The role of counter-torque holders in tightening of pedicle screw-rod constructs: a biomechanical study in a porcine model

Ming-Kai Hsieh, MD, PhD, Po-Yi Liu, PhD, Yun-Da Li, MD, Chi-Yun Wang, PhD, Chih-Chung Hu, MS, Ching-Lung Tai, PhD, Po-Liang Lai, MD, PhD

Abstract

BACKGROUND CONTEXT: Pedicle screw-rod assembly procedures following pedicle screw insertion include contouring and placing rods into screw tulips, introducing set screws into the tulip along the screw thread, applying a counter-torque holder and tightening all the set screws clockwise. Even if an appropriate pedicle screw is implanted, screw dislodgement after tightening of the tulip and set screw is not uncommon. Pedicle wall violation resulting from excessive rotational force due to inadequate use of a counter-torque holder might be the reason. However, the strain change in the pedicle during tulip-set screw tightening and the role of counter-torque have never been investigated.

PURPOSE: This study determined differences in the strain change in the outer and inner pedicle walls during tulip-set screw tightening; additionally, the influence of counter-torque on pedicle wall violation was elucidated.

STUDY DESIGN: A controlled biomechanical study; the strain values of outer and inner pedicle walls in cadaveric porcine L4-L5 vertebrae during tulip-set screw tightening with or without a counter-torque holder were measured.

METHODS: Twelve L4-L5 fresh-frozen porcine lumbar vertebrae were implanted with screw-rod constructs; the set screw was randomly locked into the tulip in the right L5, right L4, left L5 and left L4 testing groups. The maximal values from eight strain gauges (P-R-O: outer cortex of right pedicle in proximal vertebra; P-R-I: inner cortex of right pedicle in proximal vertebra; D-R-O: outer cortex of right pedicle in distal vertebra; D-R-I: inner cortex of right pedicle in distal vertebra; P-L-O: outer cortex of left pedicle in proximal vertebra; P-L-I: inner cortex of left pedicle in proximal vertebra; D-L-O: outer cortex of left pedicle in distal vertebra; D-L-I: outer cortex of left pedicle in proximal vertebra) for each specimen during tightening to 12 Nm were measured.

RESULTS: The maximal strain values of the ipsilateral strain gauges in all testing groups were almost significantly higher when a counter-torque holder was not used than when one was used. The strain values in the adjacent pedicle of specimens without a counter-torque holder were significantly increased: P-R-O and P-R-I in the right L5 group; D-R-I in the right L4 group; P-L-I and P-L-O in the left L5 group; D-L-O and D-L-I in the left L4 group.
Introduction

Pedicle screw instrumentation has become a popular and reliable method of spinal fixation for managing various spinal pathologies [1−3]. Confirmation of proper pedicle screw placement is performed via several methods, including manual palpation [4,5], fluoroscopy or computer tomographic imaging confirmation in both anteroposterior and lateral views [6,7], computer-based surgical navigation [8], and electrophysiological monitoring [9,10]. Pedicle screw-rod assembly procedures following adequate screw insertion include contouring and placing rods into the tulips of screws, introducing set screws into the tulip along the screw thread, applying a counter-torque holder, and tightening all set screws clockwise [11,12].

Even if an appropriate pedicle screw is implanted, screw dislodgement after tightening of the tulip and set screw in minimally invasive spinal surgery or short-level instrumented fusion [13,14] is not uncommon. Pedicle wall violation resulting from excessive rotational force from inadequate use of the counter-torque holder might be the reason. To the best of the authors’ knowledge, the strain change in the pedicle wall during tulip-set screw tightening and the role of a counter-torque holder have never been investigated. The present study aimed to determine any differences in the strain change in the outer and inner pedicle walls during tulip-set screw tightening. Through the analysis of strain change, the influence of counter-torque on pedicle wall violation was clarified.

Materials and methods

Specimen preparation and implantation

This study was performed using twelve L4-L5 fresh-frozen lumbar vertebrae harvested from mature pigs (weight 90-100 kg). All the animals were healthy before the vertebrae were harvested and were never exposed to any drugs or procedures that could affect the normal bone density [15]. All the specimens were separated into individual functional spinal units after the surrounding musculature, ligaments, and periosteum were stripped off. All the specimens were stored at -20°C until the day of testing and thawed for 24 hours before implantation. A pilot hole was drilled using a 2.5 mm bench drill. This trajectory was selected based on previously reported similar morphometric characteristics between humans and porcines [16,17]. The pilot track was followed with a standard straight pedicle probe to a depth of 40 mm. Polyaxial screws (SmartLoc spinal polyaxial pedicle screws, A-spine Asia Co. Ltd., Taipei, Taiwan) were chosen and randomly implanted into each pedicle of the vertebrae by an experienced surgeon. L4 to L5 paired segmental screw implantation (diameter × length dimension of 6.0 mm × 40 mm) and rod fixation (diameter × length dimension of 5.0 mm × 70 mm) were carried out in all twelve specimens.

Prior to biomechanical testing, the bone integrity and screw depth/trajectory were assessed in both the sagittal and coronal planes using X-ray images. The position of screws inside the pedicle was further evaluated in axial planes using computer tomography (CT) scan (S3002, SCENARIA, Hitachi, Kashiwa, Japan). Mechanical tests under conditions in which appropriate screw trajectories, insertional depths and alignments were achieved were performed on all the specimens, and no fractures or defects in the vertebrae in either the anterior-posterior or lateral view after instrumentation occurred. Before testing, the ventral part of the vertebral body was potted in metal boxes using specific epoxy resins (Buehler, Lake Bluff, IL, USA). Judicious potting was performed to ensure that the cement did not come into contact with any portion of the screws or pedicles.

Specimen grouping and biomechanical testing

Before strain gauge attachment, the inner and outer cortices of the pedicles were cleared of tissue and cleaned with ethanol. All the strain gauges (Showa Measuring Instruments Co., Ltd., Tokyo, Japan) were applied perpendicular to the axis of the pedicle screws using MBond 200 adhesive, an n-butyl cyanoacrylate (Measurement Group, Raleigh, NC). The configuration perpendicular to the pedicle screw axis was used to evaluate the expansile and twisting effect of the pedicle during tulip-set screw tightening.

One strain gauge was applied to the outer wall of the pedicle, and another one was applied to the inner wall; a total of eight strain gauges were applied in each specimen (P-R-O: outer cortex of right pedicle in proximal vertebra; P-R-I: inner cortex of right pedicle in proximal vertebra; D-R-O: outer cortex of right pedicle in distal vertebra; D-R-I: inner cortex of right pedicle in distal vertebra; P-L-O: outer cortex of left pedicle in proximal vertebra; P-L-I: inner cortex of left pedicle in proximal vertebra;
cortex of left pedicle in proximal vertebra; D-L-O: outer cortex of left pedicle in distal vertebra; P-L-O: outer cortex of left pedicle in proximal vertebra; P-L-I: inner cortex of left pedicle in proximal vertebra; D-L-O: outer cortex of left pedicle in distal vertebra; D-L-I: inner cortex of left pedicle in distal vertebra). The proximal vertebra was L4, while the distal vertebra was L5 (Fig. 1). The strain gauges were connected and recoded by using a strain data acquisition system (National Instruments, Compact Ltd, Austin, Texas, USA) through a wire. Balance and calibration of strain signals were performed before testing. Each test was repeated five times to assess reproducibility. The maximum and minimum strain values were recorded and calculated using FlexLogger software (National Instruments, Compact Ltd, Austin, Texas, USA). Each intact specimen was tested for five cycles at a load rate controlled to 10 Hz in torque to 12 Nm.

The testing sequences of right L5, left L5, right L4, and left L4 were randomly applied to all twelve specimens. Three steps were performed for each specimen. First, three tulip-set screws were tightened to 12 Nm by using a counter-torque holder. Second, the index testing tulip-set screw was tightened from loose to 12 Nm with a counter-torque holder. The tests were repeated for a total of five cycles. In situ calibration was performed before each test.

Third, after five cycles were finished, the index testing tulip-set screw was tightened from loose to 12 Nm without the use of a counter-torque holder, and this test was repeated for a total of five cycles (Fig. 2). All strain-time graphs of the strain gauges were recorded and analyzed.

Statistical analysis

To evaluate the difference in the eight pedicle strains in the same specimen during tulip-set screw tightening at different pedicle screws and the role of the counter-torque holder, the maximal pedicle strains were statistically compared. All of the measurements are expressed as the mean ± standard deviation (SD).

One-way analysis of variance (one-way ANOVA) and post hoc Tukey’s test were used to detect significant differences in strain values between the gauges in each specimen. Student’s t test was used to detect significant differences with or without counter-torque. Statistical software (Microsoft office Excel 2019, Microsoft Corporation, State of Washington, USA) was used for all specimens. Differences were considered to be significant at p < 0.05.

Fig. 1. Illustrations showing the sites of the eight strain gauges in each specimen. P-R-O: outer cortex of right pedicle in proximal vertebra; P-R-I: inner cortex of right pedicle in proximal vertebra; D-R-O: outer cortex of right pedicle in distal vertebra; D-R-I: inner cortex of right pedicle in distal vertebra; P-L-O: outer cortex of left pedicle in proximal vertebra; P-L-I: inner cortex of left pedicle in proximal vertebra; D-L-O: outer cortex of left pedicle in distal vertebra; D-L-I: inner cortex of left pedicle in proximal vertebra.
Results

Specimen characterization

An appropriate screw trajectory and insertional depth were confirmed using coronal and sagittal X-ray imaging prior to biomechanical testing (Fig. 3). In the coronal view, all the pedicle screws were convergently inserted into the vertebral body. In the sagittal view, both the pedicle screws in the same specimen were parallel to the superior end-plates, which is consistent with current surgical techniques. In the axial view of the CT scan (Fig. 4), paired segmental screw implantations in L4 (Fig. 4A) and L5 (Fig. 4B) showed that both screws were convergently inserted into the vertebral body without pedicle wall violation. The same screw depth could not be completely revealed in the same axial view due to the minimal asymmetric sagittal trajectory. No fractures or defects in the vertebrae were detected in either view.

Strain values in all testing groups with or without counter-torque

A strain-time graph of the eight strain gauges in one cycle of the right L5 testing groups without a counter-torque holder is shown in Fig. 5. During the initial tightening of the set screw into the tulip, the strain value obviously increased for the same side strain gauges. As the tightening reached 12 Nm, the maximal strain values of the P-R-O and P-R-I gauges were higher than those of the other gauges. When the tightening was released, all values decreased to the baseline (Fig. 5). Detailed strain values in all the testing groups are shown in Table 1. In the right L5 testing groups, the strain values with counter-torque for the P-R-O, P-R-I, D-R-O, D-R-I gauges were 140.78 ± 48.54, 97.78 ± 52.23, 54.20 ± 28.95, and 31.64 ± 24.14 microstrain, respectively; the values without counter-torque were 461.68 ± 132.11, 185.20 ± 73.79, 135.09 ± 63.12 and 94.76 ± 53.22 microstrain, respectively (Table 1). There was no significant difference between the gauges with counter-torque (Fig. 6). The maximal strain values were significantly higher without counter-torque than with counter-torque for all the strain gauges.

In the right L4 testing groups, the values were significantly higher for the D-R-I gauge without counter-torque but were not significantly different between the gauges with counter-torque (Fig. 7). The maximal strain values were significantly higher without counter-torque than with counter-torque for the D-R-I and P-R-I gauges.

In the left L5 testing groups, the values were significantly higher for the P-L-O and P-L-I gauges without counter-torque but were not significantly different between the gauges with counter-torque (Fig. 8). The maximal strain values were significantly higher without counter-torque than with counter-torque for the D-L-I, P-L-O, and P-L-I gauges.

In the left L4 testing groups, the values were significantly higher for the D-L-O and D-L-I gauges without counter-torque but were not significantly different between the gauges with counter-torque (Fig. 9). The maximal strain values were significantly higher without counter-torque than with counter-torque for the D-L-O, D-L-I, and P-L-O gauges.

Discussion

Despite the correct implantation of pedicle screws, the assembly of the final rod-screw construct is not free of complications. Interbody fusion cage dislocation due to set screw breakage after open transforaminal lumbar interbody fusion surgery has been reported [13]. Thirty patients out of...
280 consecutive patients who underwent short segment spinal fixation due to thoracolumbar fracture were reported to experience construct failure [18]. Screw-rod construct failures resulting from inappropriate rod bending, incorrect application of rods over screw tulips, set screw breakage, screw/rod dislodgement, progressive kyphosis, disengaged screw tulips, and inappropriate tulip-set screw tightening techniques have also been reported [14,18]. Even if proper

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**Fig. 3.** Photograph and X-ray images showing coronal and sagittal views prior to biomechanical testing. Paired segmental screw implantations from L4-L5 were carried out in all porcine spines. In the coronal view, both screws were convergently inserted into the vertebral body (A, C). In the sagittal view, both screws were inserted parallel to the superior endplates (B, D). An appropriate screw trajectory and insertional depth were confirmed. No fractures or defects in the vertebrae were detected in either view.

**Fig. 4.** Axial view of CT scan. Paired segmental screw implantations in L4 (A) and L5 (B) showed that both screws were convergently inserted into the vertebral body without pedicle wall violation. The same screw depth could not be completely revealed in the same axial view due to the minimal asymmetric sagittal trajectory.
pedicle screw insertion is confirmed by perioperative fluoroscopy, the postoperative pedicle wall breach can reach 11.9% to 28.9% after final rod-screw assembly [19].

Fresh frozen spines of six human and six porcine cadavers were anatomically compared with CT scans [17]. The L4-5 segments from these two specie had similar vertebral body heights, intervertebral disc heights and pedicle widths/heights, but a significantly smaller spinal canal widths and depths were observed in pigs (20mm) than in humans (40mm). In our study, using porcine L4-5 as testing specimens could not only prevent medial pedicle wall violation (40mm). In our study, using porcine L4-5 as testing specimens could not only prevent medial pedicle wall violation but also eliminate biomechanical confounding factors from non-cancellous bone purchase. In our CT scan (Fig. 4), both screws were convergently inserted into the vertebral body without pedicle wall violation. Before testing, the ventral part of the vertebral body was potted in metal boxes using specific epoxy resin.

By fixing the testing specimens, the strain change of pedicle was caused by the torque wrench alone to elucidate the effect of counter-torque. In cadaver torsos, the strain value could be confounded by the motion of other non-instrumented spinal segments, laxity of disc-vertebral joints/facet joints, rigidity of longitudinal ligament or bridging osteoarthrytes [20,21].

Strain gauges have been widely used in vivo and in vitro in recent years [22–25]. Investigations of the use of telemetry unit in combination with these gauges shows accurate measurements when load rates of 1 Hz are used even after the transmitter has been repeatedly sterilized and used for 3 months in vitro [24,25]. Accurate measurement and a consistent monitoring system have also been used to detect the onset of fusion and change in strain during postsurgical daily activities [23]. In a study evaluating the breakage of pedicle screw-connected rods, the trend of strain measurement was shown to be correlated with finite element results [22]. In our study, new strain gauges were used in each specimen, balance and calibration of strain signals were performed before each test, and the load rate was controlled to 10 Hz.

This biomechanical study is the first to evaluate the strain value of outer and inner pedicle walls during tulip-set screw tightening. In an ex vivo biomechanical test, over 1500 microstrains were detected in porcine lumbar laminae under asymmetric loading [26], which implies our data were still within the range of maximal elastic modulus. Anatomical features of pedicles that are similar to those of human pedicles and commonly used screw sizes made our strain value reliable and practical [17]. The strain value was proven to change with decreased bone mineral density [27]. In the current study, healthy mature pigs were used to prevent normal bone but osteoporotic porcine model could be applied for wider clinical reference.

The strain change on the opposite side of the tulip-set screw testing group was minimal and could be free of analysis; only the ipsilateral side was analyzed. Without the use of a counter-torque holder, the maximal strain value was significantly increased in the adjacent pedicle of the testing group: P-R-O and P-R-I in the right L5 groups; D-R-I in the right L4 groups; P-L-I and P-L-O in the left L5 groups; and

Table 1
Maximal strain value (mean ± SD, microstrain) of the same side strain gauges of the testing groups

<table>
<thead>
<tr>
<th>Testing group</th>
<th>Strain gauge</th>
<th>P-R-O</th>
<th>P-R-I</th>
<th>D-R-O</th>
<th>D-R-I</th>
</tr>
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<tbody>
<tr>
<td>Right L5</td>
<td>With counter-torque</td>
<td>140.78 ± 48.54</td>
<td>97.78 ± 52.23</td>
<td>54.20 ± 28.95</td>
<td>31.64 ± 24.14</td>
</tr>
<tr>
<td></td>
<td>Without counter-torque</td>
<td>461.68 ± 132.11</td>
<td>185.20 ± 73.79</td>
<td>135.09 ± 63.12</td>
<td>94.76 ± 53.22</td>
</tr>
<tr>
<td>Right L4</td>
<td>With counter-torque</td>
<td>123.05 ± 19.46</td>
<td>149.41 ± 87.01</td>
<td>184.25 ± 81.53</td>
<td>273.38 ± 120.72</td>
</tr>
<tr>
<td></td>
<td>Without counter-torque</td>
<td>161.98 ± 64.11</td>
<td>259.95 ± 150.74</td>
<td>107.93 ± 48.74</td>
<td>665.16 ± 273.52</td>
</tr>
<tr>
<td>P-L-O</td>
<td>With counter-torque</td>
<td>87.10 ± 39.52</td>
<td>143.24 ± 56.04</td>
<td>85.05 ± 43.11</td>
<td>81.67 ± 48.68</td>
</tr>
<tr>
<td></td>
<td>Without counter-torque</td>
<td>268.15 ± 125.94</td>
<td>510.76 ± 211.85</td>
<td>155.89 ± 59.97</td>
<td>106.85 ± 72.61</td>
</tr>
<tr>
<td>Left L5</td>
<td>With counter-torque</td>
<td>128.69 ± 65.83</td>
<td>90.47 ± 70.53</td>
<td>139.18 ± 75.20</td>
<td>115.96 ± 76.46</td>
</tr>
<tr>
<td></td>
<td>Without counter-torque</td>
<td>205.87 ± 57.59</td>
<td>122.79 ± 32.39</td>
<td>664.23 ± 223.13</td>
<td>314.76 ± 116.75</td>
</tr>
</tbody>
</table>
Fig. 6. **Average maximal values of the strain gauges in the right L5 testing groups.** The value was significantly higher for the P-R-O and P-R-I gauges than for the D-R-O and D-R-I gauges without counter-torque (p<0.05) (orange color). The values in each group were significantly increased without counter-torque compared to with counter-torque (blue color) (p<0.05). There was no significant difference between gauges with counter-torque (blue color). #ms: microstrain.

D-L-O and D-L-I in the left L4 groups (Figs. 6−9, orange color bars). The clockwise rotational force created by the torque driver of the testing groups transmitted to the adjacent pedicle screw through the rod and thus significantly increased the strain value of the adjacent pedicle. The value of the P-R-O gauge was significantly higher than that of the P-R-I gauge in the right L5 testing groups, suggesting that the clockwise force applied to adjacent pedicle screws significantly increased more values in the outer cortex than in the inner cortex. The same phenomenon was also observed in the other groups: a higher strain value for the D-R-I than for the D-R-O in the right L4 testing groups, a higher value for the P-L-I than for the P-L-O in the left L5 testing groups and a higher value for the D-L-O than for the D-L-I in the

Fig. 7. **Average values of the strain gauges in the right L4 testing groups.** The values were significantly higher for the D-R-I gauge without counter-torque (p<0.05) (orange color), but there was no significant difference between the gauges with counter-torque (blue color). The maximal strain values were significantly higher without counter-torque than with counter-torque for the D-R-I and P-R-I gauges. #ms: microstrain.
left L4 testing groups. Thus, when tightening the right distal set screws, the outer wall of the proximal pedicle has the maximal strain; when tightening the right proximal set screw, the inner wall of the distal pedicle has the maximal strain; when tightening the left distal set screws, the inner wall of the proximal pedicle has the maximal strain; and when tightening the left proximal screw, the outer wall of distal pedicle has the maximal strain. In three level fixation, we believe that when tightening the right distal set screws, the outer wall of the middle and proximal pedicle also experience maximal strain, but the value might be lower than that in our 2 level study. The same clockwise rotational force could be shared by the two proximal screws.

By the early 1990s, nontulip-based systems were popular, and these systems included 1) side-rodding systems, which consisted of knurled rod with set bolts that were locking the screw to the rod [28], and 2) an inner screw and outer nut locking system, which provided six-point contact, and allowed a firm grip of the pedicle screw to the rod [29]. However, extensive para-spinal muscle dissection, and

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**Fig. 8.** Average values of the strain gauges in the left L5 testing groups. The values were significantly higher for the P-L-O and P-L-I gauges without counter-torque ($p<0.05$) (orange color), but there was no significant difference between the gauges with counter-torque (blue color). The maximal strain values were significantly higher without counter-torque than with counter-torque for the D-L-I, P-L-O, and P-L-I gauges. #ms: microstrain.

**Fig. 9.** Average values of the strain gauges in the left L4 testing groups. The values were significantly higher for the D-L-O and D-L-I gauges without counter-torque ($p<0.05$) (orange color), but there was no significant difference between the gauges with counter-torque (blue color). The maximal strain values were significantly higher without counter-torque than with counter-torque for the D-L-O, D-L-I, and P-L-O gauges. #ms: microstrain.
complicated procedures have resulted in difficult revision and nonrigid fixation made tulip-based systems popular in modern era. We believe that the strain change in adjacent pedicle wall would be decreased in nontulip system because of multiple connecting joints. Clockwise force transmitted to the adjacent pedicle screw is expected to be distributed by multiple rod-bolts and nuts. Nonetheless, the importance of counter-torque should be emphasized in modern tulip-based spinal surgery.

The bone area fraction has been shown to be less than 64% of the outer pedicle wall compared to 99.8% of the inner pedicle wall, which implies that the outer cortex is weaker than the inner cortex [30]. Since a higher strain value was measured in the outer cortex in the right L5 (P-R-O) and left L4 (D-L-O) testing groups, caution is recommended when using a torque driver for the right L5 and left L4 to avoid construct failure related to outer pedicle wall violation. The strain value of the P-R-O gauge without counter-torque was 461.68 ± 132.11 microstrain in the right L5 testing groups, and the value of D-L-O was 664.23 ±223.13 microstrain in the left L4 testing groups, implying that higher strain was observed in distal vertebra, which was correlated with another study [30].

There was no significant difference between gauges in all the groups when counter-torque was used (Figs. 6—9, blue bars). During rotation of the torque driver, a counter-torque holder was applied relative to the implant to avoid undesirable rotational force transmitted to the adjacent vertebrae. The constraint effect created by the counter-torque restrained the excessive rotational force after the set screws and tulip were locked.

The present study had some limitations. First, only one type of screw and rod was tested in our study, and larger diameter screws/rods or mono-axial screws could produce different results. A larger screw diameter rationally increases pedicle wall strain but might risk pedicle wall violation and thus made our biomechanical data unreliable. Second, even when the screws were inserted into the medulla of the pedicle, the different proximities of the screw and two cortical walls (outer wall and inner wall) could not be completely controlled in the testing groups, which could explain why no significant difference was found for the D-R-O gauge of the right L4 testing groups. Third, different density distributions of the pedicle between pigs and humans cannot reveal the true clinical condition. Finally, lumbar vertebrae with normal bone density experimentally might not totally reflect clinical biomechanical data from osteoporotic spines. Further biomechanical evaluation using different spinal bone densities may be needed.

Conclusion

This biomechanical study demonstrated that the constraint effect of counter-torque during tulip-set screw tightening is necessary. The unintentional force by the rotational torque driver after tulip and set screws were locked and transmitted to the ipsilateral adjacent pedicle significantly increased the strain values and increased the risk of pedicle wall violation. Clockwise rotational force with a fragile lateral pedicle wall implies that caution is necessary when using a counter-torque holder to tighten the right distal and left proximal constructs.

Author contributions

M. K. Hsieh, and P. Y. Liu performed the experimental laboratory work, data analyses and manuscript drafting. Y. D. Li, C. Y. Wang and C. C. Hu provided the materials and animals and participated in the experimental design. M. K. Hsieh, P. Y. Liu, C.L. Tai and P. L. Lai advised and assisted drafting of the manuscript. All authors have read and approved the final submitted manuscript.

Federal of Competing Interest

None.

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Supplementary materials

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Reference


