Biomechanical Evaluation of an Endplate-Conformed Polycaprolactone-Hydroxyapatite Intervertebral Fusion Graft and Its Comparison With a Typical Nonconformed Cortical Graft

In the thoracolumbar region, between 7% and 30% of spinal fusion failures are at risk for pseudarthrosis. From a biomechanical perspective, the nonconformity of the intervertebral graft to the endplate surface could contribute to pseudarthrosis, given suboptimal stress distributions. The objective of this study was to quantify the effect of endplate-graft conformation on endplate stress distribution, maximum Von Misses stress development, and stability. The study design used an experimentally validated finite element (FE) model of the L4–L5 functional spinal unit to simulate two types of interbody grafts (cortical bone and polycaprolactone (PCL)-hydroxyapatite (HA) grafts), with and without endplate-conformed surfaces. Two case studies were completed. In Case Study I, the endplate-conformed grafts and nonconformed grafts were compared under without posterior instrumentation condition, while in Case Study II, the endplate-conformed and nonconformed grafts were compared with posterior instrumentation. In both case studies, the results suggested that the increased endplate-graft conformity reduced the maximum stress on the endplate, created uniform stress distribution on endplate surfaces, and reduced the range of motion of L4–L5 segments by increasing the contact surface area between the graft and the endplate. The stress distributions in the endplate suggest that the load sharing is greater with the endplate-conformed PCL-HA graft, which might reduce the graft subsidence possibility. [DOI: 10.1115/1.4023988]

1 Introduction

Lower back pain remains the second most common symptom to see a physician in the United States [1]. The total costs associated with it exceed $100 billion per year and are allied with lost wages and reduced productivity [2]. The pain may arise from any of the spinal structures (discs, facets, ligaments, vertebrae, and muscles), but one of the leading causes is spinal instability resulting from the degeneration of intervertebral disc [3,4]. This type of instability is being treated with “spinal fusion,” which is the most rapidly increasing type of lumbar spine surgery, with a rate of 220% in a decade (1990–2001) [5–10].

The use of autograft for spinal fusion is considered a gold standard. However, its availability is limited, and the additional surgical procedures increase the odds of complications, such as morbidity, bleeding during the graft collection, and postoperative pelvic pain [11,12]. Allografts have the advantage of being readily available with preprocessed shapes and geometry, but using allograft can potentially lead to transfer of infections, such as immunodeficiency virus (HIV), hepatitis B, and hepatitis C [13].

In spite of wide acceptance of fusion in the treatment of pathology, the clinical success is limited because of lack of motion, adjacent level degeneration, pseudarthrosis, and donor-site pain [14,15]. Among them, pseudarthrosis is one of the common reasons and contributes to between 7% and 30% of fusion failures [7,8]. These statistics may indicate that current techniques in spine fusion, including autograft and allograft, are not adequate to create biologically and mechanically effective bone formation.

To form a mechanically stable spinal fusion and to reduce the graft failure, the biomechanical effect of vertebral endplate engagement with the graft and the degree of micromotion between them needs to be considered. The work of Kuslich et al. [4] showed that the introduction of a relatively small implant, as compared to the higher surface area of the intervertebral space, significantly changes the pattern of stress distribution on the vertebral end plates and causes subsidence failure of the endplate due to implant penetration. Kuslich et al. [4] also proved that the failure of the endplate due to implant penetration is a potent source of postoperative pain in patients. Pearcy et al. [16] also showed that, with full-thickness tricortical iliac autografts, subsidence failure into the vertebral body under load was common if the contact surface area of the graft was less than 40% of the surface area of the vertebral end plate. Excessively high stresses due to differences between the endplate and implant geometry can lead to endplate subsidence failure and mechanical instability across the fused segment. These groups and many others have underscored that the geometry and material properties of implants are important determinants of the spinal fusion success.

The commercial allografts come in many designs, yet they do not ensure optimal engagement between the endplate and graft. Furthermore, in order to accommodate commercial allografts to the patient’s vertebral body morphology, the vertebral endplates are surgically reduced to a flat plane, which may compromise the
strength of the vertebral shell and the long-term stability of the fusion [17]. An alternative approach to address these shortcomings is to use a graft that conforms to the vertebral endplate morphology.

The objective of this study is to identify the effect of vertebral endplate-conformed graft surface on endplate kinematics distribution and on the degree of motions using a finite element (FE) model. To accomplish the research objective, an experimentally validated 3D intact ligamentous lumbar spine (L4–L5) motion segment FE model [18–20] was used. The FE model was run with two case studies to identify the difference between endplate-conformed geometry versus commercial cortical bone graft on spinal unit (FSU) stability, endplate stress distribution, and maximum endplate stresses. These case studies were run with and without posterior instrumentation inferior for a systematic approach.

2 Materials and Methods

2.1 3D Intact Ligamentous Lumbar Spine (L4–L5) Motion Segment Finite Element Model. The FE model used in this study is a slightly modified version of an experimentally validated 3D intact ligamentous lumbar spine (L4–L5) motion segment FE model generated from reconstructed computer tomography scans of an L4–L5 motion segment of a cadaveric ligamentous spine specimen [21]. The experimental validation of the FE model was done using in vitro kinematic data, facet loads, ligament strains, and disc bulge under multiple load magnitudes [18–20]. Necessary changes have been conducted on the FE model to accommodate surgical placement of the endplate-conformed graft. These changes were the removal of two-thirds of anterior annulus fibrosus (intact volume = 9.48 cm$^3$, volume removed = 3.14 cm$^3$), complete nucleus pulposus (intact volume = volume removed = 8.30 cm$^3$), and complete anterior longitudinal ligament. Regarding the endplate-conformed graft, the graft was modeled according to the endplate geometry, but the endplate kept intact. Besides changes in model constructs, the mesh density was also changed in the modified FE model. In this FE model, the mesh density is eight-fold that of the previously remodeled spine mesh [22]. This mesh density change was driven by a convergence study performed by Goel et al. [20]. Other components of the FE model were not altered.

The commercial software ABAQUS/Standard™ version 6.10 (Simulia, Inc., Rhode Island, USA) was used to construct and analyze the FE model. The model is consisting of 14,496 elements and 21,628 nodes, and it is symmetric about the midsagittal plane [23]. Table 1 summarizes the details regarding the FE model, including components, element formulation, and material properties of elements [21].

### Table 1: The material properties of elements used in the model

<table>
<thead>
<tr>
<th>Component</th>
<th>Element formulation</th>
<th>Modulus (MPa)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone structure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vertebral endplate</td>
<td>Isotropic, elastic hex elements (C3D8)</td>
<td>12,000</td>
</tr>
<tr>
<td>Vertebral and posterior</td>
<td>Isotropic, elastic hex elements (C3D8)</td>
<td>12,000</td>
</tr>
<tr>
<td>Vertebral and posterior cancellous bone</td>
<td>Isotropic, elastic hex elements (C3D8)</td>
<td>100</td>
</tr>
<tr>
<td>Graft</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conformed cortical bone</td>
<td>Isotropic, elastic hex elements (C3D8)</td>
<td>12,000</td>
</tr>
<tr>
<td>Nonconformed cortical bone</td>
<td>Isotropic, elastic tet elements (C3D4)</td>
<td>12,000</td>
</tr>
<tr>
<td>Conformed PCL + 25%HA</td>
<td>Isotropic, elastic hex elements (C3D8)</td>
<td>150</td>
</tr>
<tr>
<td>Nonconformed PCL + 25%HA</td>
<td>Isotropic, elastic tet elements (C3D4)</td>
<td>150</td>
</tr>
<tr>
<td>Intervertebral disc</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Annulus (ground)</td>
<td>Neo-Hookean, hex elements (C3D8)</td>
<td>C10 = 0.348, D1 = 0.3</td>
</tr>
<tr>
<td>Annulus (fiber)</td>
<td>Rebar</td>
<td></td>
</tr>
<tr>
<td>Ligaments</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Posterior longitudinal</td>
<td>Tension-only, truss elements (T3D2)</td>
<td>10.0(&lt;11%), 20.0(&gt;11%)</td>
</tr>
<tr>
<td>Ligamentum flavum</td>
<td>Tension-only, truss elements (T3D2)</td>
<td>15.0(&lt;6.2%), 19.5(&gt;6.2%)</td>
</tr>
<tr>
<td>Intervertransverse</td>
<td>Tension-only, truss elements (T3D2)</td>
<td>10.0(&lt;18%), 58.7(&gt;18%)</td>
</tr>
<tr>
<td>Interspinous</td>
<td>Tension-only, truss elements (T3D2)</td>
<td>10.0(&lt;14%), 11.6(&gt;14%)</td>
</tr>
<tr>
<td>Supraspinous</td>
<td>Tension-only, truss elements (T3D2)</td>
<td>8.0(&lt;20%), 15.0(&gt;20%)</td>
</tr>
<tr>
<td>Capsular</td>
<td>Tension-only, truss elements (T3D2)</td>
<td>7.5(&lt;25%), 32.9(&gt;25%)</td>
</tr>
<tr>
<td>Joints</td>
<td>Nonlinear soft contact, GAPPU1N elements</td>
<td>12,000</td>
</tr>
</tbody>
</table>
details regarding endplate-conformed and nonconformed grafts’ geometry.

While commercial grafts usually have holes for bony ingrowth, in this study, a solid geometry was used to isolate the sole effect of surface contour on endplate stress distribution and on the degree of micromotion.

Anterior lumbar interbody fusion (ALIF) was simulated for each case, in which two-thirds of anterior annulus fibrosus (intact volume = 9.48 cm³, volume removed = 3.14 cm³), complete nucleus pulposus (intact volume = volume removed = 8.30 cm³), and complete anterior longitudinal ligament were removed. Both endplate-conformed and nonconformed grafts were implanted inside the annulus fibrosus (in place of removed nucleus pulposus), where the maximum surface of both the endplates was in contact with the grafts’ surfaces. The conformed graft fits perfectly with the endplate, whereas the nonconformed graft lacks continuous surface contact with the endplate.

In the FE model, the bottom of the L5 vertebra were fixed and then the whole functional spinal unit (FSU) was loaded with 400 N of follower load and 7.5 Nm of pure moment for either the flexion or extension [15]. After the model had converged, the postprocessing was conducted to collect all the required data: (1) Von Mises stress contour plot on both adjoining endplates; (2) maximum Von Mises stress value on the adjoining endplates; and (3) total range of motion for both flexion and extension in each cases. The detailed information about each case is given below.

### 2.2.1 Case Study I.
In Case Study I, the endplate-conformed graft (CG) and nonconformed grafts (NCG) were compared under without posterior instrumentation condition. Two different materials, namely PCL + 25% HA and cortical bone, were modeled in endplate-conformed and nonconformed groups. In these models, the graft’s top and bottom surfaces were given surface-to-surface interaction with adjoining endplates. This interaction allowed
finite sliding (arbitrary motion between surfaces, which allowed separation sliding and rotation) with the constraint of nonpenetration between surfaces [24]. A coefficient of friction 0.3 was given between the graft and endplates [25]. This simulates a more physiologic situation, where the surfaces of the grafts are not fused to the endplates.

2.2.2 Case Study II. In Case Study II, the endplate-conformed graft (CG) and nonconformed grafts (NCG) were compared under with posterior instrumentation condition. Two different materials, namely PCL + 25% HA and cortical bone, were modeled in endplate-conformed and nonconformed groups. The same contact definition as described above for Case Study I was used.

In this case study, different than Case Study I, a pedicle screws and rods system was used as posterior instrumentation. The pedicle screws were firmly connected to the vertebra using kinematic coupling. The material properties of both screw and rod were defined as that of titanium (E = 115 GPa and Poisson’s ratio = 0.3).

3 Results

Following running Case Study I and Case Study II using the aforementioned FE model, the postprocessing was conducted to collect data for range of motion (ROM) both flexion and extension, for maximum endplate Von Mises stresses, and for endplate Von Mises stress contour. For each case, four different models were run: (1) endplate-conformed PCL-HA graft; (2) nonconformed PCL-HA graft; (3) endplate-conformed cortical bone graft; and (4) nonconformed cortical bone graft. The results for Case Study I and Case Study II are given below.

3.1 Case Study I: Results on Range of Motions (ROM) and Stress Distribution. The changes of ROM with the graft-endplate conformity and with different graft material were given in Fig. 3, along with the intact FSU ROM for flexion and extension motion.

The comparison on ROM for extension and flexion motion in the units of degree is given in Fig. 3. Based on FE analysis, for nonconformed cortical graft, ROM decreased 30% for flexion and 10% for extension motion compared to intact FSU. For endplate-conformed cortical bone graft, the decrease in ROM was by 50% for flexion and 10% for extension motion. The similar trend was observed for a nonconformed and endplate-conformed PCL-HA grafts. For the nonconformed PCL-HA graft, the respective reductions were 13% and 10%. Similarly, for the conformend PCL-HA graft, the respective reductions were 30% and 10%. Overall, extension did not see significant difference between conformend and nonconformed grafts with the same material. However, in flexion, greater reductions were observed in conformend grafts as compared to nonconformed grafts.

The comparison of maximum Von Mises stresses developed on L4 inferior and L5 superior endplates during extension motion is given in Fig. 4. The highest stress values were observed on L4 and L5 endplates for the nonconformed cortical bone graft. For the cortical bone graft, the maximum stress values on the L4 inferior endplate reduced from 179.6 MPa for the nonconformed graft to 29.3 MPa for the conformend graft. The maximum stress values reduced with the increased conformity by 84% compared to a nonconformed cortical graft. A similar trend was also observed on maximum stress values on the L5 superior endplate. There was a significant reduction in stress values from 142.6 MPa for the nonconformed graft to 106.3 MPa for the conformend graft, with 33% corresponding decrease on the L5 endplate. The maximum stress values were significantly lower for the PCL + HA graft group for both conformend and nonconformed graft models compared to their counterparts in cortical bone groups. The lowest value of maximum stress was observed on the L4 endplate with a value of 14.2 MPa for the endplate-conformed PCL + HA group.

The relative change in stress values for the conformend PCL + HA graft was 75% for the L4 endplate and 30% for the L5 endplate compared to the nonconformed PCL + HA graft.

Figure 5 gives the comparison of maximum Von Mises stresses developed on endplates during flexion. In flexion motion, the maximum stress decreased by 35% for the L4 endplate and 3% for the L5 endplate compared to a nonconformed cortical graft. For the PCL-HA conformend graft, the maximum stress decreased by 42% on the L4 endplate and by 27% for the L5 endplate, compared to the nonconformed PCL-HA graft.
The stress contour diagram for both conformed and nonconformed grafts are shown in Figs. 6 and 7 for extension. It can be concluded that, using the same material, the stresses in endplate-conformed grafts were more uniform and the stress values were lower compared to stresses on the nonconformed graft. Between the cortical bone grafts and PCL + HA grafts, the PCL + HA graft showed lower stress values and higher uniformity in stress distribution compared to cortical grafts. Flexion stress contour showed a similar trend (data not shown here).

Figure 8 provides the actual graft-endplate contact surface area values for all the grafts following application of 7.5 Nm of flexion and extension with 400 N of follower load. The final surface area following those loads was increased with the increased conformity for both PCL + HA and cortical bone graft.
3.2 Case Study II: Results on Range of Motions (ROM) and Stress Distribution. In Case Study II, the endplate-conformed graft and nonconformed grafts were compared under with posterior instrumentation condition.

Figure 9 shows the range of motion (ROM) data during flexion and extension in the units of degree. Based on FE analysis, the flexion and extension ROM, respectively, decreased by almost 84% and 95% with the nonconformed cortical graft as compared to intact FSU. For the conformed cortical graft, the flexion and extension, respectively, were reduced by 93% and 91%. For the nonconformed PCL-HA graft, the respective reductions were 78% and 92%. Similarly, for the conformed PCL-HA graft, the respective reductions were 89% and 92%. In flexion, the motion provided by the conformed graft is almost one-half the motion provided by the nonconformed graft of the same material.

The maximum Von Mises stresses values developed on endplates in extension motion are given in Fig. 10. The maximum stress values decreased with the increased conformity. The lowest values were observed on an endplate-conformed PCL-HA graft. In extension motion, for a conformed cortical graft, the maximum stress on the L4 inferior endplate decreased by 34%, compared to a nonconformed cortical graft, while there was an increase in maximum stress on the L5 superior endplate by 37% compared to a nonconformed cortical graft. For the PCL-HA conformed graft, maximum stress decreased by 53% on the inferior endplate and by 38% for the L5 superior endplate compared to a nonconformed PCL-HA graft.

Figure 11 gives the comparison of maximum Von Mises stresses developed on endplates during flexion in the units of MPa. In flexion motion, for a conformed cortical graft, the maximum stress decreased by 65% for the L4 inferior endplate and by 39% for the L5 superior endplate compared to a nonconformed cortical graft. The maximum Von Mises stresses with a PCL-HA conformed graft showed a similar trend. The percentage decrease in the maximum stress value was 66% on the L4 endplate and by 34% for the L5 endplate compared to the nonconformed PCL-HA graft.

For Case Study II run with spinal fixation, the stress contour diagrams for both conformed and nonconformed grafts are given in Figs. 12 and 13 for extension motion. They follow the same trend as described in Case Study I. Between the cortical bone grafts and PCL-HA grafts, the PCL-HA graft showed lower stress values and higher uniformity in stress distribution compared to cortical grafts. Flexion stress contour showed also a similar trend (data not shown here).

Figure 14 provides the actual graft-endplate contact surface area values for all the grafts following 7.5 Nm of flexion and extension with 400 N of follower load. The contact surface area was increased with the increased conformity between the endplate...
and the graft for both the PCL + HA group and cortical bone graft group. This data agree with the contact surface data obtained from Case Study I (Fig. 8).

4 Discussion

The objective of this study was to identify the effect of vertebral endplate-conformed graft surface on endplate stress distribution and on the degree of motions using a finite element (FE) model. The FE model was run with two case studies. In Case Study I, the conformed and nonconformed grafts were studied without posterior instrumentation, and in Case Study II, the conformed and nonconformed grafts were studied with posterior instrumentation.

The effect of endplate-graft conformity on range of motion (ROM) of the L4–L5 segment was also investigated in this study.
under Case Study I and Case Study II. The ROM values were compared to the intact functional spinal unit for both case studies and given in Figs. 3 for Case Study I and in Figs. 9 for Case Study II. In Case Study I, compared to the intact FSU range of motion (ROM) values, the slight decrease in ROM was observed in flexion and extension motion for all four cases (Fig. 3). The results given in Fig. 3 provided the effect of posterior instrumentation on the degree of the motion. The decrease is not significant, because there is no posterior instrumentation used in Case Study I to stabilize the segment. Another observation was that there was not any change in ROM for extension motion, while the ROM values changed in flexion motion. These slight changes in ROM values can be attributed to the absence of the two-thirds of the annulus, which might damper the motion slightly. ROM values for Case Study II (Fig. 9) showed that, compared to intact FSU, there was a significant decrease in ROM for the PCL-HA graft and cortical bone graft by 90% and 93%, respectively. Also, it should be noted that the range of motion decreased further with a conformed graft compared to a nonconformed graft with the same material. This can be attributed to the increased conformity between the surface of the graft and the endplate. Thus, the micromotions between the graft and endplate could be decreased by using conformed grafts. When ROM results compared between the studies, the significant decrease in ROM for Case Study II was observed compared to ROM values in Case Study I. The major reason for that is the utilization of posterior instrumentation in Case Study II. The posterior instrumentation further prevented the micromotions compared to no stabilization cases in Case Study I.

To identify the effect of endplate-conformity on graft performance and stress values created on an inferior endplate of L4 vertebral and superior endplate of L5 vertebra, the maximum Von Mises stresses were presented for extension and flexion motions for Case Study I (Figs. 4 and 5) and for Case Study II (Figs. 10 and 11). In both cases, similar results were observed. For both case studies, the maximum Von Mises stresses data suggested that the maximum stress values decreased on the L4 and L5 endplates with the increased conformity between the graft and the endplate. Those results emphasize the importance of endplate-graft conformity on maximum stress values generated on an L4 inferior endplate and L5 superior endplate with extension and flexion motion. A similar conclusion can be reached for Von Mises stress contours for both Case Study I (Figs. 6 and 7) and Case Study II (Figs. 12 and 13). The stress distribution for the endplate-conformed grafts was more uniform compared to nonconformed grafts in both the case studies. Furthermore, there were less stresses on the L4 inferior and L5 endplate for a conformed PCL-HA graft compared to a conformed cortical graft. This also suggests that a conformed PCL-HA graft provides better load sharing, which may reduce the chances of graft subsidence. Also, no stress concentration was seen in the conformed grafts.

To validate our results on the stress distribution contours and maximum Von Mises stresses, the graft-endplate surface area was measured following 7.5 Nm of flexion and extension with 400 N of follower load. It is obvious from the contact area measurements shown in Figs. 8 and 14 that the conformed grafts had much higher contact area than the nonconformed grafts. This supports our finding that the maximum Von Mises stresses were higher in nonconformed grafts due to lower contact surface area.

There are several variables that, if controlled, will improve the fusion rates. Conformity is one of those, which can enhance engagement between endplate and graft by providing better grip and surface area without discontinuity. Our finite element study has shed light on most of these important parameters (i.e., the maximum endplates stresses, stability (or micromotion), and stress distribution on the endplates). However, this model also has some limitations in our study. First, there are no muscle forces in our model, but this limitation is mitigated by using a follower load. As published by Patwardhan et al. [26], using a follower load provides similar kinematics response as in vivo. Secondly, the endplate in our model is uniform, with a thickness of 0.5 mm, whereas, in reality, the endplate thickness varies from the center to the periphery. However, the variation in thickness is very small and hence would not affect the outcome of our study. Thirdly, our model simulates single geometry of the spine model and thus does not account for variations in the patients/cadavers.

To translate the above finite element study into a real cadaveric study, a three-dimensional intervertebral model with appropriate geometrical and mechanical characteristics for spinal fusion application would be the way forward. Specifically, the 3D scaffold design and geometry will be based on endplate morphology to provide maximum contact between the scaffold and the endplate and thus minimize the uneven stress distribution on the endplate. In this approach, a patient’s CT data should be taken to reproduce inferior and superior endplates topography in a suitable software environment, like Mimics Innovation Suite [22] (Materialise [23]). This will then be given as a feed for 3D bioprinting in a computer-aided scaffold manufacturing system, as previously described [27]. However, this approach is beyond the scope of the current study.

5 Conclusion

This study has demonstrated the biomechanical outcome of incorporating vertebral endplate morphology to the graft design, which has not been considered thus far. The results suggest that endplate-conformed grafts provide uniform stress distribution on the endplates, decreased maximum stress, increased contact surface area, and decreased range of motion compared to the nonconformed commercially available grafts.

References


