Biomechanical comparison of unilateral semi-rigid and dynamic stabilization on ovine vertebrae

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Abstract
Using the unilateral pedicle screw fixation was thought to decrease the stiffness of the fixed segments. Various prospective, randomized studies were performed to determine whether unilateral pedicle screw fixation provides the necessities of bilateral fixation in one- or two-segment lumbar spinal fusion. In this study, four different unilateral pedicle screw fixation systems were evaluated to determine which one best approximated an intact spine with respect to biomechanics and kinematics. The four groups included an intact group, a unilateral facetectomy group with no fixation, a unilateral semi-rigid pedicle screw fixation group with a poly-ether-ether-ketone rod, and a unilateral dynamic pedicle screw fixation group. The bone mineral densities of all specimens were measured and specimens were matched with groups randomly. Flexion, lateral bending, and axial rotation tests were performed to compare the groups. For the flexion, lateral bending, and axial rotation tests, the best biomechanical outcomes were in the control group. The unilateral facetectomy group had the poorest performance and was not stable enough, compared with the control group. The dynamic and semi-rigid groups showed performance closer to that of the control group. The biomechanical responses of these two groups were also in good agreement, showing no significant statistical differences. Based on these test results, it is concluded that the unilateral dynamic and semi-rigid pedicle screw fixations can be used to provide stability to the vertebrae.

Keywords
Biomechanical testing/analysis, biomedical devices, orthopedic materials, spine biomechanics, spinal implants

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Introduction
In the last few decades, fusion with instrumentation has been a standard technique in the treatment of spondylolisthesis, scoliosis, fracture, tumor, and many other degenerative disorders of the thoracic, lumbar, or lumbosacral spine. Spinal fixation devices, such as pedicle screws, rods, and cages, are commonly used in instrumentation. Instrumentation restores disk height, decompresses nerve roots, provides stability, and yields good clinical results with a high fusion rate.

Besides its advantages, instrumentation has disadvantages too. Fusion with instrumentation increases the segmental rigidity while decreasing its mobility. The altering effects of fusion on the kinematics and biomechanics of the spine are well known. Studies have shown that to compensate for the reduction in mobility due to fusion, motion increases at the adjacent segment. In addition, it is believed that biomechanical stresses exceed the normal values with instrumentation at the mobile segment adjacent to the fusion. This changes the stress distribution and increases stiffness and mobility, which may cause degeneration at the adjacent mobile segment and disk. Additionally, bone mineral content in the fused segments decreases. Furthermore, the complication, morbidity, and reoperation rates increase with instrumentation, and fusion with instrumentation does not provide

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outstanding functional improvement and patient satisfaction in the long term.\textsuperscript{8}

To decrease the devastating effect of the fusion caused by stiffness, practitioners are starting to use less rigid fixation techniques. Using the unilateral pedicle screw fixation was thought to decrease the stiffness of the fixed segments. Kabins et al.\textsuperscript{9} concluded that clinical outcomes with unilateral screw fixation were nearly the same as outcomes with bilateral fixation in L4–L5 posterolateral fusion. Various prospective, randomized studies were performed to determine whether unilateral pedicle screw fixation provides the necessities of bilateral fixation in one- or two-segment lumbar spinal fusion.

In a prospective, randomized study by Suk et al.,\textsuperscript{10} unilateral or bilateral pedicle screw fixations were applied to patients. They studied operating time, blood loss, hospital stay time, clinical outcomes, fusion and complication rate, and medical expenses and then compared them statistically. No significant differences between the two groups in blood loss, clinically satisfactory results, or fusion and complication rate were shown. There were significant differences in other factors. Suk’s study showed that unilateral pedicle screw fixation could be used effectively instead of bilateral pedicle screw fixation in lumbar spinal fusion and unilateral fixation could also be used in two segments.

A similar prospective, randomized study by Fernández-Fairen et al.\textsuperscript{11} also showed that unilateral instrumentation used in patients with degenerative lumbar spondylolisthesis to substitute for bilateral instrumentation with one- or two-segment posterolateral fusion gave satisfactory outcomes. Xie et al.\textsuperscript{12} reported a clinical study in which patients who have lumbar degenerative disk diseases were treated with unilateral or bilateral pedicle screw fixation with interbody fusion. Interbody fusion was performed with one cage in one or two segments and the postoperative follow-up period was 3 years. The study concluded that unilateral pedicle screw fixation was as preferable as bilateral pedicle screw fixation with lumbar interbody fusion in one or two levels. In a recent study, Dahdahle et al.\textsuperscript{13} performed bilateral and unilateral minimally invasive transfemoral fulminant lumbar interbody fusion (MIS-TLIF) in patients. One year after surgery, clinical and radiographic outcomes of unilateral and bilateral instrumentation for MIS-TLIF were similar.

Conversely, there were also studies showing that the unilateral instrumentation was not sufficient to substitute for bilateral instrumentation. Harris et al.\textsuperscript{14} studied the effect of various instrumentation techniques on the flexibility of the lumbar spine. Four different TLIF techniques including a single unilateral carbon fiber cage in L4–L5 disk space, a cage with a contralateral transsleramic facet screw, a cage with unilateral pedicle screw, and a cage with bilateral pedicle screw were applied and compared with respect to flexibility. The study showed that the closest system to intact spine with respect to the L4–L5 segmental flexibility was TLIF with bilateral pedicle screw fixation. Similarly, Slucky et al.\textsuperscript{15} studied the stability of TLIF constructs on the human cadaveric spine with three different configurations including bilateral pedicle screw fixation, unilateral pedicle screw fixation, and a novel unilateral pedicle screw fixation supplemented with a contralateral facet screw construct. Specimens tested in flexion/extension, lateral bending, and axial rotation. There were no significant differences in stiffness or range of motion between the bilateral pedicle screw fixation and the novel construct. Unilateral pedicle screw fixation provided weak stability and increased the range of motion, which has impairing effects on fusion. Kasai et al.\textsuperscript{16} reported a biomechanical study comparing the unilateral and bilateral pedicle screw fixation. They also showed that the unilateral pedicle screw fixation offered unbalanced fixation in the direction of bending and rotation. Additionally, the bilateral pedicle screw fixation provided perfect stability in all directions.

There is still a debate over whether the unilateral pedicle screw fixation can compensate the requirements of the bilateral pedicle screw fixation. In this study, four different unilateral pedicle screw fixation systems were evaluated to determine which one best approximated an intact spine with respect to biomechanics and kinematics. The four groups included an intact group, a unilateral facetectomy group with no fixation, a unilateral semi-rigid pedicle screw fixation group with a poly-ether-ether-ketone (PEEK) rod, and a unilateral dynamic pedicle screw fixation group. The bone mineral densities of all specimens were measured and specimens were matched with groups randomly. Flexion, lateral bending, and axial rotation tests were performed to compare the groups.

**Experimental procedure**

**Sample preparation**

Ovine vertebrae were used in this study. Wilke et al.\textsuperscript{17} completed a study to compare human and ovine vertebrae. They have defined 21 dimensions (from pedicles, spinal canal, spinous and transverse processes, facets, endplates, and disk) by measuring five complete ovine spines. According to these definitions, they concluded that using thoracic and lumbar sheep spine can be a useful model in biomechanical studies. This is the main reference for our study on the usage of ovine models. After the lumbar vertebrae were taken from the ovines, bone mineral densities were measured for each spinal column with dual X-ray absorptiometry (DEXA). Each vertebrae satisfied healthy condition\textsuperscript{18} with 2–2.26 g/cm\textsuperscript{2} bone mineral density. All lumbar vertebrae were divided into two parts including L2–L3 and L4–L5 functional spinal units. These two segmental vertebrae were dissected from their soft tissues. At the end, each functional spinal unit consisted of only two vertebral bodies, an intervertebral disk, and ligaments.
The samples were stored in deepfreeze at $-40^\circ\text{C}$ until surgical operation.

Before the surgical operation, the fresh frozen cadaver vertebrae were taken out from the deepfreeze and thawed for 24h at room temperature. After all the vertebrae were thawed, they were randomly divided into four groups: a control group, a unilateral facetectomy group with no fixation, a unilateral dynamic pedicle screw fixation group, and a unilateral semi-rigid pedicle screw fixation group with PEEK rods. In the control group, there were no facetectomy or instrumentation operations performed. Only unilateral facetectomy operations without instrumentation were applied to the facetectomy group. In the dynamic group, after facetectomy, cosmic dynamic pedicle screws with 5 mm outer diameter, 35 mm length, and 6 mm diameter titanium rod were used for dynamic fixation. Dynamic pedicle screw (Tasarımmed Ltd) was used as a non-fusion technique. The screw is designed with a hinge joint at the head side, and hence dynamic capability is provided by this hinge joint. These screws are used with rigid rods. Dynamic screws provide axial mobility, load-sharing, and rotational stability. These also provide mobility to a segment and procure the stress level at the adjacent segment. In the semi-rigid group, semi-rigid fixation following the facetectomy was implemented with titanium (Ti6Al4V) pedicle screws (Osimplant Ltd) and a PEEK rod (Invibio Biomaterial Solutions). These standard polyaxial pedicle screws provide axial and rotational stability. The pedicle screws used in semi-rigid fixation have an outer diameter of 5 mm and length of 35 mm; additionally, the PEEK rods have a 5.5-mm diameter. There were 15 samples in each group and 60 samples in total. Following the instrumentations, the samples were stored in deepfreeze until the test to ensure uniformity.

Fresh frozen ovine cadavers were taken out from deepfreeze to be thawed for about 24h before the test. After thawing, they were kept inside physiological serum. Then, all samples were embedded in polyurethane (PU) foam blocks as shown in Figure 1. The PU blocks were used to attach the sample with test setups. Mediolateral and anteroposterior holes were drilled on both proximal and distal PU blocks for lateral bending and flexion test samples, respectively. For the axial rotation test samples, holes that are perpendicular to the instantaneous axis of rotation were drilled on proximal and distal PU blocks. After embedding the samples in PU foam blocks, flexion, lateral bending, and axial rotation tests were performed to measure and compare the biomechanical performance of all the groups.

**Flexion test**
The flexion test was completed with the use of an Instron 3300 test machine. Axial compression was applied at a cross-head speed of 5 mm/min. This speed was determined according to American Society for Testing and Materials (ASTM)'s quasi-static loading criteria. Load versus displacement values for each sample were recorded by the machine’s software. Yield moment, flexion angle, and stiffness of samples were calculated for each group. The test setup, critical measurements, and a test sample for flexion are shown in Figure 2. The force arm in the test setup was 100 mm.

**Lateral bending test**
The same testing equipment, cross-head speed, and measurement procedures were used in the case of the flexion test. The only difference between these two test setups was the orientation of the samples. Embedded functional spinal units were placed to test the setup for a rotation of $90^\circ$. On lateral bending tests, functional spinal units were unilaterally fixed on the posterior left side. The loading condition was also as in posterior left lateral bending. Yield moment, lateral bending angle, and stiffness of samples were again similarly calculated in the lateral bending test for each group. The test setup, critical measurements, and a test sample for lateral bending can be seen in Figure 3.

**Axial rotation test**
The axial rotation test was performed using the Instron 55MT micro torsion test frame. According to ASTM’s quasi-static loading criteria, the angular velocity was selected as $2^\circ/s$. In the axial rotation tests, functional spinal units were unilaterally fixed on the posterior left side as in the lateral bending tests. The loading condition was applied in the counter clockwise direction. Torque versus angle values were recorded by appropriate software of the test equipment. Yield torque, yield angle, and stiffness of samples were calculated. The test
setup and a test sample for axial rotation can be seen in Figure 4. All tests were repeated five times for each group for statistical purposes.

### Statistical analysis

Student’s t-tests and analysis of variance (ANOVA) were applied to decide whether there is a statistically significant difference between the groups with respect to the yield and stiffness values. \( p \)-Values were calculated to compare the groups.

### Experimental results

#### Flexion test results

Table 1 summarizes the results of the flexion tests, providing the mean and standard deviation of yield moments, flexion angles at yield, and stiffness.
For yield moment, the semi-rigid system had the highest value of 84.25 N m. The yield moment of the semi-rigid group was 36% higher than the control group. On the other hand, the control group was 57% and 52% higher than the facetectomy and dynamic groups, respectively.

Flexion angle, occurring at the yield point, is an important factor for stability. The flexion value of the control group was 1.31 \(^\circ\). The flexion angle values for the facetectomy, dynamic, and semi-rigid groups were 2.81, 2.47, and 2.23 times higher than the control group, respectively.

Stiffness is another important parameter when considering the flexion test results. The control group had the highest stiffness value at 84.95 N/mm, and the facetectomy group had the lowest at 63.39 N/mm. The stiffness values for the control and semi-rigid groups were close to each other. Stiffness for the control group was only 6% higher than the semi-rigid group. However, stiffness for the control group was 34% and 15% higher than the facetectomy and dynamic groups, respectively.

### Table 1. Flexion test results and statistical chart of the groups.

<table>
<thead>
<tr>
<th>Flexion test</th>
<th>Control</th>
<th>Facetectomy</th>
<th>Dynamic</th>
<th>Semi-rigid</th>
<th>a</th>
<th>b</th>
<th>c</th>
<th>d</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yield moment</td>
<td>Mean (N m)</td>
<td>61.68</td>
<td>39.36</td>
<td>40.53</td>
<td>84.15</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Std.</td>
<td>7.10</td>
<td>6.67</td>
<td>5.17</td>
<td>11.04</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flexion angle at yield</td>
<td>Mean (°)</td>
<td>1.31</td>
<td>3.67</td>
<td>3.23</td>
<td>2.91</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
</tr>
<tr>
<td>Std.</td>
<td>0.05</td>
<td>0.26</td>
<td>0.14</td>
<td>0.35</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stiffness</td>
<td>Mean (N/mm)</td>
<td>84.95</td>
<td>63.39</td>
<td>73.74</td>
<td>80.32</td>
<td>✓</td>
<td>✓</td>
<td>x</td>
</tr>
<tr>
<td>Std.</td>
<td>4.38</td>
<td>4.37</td>
<td>4.11</td>
<td>7.86</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Yield moment, flexion angle yield point and stiffness values were calculated by using static test plots and force arm length.

* a, b, c, and d letters show the statistical comparison between control and facetectomy, control and dynamic, control and semi-rigid, and dynamic and semi-rigid groups, respectively.

''✓'' means there is a statistically significant difference between groups.

''x'' means there is no statistically significant difference between groups.

### Table 2. Lateral bending test results and statistical comparison of the groups.

<table>
<thead>
<tr>
<th>Lateral bending test</th>
<th>Control</th>
<th>Facetectomy</th>
<th>Dynamic</th>
<th>Semi-rigid</th>
<th>a</th>
<th>b</th>
<th>c</th>
<th>d</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yield moment</td>
<td>Mean (N m)</td>
<td>115.50</td>
<td>60.96</td>
<td>83.16</td>
<td>87.85</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Std.</td>
<td>14.27</td>
<td>9.68</td>
<td>8.88</td>
<td>12.43</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lateral bending angle at yield</td>
<td>Mean (°)</td>
<td>3.32</td>
<td>5.21</td>
<td>3.78</td>
<td>3.63</td>
<td>✓</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Std.</td>
<td>0.56</td>
<td>0.69</td>
<td>0.49</td>
<td>0.24</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stiffness</td>
<td>Mean (N/mm)</td>
<td>88.20</td>
<td>67.12</td>
<td>80.24</td>
<td>70.28</td>
<td>✓</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Std.</td>
<td>6.33</td>
<td>7.36</td>
<td>7.37</td>
<td>9.00</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Yield moment was calculated by using yield load force arm length values.

* a, b, c, and d letters show the statistical comparison between control and facetectomy, control and dynamic, control and semi-rigid, and dynamic and semi-rigid groups, respectively.

''✓'' means there is a statistically significant difference between groups.

''x'' means there is no statistically significant difference between groups.

Figure 4. (a) Axial rotation test setup and (b) an axial rotation sample from test. The test sample is fastened to test machine horizontally and torque is applied in counter clockwise direction.

Lateral bending test results

Table 2 summarizes the results of the yield moments, lateral bending angles, and stiffness of the lateral bending test. The values are given with the mean and standard deviation values.

The control group had the highest yield moment value of 115.5 N m. The yield moment value of the control group was 89%, 39%, and 31% higher than for...
the facetectomy, dynamic, and semi-rigid groups, respectively.

The lateral bending angle was at the highest value in the facetectomy group at 5.21 N.m. The bending angle value of the facetectomy group was 57% higher than for the control group. Similarly, the bending angle values of the dynamic and semi-rigid groups were 14% and 9% higher than the control group, respectively.

Considering the results for the stiffness, the control group performed best for lateral bending loads with 88.2 N/mm. The stiffness values of the control group were 31%, 10%, and 25% higher than for the facetectomy, dynamic, and semi-rigid groups respectively.

**Axial rotation test results**

The results of the yield torque, yield angle, and stiffness tests are summarized in Table 3 with the mean and standard deviation values.

The yield torque of the control group was 17.62 N.m. When comparing the yield torque, the control group was 2.02 times the facetectomy group and only 8% higher than the semi-rigid group. Surprisingly, the yield torque value of dynamic group was 5% higher than the control group.

At 8.54°, the yield angle value of the control group was lower than for all other groups. The facetectomy, dynamic, and semi-rigid groups were 69%, 19%, and 27% higher than the control group, respectively.

The control group had a value of 1.32 N m/° for stiffness, which was 2.02 times the value for the facetectomy group. The control group was also 38% and 34% higher than the dynamic and semi-rigid groups, respectively. The stiffness values for the dynamic and semi-rigid groups were close to each other.

**Discussion**

Unilateral facetectomy may be used as a treatment in lumbar spinal pathologies, disk herniation to spinal cord and nerve roots, spinal canal stenosis, and other disorders that require facetectomy. Facetectomy may be performed partially or completely. Facetectomy decreases the spinal stability as expected and affects the biomechanics of the spine under flexion, lateral bending, and axial rotation movements.

In flexion and lateral bending tests, it was thought that facetectomy decreased the yield moment and stiffness and increased the flexion angle and lateral bending angle. There were statistically significant differences between the control and facetectomy group in the yield moment, stiffness, flexion angle, and lateral bending angle ($p < 0.05$). These results showed that the facetectomy group transferred to plastic zone under lower forces than the control group and had higher flexion and lateral bending angles. Additionally, facetectomy decreased the stiffness. From that point, the facetectomy group had the most unstable condition, as expected, and needed to be stabilized.

For the axial rotation test, there were statistically significant differences between the control and facetectomy groups in yield torque, yield angle, and stiffness ($p < 0.05$) which can be seen in Table 4. The control group had a higher yield torque and a lower yield angle in comparison. Also, the control group was stiffer than the facetectomy group. There is an agreement over the range of axial rotation of each vertebra, which is $1^{\circ} - 2^{\circ}$ in the lumbar spine. Because of this limitation, facets provide good stability to the spine. So performing facetectomy decreases the stability. On the other hand, there are converse considerations about damage threshold in a lumbar spine with axial rotation.

To prevent the instability that occurs after the facetectomy, the posterior bilateral fusion surgery was conducted. Researchers have stated that bilateral spinal fixation changes the biomechanical responses and kinematics of the spine and may cause degenerative disorders at adjacent segments and disks in the long term. To decrease the complications after instrumentation, new screw and rod types, which led to limited mobility, were designed in previous studies. Our study focused on the possibility of using such systems on unilateral fixations. This is not a comparison study based on the advantages between bilateral and unilateral systems.

PEEK rods and cosmic pedicle screws are just two of them. The main benefit of such systems is allowing slight movement after the surgery. These implants do
not provide the normal range of motion, but they provide some motion to the spine.

The ideal fixation system would provide adequate stability with maximum fusion rates. It would also prevent excessive rigidity and sustain normal spinal posture and sagittal alignment that do not cause complications in the long term.23

When considering the results of the control and dynamic systems, there were statistically significant differences between the groups for yield moment, flexion angle, and stiffness in flexion test \((p < 0.05)\). Using the dynamic system after unilateral facetectomy decreased the yield moment and stiffness and increased the flexion angle. Increasing the flexion angle may be dangerous for adjacent segments in the long term. For the lateral bending test, there was a statistically significant difference between the groups for yield moment \((p = 0.0039)\) but no difference for yield torques. The control group, the semi-rigid fixation group also exhibited similar results in the direction of lateral bending compared with the control group. Additionally, for yield angles and stiffness, there were statistically significant differences between the groups in the axial rotation test \((p < 0.05)\) but no difference for yield torques. The control group had a lower rotation angle and higher stiffness. Stiffness and mobility are important factors for instrumentation. This showed that for the lateral bending angle and stiffness in the lateral bending test, and the yield torque in axial rotation test, the dynamic group had good results with respect to similarity to the control group, because there were no statistically significant differences for these parameters. In other words, the dynamic group exhibited close results to the control group for the investigated parameters but this improvement is not sufficient.

When comparing the test results of the control and semi-rigid systems, there were no statistically significant differences between the groups for stiffness in the flexion test \((p > 0.05)\). Also, there were no differences for the lateral bending angle in the lateral bending test and for yield torque in the axial rotation test \((p > 0.05)\). For all other parameters, there were statistically significant differences \((p < 0.05)\). For the control group, the yield moment was lower in the flexion test and higher in the lateral bending test. In the flexion test, the flexion angle was higher for the semi-rigid group, and the yield angle was higher for the semi-rigid group in the axial rotation test. In addition, the stiffness was lower for the semi-rigid system in both lateral bending and axial rotation tests. PEEK rods provided stiffness, which lost with facetectomy, to stabilize the spine. However, the stabilization was not adequate because of significant differences in stiffness between the groups in lateral bending and axial rotation tests. As in the case of the dynamic group, the semi-rigid fixation group also exhibited similar responses to those of the control group.

When considering the results of the dynamic and semi-rigid group tests, except the yield moment in the flexion test \((p = 0.0003)\), there were no statistically significant differences between the groups \((p > 0.05)\). In the flexion test, the yield moment value of the semi-rigid group was approximately two times the values for the dynamic group. For many of the other parameters, both the semi-rigid and dynamic systems exhibited closer results to the control group than to each other. For this reason, it cannot be said that any of these systems is superior to the other.

**Conclusion**

In this study, a semi-rigid fixation with a PEEK rod and dynamic fixation with a cosmic pedicle screw were
biomechanically tested and compared with control and unilateral facetectomy groups. For the flexion, lateral bending, and axial rotation tests, the best biomechanical outcomes were in the control group. The unilateral facetectomy group had the poorest performance and was not stable enough, compared with the control group. The dynamic and semi-rigid groups showed performance closer to that of the control group. The biomechanical responses of these two groups were also in good agreement, showing no significant statistical differences. Based on these test results, it is concluded that the unilateral dynamic and semi-rigid pedicle screw fixations can be used to provide stability to the vertebrae.

Limitations

- Although there is a slight difference in anatomy of L2–L3 and L4–L5 levels, these levels were used for the biomechanical tests because of limitations in the number of specimens available.
- Although the current almost “gold standard” method for testing the stability of instrumentation is to find the “neutral zone” and “range of motion” of a segment, this study was based on using the theoretical instantaneous motion center as the loading axis. This should be taken in account while evaluating the results of this study for clinical applications.

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Declaration of conflicting interests

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