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Complications associated with the Dynesys dynamic stabilization system: a comprehensive review of the literature

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The Dynesys dynamic stabilization system is an alternative to rigid instrumentation and fusion for the treatment of lumbar degenerative disease. Although many outcomes studies have shown good results, currently lacking is a comprehensive report on complications associated with this system, especially in terms of how it compares with reported complication rates of fusion. For the present study, the authors reviewed the literature to find all studies involving the Dynesys dynamic stabilization system that reported complications or adverse events. Twenty-one studies were included for a total of 1166 patients with a mean age of 55.5 years (range 39–71 years) and a mean follow-up period of 33.7 months (range 12.0–81.6 months). Analysis of these studies demonstrated a surgical-site infection rate of 4.3%, pedicle screw loosening rate of 11.7%, pedicle screw fracture rate of 1.6%, and adjacent-segment disease (ASD) rate of 7.0%. Of studies reporting revision surgeries, 11.3% of patients underwent a reoperation. Of patients who developed ASD, 40.6% underwent a reoperation for treatment. The Dynesys dynamic stabilization system appears to have a fairly similar complication-rate profile compared with published literature on lumbar fusion, and is associated with a slightly lower incidence of ASD.

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KEY WORDS complications; infection; screw loosening; screw fracture; adjacent-segment disease; reoperation; Dynesys

Dynamic stabilization of the spine is a potential alternative to rigid lumbar fusion for lumbar degenerative spinal disease.[34,40,41,51,59] Recently, a nonfusion stabilization system with motion preservation (Dynesys system, Zimmer Spine) has been explored as an alternative to fusion in an effort to reduce adjacent-segment disease (ASD) and maintain greater physiological movement and function.[31,32,47,61] Dynesys is a pedicle screw–based dynamic stabilization system that has been used since 1994 and consists of pedicle screws, flexible spacers, and cords.[26,41] This assembly attempts to neutralize the abnormal forces after surgical intervention at the lumbar spine and maintain a more favorable biomechanical environment for segmental motion.[7,62] Many follow-up studies have shown good results for a variety of degenerative spinal conditions.[11,27,32,47,55,60,62] However, currently lacking is a comprehensive report on complications associated with the implantation of this system.

In this article, we provide a comprehensive review of the literature to identify all reported complications after use of the Dynesys dynamic stabilization system. Knowledge of these events will assist surgeons in maintaining a high index of suspicion with these potential postoperative complications.

Methods

We conducted a comprehensive review of the English-language medical literature reported via PubMed (from 1967 to August 16, 2015) to find all studies involving use of the Dynesys dynamic stabilization system. Literature was found using the search equation "dynamic neutralization system" OR "dynamic stabilization system" OR "dynesys" OR "dynesis." All resulting articles were reviewed in search of clinical studies that used the Dynesys system and reported complications or adverse events. The refer-

ABBREVIATIONS ASD = adjacent-segment disease; ASP = adjacent-segment pathology.

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ence lists of these articles were subsequently reviewed to identify additional English-language studies that may not have been identified by the initial electronic search. Case reports were not included. This search protocol was conducted by 2 reviewers (M.H.P. and V.A.M.).

Articles that met search criteria were further examined for the following parameters: study design, number of patients, age, sex, diagnoses treated, follow-up time, number of levels treated, and all reported complications or adverse events related to implantation of the Dynesys dynamic stabilization system.

Results

Twenty-three studies were identified, which described use of the Dynesys dynamic stabilization system with a description of subsequent complications. Two studies were excluded because the authors used the same cohort of patients in subsequent studies that were also included in our search results.[15,57] A total of 21 studies were used for analysis (Table 1). Included in these studies was 1 Executive Summary for the Dynesys system written by the FDA.[16]

Published studies found ranged in publication year from 2002 to 2014. Of these, 9 were prospective studies and 12 were retrospective reviews. There were a total of 1166 patients (568 men and 598 women) with a mean age of 55.5 years (range 39–71 years). The mean follow-up time was 33.7 months (range 12.0–81.6 months). Diagnoses treated included all forms of lumbar degenerative disease, which included but were not limited to degenerative disc disease, discopathy, spinal stenosis, spondylolisthesis, degenerative scoliosis, disc herniation, and ASD. Only 1 study did not report data on number of levels treated with the Dynesys system.[22] Among all other studies, there was 1-segment stabilization in 509 patients (49.2%), 2-segment stabilization in 382 patients (36.9%), 3-segment stabilization in 125 patients (12.1%), 4-segment stabilization in 12 patients (1.2%), 5-segment stabilization in 2 patients (0.2%), and 6-segment stabilization in 4 patients (0.4%) (Table 2).

Wound Infections

Thirteen studies specifically mentioned wound-infection rates (Table 3). Among these, 40 of 923 patients (4.3%) developed wound infections after dynamic stabilization surgery over a mean follow-up period of 34.8 months (range 16.0–81.6 months). These infections included superficial wound infections managed with antibiotic care as well as deep infections requiring reoperation with irrigation and debridement.

Screw Loosening and Fracture

Fourteen studies described the occurrence of either pedicle screw loosening or pedicle screw fracture after use of the Dynesys system (Table 4). Ninety-six of 822 patients (11.7%) had pedicle screw loosening and 13 of 822 patients (1.6%) had pedicle screw fracture over a mean follow-up period of 30.0 months (range 16.4–54.0 months).

The diagnosis of pedicle screw loosening was not uniform and was not always described in these articles. Several studies clarified their definition of screw loosening by looking for radiolucent zones surrounding the screw on radiographs, which has been previously described as a

TABLE 1. Studies that used the Dynesys system and subsequently described associated complications

Authors & Year	Study Type	No. of Pts (M/F)	Mean Age (yrs)	Mean Follow-Up (mos)
Stoll et al., 2002	Prospective	83 (34:49)	58.2	38.1
Grob et al., 2005	Retrospective	31 (11:20)	50.0	24.0
Putzier et al., 2005	Prospective	35 (22:13)	39.0	34.0
Sapkas et al., 2007	Retrospective	68 (42:26)	42.8	36.2
Bothmann et al., 2008	Prospective	54 (28:26)	56.0	16.0
Lee et al., 2008	Retrospective	20 (13:7)	61.0	27.3
Schaeren et al., 2008	Prospective	26 (8:18)	71.0	52.0
Würgler-Hauri et al., 2008	Prospective	37 (15:22)	58.0	12.0
FDA, 2009	Prospective	253 (121:132)	56.9	24.0
Di Silvestre et al., 2010	Retrospective	29 (7:22)	68.5	54.0
Ko et al., 2010	Retrospective	71 (32:39)	59.2	16.6
Hu et al., 2011	Retrospective	32 (19:13)	58.0	16.4
Lutz et al., 2012	Retrospective	49 (26:23)	48.0	43.0
Sapkas et al., 2012	Retrospective	114 (66:48)	49.0	81.6
Yu et al., 2012	Retrospective	35 (15:20)	60.8	36.0
Haddad et al., 2013	Retrospective	32 (19:13)	40.6	48.0
Fay et al., 2013	Prospective	72 (37:35)	61.4	46.7
Lee et al., 2014	Retrospective	28 (7:21)	65.3	30.7
Liu et al., 2014	Prospective	37 (21:16)	40.5	20.0
Payer et al., 2014	Prospective	30 (8:22)	66.0	24.0
Yang et al., 2014	Retrospective	30 (17:13)	56.0	26.6

Pts = patients.

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TABLE 2. Number of patients categorized by number of segments stabilized with Dynesys across all studies

No. of Segments Stabilized	No. of Pts (%)
1	509 (49.2)
2	382 (36.9)
3	125 (12.1)
4	12 (1.2)
5	2 (0.2)
6	4 (0.4)

"halo sign" or "double-halo sign" signifying screw loosening.[10,34,52,62] Some studies diagnosed screw loosening by a radiologist's interpretation, whereas other studies did not explain their methods.

Adjacent-Segment Disease

Twelve studies characterized the development of ASD after use of the Dynesys dynamic stabilization system (Table 5). Of a total of 456 patients, 32 (7.0%) subsequently developed ASD over a mean follow-up period of 33.5 months (range 12–54 months).

Reoperation Rate

Seventeen articles reported reoperations for various reasons (Table 6). One hundred seventeen of 1032 patients (11.3%) required a reoperation over a mean follow-up period of 35.9 months (range 12.0–81.6 months). Indications for repeat surgery included infection, hardware revision, hardware removal, ASD, further decompression, vertebral body fracture, CSF fistula, and epidural hematoma.

Nine studies reported reoperation rates associated with the development of ASD after use of the Dynesys system (Table 7). In these studies, a total of 354 patients were followed over a mean period of 35.7 months. Of the 32 patients who developed ASD, 13 (40.6%) required reoperations for treatment. These 13 revision surgeries constituted part of a total of 57 reported reoperations for any indication in this group.

TABLE 3. Studies reporting surgical-site infection rates after use of the Dynesys system

Authors & Year	Total No. of Pts	No. of Pts w/ SSI
Stoll et al., 2002	83	1
Grob et al., 2005	31	1
Putzier et al., 2005	35	1
Sapkas et al., 2007	68	1
Bothmann et al., 2008	54	1
FDA, 2009	253	19
Ko et al., 2010	71	0
Lutz et al., 2012	49	11
Sapkas et al., 2012	114	2
Yu et al., 2012	35	1
Fay et al., 2013	72	0
Lee et al., 2014	28	2
Yang et al., 2014	30	0

SSI = surgical-site infection.

TABLE 4. Studies reporting pedicle screw loosening or fracture after use of the Dynesys system

Authors & Year	Total No. of Pts	No. of Pts w/ Screw Loosening	No. of Pts w/ Screw Fracture
Stoll et al., 2002	83	7	0
Putzier et al., 2005	35	0	0
Sapkas et al., 2007	68	3	0
Bothmann et al., 2008	54	7	1
Lee et al., 2008	20	0	0
Schaeren et al., 2008	26	3	1
Würgler-Hauri et al., 2008	37	0	3
FDA, 2009	253	18	6
Di Silvestre et al., 2010	29	4	0
Ko et al., 2010	71	14	0
Hu et al., 2011	32	0	0
Lutz et al., 2012	49	36	2
Lee et al., 2014	28	4	0
Liu et al., 2014	37	0	0

Discussion

Dynamic stabilization as an alternative to fusion offers several advantages. These include stabilization of spinal segments without instrumentation and fusion, unloading at the motion segment of the disc and facet joints, and greater preservation of physiological function.[31,32,47,61] With regard to this article, however, it is important to note that the Dynesys system has only received US FDA approval for use as an adjunct to spinal fusion. Although commonly used as a nonfusion implant, placement of this system for the purposes of dynamic stabilization is an off-label use in the US.

Recent publications have shown that use of the Dynesys system as a nonfusion pedicle screw stabilization

TABLE 5. Studies reporting the development of ASD after use of the Dynesys system

Authors & Year	Total No. of Pts	No. of Pts w/ ASD
Stoll et al., 2002	83	7
Putzier et al., 2005	35	0
Bothmann et al., 2008	54	3
Lee et al., 2008	20	0
Schaeren et al., 2008	26	9
Di Silvestre et al., 2010	29	1
Lutz et al., 2012	49	1
Yu et al., 2012	35	6
Lee et al., 2014	28	2
Liu et al., 2014	37	0
Payer et al., 2014	30	3
Yang et al., 2014	30	0

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TABLE 6. Studies reporting reoperations after use of the Dynesys system

Authors & Year	Total No. of Pts	No. of Pts Undergoing Reop	Described Reasons for Reop (no. of instances)
Stoll et al., 2002	83	17	Not mutually exclusive: "dural lesion" (1); paresis requiring revision & extension (1); drainage of seroma (1); excision of neuroma scar (1); revision of screw malposition (1); screw loosening causing symptoms (1); complete implant removal (8); Dynesys extension (2); decompression of adjacent segment (2); laminectomy of index segment (1); ASD (7)
Grob et al., 2005	31	8	Removal of device (3); removal & fusion (4); infection (1)
Sapkas et al., 2007	68	2	Infection w/ removal & fusion (1); persistent leg pain w/ removal & fusion (1)
Bothmann et al., 2008	54	11	Not mutually exclusive: bilat partial pedicle fracture & hardware loosening (1); screw fracture (1); screw loosening (7); infection (1); Dynesys extension (1); decompression of adjacent segment (1); adjacent-segment instability (3)
Lee et al., 2008	20	3	Implant removal for allergic reaction (1); further decompression (1); further decompression & fusion (1)
Schaeren et al., 2008	26	4	Further decompression (1); osteoporotic fracture at index level (2); ASD (1)
Würgler-Hauri et al., 2008	37	7	Removal w/ fusion (4); replacement of misplaced screws (2); repair of CSF fistula (1)
FDA, 2009	253	33	Reasons for revision surgeries: additional decompression, removal of hardware w/ fusion, infection, ASD, epidural hematoma
Di Silvestre et al., 2010	29	2	Replacement of misplaced screw (1); ASD (1)
Ko et al., 2010	71	0	
Lutz et al., 2012	49	17	Infection (10); screw fracture & infection (1); screw fracture (1); screw revision (1); screw loosening w/ migration (1); instability (1); nerve root compression (1); ASD (1)
Sapkas et al., 2012	114	6	Screw loosening (3); infection w/ fusion (2); implant removal (1)
Yu et al., 2012	35	0	
Haddad et al., 2013	32	4	Reasons for revision surgeries: persistent symptoms, malpositioning of screws, symptomatic screw loosening
Fay et al., 2013	72	0	
Lee et al., 2014	28	2	Infection (2)
Payer et al., 2014	30	1	ASD (1)

construct has favorable outcomes with shorter hospital stays compared with spinal fusion.[4,8,18,24,46,53,58,62,67,70] This stabilization system also reportedly provides enough stability to prevent progression of low-grade spondylolistheses.[27,55,57,62] The maintenance of biomechanical mobility in the lumbar spine plays a significant role in patient quality of life, and dynamic stabilization helps to maintain this mobility.[18,47,53,58,62] Without the need for fusion, there are no risks of bone graft donor-site complications such as pain, hematoma, or fracture. No allograft materials are required, also preventing the already low risk of disease transmission associated with these products.[45,55,67,71] However, the Dynesys system is not without its own set of complications and adverse events, which we aimed to characterize with this review.

Postoperative surgical-site infection is a significant complication that can progress to further morbidity. Patients with infections have worse pain-related outcomes, increased deformity, higher medical costs, and longer hospital stays.[3,6,19,39] We found an overall reported infection rate of 4.3% over a mean follow-up period of 34.8 months in this review of studies in which the Dynesys dynamic stabilization system was used. This is similar to the reported literature on infection rates for lumbar fusion, which range from 1% to 5%.[6,14,42,43,66] Chaichana et al. recently reviewed their experience with 817 consecutive patients who underwent posterior instrumented lumbar fusion specifically for degenerative spine disease.[6] They found that 37 patients (4.5%) developed a postoperative infection that was diagnosed at a median of 0.6 months after surgery. Twenty-one patients (57%) required reoperation for incision, drainage, and/or debridement. They found that age greater than 70 years, diabetes, obesity, previous spinal surgery, and a hospital stay of more than 7 days were independently associated with an increased risk of infection.

In this comprehensive review, 13 studies specifically mentioned the occurrence or absence of postoperative surgical-site infection. We did not count studies that were vague or did not address infection as a complication. However, several articles did comment on a general lack of complications in their patient groups, although they did not specifically state a lack of wound infections.[11,24,33] It

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TABLE 7. Studies reporting reoperation rates for ASD after use of the Dynesys system

Authors & Year	Total No. of Pts	No. of Pts w/ ASD	No. of Pts Undergoing Reop for ASD
Stoll et al., 2002	83	7	7
Bothmann et al., 2008	54	3	3
Lee et al., 2008	20	0	0
Schaeren et al., 2008	26	9	1
Di Silvestre et al., 2010	29	1	1
Lutz et al., 2012	49	1	1
Yu et al., 2012	35	6	0
Lee et al., 2014	28	2	0
Payer et al., 2014	30	3	1

is possible that our finding of a 4.3% infection rate may overestimate the true risk of infection by excluding studies that had no infection rates.

Because there is no rigid fusion, the long-term repetitive demands on construct durability and mechanical strength are higher for the Dynesys system. This manifests itself through pedicle screw loosening and fracture, suggesting an abnormal range of motion in the stabilized lumbar spine segments that is higher than expected.[27] Dakhil-Jerew et al. described the findings of a "halo zone" and "double-halo zones" to diagnose loose pedicle screws in dynamic stabilization systems based on plain radiographs.[10] Although several studies reported identification of screw loosening via these techniques, articles were not always uniform in describing how they arrived at the finding of a loose screw. Also, 8 studies were published before the description of the halo zone to assist in the diagnosis of this complication.[5,21,32,47,54,55,62,68]

We found that 11.7% of patients developed pedicle screw loosening and 1.6% of patients were found to have a pedicle screw fracture over a mean follow-up period of 30.0 months. Our screw fracture rate of 1.6% is on the lower end of reported screw breakages for lumbar fusion, which are reported from 1.3% to 21% but are mostly within the 4%–6% range.[12,13,38,63,69,72] These results suggest that the Dynesys system offers more biomechanical flexibility than rigid instrumented fusion constructs, which minimizes the incidence of broken screws.[27,56] This flexibility, however, may be the cause of screw loosening, which was found in a significant number of patients.

Although the radiographic finding of screw loosening can be problematic, some studies have shown that overall outcomes are similar regardless of screw issues. Ko et al. found similar results on the visual analog scale for low-back pain and the Oswestry Disability Index for functional disability, regardless of screw loosening, in their group of 71 patients.[27] They concluded that the loosening of screws had no adverse effect on clinical improvement. Similarly, Schaeren et al. noted that their patients did not experience any symptoms or back pain with screw fractures or loosening.[55] In contrast, Bothmann et al. believed that persistent back and leg symptoms in their 7 patients with screw loosening could be attributed to the hardware, and all patients underwent revision surgery.[5] Other studies have also described symptomatic screw loosening that required reoperation for revision or removal of the hardware.[22,34,53,62]

Lutz et al. reported by far the highest rate of screw loosening in 36 of their 49 patients (73.5%) compared with all other reporting studies, for which the average was 60 of 773 patients (7.8%).[34] Lutz and colleagues diagnosed their loose screws using single- or double-halo zones on follow-up radiographs of patients operated on between May 2002 and September 2008 with a mean follow-up of 43 months. They hypothesized that the high rate of screw loosening was possibly due to poor integration at the bone-screw interface due to biomechanical screw design. They stated that since their study was done, hydroxyapatite-coated screws have been developed to achieve better osseointegration, which may reduce the risk of screw loosening in future patients.

One of the goals of the Dynesys system is to avoid ASD by using dynamic stabilization to reduce biomechanical stress on segments adjacent to the index stabilized levels.[17,55] ASD is a significant complication of lumbar spine surgery that theoretically occurs due to an overloading of these adjacent segments.[1,50] Unfortunately, this term is vague and it is often unclear in the general literature if the reported ASD pathology was diagnosed purely by radiographic criteria or if there was a correlated clinical effect. Lawrence et al. proposed the use of an umbrella term, adjacent-segment pathology (ASP), under which radiographic ASP and clinical ASP could then categorize radiographic findings of degenerative changes versus clinical manifestations that correlate with radiographs, respectively.[30] In this manner, patients with ASD who present with pain, radiculopathy, or myelopathy could be studied specifically to determine ideal treatment algorithms based on outcomes, without the dilution of clinically silent ASD. Many studies in this review, however, did not expand upon their definition of ASD; therefore, the actual number of patients who presented with clinical symptoms is unclear.

In this review of Dynesys dynamic stabilization, we found that ASD developed in 7% of patients over a mean follow-up period of 33.5 months. This seems to be on the lower end of the range when compared with the reported incidences of ASD in lumbar fusion, but these incidences are also highly variable. A systematic review by Park et al. on ASD of the lumbar spine after lumbar fusion found the incidence of radiographically diagnosed ASD to be from 8% to 100%, whereas in studies focusing on clinically symptomatic ASD the incidence ranged from 5.2% to 18.5%.[44] Radcliff et al. reviewed the literature and found ASD rates after lumbar fusion in noncontrolled cohort studies to be between 1.9% and 30.3% at 5 years, with the largest study reporting 13% at 5 years and 22% at 10 years, with a mean annual incidence of 2.5%.[49] Another recent review, which performed survival analyses, determined that clinically relevant ASD occurred at a mean annual incidence of 0.6%–3.9% after lumbar fusion.[30]

It is possible that the Dynesys system allows for enough physiological motion to spare abnormal biomechanical stress at adjacent segments after stabilization. Nevertheless, several studies in our review reported fairly high rates

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of ASD. In their retrospective review, Yu et al. found that 6 of their 35 patients (17.1%) developed ASD.[71] Schaeren et al. reported an even higher incidence of 47% when including only those patients who completed the full 4-year follow-up in their prospective series.[55] Despite the intent of a nonfusion dynamic stabilization system, the Dynesys construct may have high enough intrinsic stability that it acts similarly enough to fusion to overload the adjacent segments.[2,55,56]

It remains unclear whether adjacent-segment degeneration is due to the increased biomechanical stress of instrumented surgery or if it is simply a manifestation of the natural history of the degenerated lumbar spine. Nevertheless, the development of ASD may not be clinically relevant over the long term. A recent study by Mannion et al. reviewed long-term follow-up from 4 randomized controlled trials to examine the effect of ASD on patient self-rated outcomes.[36] Over a mean follow-up period of 13 years, they found no correlation of adjacent-level disc-space height with Oswestry Disability Index or pain scores. This finding would dampen the presumed benefits of dynamic stabilization in its expected reduction of ASD if the adjacent degeneration has no significant clinical effect.

Of a total of 1032 patients in 17 studies that reported revision surgeries, we found that 117 patients (11.3%) underwent a reoperation. Of patients who developed ASD, 40.6% were reported to have had a reoperation for this complication. The majority of other reoperations were for infection, hardware revision, or hardware removal, often with subsequent instrumentation and fusion. This is fairly consistent with reoperation rates in lumbar fusion reported in the literature. Radcliff et al. performed a subgroup analysis of the Spine Patient Outcomes Research Trial (SPORT) and found a 13% reoperation rate within 4 years for patients who had undergone surgery for lumbar spinal stenosis.[48] For patients with lumbar spondylolisthesis, Lad et al. reviewed 16,556 patients through a database search and found overall reoperation rates ranging from 10.6% to 18.4%, depending on whether patients underwent decompression alone versus instrumented and uninstrumented arthrodesis.[29] Many other studies on lumbar fusion have reported similar ranges of reoperation rates.[9,20,23,25,28,35,37,64,65] This suggests that overall reoperation rates after lumbar spine surgery may be a function of both the presenting diagnosis combined with open surgical intervention at the lumbar spine.

This study has several limitations. The populations of these 21 studies were extremely diverse in terms of age, sex, diagnosis, and number of levels treated. The indications for surgery spanned the breadth of lumbar degenerative disease, for which the overall outcomes and complication rates may differ among specific diagnoses such as spinal stenosis, spondylolisthesis, degenerative scoliosis, or disc herniation. Many of the surgical case series we found were retrospective reviews, in which there inherently may be some bias. The information available to us from the articles reviewed was not always complete. Furthermore, the way that studies defined infection, screw loosening, or ASD was not always provided. As mentioned previously, if studies stated a general lack of complications but did not specifically state which complications they had reviewed, they were excluded from our analysis. Despite these limitations, we think the information gleaned through this comprehensive review is able to put into perspective complication rates associated with implantation of the Dynesys dynamic stabilization system. Dynesys, and other similar stabilization systems, need further studies to determine their true utility and associated risks and benefits.

Conclusions

The Dynesys system was developed as an alternative to rigid instrumentation and fusion constructs. A review of complications associated with this system found similar infection rates and reoperation rates when compared with published literature on lumbar fusion. There was a higher incidence of pedicle screw loosening although there was a lower incidence of screw fractures, the former probably due to the long-term repetitive demands on nonrigid hardware. The overall incidence of ASD appeared to be lower than that of many published rates after lumbar fusion, which may support an offloading of biomechanical stress at the adjacent segment.

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Conception and design: Pham. Acquisition of data: Pham, Mehta. Analysis and interpretation of data: Pham, Mehta. Drafting the article: Pham, Mehta, Patel, Jakoi. Critically revising the article: all authors. Reviewed submitted version of manuscript: all authors. Study supervision: Acosta.

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