ABSTRACT

NuVasive is a leading medical device company that develops minimally invasive surgical devices for spinal procedures. NuVasive requires a fully adjustable drill-tap-screw (DTS) guide for an ACDF (anterior cervical discectomy and fusion) surgery plate, allowing for a variable drill angle and depth into the vertebrae. Within the scope of this project, a complete design of the DTS guide was created along with a testable proof of concept model of the device. Extensive testing and analysis was conducted to ensure the device satisfies the design requirements.

DESIGN OVERVIEW

The three design requirements are satisfied by the following mechanisms:

1. Attachment to plate: a trigger below the handle engages and disengages the cervical plate by means of a spring loaded clamp.
2. Barrel angle adjustment: a rotating knob at the top of the stem actuates a gear system that adjusts the barrel angle in the sagittal plane.
3. Drill depth adjustment: a set of color coded caps of different lengths can be attached to the end of the barrels to accommodate varying drill depths.

The intent of this project is to design an adjustable DTS guide with the features shown in Table 1. In order to abide by standard medical device criteria, the DTS guide must also be made from medical grade stainless steel (for autoclave use and biocompatibility) and have ergonomic qualities for ease of use.

Table 1. Highlighted project requirements.

<table>
<thead>
<tr>
<th>Features</th>
<th>Requirements</th>
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</thead>
<tbody>
<tr>
<td>(1) Attachment to plate</td>
<td>Hold 4 lbs. max when engaged to plate</td>
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<tr>
<td>(2) Barrel angle adjustment</td>
<td>0° - 15° range, 3° max increments, 3 lb. max off-axis loading</td>
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<tr>
<td>(3) Drill depth adjustment</td>
<td>11 – 19 mm depth range, 1 mm max increments, 10 lb. axial load</td>
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ANALYSIS

FEA analysis was conducted on the 3D CAD model to ensure the design satisfies the project load requirements. Interference checks were performed on the model to verify component compatibility.

TESTING AND RESULTS

A fully testable, integrated, 2X scale proof of concept model was fabricated and tested with respect to the design requirements. The force and depth requirements were adjusted appropriately with respect to the scaling factor. The DTS guide proof of concept successfully: (1) attached and detached from the plate which held the 4 lb. load requirement, (2) adjusted the guide barrels between 0 and 15° withstand a force of 3 lb., (3) adjusted the drill depths between 11 and 19 mm and withstood the 10 lb. axial force on the barrels. The adjustable DTS guide will facilitate a more efficient minimally invasive surgical procedure aiding a speedier patient recovery.

Acknowledgments

UCSB: Steve Laguette, Sharice Handa, Trevor Marks, Alex Russell, Andy Weinberg, Nicole Holstrom
NuVasive: Shaeffer Bannigan, Michael Brotman

References

[1] Image credit: Mayfield Clinic