

# Long-term Course in a Patient with a Broken U-stabilizing Device in the Lumbar Spine

Fumihiko Hara<sup>1</sup>, Masakatsu Saitoh<sup>2</sup>, Masamichi Oh<sup>3</sup>, Ichiro Miyagi<sup>4</sup>, Jin Nakashima<sup>5</sup>, Sei Mihira<sup>5</sup>, Wataru Shimada<sup>5</sup> and Hiraku Kikuchi<sup>5</sup>\*

<sup>1</sup>Outcome Clinic, Hara Orthpaedic Surgery, Nara, Japan

<sup>2</sup>Department of Orthopaedic Surgery, PL Hospital, Osaka, Japan

<sup>3</sup>Outcome Clinic, Oh Orthpaedic Surgery, Osaka, Japan

<sup>4</sup>Department of Orthopaedic Surgery, Kasuganokai Hospital, Hyougo, Japan

<sup>5</sup>Department of Orthopaedic Surgery, Sakai Sakibana Hospital, Osaka, Japan

\*Corresponding Author: Hiraku Kikuchi, Department of Orthopaedic Surgery, Sakai Sakibana Hospital, Osaka, Japan.

Received: October 31, 2022; Published: Novemver 17, 2022

#### **Abstract**

**Objective:** We report a case wherein a semi-rigid interspinous "U-stabilizing device" fixation system was used for lumbar spine fenestration, with breakage that occurred 19 years ago.

**Subject and Clinical Course:** A 62-year-old male physician was received that fenestration and U- stabilizing device fixation were performed between the two vertebrae of lumber 3/4 and 4/5 for spinal canal stenosis with spondylolisthesis. On 5 years after the surgery, X-ray revealed breakage in the center of the U-stabilizing device at the lumber 3/4 vertebra. At 15 years after surgery, a vacuum phenomenon in discs was observed. In 2022, the patient was able to perform activities of daily living as a retiree at 86 years of age. The functional X-ray imaging showed that the facet joint was maintained and no ankylosis or fracture was observed.

**Discussion:** Regarding breakage of the U-stabilizing device, J. Samani, who was responsible for its development, mentioned that there was no report of breakage in 2003. At present, endoscopic fenestration is performed in similar cases, and the U-stabilizing device has not been used since 2001.

Conclusion: Long term follow-up in a patient with a broken U-stabilizing device in the lumbar spine for male physician.

Keywords: U-stabilizing; Fenestration; phenomenon; lumbar spine

## **Abbreviations**

U-device: U-Stabilizing Device Fixation System; L: Lumber; MPa: Mega Pascal; PA: Posterior-Anterior

## **Introduction and Objective**

Early ambulation and decompression maintenance have been attempted using various instruments for spinal surgery. However, since metals have different strengths from those of bones and have no affinity, they are occasionally associated with complications, such as fracture, breakage, dislocation, foreign body sensation, infection, and allergy [1]. We report a case wherein a semi-rigid interspinous "U- stabilizing device" fixation system [2] (U-device: Fixano, France) was used for lumbar spine fenestration, with early dislocation that occurred 24 years ago and breakage that occurred 19 years ago.

## **Subject and Clinical Course**

A 62-year-old male physician (height: 161 cm, weight: 72 kg) visited the Department of Orthopedic Surgery, Sakai Hospital, Kinki University School of Medicine, on April 25, 1998. Fenestration and U- device fixation were performed between the two vertebrae of lumber (L) 3/4 and 4/5 for spinal canal stenosis with spondylolisthesis with numbness and muscular weakness of the lower extremities and intermittent claudication (Figure 1). The patient was able to get out of bed with a canvas corset from the day after surgery, and the symptoms improved (Figure 2). On the 5<sup>th</sup> day after surgery, when the patient tried to pick up an object and bent the lumbar spine forward, the U-device at the L 3/4 vertebra severed the supraspinous ligament preserved by re-suturing and was dislocated posteriorly (Figure 3). A U-device was re-inserted at the L 3/4 vertebra on May 1 and a body cast was used for fixation for 3 weeks. The patient was discharged from the hospital on May 15; he returned to outcome clinic physical work as a doctor and was able to work in the field as a hobby (family farm and carp breeding). On June 18, 2003 (5 years after the surgery), low back pain occurred without cause. A multi-directional X-ray imaging (posterior-anterior: PA view, and lateral functional view) revealed breakage in the center of the U- device at the L 3/4 vertebra (maximum stress acts part of the U shape, in figure 4, physical function for lumber flection and extension was not lost). Low back pain improved with a canvas corset, and re- operation was not required. The area around the U-device was considered to be covered with fibrous tissue during the period until a stress fracture occurred at the center of the U-device.



Figure 1: Pre-operative X-ray analysis for lumber canal stenosis. From left to right: PA, flexion, neutral and extension views.



Figure 2: Post-operative X-ray analysis using U-device fixation. From left to right: PA, flexion, neutral and extension views.



Figure 3: Dislocated L3/4 U-device posteriorly: arrow.

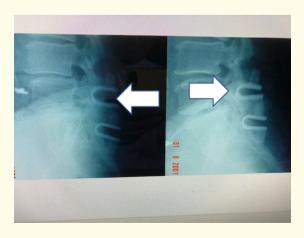
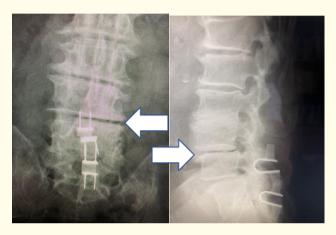
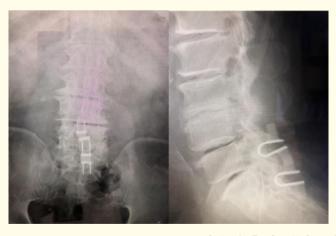


Figure 4: Breakage in the center of the U-device at the lumber 3/4 vertebra: arrows. Left: flexion, right: extension functional views.

Subsequently, we examined the X-ray images over time. At 15 years after second surgery, a vacuum phenomenon in discs was observed at both intervertebral disc levels of L 3/4 and 4/5 for inter spinous process space narrowing strongly L 3/4 more than L 4/5 (Figure 5); however, there was no loosening in the spinous process to which the device was fixed and no deformation caused by broken U-device or effects on the dura mater tube due to metallosis and granulomatous fibrosis. Compare the shear stress inter vertebral body to spinous process reported 380 mega Pascal (MPa) versus 30 MPa by spine motion stabilization [3]. In 2022, the patient was able to perform activities of daily living as a retiree at 86 years of age (Figure 6). The functional imaging showed that the facet joint was maintained and no ankylosis or fracture was observed.



**Figure 5:** At 15 years after second surgery, a vacuum phenomenon was observed: arrows and broken U device at L3/4. Left: PA view and right: lateral neutral view.



**Figure 6:** At 24years, inter spinous process space narrowing strongly L 3/4 (broken U-device) more than L 4/5. Left: PA view and right: lateral neutral view.

### Discussion

On 1998, regarding dislocation of the U-device, after contacting the manufacturer, Fixano, the new improved U-device served that a backing out prevention mechanism was added (Figure 7). On 2003, regarding breakage of the U-device, J. Samani, who was responsible for its development, mentioned that there was no report of breakage in 2003 (Table 1) [4]. We performed fixation using a U-device in seven patients until 2000 and encountered breakage in two patients. Both the patients had low back pain only at the time of breakage and did not require re-operation. The other patient (a 66-year-old man, manual worker) could not be followed up for a long period after breakage. Both of them were highly active men. If the U-device was broken in a Japanese individual with a lower body mass index and body weight than those of Europeans, it may have been caused by more frequent lumbar spine bending and stretching action or by a problem with the imported lot. The results of this long-term observation study cannot be compared with the operation results of patients only with fenestration. However, the broken U-device did not show adverse effects because decompression was achieved for a certain time period and the intervertebral joint was protected. Naturally, the patient did not want it to be removed. At present, endoscopic fenestration is performed in similar cases, and the U-device has not been used since 2001.



Figure 7: U-device served that a backing out prevention mechanism was added. Left: first device and right: revised device.

It is hard to be certain about the origin of the breakage, but it is probably due to a raw material failure. The X-rays seem to show a mobility of both parts of the device. Of course, there isn't any neurologic risk, because the total is stuck onto a fibrose avoiding any posterior migration, even less anterior, all the more because each part of the U-device is linked to the spine by the wings. So, if no pain is felt by the patient, I don't recommend to re-operate for the moment. Follow every year by X-rays. Of course, at the moment, the device doesn't fulfill its shock absorber function. We are in the case where the laminectomy has been done without posterior stabilization on this area. The only problem could be a potential metallosis around the breakage, but Magnetic Resonance Imaging would reveal it. As a conclusion, there is no risk in the future. I advise to do check-up X-rays, perhaps a Nuclear Magnetic Resonance, and not to re-operate the patient for the moment, as long as there isn't any symptom. (Original: French). Lyon, November 24, 2003 by Jacques Samani.

Table 1: Answer report from Dr J. Samani (Fixano, France) to Dr. Kikuchi via KISCO medical institute in Japan.

## Conclusion

Long-term follow-up in a patient with a broken U-device among lumber spinous process did not show adverse effects.

## Acknowledgements

Special thanks for the director general Dr Keiji Inoue (keijin-Kai group).

### **Conflict of Interest**

No potential conflict to this article was reported.

## **Bibliography**

- 1. Joachim Feger. "Complications of spinal surgery". Radiopaedia.org.
- 2. Jacques Samani. "Study of a semi-rigid interspinous "U" fixation system. 106 patients over six years". LYON. Produced by www.fixano. com (2000).
- 3. Minhyeok Heo., *et al.* "Design of lumber interspinous fixation device for minimally invasive surgery and spine motion stabilization". *Journal of Medical and Biological Engineering* 40 (2020): 1-10.
- 4. Jacques Samani. "Personal communication: Reports from Lyon" (2003).

Volume 13 Issue 11 November 2022 ©All rights reserved by Hiraku Kikuchi., et al.