higher stress concentration and the risk of rod fracture.

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• Conflicts of Interest
The authors report no conflict of interest. The authors alone are responsible for the content and writing of this paper.

REFERENCES