Revisiting Anterior Stand-Alone Fixation (ASAF) Devices for the Treatment of Single Level Lumbosacral Degenerative Disease

Blair Ashley MD
Vincent Arlet MD

Department of Orthopaedic Surgery
School of Medicine
University of Pennsylvania
Philadelphia, Pennsylvania, USA

Low back pain (LBP) affects 50-80% of the population at some point in their lifetime and is a frequent cause of decreased mobility and unemployment. Fusion of lumbar motion segments continues to be the foundation of treatment of intractable LBP secondary to degenerative disc disease (DDD), and can be achieved via anterior-only, posterior-only and anteroposterior approaches. Historically, the majority of fusions are performed via posterior surgical approaches. However, fusions performed via posterior surgical approaches, whether with or without instrumentation or with or without additional interbody fusion, have suffered from complications such as graft site morbidity, screw loosening, pseudoarthrosis, sagittal imbalance, high rates of adjacent level pathologies, and considerable complication and reoperation rates.[1,2] Additionally, the posterior approach has been shown to result in muscle atrophy which in itself becomes a new LBP generator.[4,5] As an attempt to mitigate these negative side effects, posterior percutaneous techniques gained some popularity as a less invasive, more muscle sparing alternative; however, minimally invasive techniques resulted in higher x-ray exposure and significantly increased rates of adjacent level facet joint violations.

In order to avoid the aforementioned complications, anterior stand-alone fusion (ASAF) devices have been introduced as an alternative method to avoid damage to the paravertebral muscles, to prevent screw displacement-related neurological and vascular complications and to reduce the rate of adjacent segment degeneration. ASAF devices provide a potential advantage by avoiding posterior muscle trauma, avoiding violation of the cranial facet joints and permitting improved sagittal balance reconstruction.

Despite reduced invasiveness and previously reported reduced infection rates, historical data exists that reports contradictory results regarding significant rates of nonunion associated with ASAF devices. This can be partially attributed to implants previously utilized to perform anterior interbody fusions, which were not stable enough to reliably achieve fusion, and thus resulted in high rates of pseudoarthroses. However, new implants have been designed which are anterior stabilized, e.g. with plates and locking screw technology, which significantly augments the overall construct strength and rigidity. The goal of the anterior stabilized stand-alone device is to negate the need for posterior fixation by promoting stability of the implant via the locking screws. The benefit of creating an anterior stand-alone fixation device is that the spine surgeon can achieve adequate stabilization to ensure fusion while avoiding the increased morbidity associated with the posterior approach. Schleicher et al published one of the early biomechanical studies using a human cadaver model comparing the Anterior stabilized stand-alone device implants to an established stand-alone interbody implant.[3] The study showed greater stiffness in lateral bending for the anterior stabilized stand-alone device compared to the established implant. Additionally, the study showed that for the anterior stabilized stand-alone device, the anterior cage takes most of the load during flexion, whereas the screws and the screw-plate junction assume most of the load during extension, and it's this augmentation of stability in extension moments that is especially important to the success of stand-alone interbody fusion.[3] In practice, the cage provides the stability lost by resection of the anterior longitudinal ligament in extension, which is the main biomechanical limitation of anterior lumbar interbody fusion (ALIF) procedures. The net effect of the implant design is that the compressive loads are evenly distributed across the implant, whereas the anterior stabilization plate and divergent locking screws serve to neutralize the tensile forces.[3]

Examining the effects of these new ASAF devices in practice, Strube et al performed a prospective cohort study comparing patients undergoing anteroposterior fusion (ALIF with transpedicular fixation: APLF) to patients undergoing anterior lumbar interbody fusion (ALIF) alone using the anterior stabilized stand-alone device. They found that the blood loss and duration of surgery were significantly lower in the ALIF group, and that while the Visual Analog Scale (VAS) and Oswestry Disability Index (ODI) scores improved in both groups, they were significantly better in the ALIF group. Additionally, rates of fusion were not statistically significant between groups at long term (41 month) follow up and only a 5% complication

rate was observed with the ALIF group[2]. Similarly, Siepe et al recently performed a prospective study including 71 patients with monosegmental DDD at the lumbosacral junction.[1] They showed an improvement in VAS and ODI at all stages of follow up, and 77.5% of patients reported satisfactory or highly satisfactory outcomes. Impressively, there was a 97.3% overall fusion rate shown on CT scan and only an 11.3% complication rate. Behrbalk et al and Burkus et al showed similar rates of fusion (90.6% and 94.5%, respectively) with the use of anterior plate in cage implant and recombinant human bone morphogenetic protein-2 and tapered interbody cages with rhBMP-2, respectively.[7,8] An additional benefit of anterior interbody fusion is its ability to restore lumbar lordosis, and to distribute it in an anatomic distribution. GuiGui et al have shown 80% of total lumbar lordosis is normally distributed between L4 and S1. This distribution of lordosis can improve sagittal balance, and may result in less pain, as the cephalad facets no longer need to hyperextend to compensate for reduced lordosis.[1,6,9]

In summary, anterior stand-alone fusion devices provide an excellent alternative to the currently more popular posterior surgical approach when treating low back pain, particularly in single level lumbosacral disease. Though historically there were concerns regarding adequate stability and an increased risk of pseudoarthroses, the advent of new technologies integrating anterior cages and plates provide the necessary stability to meet and exceed the fusion rates seen in the posterior or anteroposterior approaches for single level degenerative disease. Equivalent fusion rates and improved patient satisfaction scores are achieved with reduced complication rates, reoperation rates, surgical time and blood loss which are beneficial both to the patients and to the hospital system. ASAF of the lumbosacral junction achieved excellent rates of fusion, significant lordosis reconstruction and low reoperation rates, while avoiding weakening of the adjacent segments due to cranial facet joint violation and sagittal imbalance secondary to collateral muscle damage characteristic of the posterior approach. Thus, anterior stand-alone fixation devices for the treatment of the appropriately selected patient with lumbosacral degenerative disease provides an exciting alternative treatment modality to achieve successful fusion while minimizing complication and reoperation rates as well as reducing surgical morbidity and hospital costs.

References:

1. Siepe CJ, Stosch-Wiechert K, Heider F, Amnajtrakul P, Krenauer A, Hitzl W, Szeimies U, Stabler A, Mayer HM. Anterior stand-alone fusion vrevisited: a prospective clinical, x-ray and CT investigation. *Eur Spine J* 2015. 24:838-851.

2. Strube P, Hoff E, Hartwig T, Perka CF, Gross C, Putzier M. Stand-alone anterior versus anteroposterior lumbar interbody single-level fusion after a mean follow up of 41 months. *J Spinal Disord Tech* 2015. 25: 362-369.

3. Schleicher P, Gerlach R, Schur B, Cain CMJ, Achatz W, Pflugmacher R, Haas NP, Kandziora F. Biomechanical comparison of two different concepts for stand alone anterior lumbar interbody fusion. *Eur Spine J* 2008; 17:1757-1765.

4. Fan S, Hu Z, Zhao F, *et al.* Multifidus muscle changes and clinical effects of one-level posterior lumbar interbody fusion: minimally invasive procedure versus conventional open approach. *Eur Spine J.* 2010; 19:316-324.

5. Mayer TG, Vanharanta H, Gatchel RJ, *et al.* Comparison of CT scan muscle measurements and isokinetic trunk strength in post-operative patients. *Spine* (Phila PA 1976). 1989; 14:33-36.

6. Konig MA, Ebrahimi FV, Nitulescu A, Behrbalk E, Boszczyk BM. Early results of stand-alone anterior lumbar interbody fusion in iatrogenic spondylolisthesis patients. *Eur Spine J* 2015. 22:2876-2883.

7. Burkus JK, Gornet MF, Dickman CA, Zdeblick TA. Anterior lumbar interbody fusion using rhBMP-2 with tapered interbody cages. *J Spinal Disord Tech* 2002. 15:337-349.

8. Behrbalk E, Uri O, Parks RM, Musson R, Soh RC, Boszczyk BM. Fusion and subsidence rate of stand-alone anterior lumbar interbody fusion using PEEK cage with recombinant human bone morphogenetic protein-2. *Eur Spine J* 2013. 22:2869-2875.

9. Vialle R, Levassor n, Rillardon L, *et al.* Radiographic analysis of the sagittal alignment and balance of the spine in asymptomatic subjects. *JBJS* 2005.87:260-267.