Patient-Specific Templating of Lumbar Total Disk Replacement to Restore Normal Anatomy and Function

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Over the years, there has been an increased focus on restoration of both anatomy and function in orthopedic surgery. This is evidenced by newer techniques in anterior cruciate ligament repair and hip replacement that attempt to better restore native mechanics.\(^1,2\) For lumbar spinal degenerative disk disease, conventional posterior fusion and instrumentation techniques have been implicated in accelerated degeneration of adjacent segments.\(^3,4\) and with the introduction of stable “stand-alone” anterior fusion devices, there has been a resurgence of anterior fusion techniques to stabilize the segment, restore disk height, and optimize lumbar lordosis. Fusion by any approach, however, does not restore or preserve motion. Lumbar total disk replacement (TDR) has the potential to restore disk height and lordosis and maintain or restore motion. Clinical trials have delivered favorable outcomes of TDR when compared with anteroposterior “360°” and anterior-only fusion; however, these implants have also failed to achieve global acceptance and use.

Degenerative disk disease affects a large proportion of the population and is associated with significant direct medical and indirect economic costs. Total disk replacement is indicated when degeneration is localized to 1 or 2 levels in patients without segmental instability or associated facet degeneration and dysfunction. The theoretical advantage of TDR over fut...
sion is that, although both can restore disk height and lumbar lordosis, only TDR has the potential to restore or maintain motion without disrupting or interfering with the function of posterior musculature. Additionally, the incidence of adjacent level degeneration has been shown to be significantly lower among patients undergoing TDR compared with fusion. However, when the range of motion (ROM) achieved with TDR is less than 5°, the incidences of adjacent segment disease and poor patient outcomes increase.

Facet-mediated pain at the operative level is also a factor that may compromise the clinical outcome of patients undergoing TDR. Approximately one-fourth to one-third of patients report facet-mediated pain in the postoperative period.

The authors believe that these issues are related to a mismatch between patient anatomy, specifically vertebral size and facet orientation, and the mechanics of the implant selected. In the United States, limited implants are available for implantation, having a limited range of dimensions and a fixed or limited axis of rotation; however, considerable variability exists in the size and shape of patients requiring treatment for degenerative disk disease. Also, selecting an appropriate implant but placing it in a “nonideal” location can compromise the clinical outcome. The authors hypothesize that by matching the anatomy and mechanics of patients to the dimensions and mechanics of implants, surgeons will maximize the ROM achieved, deliver the best possible clinical outcome in terms of improvement in both pain and function, and limit adjacent level disease progression.

The authors have developed a novel patient-specific tool to identify patients whose anatomy is compatible with the available implants and to produce a surgical template to indicate the ideal location to place the implants intraoperatively. This tool creates a patient-specific 3-dimensional (3D) model from a computed tomography (CT) scan and uses finite element analysis (FEA) to “virtually” implant the various implants available and determine which is most likely to deliver the best results. The custom software tool uses a CT scan with appropriate resolution and computer-aided design files of the implants to create an FEA model to assess the segmental motion.

### MATERIALS AND METHODS

#### Statistical Shape Modeling

Approval for this study was obtained from the Colorado Multiple Institutional Review Board. Patients who had undergone either a single or a 2-level lumbar fusion or disk replacement at the University of Colorado Hospital since 2008 and who had a preoperative CT scan or CT diskogram with sufficient resolution (pixel size, 0.31 mm; slice thickness, 1 mm) were identified. The lumbar spine from L1 to S1 was segmented and 3D patient-specific FEA models were developed. Fifty-two patients with a mean age 35 years (range, 20-58 years) were part of the analysis. Anatomical variations were identified. Variables were identified that influenced the potential ROM that could be achieved following the virtual implantation of a ProDisc-L (DePuy Synthes, Raynham, Massachusetts) TDR.

To characterize variability in the lumbar spine (L1-S1), a statistical shape modeling approach was employed. After establishing correspondence, statistical shape modeling describes the variation in the population as a series of models. The first 4 modes of variation described independent changes in scaling, disk height, disk angle (lordosis), and facet height and captured 60.9% and 63.7% of the variation for the L4-5 and the L5-S1 segments, respectively. The greatest variability between patients was related to the overall size of the vertebra.
Other measures assessed included facet orientation, vertical slope and sagittal vs coronal orientation of the articular surface, and the distance of the facet joint to the center of the vertebral body (Figure 3). These variables impact the normal rotations that can occur through the specified intervertebral segment and should be matched by the geometry and mechanics of the implant to reproduce normal motion.

**Determination of the Ideal Implant Size and Placement**

The native disk has a variable axis of rotation in flexion and extension as a result of the anatomical constraints and the flexible nature of the nucleus. The annular fibers provide stability and, with the facet orientation, the limits of the ROM of the functional spinal unit. The ProDisc-L implant is a ball and socket articulation that rotates around a single, fixed axis of rotation located in the inferior vertebra of the motion segment. Two footprint sizes are currently available in the United States (medium, 27 × 34.5 mm; large, 30 × 39 mm). The superior endplate of the implant effectively translates forward in flexion and backward in extension as it rotates over the polyethylene ball of the implant. Thus, unless the anatomical arrangement and orientation of the facet joints perfectly matches the mechanics of the implant and its axis of rotation, implant rotation can result in closure or compression of the facets in flexion and distraction or opening in extension (Figure 4).

The ProDisc-L computer-aided design files were provided by the manufacturer and used to virtually implant the artificial disk into the patient-specific 3D FEA model of the functional spinal unit. The implant was placed in the midline of the disk space so that its posterior margin was level with the posterior aspect of the vertebral body, so as not to encroach on the spinal canal. The ROM of the functional spinal unit was then determined in this location, with extension usually blocked by impingement of the components of the implant and flexion usually blocked by the facet joints. The implant was then moved in 1-mm increments toward the front of the vertebra and an analysis of the ROM was repeated to identify the location where the maximum range of both flexion and extension was achieved.

During this analysis, another variable was identified that has a significant impact on the ROM that could be achieved. The superior and inferior endplates of the ProDisc-L implant can be advanced independently, or at least not uniformly, and the positioning of the patient on the operating table at the time of TDR surgery may result in a degree of either anterolisthesis or retrolisthesis of the superior vertebra relative to the inferior vertebra. Thus, when the polyethylene insert is secured and load is applied to the spine, the ball of the articulation relocates into the socket. If the superior endplate is anterior relative to the inferior endplate, relocation will result in posterior translation of the superior vertebra (retrolisthesis), leading to opening or separation of the facet joints. This may lead to a greater ROM in flexion because facet contact is less likely to occur in this situation, but may also lead to facet-mediated pain and an inferior clinical outcome due to capsular tension and altered facet mechanics. The reverse may also occur: posterior placement of the superior endplate relative to the inferior endplate. This will lead to facet impingement because the superior vertebra will be translated anteriorly (anterolisthesis) as the ball and socket engage under load. The result will be a reduced ROM in flexion due to early or preexisting facet impingement, leading to a reduced ROM and possibly also facet-mediated pain (Figure 5).

**Evaluation of the Model**

To date, several forms of evaluation of the model have been undertaken. The first was to validate the model and to confirm that the ROM determined through the virtual implantation of the implant was accurate. Pre- and postoperative images of patients

**Figure 3:** Graphic representation of the facet orientation (top) and the distance from the center of the vertebral body to the anterior portion of the superior facet of L5 (bottom).

**Figure 4:** Representation of the ProDisc-L (DePuy Synthes, Raynham, Massachusetts) implant in flexion (left), neutral alignment (center), and extension (right) showing the anterior and posterior translation of the implant around the axis of rotation on flexion and extension, respectively.
who had undergone lumbar TDR were analyzed. Patient-specific FEA models were created for these patients (Figure 6).

Postoperative flexion and extension radiographs were used to determine the actual ROM achieved postoperatively. The implant used was then positioned in a location identical to that evident on the imaging and an analysis was undertaken in a blinded fashion to determine the predicted ROM that could be achieved. The final component of the analysis was to determine the ideal implant size and configuration and to assess what ROM might have been achieved had a different implant been used or had the same implant been located in a different position. Seventeen patients, 12 having undergone a single-level procedure and 5 having had a 2-level TDR, were part of the analysis. The results are presented in Figure 7.

This analysis indicated good correlation between actual and predicted ROM of the operated on levels, with Pearson’s r being 0.94 and the average difference being 11.8% (range, 2.9%-27.1%). The analysis also indicated that 16 of the 22 operated on levels could have achieved a greater ROM had a different implant been used or had the same implant been located in a different position. Seven patients could have achieved an increased ROM of more than 1° and 2 patients could have achieved an increased ROM of more than 3.5°. Only 1 patient was identified whose anatomical features did not match the mechanics of the implant and who achieved less than 5° of motion for all implant configurations and locations. This patient may have been better off undergoing a fusion rather than a disk replacement.

RESULTS

Several of the patients involved in the analysis described here were enrolled in the Food and Drug Administration Investigational Drug Exemption for TDR and also had preoperative and postoperative clinical outcome data that could be analyzed. Of the patients who underwent a ProDisc-L TDR at L5-S1, the patient with the best clinical outcome had a decrease in Oswestry Disability Index score of 58 points and achieved a postoperative ROM of 5.5°. For this patient, trialing other implants and the same implant in different locations indicated that the appropriate implant had been used and that it was located close to the ideal position. The predicted ROM improved by only 0.1° with the implant positioned slightly more posteriorly. The patient with the worst clinical outcome still showed improvement, but the decrease in this patient’s Oswestry Disability Index score was only 22 points and the actual ROM was 3.75°, below what is considered the minimum clinically acceptable ROM of 5.0°.8-10 A
large 6° implant with a 10-mm insert was used for this patient. However, the current authors’ analysis indicated that the ideal implant would be a medium 11° implant with a 10-mm insert and that locating the implant a little farther back in the vertebral body would have been ideal. In the ideal location, this implant would have nearly doubled the total predicted ROM to 6.4°. Whether the predicted improvement of ROM would lead to actual improvement in ROM and subsequently pain and function has yet to be elucidated.

**Future Directions**

During the past 3 years, the authors have used this 3D templating to evaluate the complex interaction among individual patient anatomy, implant geometry, and intraoperative implant alignment. The ideal implant size and location is determined and a surgical template is created to assist the surgeon during the operation in placing the implant in the ideal location. An example of one of these surgical templates is shown in Figure 8.

Identifying patients with compatible anatomy for implant mechanics and the ideal implant size and location are not the only factors that determine the ROM that can be achieved with TDR surgery. Another key factor is ensuring that appropriate mobilization of the segment is achieved without overdistraction of the segment. The model enables evaluation of the distraction or mobilization of the disk required to achieve the maximal ROM (Figure 9). Where adequate mobilization of the segment is not achieved, the postoperative ROM that can be achieved is likely to be limited, even if the ideal implant is placed in the ideal location.

It is also important to evaluate the images and measurements obtained to ensure that the selected implant will not result in overdistraction of the segment, specifically the facet joints, as this may also lead to facet-mediated pain or excessive motion and instability postoperatively.

One early patient assessed preoperatively using this process was a female of small stature enrolled in the military. Her maximal template ROM was impressive at 14° with the implant located 1.0 mm anterior to the posterior margin of the vertebra (Figure 10). However, the majority of this ROM is achieved in flexion and such ROM is usually limited by facet impingement. Figure 11 indicates the reason for this impressive ROM, in that the place-
ment of the smaller implant with the lowest insert, 10 mm, resulted in the need to distract the segment by 7 mm. This resulted in overdistraction and near dislocation of the facet joints that enabled the flexion achieved in the model. As the flexion was simulated in the model, no facet impingement occurred, and since the inferior facet of L4 was elevated as forward translation of L4 occurred, discussed earlier and illustrated in Figure 4, no impingement against the superior facet of L5 was evident. In this case, the degree of distraction needed was considered excessive. The patient was advised against proceeding with a TDR and instead underwent an anterior fusion, returning to full active duty 6 months after surgery.

Although this work is still in its early stages with data collection and analysis ongoing, it shows great potential to inform TDR surgical planning and implant design. Continuing activities include preoperative templating of patients undergoing TDR surgery and correlation of the clinical outcomes with the ROM achieved and the incidence of adjacent level disease.

CONCLUSION

Treatment of degenerative disk disease with TDR has been shown to reduce the incidence of adjacent level degeneration in appropriately selected patients and where anatomical, mechanical, and surgical parameters are aligned. Obtaining reliable and reproducible results is challenging, but it is clear that the application of this new technology can be further enhanced and that the combination of this sort of analysis with engineering principles can lead to optimal restoration of anatomy, normal ROM, and function. Through this project, it became evident that, although adequate ROM and function may be achieved with placement of the implant in several locations, optimal placement is generally quite localized. The identification of the optimal position for each patient and placement of the prosthesis in that position is expected to improve function and reduce pain.

Patient-specific templating of lumbar motion segments for patients considered for TDR surgery has proven to be a valuable clinical tool to identify those patients whose anatomy is compatible with the available TDR implants, the most appropriate implant make, size, and geometry, and where to place the implant to maximize the ROM and clinical outcome that can be achieved. It is also possible that no correlation will be identified between these parameters and patients’ clinical outcomes, in which case several new questions will be raised regarding the benefits of this technology over conventional techniques, namely fusion, to address localized degenerative disorders of the lumbar spine.

REFERENCES


