Failure analysis of C-5 after total disc replacement with ProDisc-C at 1 and 2 levels and in combination with a fusion cage: finite-element and biomechanical models

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OBJECT The purpose of this study was to evaluate the failure risk of cervical vertebrae after total disc replacement with a keel-design prosthesis (ProDisc-C), taking into consideration the effects of vertebral body height, multilevel replacement, and the association with an adjacent fusion cage. Although promising clinical results have been reported for the ProDisc-C, some clinical studies have reported vertebral body–splitting fractures at single- and multilevel arthroplasty sites. This implant has central keels to provide solid initial stability, and some authors associate the potential risk of vertebral body failure with the keel design, especially in patients with small vertebral body height or when the implant is used at multiple levels.

METHODS The study was performed using a specimen-specific C4–6 cervical-segment finite-element model to assess the compressive strains on the C-5 vertebral body for each cervical segment configuration, and synthetic polyurethane models to experimentally predict the compressive load at failure for 3 vertebral body heights.

RESULTS The use of a keeled ProDisc-C prosthesis at multiple levels or in combination with a fusion cage increases by a factor of 2–3 the compressive strains at the C-5 vertebral body relative to single-level arthroplasty. All implanted segment configurations tested demonstrated a continuum of the load at failure and the vertebral body height, but no significant differences were found between the 3 vertebral body heights in each segment configuration.

CONCLUSIONS The use of a keeled ProDisc-C prosthesis at 2 adjacent levels or combined with a fusion cage presented the lowest load-at-failure values, 2 times higher on average than the ones occurring during physiological tasks. This fact indicates an identical and limited risk of vertebral body failure for these 2 segment configurations, whereas vertebral body height appears to slightly affect this risk. However, for some tasks that place higher physical demands on the neck, beyond what was represented by our models, there may also be risk of microdamage initiation, which is not present in the single-level arthroplasty.

http://thejns.org/doi/abs/10.3171/2014.10.SPINE14217

KEY WORDS split fracture; cervical spine; total disc replacement; arthroplasty; patient-specific finite element model; experimental study
life, which could potentially lead to complications such as fracture and device subsidence postoperatively. ProDisc-C (Synthes Spine) is one of the cervical artificial discs in current use, and very promising clinical results have been reported for this device. However, recent clinical studies have reported vertebral body split fractures associated with single and multilevel cervical arthroplasty using the ProDisc-C prostheses. The same kind of fracture was also found with use of the ProDisc-L prosthesis in lumbar vertebrae. The ProDisc-C prosthesis has central keels on the plates, which is a particular design characteristic that differentiates this prosthesis from other current market implants. Solid initial stability is a distinct advantage of the keel design of the prosthesis, but some authors have related the potential risk of vertebral body fracture to the keel design, especially in patients with low vertebral body height or when the device is used at multiple levels. This issue has not yet been fully answered and requires further studies and analysis.

The purpose of this study was to evaluate the failure risk of cervical vertebrae after TDR with a keel-design prosthesis (ProDisc-C). In particular, the effects of vertebral body height, the procedure being done at multiple levels, and the association with an adjacent fusion cage (the Fidji cage) were assessed. The study was performed using a specimen-specific cervical C4–6 finite element model to assess the structural behavior of the C-5 vertebral body for each segment configuration, complemented with synthetic polyurethane construct models to predict experimentally the compressive load at failure for 3 vertebral body heights.

Methods

Numerical Model of Patient-Specific C4–6 Cervical Segment

Four specimen-specific finite-element models were developed for this study: an intact C4–6 segment model (intact model), a single-level arthroplasty model (1-level ProDisc), a multilevel arthroplasty model (2-level ProDisc), and finally a model that combines a single-level arthroplasty with a fusion cage at the adjacent level (ProDisc+cage) (Fig. 1). These digital models were constructed based on a single healthy male subject aged 42 years with a body mass index of 23 kg/m² and without a history of cervical spine disc pathology. The C4–6 vertebral bodies were generated with the aid of CT using semi-automated segmentation tools (ScanIP, Simpleware Ltd.). The vertebral body structures were semi-automatically meshed using 10 tetrahedral elements (Table 1) (ScanFE, Simpleware Ltd.) with the mapped specimen-specific bone material properties from CT data (slice thickness 0.5 mm). The linear relationship between the apparent density of vertebral bone and Hounsfield units (HU) used in this study was based on reference literature. The relationship between bone material properties and apparent density for the isotropic material was considered for the vertebral bone (Table 1). The intervertebral discs were represented as a continuum structure occupying the intervertebral space. The disc structure was subdivided into a nucleus pulposus (comprising approximately 50% of the cross-sectional area of the total disc), which was constructed using hexahedral solid elements (Table 1), and the annulus fibrosus, which was modeled as a composite configuration wherein a series of fibers were embedded in a ground substance surrounding the nucleus. The fibers were modeled utilizing the “Rebar” parameter with a “no compression” option such that the fiber elements could work only in tension (Table 1). The ligaments between vertebrae, including the anterior longitudinal ligament, posterior longitudinal ligament, interspinous ligament, ligamentum flavum, and capsular ligaments (Table 1), were modeled using 3D trust elements. These elements were defined to act nonlinearly in tension, via the hypoelastic material option with a “neutral zone” (Table 1). The implanted models were obtained from the intact specimen-specific model by including the ProDisc-C prosthesis (Synthes Spine) and the Fidji cage (Zimmer, Inc.) (Fig. 1). The implant geometries were created with the CAD modeling package Catia V5 (Dassault-Systèmes) after 3D digitalization. The vertebral cuts to accommodate the Fidji cage and the ProDisc-C implants were done on the intact C4–6 segment model with ScanIP masking tools under the direction of an experienced orthopedic cervical surgeon (Fig. 1).

The anterior longitudinal ligament was removed for the implanted models. Frictionless contact was defined between the articular surfaces of the facet joints. The interactions between implants and vertebral surfaces were
TABLE 1. Material properties and model characteristics of the C4–6 cervical spine model

<table>
<thead>
<tr>
<th>Group</th>
<th>Young’s Modulus (Mpa)</th>
<th>Poisson’s Ratio</th>
<th>Cross-Sectional Area (mm²)</th>
<th>Element Type</th>
<th>Number of Elements</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Intact 1-Level 2-Level 1-Level + Cage</td>
</tr>
<tr>
<td>Vertebral cortical bone</td>
<td>$E = 2065\rho^{3.09}$</td>
<td>0.3</td>
<td>—</td>
<td>C3D10M</td>
<td>224,834 222,956 221,103 221,982</td>
</tr>
<tr>
<td>Vertebral cancellous bone</td>
<td>$E = 1904\rho^{1.84}$</td>
<td>0.3</td>
<td>—</td>
<td>C3D10M</td>
<td>— — — —</td>
</tr>
<tr>
<td>Annulus ground substance</td>
<td>4.2</td>
<td>0.25</td>
<td>—</td>
<td>C3D20</td>
<td>— — — —</td>
</tr>
<tr>
<td>Annulus fibers</td>
<td>450</td>
<td>0.45</td>
<td>—</td>
<td>Rebar</td>
<td>1533 782 — —</td>
</tr>
<tr>
<td>Nucleus</td>
<td>0.1</td>
<td>0.499</td>
<td>—</td>
<td>C3D20</td>
<td>— — — —</td>
</tr>
<tr>
<td>Anterior longitudinal ligament</td>
<td>15 (&lt;12%); 30 (&gt;12%)</td>
<td>0.3</td>
<td>33</td>
<td>T3D2</td>
<td>— — — —</td>
</tr>
<tr>
<td>Posterior longitudinal ligament</td>
<td>10 (&lt;12%); 30 (&gt;12%)</td>
<td>0.3</td>
<td>33</td>
<td>T3D2</td>
<td>— — — —</td>
</tr>
<tr>
<td>Ligamentum flavum</td>
<td>7 (&lt;12%); 30 (&gt;12%)</td>
<td>0.3</td>
<td>50.1</td>
<td>T3D2</td>
<td>— — — —</td>
</tr>
<tr>
<td>Interspinous ligament</td>
<td>5 (&lt;25%); 30 (&gt;25%)</td>
<td>0.3</td>
<td>13</td>
<td>T3D2</td>
<td>— — — —</td>
</tr>
<tr>
<td>Capsular ligaments</td>
<td>15 (20–40%); 30 (&gt;40%)</td>
<td>0.3</td>
<td>46.6</td>
<td>T3D2</td>
<td>— — — —</td>
</tr>
<tr>
<td>ProDisc-C (14 × 17 × 7 mm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>— — — —</td>
</tr>
<tr>
<td>Endplates—CoCrMo</td>
<td>210,000</td>
<td>0.3</td>
<td>—</td>
<td>C3D10</td>
<td>— 5185 10,370 5185</td>
</tr>
<tr>
<td>Inlay polyethylene core—UHMWPE</td>
<td>2500</td>
<td>0.45</td>
<td>—</td>
<td>C3D10</td>
<td>— — — —</td>
</tr>
<tr>
<td>Fidji cage (14 × 16 × 7 mm)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>— — — —</td>
</tr>
<tr>
<td>Body in PEEK</td>
<td>4500</td>
<td>0.36</td>
<td>—</td>
<td>C3D10</td>
<td>— — — —</td>
</tr>
<tr>
<td>Cancellous bone graft (filling Fidji cage cavity)</td>
<td>450</td>
<td>0.3</td>
<td>—</td>
<td>C3D10M</td>
<td>— — — —</td>
</tr>
</tbody>
</table>

CoCrMo = cobalt-chromium-molybdenum alloy; PEEK = polyetheretherketone; UHMWPE = ultra-high-molecular-weight polyethylene.
defined to simulate 2 clinical scenarios: First, to simulate a clinical situation immediately after surgery, all implant-vertebra interfaces were considered to be in contact, with a friction coefficient of 0.8 to mimic the effect of the cage’s small teeth and prosthesis surface asperities (that facilitate implant anchorage in the vertebral surface). The cancellous bone that fills the Fidji cage frame was considered frictionless. The second scenario simulates a long-term clinical situation, where full osseointegration occurs at all implant-vertebra interfaces. These were considered rigidly bonded. In both scenarios, the metal-on-polyethylene contact (ProDisc-C) was modeled with a friction coefficient of 0.08. All contacts were modeled with a surface-to-surface contact algorithm and with the augmented Lagrange formulation method. A severe physiological neck load was applied at the C-4 vertebra, which is representative of an extension neck exercise with a compression force of 1164 N and an anteroposterior force of 133 N. Constraints were applied at the inferior endplate of the C-6 vertebra. All simulations were conducted using the commercial software Abaqus v. 6.10 (Dassault Systèmes Simulia Corp.). Nonlinear geometry effects were accounted for in all simulations. For each C4–6 segment condition, comparative analysis of contour-plot patterns and peak values of maximal (tension) and minimal (compression) principal strains at the C-5 vertebral body were made.

Experimental Simplified Model of C4–6 Cervical Segment

Twelve simplified experimental cervical-segment constructs were evaluated, corresponding to the combination of the 4 segmental conditions with 3 C-5 vertebral body heights (Fig. 2). To avoid the variability produced by human cadaveric tissue (including bone mineral density and endplate geometries) and since synthetic cervical vertebrae were not commercially available, solid rigid polyurethane was selected as the biomechanical material for the simplified C4–6 vertebral bodies. This polyurethane foam provides consistent and uniform material data, with properties in the range of human cancellous bone (ASTM F-1839–08). The C4–6 vertebral bodies (without transverse and spinous process) were produced by CNC (computer numerical control) machining of solid rigid polyurethane foam (0.32 g/cm³ density) blocks (Model 1522–03, Pacific-Research-Labs, WA, USA). The simplified geometry of the vertebral bodies was approximated from morphological studies of cervical vertebrae. The sizes of the vertebral bodies are presented in Table 2. To study the failure risk associated with C-5 vertebral body height, each segment condition was tested with 3 different vertebral body heights: a standard height of 12 mm and heights 17% lower (thinnest, 10 mm) and 17% greater (thick, 14 mm) than the standard vertebral height (Table 2). The intervertebral intact disc was made of silicon rubber material (Fig. 2) with a Young’s modulus of 5 MPa and a mean thickness of 5 mm. The disc was glued.

![FIG. 2. Experimental synthetic polyurethane C4–6 cervical-segment models for various heights of the C-5 vertebral body. Upper: Before failure. Lower: After C-5 failure. Figure is available in color online only.](image)
Failure analysis after total disc replacement with ProDisc-C

J Neurosurg Spine Volume 22 • June 2015

643

to the vertebral bodies. The ProDisc-C and Fidji cage implants were tested only in contact with the vertebral body surfaces to simulate an immediate postoperative clinical scenario. Each construct was subjected to a uniaxial compression (Shimadzu AGS-10KnXD) load-at-failure test, performed at a constant rate of 2.5 mm.s⁻¹. The corresponding peak load before vertebral body failure was recorded (Fig. 2). The maximum applied compression load was limited to 3000 N to not exceed the maximum compressive strength of the solid rigid polyurethane vertebrae and polyethylene disc implant. The peak load at failure was averaged over 5 tests for each C-5 vertebral body height, and the standard deviations were determined. An exploratory data analysis was made to check the normal distribution of all data. Paired t-tests were performed using SPSS software (SPSS, Inc.) to evaluate the statistical significance of the difference of load at failure between segment conditions. Differences were considered statistically significant with p values less than 0.05.

Results

The minimal (compressive) and maximal (tension) principal strain patterns at the C-5 vertebra (midsagittal and midfrontal planes) for the clinical scenario representative of the immediate postoperative condition (implant-vertebra interfaces in friction contact) are presented in Fig. 3. The strain patterns of the intact and 3 implanted models were very different. Generally, the magnitudes of the minimal principal strains were greater (+37%) than the maximal principal strains for all assessed models. The intact model presented the highest principal strains at the superior and inferior endplate regions, with peak values occurring at the disc nucleus region. The single-level arthroplasty model (1-level ProDisc) presented a mean increase of 85% of both principal strains at the vertebral body core and above 200% at the keel cut region for compressive strains when compared with the intact model. On the multilevel arthroplasty model (2-level ProDisc), the central vertebral region between the 2 keel cuts presented the highest compression strains of all analyzed models, with a mean strain increase of 350% relative to the intact model and 150% relative to the single-level arthroplasty model. The ProDisc-C prosthesis model combined with the fusion Fidji cage (ProDisc+cage) showed a compression strain increase of 200% at the keel cut region when compared with the intact model, as well as peak strains (+300%) at the upper endplate at the cage support rim location. The strain patterns of the models representative of a full implant-vertebra osseointegration presented strain patterns very similar to the model for the immediately postoperative situation (Fig. 3), with peak strain values 10% to 20% lower.

| TABLE 2. Size of the experimental synthetic polyurethane C-4, C-5, and C-6 vertebral bodies |
|--------------------------------------------------|----------------|
| Measurement                                       | Value (mm)    |
| C-4                                              | C-5 | C-6 |
| Vertebral body depth                              | 18.5| 20.6| 21.6|
| Vertebral body width                              | 24.2| 25.4| 28.5|
| Thick—vertebral body height (14 mm)               | 14  |
| Standard—vertebral body height (12 mm)            | 12.3| 12  | 13.2|
| Thinnest—vertebral body height (10 mm)            | 10  |

![FIG. 3. Minimal (compressive) and maximal (tension) principal strains at the midsagittal and frontal planes of the C-5 vertebral body. Figure is available in color online only.](image-url)
The mean and standard deviations of compressive load-at-failure values for the 3 vertebral body heights are presented in Fig. 4, for each segment construct. For the intact condition, there was no vertebral body failure until the maximum compressive load of 3000 N was reached for all vertebral body heights tested. For all implanted constructs, the load-at-failure standard deviation was less than 8% of the mean. The single-level arthroplasty construct presented the highest load-at-failure value of all implanted segment constructs for each vertebral body height tested. The lowest load at failure occurred for the thinnest vertebra, with a mean difference of 7% relatively to the peak load at failure of the thick vertebra. No significant differences (p = 0.11) were found between the 3 C-5 vertebral body heights. The multilevel arthroplasty construct (2-level ProDisc) presented a similar behavior to the single-level construct, but with a mean lowest load at failure of 12% for all the C-5 vertebral body heights. Also, no significant load-at-failure differences (p = 0.12) were found between the thick and the thinnest vertebral bodies. The ProDisc plus Fidji cage construct (ProDisc+cage) presented the lowest values for load at failure for all constructs, for the 3 vertebral body heights tested. The thinnest and standard vertebral bodies’ height presented a mean reduction of 7% and 15% for the load at failure when compared with the single- and multilevel arthroplasty respectively. Significant differences of load at failure between the thinnest (p = 0.03) and standard (p = 0.04) body heights were found relative to the thick vertebral body.

Discussion

The aim of this study was to evaluate the failure risk of cervical vertebra after TDR with a keel-design prosthesis (ProDisc-C), taking into consideration the effects of vertebral body height, replacement at multiple levels, and the association with an adjacent fusion cage (Fidji).

Study of the strain changes of the vertebral body through a specimen-specific cervical-segment finite-element model is supported by evidence that the onset of bone failure is consistent with a strain criterion. The critical factor of the bone structure under load transfer devices, such as cervical disc prostheses or fusion cages, is the risk of failure of the supporting cancellous bone in compression. The failure process of cancellous bone can be due to overload, normally through a fatigue mode, and it may occur if compressive strains are increased by 50% to 100% due to prosthesis implantation. The strain results showed that the vertebral bodies are not structurally immune to the type and number of implants of the adjacent joints, demonstrating different strain patterns and peak strain values between implanted and intact models. No major strain differences were found between the 2 implant-vertebra interface conditions, representative of 2 clinical scenarios (postoperative and long term), and this may be related to the high friction coefficient (µ = 0.8) of the rough implant surfaces used in the postoperative scenario, which approximates the structural behavior of a rigid bonded interface used in the long-term scenario.

Of all the analyzed models, the multilevel arthroplasty model was the one that presented the highest compressive strain increase at the region of the keel cuts, on average 3 times higher than in the intact model, followed by the single-level arthroplasty and ProDisc+Fidji cage models, with a mean compressive strain increase of 2 times at the same region of the vertebra. However, the ProdDisc+Fidji cage model presented, at the cage support rim location, strain increases comparable to the highest values found in the multilevel arthroplasty model, which overloads the bone and increases the risk of subsidence. Undoubtedly, from a structural point of view, the lowest compressive strain increase relative to the intact model can be related to the lowest failure risk, while the highest strain increase may be related to a higher vertebral body failure risk. Thus, the single-level arthroplasty model presents a lower failure risk than the multilevel and ProDisc+Fidji cage models,
which presented similar compressive strain increases at the C-5 vertebral body, despite the different peak strain locations. Nagaraja et al. in a cancellous bone microdamage and microstructure study involving uniaxial compression, concluded that microdamage initiation occurred prior to apparent yield and for local principal strains of 0.46%–0.63% in compression, which are in the range of the principal compression strains found in this study (extension neck exercise with a compression force of 1164 N) for the multilevel arthroplasty and the ProDisc+Fidji cage models.

Using synthetic polyurethane models, the compressive load at failure of the C-5 vertebral body was quantified and compared for the 3 vertebral body heights on the 4 segmental constructs. We used synthetic testing to reduce the variability and legal issues associated with human cadaveric tissue testing. The use of synthetic fixation media for the mechanical evaluation of spinal instrumentation has been documented in a number of studies. The standard deviation of the measured load at failure was 8%, which is in the range of previous studies that used similar test materials. For the intact construct, as expected, no vertebral body failure occurred for any of the vertebral body heights tested. In all implanted tests, independent of the vertebral body height, the C-5 vertebral fracture occurred before the maximum test load was reached through a vertical split line that passed always through the keel cut, associating the keel cut with a geometrical defect that can act as stress raiser, promoting the vertebral body fracture. As expected, the single-level construct exhibited the highest load-at-failure values for all vertebral body heights, and these values were significantly different from those obtained with the 2 other implanted constructs. This construct demonstrated a continuum of the load at failure and the vertebral body height, but no significant differences were found between load-at-failure values for the 3 vertebral body heights. The multilevel construct had the second-highest load at failure for each vertebral body height tested. This experimental behavior evidences an increase of the vertebral body fracture risk in the multilevel arthroplasty compared to the risk in single-level arthroplasty, in line with the findings of the specimen-specific finite-element model. However, the load-at-failure value found in the multilevel arthroplasty (≈2200 N) construct was on average 2 times higher than the largest compression force (≈1164 N) that occurs during an extension neck exercise, which indicates a limited risk of vertebral body split fracture while performing physiological tasks. Nevertheless, the risk of bone microdamage initiation is present for an extension neck exercise, and this type of microdamage can lead to bone fatigue failure in the long term. Contrary to what was expected, the ProDisc+Fidji cage construct presented the lowest load-at-failure values of all constructs for the 3 vertebral body heights tested. In the comparison with the multilevel arthroplasty construct, no significant differences in load at failure were found for any of the vertebral body heights, which places these 2 constructs at the same statistical level concerning failure risk. The lowest load at failure obtained with the ProDisc+Fidji cage construct can be related to the cage support rim and the toothed ridges, which benefit the subsidence of the cage in the vertebral body. In all ProDisc+Fidji cage constructs tested we observed the subsidence of the cage in the C-4 and C-5 vertebral bodies, which contributes to the weakening of the vertebrae and can explain the lowest load-at-failure values. Despite the different biomechanical parameters analyzed, specimen-specific finite-element and experimental results point to the same trend: the vertebral body failure risk increases with the single-level arthroplasty relatively to the intact situation, and multilevel arthroplasty, as well as single-level arthroplasty combined with a fusion cage, increases this risk relative to single-level arthroplasty. However, the clinical relevance of this structural behavior is not fully known, since in the short-term follow-up there are only sparse reports of keel-related fractures in patients treated with single- and multilevel arthroplasty and ProDisc-C prostheses.

Like other experimental-numerical studies, the present study presents some shortcomings. The finite-element model results depend strongly on inputs such as material properties, loading conditions, and implant locations. For example, by shifting the implant in the vertebral endplates, the biomechanics might be altered. However, in the present study, the vertebral locations of the implants were confirmed by an experienced cervical spine orthopedic surgeon. The other limitation is the use of simplified applied loads, without muscle contribution. Despite this limitation, they are representative of the major loads acting upon the vertebral body in a demanding physiological task and were used in all constructs for consistency. In addition, this study does not take into account bone quality, loss of density in the adjacent cancellous bone, or the overall remodeling changes that will naturally occur in the vertebrae in vivo. In a clinical setting, these parameters will affect the risk of failure of the vertebral body risk. Nevertheless, it is reasonable to expect that these conditions will affect the different cervical constructs analyzed in the same way.

Conclusions

The main insight provided by the present study is that the use of a keeled ProDisc-C prosthesis at 2 adjacent levels or combined with an adjacent fusion cage presented the lowest load-at-failure values, 2 times higher on average than the values that occur while performing physiological tasks, which indicates an identical and limited risk of vertebral body failure for these 2 segment configurations, whereas the vertebral body height appears to only slightly affect this risk. However, a risk of microdamage initiation can be present for some more demanding neck tasks, not identified in the single-level arthroplasty model. These findings may improve the surgical decision-making process, based on scientific understanding and advanced prediction tools.

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J Neurosurg Spine Volume 22 • June 2015 645
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Author Contributions
Conception and design: Completo, Nascimento. Acquisition of data: Completo. Analysis and interpretation of data: Completo, Nascimento, Ramos. Drafting the article: Completo. Critically revising the article: Simões. Reviewed submitted version of manuscript: Simões. Approved the final version of the manuscript on behalf of all authors: Completo. Administrative/technical/material support: Ramos. Study supervision: Completo.

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