Biomechanical Evaluation of Syndesmotic Screw Design via Finite Element Analysis and Taguchi’s Method

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Background: Screw fixation of syndesmotic injuries facilitates ligament healing and restoration of ankle stability, but failure of the screw might threaten the success of the treatment. Screw design parameters, such as outer diameter, inner diameter, thread pitch, leading edge radius, trailing edge radius, leading edge angle, and trailing edge angle, might have effects on the stresses that occur in the screws. This is the first study, to our knowledge, to investigate which geometric screw parameters play key roles in stresses that occur in screws used for syndesmotic fixation.

Methods: A three-dimensional finite element model of an ankle was reconstructed. Four different types of titanium screws—4.5-mm malleolar, 4-mm cancellous, 4-mm machine, and 3.5-mm cortical—were placed on this model. Physiologic load was applied to evaluate the stress in the screw. Then the contribution of each design factor to stress in the screws was analyzed systematically by Taguchi’s robust design method.

Results: The maximum equivalent ductile failure (von Mises equivalent stress) value was found in the 4-mm cancellous screw (402 MPa). Taguchi’s analysis showed that the descending order of contribution of the design factors to stress emerging on the screw is inner diameter, leading edge angle, thread pitch, outer diameter, and trailing edge angle.

Conclusions: Stress that occurs in syndesmotic screws is closely related to their geometry and dimensions. According to the results, a 3.5-mm cortical screw with the ideal screw design regarding optimal parameters to resist against stresses in the syndesmosis seems more reasonable to choose in syndesmotic fixation. (J Am Podiatr Med Assoc 105(1): 14-21, 2015)
acteristics, the manufacturers traditionally have provided an implant system at a constant pitch and depth.

Syndesmosis fixation is one of the crucial orthopedic surgical interventions because diastasis of even 1 to 2 mm of the distal tibiofibular joint results in nonphysiologic pressure distribution and permanent arthritic sequelae at the ankle joint. So, syndesmotic injuries with or without ankle fracture should be managed with great attention to prevent permanent arthritic sequelae. If the indication for surgical intervention is present, the ideal fixation technique should be performed. There are many clinical and biomechanical studies to evaluate the optimal position and screw type for syndesmosis fixation. The generally accepted recommendation is to place a 3.5-mm cortical screw 20 to 40 mm proximal to the tibiotalar joint and parallel to the joint line, angled at 30° anteriorly. None of these studies clarified which geometric screw parameter(s) played a key role in optimal syndesmotic fixation stability.

In this study, the stress distribution in four types of syndesmotic screws was assessed by straight axial-loading tests via finite element models. Then, the contribution of each design factor to stress in the screws was analyzed systematically by Taguchi's robust design method.

Materials and Methods

Structures and Finite Element Analysis of the Bones and Screws

A three-dimensional solid model of the ankle of a male patient (age, 32 years; height, 174 cm; and weight, 83 kg) in the midstance phase was reconstructed by using Mimics software (Materialise, Leuven, Belgium) on available computed tomographic data, which were obtained by scanning with an 8-channel Siemens Sensation 40 (120 kV, 65 mAs, 512 × 512-pixel resolution) (Siemens AG, Munich, Germany) with a slicing distance of 0.4 mm. To repair the possible irregularities of the models, those were transferred to the plug-in Remesh in Mimics software and then to SolidWorks software (SolidWorks, Waltham, Massachusetts) for conversion to nonuniform rational basis B-spline. After that, these models were imported to ANSYS v12 finite element software (ANSYS Inc, Canonsburg, Pennsylvania), and analysis operations were performed. Bones were defined as isotropic, linear elastic, and homogeneous. Young's modulus and Poisson's ratio values of the cortical and cancellous parts of the bones and of the screws are given in Table 1.

In the present study, four different types of commercially available titanium screws that have different biomechanical properties were used for syndesmosis fixation: 4.5-mm malleolar, 4-mm cancellous, 4-mm machine, and 3.5-mm cortical screws, with 45 mm of length. Three-dimensional models of medical screws made of Ti-6Al-4V were performed on the basis of ASTM F543-02 standards (Fig. 1 and Table 2).

The parametric properties of the syndesmotic screws used in this study are different. Thread forms of malleolar, cortical, and cancellous screws are similar, but that of the machine screw is different from the others. Table 2 shows the main parametric values of the thread profiles.

These four different screws were placed 30 mm from the tibiotalar joint and were angled 30° anteriorly through the fibula, with a purchase of three cortices separately. In this study, evaluations were performed under the assumption that the syndesmotic ligaments were completely torn. The width, length, and stiffness of the anterior talofibular ligament, calcaneofibular ligament, posterior talofibular ligament, lateral talocalcaneal ligament, deep deltoid ligament, cervical ligament, interosseous talocalcaneal ligament, and interosseous membrane of the model were obtained from published data (Fig. 2 A-C). Finite element models of the ankle joint were composed of approximately 125,717 elements and 26,000 nodes. Three-dimensional ten-node tetrahedral structural solid elements were used to model the ankle (Fig. 2D). A nonlinear contact interface was defined between the screws and the bones. The contact layers between the screws and the bones were meshed more frequently. The element size was 0.3 mm for the screw, and the contact size between the screw and the bone was 0.3 mm. In this model, all of the bones were defined with respect to the calcaneus, which was fully constrained, and the

<table>
<thead>
<tr>
<th>Bone/Material</th>
<th>Young's Modulus (E) (MPa)</th>
<th>Poisson's Ratio (ν)</th>
<th>Ultimate Tensile Strength (MPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cortical bone</td>
<td>17,000</td>
<td>0.3</td>
<td>N/A</td>
</tr>
<tr>
<td>Cancellous bone</td>
<td>700</td>
<td>0.2</td>
<td>N/A</td>
</tr>
<tr>
<td>Titanium screws (Ti-6Al-4V)</td>
<td>106,000</td>
<td>0.33</td>
<td>896</td>
</tr>
</tbody>
</table>

Abbreviation: N/A, not applicable.
other bones moved around the calcaneus as the pivot point. The talus was constrained only for anteroposterior translation owing to absence of the forefoot in this model, and the tibia was constrained for internal/external rotation. The fibula was free of external constraints and was bounded by the proximal and distal tibiofibular articulations and ligamentous tissue according to previously published data.11 We applied physiologic loads approximating those during the midstance phase in normal gait for this ankle system according to previously published data.14 Compressive force of 2,352 N and tangential forces of 235 N for the midstance phase were applied against the lateral and medial plateaus of the tibia (Fig. 2E). At the end of this analysis, we obtained equivalent ductile failure in the screws (Fig. 3).

### Factorial Analysis by Taguchi’s Method

Seven design factors of three screws (4.5-mm malleolar, 4-mm cancellous, and 3.5-mm cortical screws) that had similar thread forms were studied: A) trailing edge angle ($\beta$), B) leading edge angle ($\alpha$), C) outer diameter ($d_1$), D) inner diameter ($d_5$), E) thread pitch ($p$), F) leading edge radius ($r_4$), and G) trailing edge radius ($r_5$) (Table 3). The results of the finite element analysis were transformed into a smaller-the-better signal-to-noise ratio.

$$S/N = -10 \log \left( \frac{1}{n} \sum_{i=1}^{n} y_i^2 \right)$$

where $y_i$ indicates the result of the $i$th study (Table 4). SPSS v20.0 software (SPSS Inc, Chicago, Illinois) was used to perform the statistical analysis. Analysis of variance was used to investigate the contribution and significance of each design factor to stresses that occurred in screws.15

### Results

#### Finite Element Models

First, we compared stress values in four different screws with standard parameters in the ankle system. It was detected that maximum equivalent stress values in the screws emerged at the point of

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**Note:** Data are given in millimeters.

Abbreviation: N/A, not applicable.
contact of the retaining screw in the tibial cortices. The maximum equivalent ductile failure value was found in the 4-mm cancellous screw (402 MPa). The equivalent ductile failure values that occurred in the other screws were as follows: 384 MPa for the malleolar screw, 356 MPa for the 3.5-mm cortical screw, and 312 MPa for the machine screw (Fig. 3).

**Factorial Analysis by Taguchi’s Method**

The responses given in Table 5 contain a row for the average S/N ratio for each factor level, delta, and

![General view of Ankle](image)

**Figure 3.** The results of equivalent ductile failure of four different syndesmosis screws. Max, maximum; min, minimum.

### Table 3. Levels for Each Factor Design

<table>
<thead>
<tr>
<th>Letter</th>
<th>Parameter Name</th>
<th>Level 1</th>
<th>Level 2</th>
<th>Level 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>$\beta$ (trailing edge angle)</td>
<td>$3^\circ$</td>
<td>$5^\circ$</td>
<td>N/A</td>
</tr>
<tr>
<td>B</td>
<td>$\alpha$ (leading edge angle)</td>
<td>$25^\circ$</td>
<td>$35^\circ$</td>
<td>N/A</td>
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<tr>
<td>C</td>
<td>$d_1$ (outer diameter)</td>
<td>4</td>
<td>4.5</td>
<td>3.5</td>
</tr>
<tr>
<td>D</td>
<td>$d_6$ (inner diameter)</td>
<td>1.9</td>
<td>2.1</td>
<td>2.4</td>
</tr>
<tr>
<td>E</td>
<td>$p$ (thread pitch)</td>
<td>1.75</td>
<td>2</td>
<td>1.5</td>
</tr>
<tr>
<td>F</td>
<td>$r_4$ (leading edge radius)</td>
<td>0.8</td>
<td>0.86</td>
<td>N/A</td>
</tr>
<tr>
<td>G</td>
<td>$r_5$ (trailing edge radius)</td>
<td>0.3</td>
<td>0.42</td>
<td>0.2</td>
</tr>
</tbody>
</table>

Note: Values for C through G are given as millimeters. Abbreviation: N/A, not applicable.
rank. Delta is the difference between the maximum and minimum average S/N ratios for the factor. The rank is the rank of each delta, where rank 1 is the largest delta (int1). According to this table, the factor D (inner diameter) is the most effective parameter, and others are E (thread pitch), B (leading edge angle), C (outer diameter), A (trailing edge angle), G (trailing edge radius), and F (leading edge radius), respectively.

Results of variance analysis regarding the best S/N ratio are given in Table 5. Some of the results obtained in Tables 5 and 6 were paralleled; on the other hand, some of the others presented discrepancies when the data in both tables were compared. Inner diameter (factor D) was also found to be the most efficient parameter according to the variance analysis table ($P < .05; F = 10.92$). Thread pitch (factor E) is found as the second efficient parameter according to Table 4, when the difference between delta values is taken into account, edge angle (factor B) becomes as so according to the variance analysis table ($P < .05; F = 5.84$; according to $F$ and $P$ values, factors E and B are both greater than the 95% confidence interval).

As a result, the variance analysis table showed that design factors D, B, and E have more effect on screw performance in syndesmotic fixation than the other four factors (Table 6). On the other hand, leading edge radius (factor F) and trailing edge radius (factor G) design factors have nearly no effect on the performance of the syndesmotic fixation.

<table>
<thead>
<tr>
<th>Experiment no.</th>
<th>(A) β (Trailing Edge Angle) (°)</th>
<th>(B) α (Leading Edge Angle) (°)</th>
<th>(C) d1 (Outer Diameter) (mm)</th>
<th>(D) d5 (Inner Diameter) (mm)</th>
<th>(E) p (Thread Pitch) (mm)</th>
<th>(F) r2 (Leading Edge Radius) (mm)</th>
<th>(G) r5 (Trailing Edge Radius) (mm)</th>
<th>Equivalent von Mises Stress Value</th>
<th>S/N Ratio</th>
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<tbody>
<tr>
<td>1</td>
<td>3</td>
<td>25</td>
<td>4</td>
<td>1.9</td>
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<td>0.3</td>
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<td>2</td>
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<td>25</td>
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<td>0.42</td>
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<td>2.4</td>
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<td>0.2</td>
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<td>–50.89</td>
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<td>0.2</td>
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<td>2.4</td>
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<td>408.40</td>
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<td>0.86</td>
<td>0.42</td>
<td>402.50</td>
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<td>0.2</td>
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<td>2.4</td>
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<td>0.86</td>
<td>0.3</td>
<td>364.10</td>
<td>–51.22</td>
</tr>
<tr>
<td>15</td>
<td>5</td>
<td>35</td>
<td>3.5</td>
<td>1.9</td>
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<td>0.8</td>
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<td>0.2</td>
<td>378.80</td>
<td>–51.57</td>
</tr>
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</table>

Table 5. Response Table for Signal-to-Noise Ratios (Smaller is Better)

<table>
<thead>
<tr>
<th>Level</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>–51.80</td>
<td>–51.65</td>
<td>–52.00</td>
<td>–52.22</td>
<td>–51.70</td>
<td>–51.86</td>
<td>–51.84</td>
</tr>
<tr>
<td>2</td>
<td>–51.91</td>
<td>–52.27</td>
<td>–51.92</td>
<td>–52.16</td>
<td>–51.54</td>
<td>–51.84</td>
<td>–51.91</td>
</tr>
<tr>
<td>3</td>
<td>N/A</td>
<td>N/A</td>
<td>–51.64</td>
<td>–51.18</td>
<td>–52.32</td>
<td>N/A</td>
<td>–51.82</td>
</tr>
<tr>
<td>Delta</td>
<td>0.11</td>
<td>0.63</td>
<td>0.36</td>
<td>1.04</td>
<td>0.78</td>
<td>0.03</td>
<td>0.09</td>
</tr>
<tr>
<td>Rank</td>
<td>5</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>7</td>
<td>6</td>
</tr>
</tbody>
</table>
Finally, Taguchi’s analysis showed that the descending order of contribution of the design factors was inner diameter, leading edge angle, thread pitch, outer diameter, and trailing edge angle (factors D, B, E, C, and A, respectively).

Although the machine screw was excluded from Taguchi’s analysis because of differences in thread forms, a low equivalent ductile failure value in this screw (312 MPa) would be attributed to its larger inner diameter.

The S/N graph of minimum and maximum equivalent ductile failure values at different levels of each design factor are given in Figure 4. According to this graph, effective levels for each factor were found to be A1, B1, C3, D3, E2, F2, and G3 (Table 7).

At the end of the present study, the new experimental screw design was formulated by combining the effective levels of each design factor. The estimated maximum ductile failure value that the newly designed screw would be exposed to and the predicted S/N ratio are given in Table 7.

**Discussion**

Because screw fixation is one of the most common surgical options for treating syndesmotic injuries, it is normal to see many cadaveric, clinical, and biomechanical studies that investigate the optimal size of the screw configuration, use of one or two screws, the optimal number of cortices, the position of the screws relative to the tibiotalar joint, time to weightbearing in syndesmosis fixation, etc. According to all of these studies, fixation with one 3.5- or 4.5-mm cortical screw is a popular treatment option for syndesmosis injuries because it provides the best anatomical reduction, shortens the healing period, and allows patients to resume weightbearing more quickly. However, we found only three studies that directly compared two sizes of screws (3.5 versus 4.5 mm). Thompson and Gesink and Markolf et al reported in their biomechanics studies that there is no biomechanical advantage of a 4.5-mm screw over a 3.5-mm one in fixation of the syndesmosis. However, Hansen et al found that specimens fixed with a single 4.5-mm quadricortical screw had a higher load-to-failure value for applied shear force than those fixed with a 3.5-mm screw. Of those, the study by Markolf et al was the most comprehensive regarding study design in that three types of ankle-loading tests were performed: the ankle dorsiflexion test, external foot torque test, and axial loading test. However, none of these studies had answered the question of which design factors of the screws play a major role in the resistance of syndesmotic fixation.

Despite its popularity, screw fixation has some drawbacks, of which fatigue failure of the screws while weightbearing is the leading one. The present study is the first, to our knowledge, to try to find out which screw design factors play a major role in the resistance of syndesmosis fixation to breakage or loosening and which combination of screw parameters creates the ideal syndesmotic screw. First, it must be known that the aim of syndesmosis fixation is to hold the distal tibiofibular joint in the reduced position during the healing of disrupted ligaments but not to compress the distal tibiofibular joint. This can be achieved by the screw that can optimally resist deformation and pullout forces generated by the physiologic loadings of the ankle joint during the healing process. Because the stress values in the...
screw after loading can be used as predictive data to estimate the risk of fatigue failure and loosening of the screw, in the present study we focused on the stresses that occurred in the screws. Because the highest mean fibular force was found with 10 Nm of external foot torque applied to a dorsiflexed foot under 1,000 N of axial force in a cadaveric biomechanical study, it may be advisable to use a brace that prevents extreme dorsiflexion to limit displacement of the distal fibula during the ligament-healing process and rehabilitation period of a syndesmotic injury after surgical repair. In clinical application, if a stable osteosynthesis is achieved with placement of a syndesmotic screw, weight-bearing in a plaster cast could be allowed. Because the ankle position in the midstance phase of gait most likely mimics the loading of the ankle in the plaster cast, we chose the loading characteristics of this period.

Physiologic loads occur under anatomical circumstances, thus simulations for those should also contain the appropriate model of physiologic loading, but it is almost impossible to simulate complex ankle joint kinematics and loadings with experimental techniques. Because of these technical difficulties, a finite element modeling technique was developed, and it has been widely used and validated in the field of foot and ankle studies. The physical validation of the finite element model of the ankle regarding contact stresses of tibiotalar articular surfaces had been proved by a cadaveric experimental test. Another comprehensive study in this area was published by Haraguchi et al. They had performed a study to validate the model of the ankle regarding contact stresses and ligament tensions in the ankle during walking cycles.

Besides the advantages of the model, limitations of it must also be emphasized. First, the osseous configuration was based on the computed tomographic images from a single patient, and the material properties for soft tissues were obtained from the literature, not from actual measurements. Second, the simulated loadings were only for one phase of walking and were not cyclic. Third, we focused on ligament tensions rather than on contact stresses to evaluate the stresses on the syndesmotic screw. So, we did not take the contact stress values into account. Fourth, because the model did not have complete freedom of motion of any bone except the fibula, stresses on the syndesmotic screw might have been overestimated. Fifth, we did not use live or experimental models to prove the results. Live models may not be obligatory because we tried to compare stress values in screws but not effects on bone healing in this study. Finally, although these previously published studies put forth the validity of the ankle model, specific experimental testing with cadaveric specimens is still needed to validate the results.

Taguchi’s method for experimental design is straightforward and easy to apply to many engineering situations, making it a powerful yet simple tool. L18 orthogonal array and 18 runs of the analyses were used instead of the $2^3 \times 3^4 = 648$ runs for the full factorial design. The effects of each factor can be calculated independently, particularly in interaction situations. The results of the analysis showed that the descending order of the effective design factors was inner diameter, leading edge angle, thread pitch, outer diameter, trailing edge angle, trailing edge radius, and leading edge radius, respectively, according to the variance analysis. The leading edge radius and trailing edge angle had negligible effects in this study. Dimensions of current screws were used, and real-life conditions were considered to have a comprehensive assessment of the relative contribution to the design factors. In a previously published study, the bone-holding power of tibial locking screws was assessed by mechanical testing and finite element analysis, and Taguchi’s analysis showed that the descending order of contribution of the design factors was outer diameter, pitch, half angle, and inner diameter. The stress value that occurred in the syndesmotic screws was closely related to their geometry and dimensions. Taguchi’s method could analyze the effects of each design factor independently and could be used for design optimization of different kinds of orthopedic screws. This model may assist manufacturers in evaluating their screw designs and assist surgeons in selecting suitable screws for their operations.
Conclusions

In the present study, the model of the proposed dimensions showed that the inner diameter, leading edge angle, and thread pitch contributed significantly to screw strength in the syndesmotic region. When Figure 4 is taken into account, screws with a larger inner diameter, lower leading edge angle, and larger thread pitch would resist against stresses in the syndesmosis more effectively. Because the 3.5-mm cortical screw used in this study had the geometric screw parameters that mostly matched the ideal ones regarding inner diameter, leading edge angle, thread pitch, outer diameter, and trailing edge angle (ideal factor D: 2.4 mm; B: 35°; E: 1.5 mm; ideal factor C: 3.5 mm; and ideal factor A: 3 mm) to effectively resist against the stresses in the syndesmosis, it seems more preferable in syndesmosis fixation.

Financial Disclosure: None reported.

Conflict of Interest: None reported.

References


