Biomechanical analysis of a newly designed bioabsorbable anterior cervical plate

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Object. The authors present a biomechanical analysis of a newly designed bioabsorbable anterior cervical plate (ACP) for the treatment of one-level cervical degenerative disc disease. They studied anterior cervical discectomy and fusion (ACDF) in a human cadaveric model, comparing the stability of the cervical spine after placement of the bioabsorbable fusion plate, a bioabsorbable mesh, and a more traditional metallic ACP.

Methods. Seven human cadaveric specimens underwent a C6–7 fibular graft–assisted ACDF placement. A one-level resorbable ACP was then placed and secured with bioabsorbable screws. Flexibility testing was performed on both intact and instrumented specimens using a servohydraulic system to create flexion–extension, lateral bending, and axial rotation motions. After data analysis, three parameters were calculated: angular range of motion, lax zone, and stiff zone. The results were compared with those obtained in a previous study of a resorbable fusion mesh and with those acquired using metallic fusion ACPs. For all parameters studied, the resorbable plate consistently conferred greater stability than the resorbable mesh. Moreover, it offered comparable stability with that of metallic fusion ACPs.

Conclusions. Bioabsorbable plates provide better stability than resorbable mesh. Although the results of this study do not necessarily indicate that a resorbable plate confers equivalent stability to a metal plate, the resorbable ACP certainly yielded better results than the resorbable mesh. Bioabsorbable fusion ACPs should therefore be considered as alternatives to metal plates when a graft containment device is required.

KEY WORDS • anterior cervical plate fixation • anterior cervical discectomy and fusion • bioabsorbable plate • cadaver dissection

The authors of biomechanical studies have demonstrated additional stability provided by ACPs compared with bone graft alone. The risk-to-benefit ratio of adding an ACP to a single-level discectomy and fusion is controversial because the fusion rate is high in the cervical region in cases of uninstrumented fusions. In recent studies, however, investigators have demonstrated an increase in fusion rates after single-level ACDF from 90 to 96% when ACPs are added. There were no clinically significant complications related to the instrumentation in the plate-treated group. These investigators also reported a significant decrease in graft-related complications in the instrumentation-treated cohort. In multilevel anterior cervical discectomies, the pseudarthrosis rates are significantly higher in patients treated without plate fixation. In two-level ACDFs without plates, pseudarthrosis rates in large series range from 25 to 28%.

Abbreviations used in this paper: ACDF = anterior cervical discectomy and fusion; ACP = anterior cervical plate; DDD = degenerative disc disease; LZ = lax zone; MR = magnetic resonance; PLA = poly(L-lactide-co-D,L-lactide); ROM = range of motion; SZ = stiff zone.
to a two-level discectomy without an autograft has been reported to reduce fusion failure.10

Anterior cervical plates function mechanically as a tension band and a buttress plate. These devices are relatively efficient at resisting cervical extension, axial rotation, and lateral bending; however, they are weakest in resisting neck flexion, particularly if the cervical posterior elements have been disrupted (that is, after laminectomy, facet joint fracture, and hyperflexion injuries with ligamentous tears). The extent of fixation depends on a patient’s bone mineral density. Dense bone provides a strong anchor for the screws whereas osteoporotic bone provides only poor screw purchase. Cervical plates can act to prevent movement of unstable vertebrae, prevent graft extrusion or displacement, and maintain compression of graft materials.

Currently, most cervical plates are composed of titanium alloys, the most popular of which is Ti-6Al-4V. These plates provide significant rigidity across the fused segment and are typically associated with low rates of hardware-related complications such as infection, fracture, and screw backout. Nevertheless, titanium produces substantial artifact on MR images that may make postoperative images difficult to interpret at the instrumented levels. Computerized tomography myelography is often required if imaging is necessary to assess accurately the spinal canal after implantation of a titanium plate. Additionally, it has been postulated that an adjunctive plate may increase the incidence of adjacent-segment DDD. The origin of DDD is uncertain but has been hypothesized to be related to increased dissection of the anterior longitudinal ligament close to the adjacent levels.11 It is possible that the high rigidity conferred to the fusion segment by a stiff titanium plate may contribute to adjacent-segment DDD, particularly if the ends of the plate are close to the adjacent levels.

The minimal mechanical characteristics necessary for a specific material to function effectively as a plate, to increase fusion rates more than bone graft alone, and to prevent complications such as graft dislodgment for the ACDF indication are unknown. Most likely, there is a minimal degree of rigidity that the implant must create and maintain across the segment to promote arthrodesis. A minimal amount of load sharing with the graft must be maintained and a minimal amount of time must pass while the fusion is occurring. These minimal construct-based properties are a function of the mechanical properties of the implant material, its design elements, the way in which it is applied, the preexisting biomechanical properties of the cervical segment, implant–host reaction characteristics, and native and induced host bone biological behavior (Table 1).

Resorbable polylactide polymers have been used for several years in numerous human clinical applications, particularly craniofacial fixation.6,14 The potential advantages of using a fully MR imaging–compatible, resorbable nonmetallic material for a cervical plate include the following: 1) complete radiolucency and lack of MR imaging artifact from time of implantation; 2) increased load sharing at immediate and long-term time points as the plate and screws bend while the material slowly resorbs; 3) no permanent encroachment on adjacent segments if subsidence occurs and the plate’s position shifts because the implant resorbs; 4) the implant is completely transparent and thus it is easy to see the graft position at time of plate insertion; 5) revision surgery is theoretically much easier as the plate is completely resorbed by 18 months and does not need to be removed if the adjacent segment requires plate fixation; and 6) there is no permanent foreign material in the retropharyngeal space. Vaccaro, et al.,18 found that in seven (77%) of nine patients who underwent allograft interbody fusion and subsequent placement of a Hydrosorb resorbable ACP, there was radiographic evidence of fusion at 6 months postoperatively. In a previous study, we examined the stability created by a mesh of 70/30 PLA (MacroPore Biosurgery, San Diego, CA), placed with two or three screws per vertebra across a bone graft construct after single-level discectomy.2 The mesh was associated with a slight improvement in stability over the graft alone but did not perform as well as a metallic plate.1–3 Newly designed MacroPore ACPs have since become available. The rationale for using these implants is that they are shaped more like standard metallic ACPs and may therefore provide stability that is more comparable with a metal plate while still offering the advantages of a bioabsorbable material (Fig. 1). The purpose of the present study was to examine the biomechanical stability offered by the newly designed plate and to compare this stability with that created by the earlier MacroPore cervical mesh and by a conventional metallic plate.

### Materials and Methods

#### Cadaveric Specimens

Seven human cadaveric specimens were studied (Table 2). In all cases, the surgically treated level was C6–7. Specimens were thawed in a bath of 0.9% saline solution at 30°C for preparation and testing. All muscle tissues were carefully dissected to preserve all ligaments, joint capsules, discs, and osseous structures. Household wood screws were inserted in the distal ends of the specimen and the heads of the screws were embedded in polymethylmethacrylate poured in metal testing fixtures. During testing, specimens were wrapped in saline-soaked gauze to prevent dehydration. Each specimen required four freeze–thaw cycles to complete testing: once for dissecting and potting, once for normal testing, once for surgery, and once for postsurgical testing. Repeated freezing and thawing has minimal impact on the biomechanical properties of cadaveric specimens.17

#### Instrumentation Procedure

For discectomies, distraction and endplate preparation were con-
ducted in an identical fashion in every specimen. A scalpel, curette, and pituitary rongeurs were first used to remove disc material at the C6–7 interspace. The distractor from the Cornerstone-SR set (Regeneration Technologies, Inc., Alachua, FL) was then used to achieve linear distraction of the interspace. The Cornerstone-SR cutter and interspace sizers were used to standardize graft size and thus graft compression forces.

After placing the graft, a one-level resorbable plate was attached (Fig. 1 right). In all cases, the rostrocaudal hole spacing was 26 mm. After dipping in a hot water bath (65˚C) the plate was contoured by hand using standard surgical tools (forceps and a curette handle) to match the anterior surface of the spine. Two resorbable screws were used in each vertebra of the motion segment to secure the plate. We chose the 70/30 PLA polymer as the plate material because of its ability to retain a significant amount of its initial strength over time (Fig. 2).

Importantly, all procedures in this study and in the previous study in which MacroPore mesh was tested biomechanically, and newly designed MacroPore ACP (right). The shape of the new plate is more similar to the shape of a standard metallic ACP.

Flexibility Testing

The specimens were nondestructively tested using a standard flexibility testing method. They underwent flexibility testing once in the normal intact condition and a second time after discectomy and graft and plate placement. For flexibility testing, nonconstraining, nondestructive pure moment (torque) loading was applied to each specimen by using a system of cables and pulleys in conjunction with a standard servohydraulic test system (MTS, Minneapolis, MN), as we have previously described. Three cycles of preconditioning (ramp 0–1.5 Nm) were used. Loads were applied around the appropriate anatomical axes to induce three different types of motion: flexion–extension, lateral bending, and axial rotation. After allowing the specimen to rest for 60 seconds at zero load, the specimens were loaded quasistatically to a maximum of 1.5 Nm in 0.25-Nm increments. Each load was held for 45 seconds. Data were collected at 2 Hz.

The three-dimensional motion of the specimen in response to the loads was determined using the Optotrak 3020 system (Northern Digital, Waterloo, ON, Canada). This system measures stereophotometrically the three-dimensional displacement of infrared-emitting markers rigidly attached in a noncollinear arrangement to each vertebra. Marker position was related to the x (lateral), y (rostrocaudal), and z (anteroposterior) axes of the specimens by identifying landmarks with a digitizing probe and customized software. This software also converted the marker coordinates to angles around each of the anatomical axes, using a method that models the vertebrae as stacked cylinders.

Data Analysis

Three parameters were generated from the quasistatic load-defor-
represents angular position data recorded quasistatically after holding steady load for 45 seconds at the seven different applied loads. The boundary between LZ and SZ is the displacement where a line through the upper SZ is extrapolated to a zero load. The LZ and SZ sum to form the ROM. Shown here is the positive half of a bidirectional motion (for example, flexion). Each positive curve has a corresponding negative curve (for example, extension). The neutral position is by definition halfway between the positive LZ/SZ boundary and the negative LZ/SZ boundary.

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Fig. 3. Schematic illustrating the different parameters studied. Each circle represents angular position data recorded quasistatically (after holding steady load for 45 seconds) at the seven different applied loads. The boundary between LZ and SZ is the displacement where a line through the upper SZ is extrapolated to a zero load. The LZ and SZ sum to form the ROM. Shown here is the positive half of a bidirectional motion (for example, flexion). Each positive curve has a corresponding negative curve (for example, extension). The neutral position is by definition halfway between the positive LZ/SZ boundary and the negative LZ/SZ boundary.

Results

After testing, no bone fractures were found in specimens, and examination of the screws, rods, and plates showed no signs of fracture, loosening, or breakage.

The angular LZ and ROM values were statistically significantly smaller than normal after instrumentation with any plate type (Table 3 and Fig. 4). The angular SZ was also smaller than normal after the implantation of any plate type, although the difference was not statistically significant in any loading mode. The new MacroPore plate produced a significantly smaller nonnormalized ROM during extension, as did SZ during axial rotation, than the MacroPore mesh (two screws; Table 3). The new MacroPore plate did not exhibit a significantly different LZ than the previously studied MacroPore mesh during any loading mode. The new MacroPore plate also allowed ROM, LZ, and SZ that were closer in magnitude to those of the Atlantis plate than the previously studied MacroPore mesh; in fact, there was little significant difference between the

### TABLE 3

Mean single-level angular motion in each condition

<table>
<thead>
<tr>
<th>Loading Mode &amp; Parameter</th>
<th>Normal</th>
<th>MacroPore Plate</th>
<th>MacroPore Mesh</th>
<th>Atlantis Plate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Graft Only</td>
<td>2 Screws</td>
<td>3 Screws</td>
</tr>
<tr>
<td>flexion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LZ</td>
<td>7.64 ± 4.76</td>
<td>1.76 ± 1.96</td>
<td>3.64 ± 3.75</td>
<td>3.97 ± 2.48</td>
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<tr>
<td>SZ</td>
<td>2.51 ± 0.81</td>
<td>1.91 ± 1.01</td>
<td>3.03 ± 0.83</td>
<td>2.68 ± 0.66</td>
</tr>
<tr>
<td>ROM</td>
<td>6.33 ± 2.73</td>
<td>2.75 ± 1.82</td>
<td>4.85 ± 2.41</td>
<td>4.66 ± 1.73</td>
</tr>
<tr>
<td>extension</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LZ</td>
<td>7.64 ± 4.76</td>
<td>1.76 ± 1.96</td>
<td>3.64 ± 3.75</td>
<td>3.97 ± 2.48</td>
</tr>
<tr>
<td>SZ</td>
<td>1.82 ± 0.88</td>
<td>0.64 ± 0.78</td>
<td>2.20 ± 0.58</td>
<td>1.16 ± 0.44</td>
</tr>
<tr>
<td>ROM</td>
<td>5.64 ± 2.78</td>
<td>1.53 ± 0.98</td>
<td>4.02 ± 2.18</td>
<td>1.47 ± 1.14</td>
</tr>
<tr>
<td>lat bending</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>LZ</td>
<td>5.90 ± 3.42</td>
<td>2.09 ± 3.07</td>
<td>3.49 ± 3.35</td>
<td>3.47 ± 2.69</td>
</tr>
<tr>
<td>SZ</td>
<td>1.41 ± 0.30</td>
<td>1.33 ± 0.61</td>
<td>1.69 ± 0.56</td>
<td>1.79 ± 0.62</td>
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<tr>
<td>ROM</td>
<td>4.36 ± 1.88</td>
<td>2.38 ± 1.93</td>
<td>3.43 ± 2.05</td>
<td>3.53 ± 1.87</td>
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<tr>
<td>axial rotation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LZ</td>
<td>3.80 ± 1.52</td>
<td>1.52 ± 1.59</td>
<td>2.20 ± 2.34</td>
<td>2.41 ± 2.30</td>
</tr>
<tr>
<td>SZ</td>
<td>1.26 ± 0.37</td>
<td>0.25 ± 0.07</td>
<td>1.62 ± 0.54</td>
<td>1.68 ± 0.55</td>
</tr>
<tr>
<td>ROM</td>
<td>3.16 ± 0.93</td>
<td>1.07 ± 0.29</td>
<td>2.72 ± 1.59</td>
<td>2.89 ± 1.65</td>
</tr>
</tbody>
</table>

* Values are presented as the means ± standard deviations.
MacroPore and Atlantis plates. During some loading modes, the new MacroPore plate actually decreased ROM, LZ, and SZ to a value slightly smaller than that of the Atlantis plate (difference not significant), although the destabilization was more severe in the Atlantis plate study. The SZ, however, was significantly smaller for the Atlantis plate than the MacroPore plate during flexion (Table 4).

**Discussion**

**Comparison of Normal and Experimental Values**

We found that the new MacroPore plate reduced LZ and ROM to significantly within the normal range during most loading modes. As a rule, fusion-promoting hardware should reduce motion to well within what is observed in the normal case for an optimal fusion environment; however, the ideal degree of immobilization required to promote fusion is unknown.

**Comparison of Bioabsorbable ACP and Mesh**

During all loading modes, the new MacroPore ACP consistently outperformed the older MacroPore mesh. Only a few statistical comparisons were significant, but all mean values of ROM, LZ, and SZ during each loading mode were smaller when the plate rather than the mesh was attached. The validity of comparisons between MacroPore mesh and MacroPore plate is exceptionally good because the same surgeon applied both types of hardware and used the same tools for discectomy and grafting. Intergroup values of normal ROM, LZ, and SZ were nearly identical in most cases, lending further validity to this comparison.

**Comparison of Bioabsorbable ACP and Atlantis Plate**

A comparison of the bioabsorbable plate–derived data with ACDF/Atlantis plate–derived data showed that the latter (metal) plate tended to resist motion only slightly better than the MacroPore bioabsorbable plate. In only one mode (SZ during flexion) did the metal plate allow significantly less motion than the MacroPore bioabsorbable plate (Table 4). These findings support the argument that new MacroPore ACPs are approximately equivalent to metal plates in resisting loading. That a difference was observed in SZ but not in ROM or LZ implies that the MacroPore plate and/or the bone–screw plate interface was able to bend more easily than was the metal Atlantis plate and/or the bone–metal screw/metal plate interface.

**Limitations of the Study**

This in vitro research allowed quantification of how the new MacroPore plate performs in resisting particular loads in an immediate postoperative condition without the stabilizing influence of surrounding musculature or (substantial) gravitational compression. These limitations should be kept in mind when considering the application of our findings in a clinical setting.

Another limitation of this research is the relatively small number of specimens studied per group, which leads to low statistical power (probability of avoiding Type 2 or false-negative error). Typically, a power of 0.8 is desired when making assertions that there was no significant intergroup difference; however, in many instances, the power was less than 0.8. A Type 2 error is difficult to avoid in this type of research because of the expense and time required to test large numbers of samples. We assumed that differences too small to become apparent in testing seven specimens were too small to be clinically significant.

**Conclusions**

We found that the new MacroPore bioabsorbable plates provided better stability than the previously used MacroPore mesh and that the former would be preferred clinically. Although our results do not necessarily indicate that the new MacroPore plate is equivalent to a metal plate in the stability it provides, the new ACP provides stability that is certainly closer to that of a metal plate than the previous mesh. Although graft containment was not measured, the screw design was similar between the new plate and the previous mesh. Therefore, as with the mesh, the surgeon can consider the new MacroPore plate to be an excellent alternative if a graft containment device is needed.

**Disclosure**

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