The Rationale Behind TRANSITION

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Unsolicited Thoughts after 80 Cases

1. Not all Spinal Fusions are “Created Equal”

We’ve all been to spine meetings at the start of a Discussion session when a crusty member of the SRS stands up and admonishes the speakers “Either the spine had fused or it has not”. It turns out that spinal arthodesis is not an all or none phenomenon, not either black or white. Not all spinal fusions are equal biomechanically and a hypertrophic fibrous union can be more stable than a spinal segment with bony continuity from one level to the next if the cross-sectional area of the contiguous bone mass is small.

John Charnley’s original landmark work was not in total hip replacement, it was for describing “The Closed Treatment of Common Fractures” (The Closed Treatment of Common Fractures by Sir John Charnley, Churchill, Livingston, London, 1974). A hypertrophic union is biomechanically stronger and a patient can walk on it, compared to an atrophic union.
A fracture callus with no bone bridging directly from one fragment to the next but it is very rigid and stable due to the fracture callus having a large cross-sectional area.

Charnley’s illustration depicting why the fracture can be so stable in the early healing phase even before there is trabecular bridging bone across the fracture site. This situation is, in fact, more biomechanically preferable to the situation below where there happens to be modest trabecular bridging = an atrophic union. The fracture has technically healed but it is not as stable as the situation above.
In the spine this principle is true also. The first biomechanical study I performed at Johns Hopkins was when John Regan was my first spine fellow –


Both of the above animals had undergone anterior interbody fusions using iliac crest bone graft and fibular bone. They were both 6 months after surgery. Histologic examination revealed trabecular bony bridging from one vertebral body to the next on Spine A but not for Spine B. In fact the Spine pictured in B, on the right has a radiolucent line still present across the disk space, interpreted as a “fibrous pseudarthrosis”. As it turns out the structural stability of the spine on the right was much greater than the spine on the left, both the torsional stiffness (N-m/degree) and the axial compressive stiffness of Spine B were superior to Spine A. This is due to the greater cross sectional area of the entire “fracture callus” or “spinal fusion mass”. This study as well as the clinical situation show that the definition of “Spinal Fusion” and the goals of spinal surgery to achieve a spinal fusion are three dimensional and complex.

Proof that all spine fusions are not created equal can be seen in a symposium published in the Spine Journal.

There was a large difference of opinion in the definition of a successful spinal fusion from Manohar Panjabi to Scott Boden to Tom Zdeblick—if the goal of spinal fusion is not defined the same and there is no consensus among experts then maybe different situations call for different degrees of rigidity—not all spine fusions are created equal. The goal is that a gradation of movement is needed from the totally rigidly fused L4-L5 spondylolisthesis, for example up to the freely mobile upper and middle lumbar spinal motion segments. Perhaps there should be a transition segment at L3-L4 in this situation to act as a cushion between the rigidly fused 360 arthrodesis at L4-L5 and the upper spine?
In my initial series of 80 patients the most common indication for TRANSITION is L4-L5 degenerative spondylolisthesis. The patient is symptomatic with neurogenic claudication from severe spinal stenosis. At L3-L4 there is no translational deformity but there is “moderate” spinal stenosis of a degree that the pathology warrants decompression but not necessarily a rigid 360 arthrodesis. The optimum spinal reconstruction should correct the instability and translational spondylolisthesis at L4-L5 (360 degree fusion TLIF and pedicle screws and posterolateral fusion). All surgeons would agree that L2-3 and L1-L2 should remain freely mobile, but with time the adjacent segment at L3-L4 needs a less rigid treatment than at L4-L5. TRANSITION instrumentation allows the surgeon to give the patient the best chance for a successful long term outcome—Gradations of micro-movement because not all fusions are “created equal”. Spinal fusions have different degrees and different extremes of rigidity (in flexion-extension, rotation, and compression-distraction). TRANSITION allows some degree of micromovement, a degree of cushioning in all three axes—6 Degrees of Freedom Cushioning.

TRANSITION 80 Patients – first 6 month report

--All indications were on-label.
--No Device failures, no instrumentation failures
--No Iatrogenic neurologic deficits
--1 return to OR for removal for infection
--No instrumentation revisions.

**Technical Points**

1. Need meticulous rod contouring. It may not affect long term durability but I notice that if you force the rod into more lordosis than you have accounted for in the solid portion, this lordosis is translated to the one segment with the sleeve and the sleeve takes on an eccentric trapezoidal appearance. In order to avoid the trapezoidal appearance of the cylindrical rod sleeve one needs to recontour the rod in a more meticulous fashion. I do not have proof that this will negatively influence durability but it makes sense to not “pre-load” or “pre-stress” the rod sleeves.

The rod could easily be forced into the tulips if this was a solid Revere rod. However, with the TRANSITION this segment is more lordotic than the current rod contouring. Observe the orthogonal nature of the Rod sleeve at the dynamic segment.
Notice that the rod can easily be manipulated into the tulips but the rod sleeve at the dynamic segment is “trapezoidal” indicating some degree of pre-stressing or pre-loading. Other systems such as Medtronic’s Agile and Synthes’ N-Hance had rod breakage, cable kinking, and construct failure in this situation. I would recommend removing the TRANSITION rod and contouring in enough lordosis such that the rod sleeves and bumpers retain a “neutral zone” orthogonal configuration intraoperatively. Naturally the patient’s preoperative positioning on the operating table should be in the neutral zone with the hips and knees flexed 45 degrees. It makes no sense to perform spinal instrumentation attempting to balance the patient’s global spinal motion between flexion and extension if the patient is placed in an extreme pre-loaded spinal position for the surgery. The overall position of the patient should be with the legs, pelvis, and spine approximately halfway between the sitting and standing position. Avoid the full “knee-chest“ position, for example when the instrumentation is going in.
There is currently no data to show any detriment to long term durability but personally I would readjust the TRANSITION instrumentation in order to avoid a pre-loaded trapezoid like the above.
The instrumentation was redone with better rod contouring and adjusting the heights of the tulips to make a more gentle lordotic curve rather than an abrupt bend. The rod sleeve now has a more orthogonal “neutral zone” type appearance. Avoid the trapezoid. The second thing the above slide demonstrates is that the bumper does not impinge the facet joint. This is one of the most common questions asked about TRANSITION and I have not had the bumper impinge on the upper facet joint in a single case to date. If one turns the rod upside down such that the bumper is at a hyperlordotic sacrum then the bumper can touch the sacrum with a sacral screw. The excess osteophytes can be removed and the screw can be placed in a less buried position to avoid this potential problem.

2. One unanticipated Advantage of TRANSITION is that it allows unobstructed visualization of the bony fusion mass compared to titanium and stainless steel instrumentation.
The AP is above, the lateral is below and this is only 6 weeks postoperatively using autologous local bone graft augmented with NuBone.

3. Spinal reconstruction after Lumbar Disk replacement

Another situation which seems to be appropriate for TRANSITION in the early experience is to correct prior instrumentation problems such as the “Z-deformity” from
rotational instability following lumbar disk arthroplasty. We described this previously in an elegant biomechanical study performed primarily by two of our former spinal Fellows, Farhan Sidiqi and Victor Hayes:

McAfee, Paul C; Cunningham, BW; Hayes, V; Sidiqi, F; Dabbah, M; Sefter, Hu, NB; and Beatson,H: Biomechanical Analysis of Rotational Motions after Disc Arthroplasty. Implications for Patients with Adult Deformities. Spine 31; No 19; S 152 – S 160, 2006.

This is a figure from the article illustrating that because the anterior annulus, the anterior longitudinal ligament and the posterior longitudinal ligament are all removed in a conventional anterior disk replacement procedure, multiple levels can give rise to a “Z deformity” with two adjacent levels showing opposite oblique disc asymmetry. This is indicative of rotational instability. The picture below shows correction of a similar case using TRANSITION and posterolateral bone graft. The patient’s leg pain was relieved immediately post-operatively due to decompression of the lateral recesses and realignment of the lumbar spinal segments.
Notice that even in the early postoperative phase the spine has been realigned and that the TRANSITION rod sleeves are orthogonal and evenly spaced.

4. **Lumbar Scoliosis**

Below illustration is PRE-OP Paradigm Spine DSS
This is a 60 year old man with several prior procedures which left him with continued spinal stenosis, post-laminectomy syndrome, and a 17 degree degenerative lumbar scoliosis. The pre-operative CT myelogram demonstrated nerve root compression from L2 to L5, therefore a decompression and fusion were indicated.

**Below illustration is POST-OP Paradigm Spine DSS**

![Illustration of Paradigm Spine DSS](image)

As the illustration above indicates the lumbar scoliosis was corrected with a Paradigm Spine DSS spring-type construct (17 down to 2 degrees). The lateral listhesis where L3 was shifted to the left of L4 was also corrected.

Globus Medical has extensive preclinical testing with spring–type constructs and they were fully evaluated and discarded by the product development team, both on biomechanical and on clinical grounds. Metallic spring-type devices did not have the long term durability of PET- PCU biomaterials. This construct also had a high fiddle factor as each segment had to be individually instrumented compared to TRANSITION which can be either “build your own” or prefabricated. TRANSITION can be constructed for the individual patient in a modular fashion but it is important to realize that it is still inserted as one unit, as one stable construct on each side and does not have to be assembled inside the patient at each level as the construct requires.

**Post-Op Medtronic Agile Failure**

I have performed ten Agile cases on patients and was happy with the early clinical outcomes. Unfortunately the device was taken off of the market due to failure and
breakage of the cable. There were technical measures which I specifically undertook to prevent crimping or deformation of the cable during insertion. In fact a specific device known as the double-barreled anti-torque was specifically used by myself in my ten cases. Unfortunately the case shown below presented with breakage of both cables at one year post-operatively despite the deliberate measures I undertook intraoperatively to avoid pre-stressing and avoid pre-loading the cables. The patient presented one year after surgery with localized mechanical back pain and left leg radicular pain which localized to the left L4 pedicle screw. In fact, his pain was temporarily relieved with steroid and anesthetic injection into the area of the left L4 pedicle. Notice that there is a radiolucent line surrounding both L4 pedicle screws and than both cables are fractured.
The following two radiographs demonstrate that there is kinking and acute deformation of the Agile cables which occur with natural extension of the spine. At an adjacent level to a spinal fusion the upper vertebra, in this case L4 is forced posteriorly in retrodisplacment in spinal extension. In flexion the posterior margins of the L4 and L5 vertebral bodies are lined up. This flexion–extension series demonstrates that regardless of the preventative measures that the surgeon takes intraoperatively, the cables will be kinked in spinal extension.
Notice that both L3 pedicle screw heads have been forced in retrodisplacement in the extension position.

5. **TRANSITION at the end of a Long Spinal Segment—so called “Topping Off”**

Particularly if spinal instrumentation is abruptly ended at the thoracolumbar junction proximal kyphosis or “topping off” syndrome has been described. The portion of this deformity can also be associated with retrolisthesis and this is the mechanism for the cause of the development of severe post-instrumentation neurologic deficit. This absolutely requires surgical intervention and instrumentation revision. Multiple presentations and publications in the Scoliosis Research Society describe the frustrating reoccurrence of the syndrome multiple times in the same patient. This occurs as each
successive level is added, a cascading spine whereby each surgical correction has a domino effect and the topping off simply reoccurs one or two years after each procedure. The ultimate reconstructive method is not clear but theoretically TRANSITION with its graded degrees of rigidity in its fusion masses at different vertebral levels should be well suited in prevention of topping off syndrome. Obviously at only 6 months follow up I do not have a series of patients followed long enough to prove that we can prevent proximal junctional kyphosis but I have had great success in treating Topping Off syndrome using TRANSITION instrumentation.

Two Years Post-op with new Spinal Stenosis Symptoms due to Adjacent Segment Retrodisplacement at L2-L3
Post op TRANSITION has prevented the “Topping off” Deformity and Symptoms

If you have additional cases, questions, or experience to add please feel free to E-mail me at MACK8132@gmail.com. The above writing is intended for surgeons who are treating spinal patients and does not represent any official or unofficial opinions of Globus Medical Company. The writing is intended to be 100% educational for surgeons whose goal is to provide better care for their patients.

My disclosures are publically recorded on my website and NASS—

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