

Clinical Studies

Incidence of contraindications to total disc arthroplasty: a retrospective review of 100 consecutive fusion patients with a specific analysis of facet arthrosis

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Abstract

BACKGROUND CONTEXT: The role of total disc arthroplasty (TDA) in the treatment of spinal pathology is unclear. TDA has been touted as an alternative to fusion. However, not all back pain is purely discogenic in origin. Contraindications to TDA exist. At Spine Week in Porto, Portugal, Cammisa's group from the Hospital for Special Surgery in New York presented a series of 56 fusions where 100% of patients had one or more of 10 contraindications to TDA. En face, this appears to be an extremely large number.

PURPOSE: The purpose of the study was to repeat the Hospital for Special Surgery study in another cohort of fusion patients.

STUDY DESIGN/SETTING: This study was an independent, retrospective record review of 100 consecutive lumbar spinal fusions performed at a tertiary care private medical center.

PATIENT SAMPLE: All adult patients having primary 1–3 level lumbar spinal fusions from January 2003 to May 2004 were assessed.

OUTCOME MEASURES: Physiologic measures included imaging, range of motion, and response to facet blocks.

METHODS: A retrospective chart review was performed of 100 consecutive patients having primary 1–3 level lumbar fusion by all five active staff spinal surgeons (3 orthopedic and 2 neurosurgeons). The review was performed independently by the doctorate level physiotherapist who serves as the medical center's research coordinator, reporting to the chairman of the Hospital institutional review board. The same 10 contraindications from Cammisa's study were noted. Additional facet arthrosis data were collected, including mention on imaging reports or operating room notes. Clinical notes were reviewed for documentation of range of lumbar motion (ROM) and whether there was restricted or painful extension ROM. Note was made if patients had facet blocks as another clinical indicator of facet arthrosis.

RESULTS: All 100 patients had at least one contraindication to TDA. The average was 3.69 (range 1–7). Only one patient had facet arthrosis as their only contraindication. Facet arthrosis was documented on imaging reports or operating room notes in 97/100. Reduced extension was present in 71/75 charts that documented ROM. Facet blocks were performed in 12/100 and gave greater than 50% relief in nine.

FDA device/drug status: approved for this indication (spinal instrumentation).

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CONCLUSIONS: Both our study and Cammisa's indicate that all lumbar fusion patients in our two institutions have at least one contraindication to TDA. The average fusion patient does not appear to have isolated discogenic pain. A large proportion of the patients appeared to have facet arthritis. The point where facet arthrosis definitely constitutes a contradiction to TDA will require analysis during long-term arthroplasty follow-up studies. Suitable patients for TDA may not represent a significant cohort presently undergoing lumbar fusion. © 2007 Elsevier Inc. All rights reserved.

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Introduction

The role of total disc arthroplasty (TDA) in the treatment of spinal pathology is unclear [1–4]. TDA has been touted as an alternative to fusion which would allow resolution of discogenic pain while still maintaining spine motion [1–7] and reducing the incidence of adjacent segment degeneration [3,8,9]. However, it is recognized that not all mechanical back pain is discogenic in origin [9] and that there are a number of decisive and relative contraindications to TDA (Tables 1 and 2) [3,8–20]. At Spine Week in Porto, Portugal, June 2004, Huang and Cammisa's group from the Hospital for Special Surgery in New York presented their study evaluating the presence of 10 relatively decisive contraindications to TDA [10] (Table 1) evaluated in a single-surgeon consecutive series of 100 patients undergoing spinal surgery at their institution. The results have subsequently been published [10]. They found that 56/56 (100%) of the patients having a lumbar fusion had one or more of 10 recognized definite contraindications to TDA. Only 5 of the 44 patients having decompressive/nonfusion operations were without TDA contraindications on review of their medical records. En face, this seems to be an extremely high number of patients with contraindications to TDA.

These results highlight the profound difficulty of accurately defining the limits in the lumbar degenerative process that would be optimal for the use of the TDA. Kirkaldy-Willis et al. [21,22] divided the stages of degeneration of a spinal motion segment into three phases (normal, unstable, stable). Macnab [23] defined X-ray signs of the transition between the normal and unstable phases (the Macnab "Traction Spur"). Farfan and Kirkaldy-Willis [24] suggested that in the degenerative process, the spinal motion segment be viewed as primarily a "three joint complex" (disc and two facet joints). These concepts worked well even in the era before more modern and sophisticated imaging studies and still form the basis for subsequent classifications that have been proposed to take into account pathologic changes seen by more modern techniques of histologic analysis and imaging modalities such as magnetic resonance imaging. Thompson et al. [25] described a five-stage classification based on a pathological analysis of disc degeneration. Thalgott et al. [26] proposed a -classification which also began to look at the posterior elements.

The 10 contraindications to TDA used by Huang and Cammisa in their review appear to be the most consistent and decisive through various publications (facet arthrosis, central spinal stenosis, lateral recess spinal stenosis, spondylolysis, spondylolisthesis, herniated disc with radiculopathy, scoliosis, osteoporosis, pseudoarthrosis, deficient posterior elements) (Table 1). Although these 10 represent the most definite contraindication to TDA, more than 50 other contraindications have also been cited (Table 2).

In our view, facet arthrosis appeared to be the contraindication with a relatively imprecise diagnosis and wide clinical spectrum that was most likely to represent a patient selection dilemma for the spine surgeon.

The Hospital for Special Surgery study [10] brought attention to the issue that TDA may not represent a "better" or even an "alternative" surgical procedure to the majority of patients presently undergoing spinal fusion. Their paper broke new ground on this issue. However, as their study was a single-surgeon (F. Cammisa) series, performed in an orthopedic department at an academic medical center, their paper generates another tier of questions to be answered:

- 1) Do the results reflect the referral pattern of one particular orthopedic spine surgeon, or do they apply over multiple surgeon practices?
- 2) Are the findings consistent across different subspecialties (orthopedic surgery, neurosurgery)?
- 3) Are the findings consistent across different practice settings (academic vs. private medical center)?

Table 1
Ten primary contraindications to total disc arthroplasty used in record review by Huang and Cammisa [10] and the present study

1.	Facet arthrosis
2.	Central spinal stenosis
3.	Lateral recess spinal stenosis
4.	Spondylolysis
5.	Spondylolisthesis
6.	HNP with radiculopathy
7.	Scoliosis
8.	Osteoporosis
9.	Pseudoarthrosis
10.	Deficient posterior elements

Table 2
Fifty additional contraindications from the medical literature

■ Obesity
■ Weight >1 σ ideal body wt.
■ Old age
■ Pregnancy
■ Ankylosing spondylitis
■ Spondylodiscitis
■ Rheumatoid arthritis
■ DISH
■ Facet ankylosis
■ AIDS
■ Autoimmune disease
■ Discitis
■ Osteomyelitis
■ Active infection nonspine site
■ Previous vascular surgery
■ Previous abdominal surgery
■ Previous radiation treatment
■ Vascular calcification
■ Facet Ankylosis
■ Metal allergy
■ Bone growth stimulator
■ Paget's disease
■ Tumor
■ Fracture
■ Osteopenia
■ Concave end plates
■ Retrolisthesis
■ Disc ht. <4 mm
■ Bone disease
■ Positive SLR
■ Root compression
■ Dominant leg pain
■ Arachnoiditis
■ Transitional vertebrae
■ Unable comprehend instructions
■ Inability comply follow-up
■ Inability comply X-ray
■ Enrolled other IDE study
■ Workers compensation
■ Previous fusion
■ Aberrant vascular anatomy
■ Osteopathy
■ Pseudoarthrosis
■ Physiological dysfunction
■ Kyphosis
■ Laminectomy
■ Facetectomy
■ Fibromyalgia
■ Psychiatric disorder
■ Chronic disease major systems
■ Cardiac
■ Diabetes
■ Hepatitis

- 4) Was the incidence of the 10 contraindications specified weighted more towards the “hard” contraindications (such as herniated disc or spinal stenosis with radiculopathy) or more frequently a relatively “soft” contraindication (such as facet arthrosis)?
- 5) If facet arthrosis is viewed as a relative rather than absolute contraindication to TDA, what is the clinical spectrum of this pathology in patients having surgical fusion?
- 6) Can patients with facet arthrosis be subdivided into clinically relevant subgroups in a manner that would assist with surgical treatment decision?

This study was undertaken to compare the contraindications found in a cohort of patients undergoing fusion at our private medical center with the group at the Hospital for Special Surgery. Patients from both the Orthopedic and Neurosurgery Departments, from several different practice groups were reviewed. A further in-depth chart review was performed to analyze the diagnosis of facet arthrosis and determine the incidence of clinically significant facet disease which likely represented a definite contraindication to TDA.

Methods

This was a retrospective review of the medical records of 100 consecutive patients undergoing a primary 1–3 level lumbar spinal fusion at Presbyterian St. Luke's Medical Center, Denver between January 2003 and May 2004. Patients from all five spinal surgeons on staff were included (two neurosurgeons and three orthopedic spine surgeons from three separate practices). The patients' medical records were reviewed independently by Presbyterian St. Luke's Medical Center's director of spinal research, a doctorate level physiotherapist. Demographic data, surgical data, and the presence of one or more contraindications to TDA were collected. The same 10 contraindications used in the Hospital for Special Surgery study were similarly employed in this review.

A further breakdown of patients with facet arthrosis was performed in an effort to identify patients with clinically significant facet disease that would constitute a potential contraindication for TDA. Recognition of the severity of facet arthritis and the impact of facet disease on the patient's overall pain syndrome has profound implications for the decision on whether the patient is a suitable candidate for TDA. In combining the facet morphology and the patient's clinical symptomatology, we divided subjects into four groups outlined in Table 3 (Group A—no facet arthrosis; Group B—facet arthrosis, not likely clinically significant; Group C—facet arthrosis possibly clinically significant; Group D—facet arthrosis likely clinically significant). Records were examined for indications of facet arthrosis in the clinical notes (restricted range of motion in extension, pain on extension), imaging reports (facet arthrosis, hypertrophy, overgrowth), injection reports (facet blocks), and operating room reports (facet arthrosis, hypertrophy, overgrowth, synovial cyst, foraminal stenosis, lateral recess stenosis, surgical foraminotomy). Patients were deemed to be in Group A (no facet arthrosis) if there was no indication of facet pathology in any of the records reviewed (clinic notes, imaging, surgical reports). There was no concern of a clinically significant facet contraindication to TDA in this group. Group B (facet arthrosis, not likely clinically significant) included those patients with facet pathology by imaging or operating room reports without indication of clinical involvement (limited or painful

Table 3
Subgroups of facet degeneration

Group	Facet disease	Imaging/OR notes	Clinical ROM	Facet blocks	# Patients
A	Not clinically significant	Normal	Normal	N/A	3
B	Not likely clinically significant	Facet degeneration	Normal	N/A	12
C	Possibly clinically significant	Facet degeneration	↓ ROM/pain on extension	N/A or no relief	76
D	Definitely clinically significant	Facet degeneration	↓ ROM/pain on extension	Relief >50%	9
Total					100

N/A=not applicable; ROM=range of motion; OR=operating room.

extension range of motion [ROM] and not sent for facet blocks). It was felt that these patients would still be potential candidates for a TDA. Group C (facet arthrosis possibly clinically significant) had indications of facet arthrosis on one or more of clinical notes, imaging reports, and there were mild clinical indications of facet pathology (limited ROM/pain on extension, sent for facet blocks with none or <50% relief). These patients were deemed to be questionable candidates for TDA. Patients were relegated to Group D (facet arthrosis likely clinically significant) if there was clinical note, imaging or operating room note indication of facet pathology plus significant relief of back pain (>50%) with facet blocks. Facet arthrosis was deemed to be of sufficient concern that TDA was not a good surgical option in this latter group.

No standardized protocol for evaluation of back pain was in place during the period of this retrospective review. Facet blocks were not universally performed. This limitation in the methodology restricts the capability to more precisely define the number of patients with clinically significant facet disease.

In patients felt to have facet disease that was definitely or possibly clinically significant, statistical analysis was carried out to identify risk factors predisposing to symptomatic facets. Factors reviewed included patient demographic data (age, sex, workers compensation status), diagnostic criteria (facet disease on operative notes, imaging reports or clinical notes, results of injection studies), number of contraindications to TDA present (0–10), numbers of levels fused (one, two, or three), and specialty of the surgeon performing the fusion (orthopedic or neurosurgeon).

Results

All 100 patients had at least one contraindication to TDA. Only one patient had facet arthritis as their only contraindication. The average number of contraindications per patient was 3.69 (Fig. 1). At the low end of the range, three patients had a single contraindication. The maximum number of contraindications was seven in one patient.

The relative incidence of the 10 specific contraindications was quite varied (Fig. 2), but appeared to self-stratify into three segments. Only one diagnosis rests on the upper strata. Facet arthrosis was the most common finding in 97/100 of our patients. The second strata contains two

diagnoses, spondylolisthesis 75/100 and central spinal stenosis (72/100). The third level has frequencies in the thirties and below. These include lateral recess spinal stenosis 33/100, HNP with radiculopathy 31/100, spondylolysis 25/100, deficient posterior elements 16/100, and scoliosis 15/100. Both osteoporosis and pseudarthrosis were found in 2/100 patients.

Demographics

The population consisted of 40 males (average age 54.3, range 28–76) and 60 females (average age 56.4, range 21–80). Fusion was predominately one-level (85 patients). Multilevel fusions were carried out at two levels in 13 patients and at three levels in two patients (Fig. 3).

Additional facet data (Fig. 4)

Facet pathology had the highest frequency (97/100) of the 10 contraindications. Facet arthrosis was documented most commonly (95/100) in operating room notes (foraminotomy, facet hypertrophy, facet spurs, facet cyst, annular hypertrophy, lateral recess stenosis, foraminal stenosis). Imaging studies had reports of facet arthritis present in 70/100. Facet pathology was inferred on a clinical basis

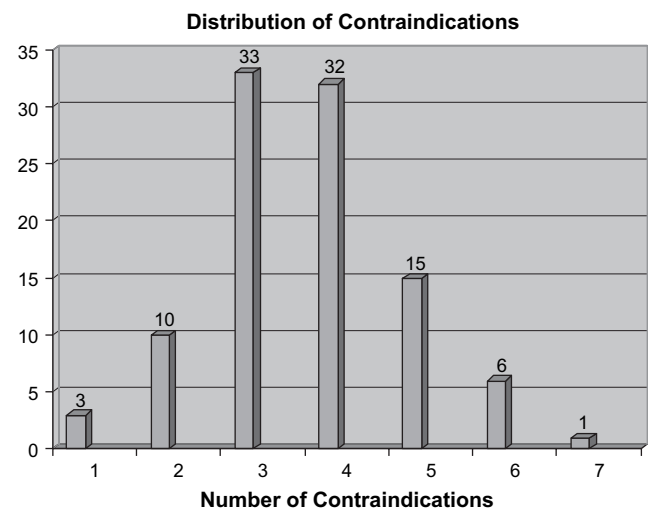


Fig. 1. Frequency distribution of number of contraindications per patient. The average number of contraindications per patient was 3.69. Three patients had only one contraindication, and the highest frequency was seven contraindications in one patient.

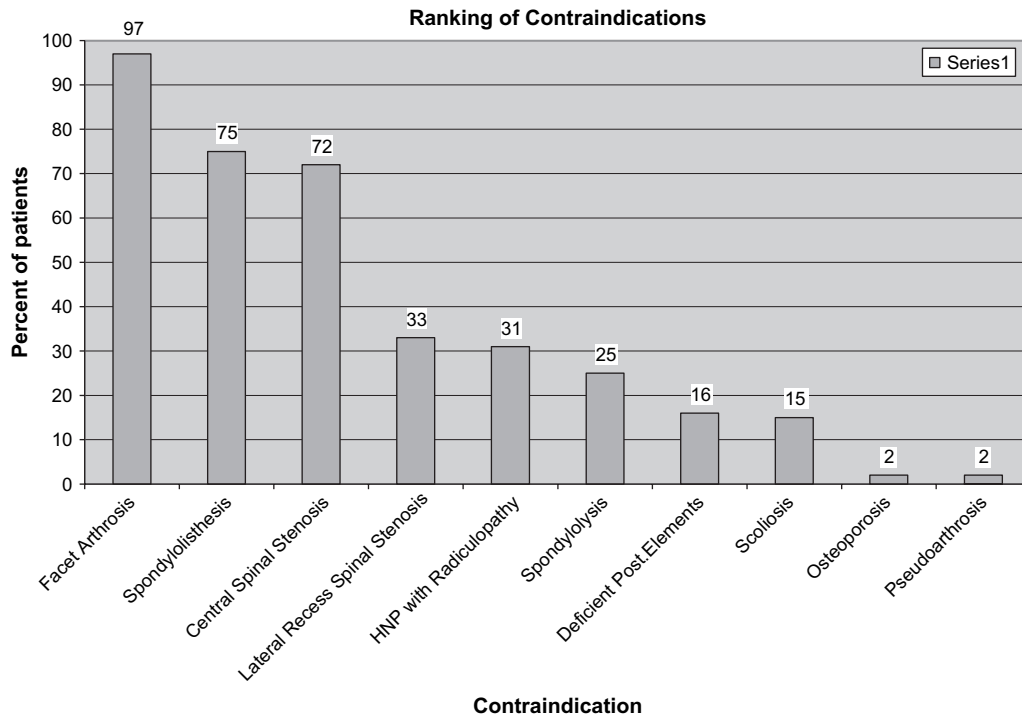


Fig. 2. Frequency of 10 contraindications. Facet arthrosis had the highest frequency and was found in 97 of 100 patients. Two contraindications (spondylolisthesis and central spinal stenosis) had frequencies in the seventies (75% and 72% respectively). The relative incidence of the remaining seven contraindications were at much lower levels (lateral recess spinal stenosis 33%, HNP with radiculopathy 31%, spondylolysis 25%, deficient posterior elements 16%, scoliosis 15%, osteoporosis 2%, and pseudoarthrosis 2%). As illustrated in Fig. 1, most patients had multiple contraindications.

(painful extension motion) in 71 of the 75 patients where the clinical notes described range of motion and whether there was pain on extension. Four patients had limited extension range of motion, but no significant pain. Twelve patients were sent for facet blocks, also inferring a clinical suspicion of facet arthritis; 9 of the 12 had significant relief (>50%) from facet blocks, suggesting a more definite clinical association with the patient’s pain syndromes.

The question of clinically significant facet disease (Table 3)

Three patients had no indication of facet disease in any of the medical records or clinical categories (3% of the total fusion population). Overall, taking into account inclusion redundancy across multiple categories, some indication of facet disease was found in 97 of 100 patients. Of these patients, 12 were felt to have asymptomatic facets (8 patients no limited ROM, 4 patients with limited ROM but no pain) (12% of the total fusion population). The proportion felt to have definite clinically significant facet disease (decreased extension ROM with pain and facet block relief) was 9/97 (9% of the total fusion population) (Table 3). The remaining 76 patients had facet disease that could possibly be clinically significant (painful extension on clinical testing and including the 3 patients with negative facet blocks).

In the statistical analysis of variables predisposing to symptomatic facets, four factors were found to be

statistically significant. These were age, numbers of contraindications to TDA present, presence of lateral recess stenosis, and numbers of levels fused.

Discussion

The ideal indication for lumbar TDA seems clear (isolated discogenic low back pain only). However, the relative

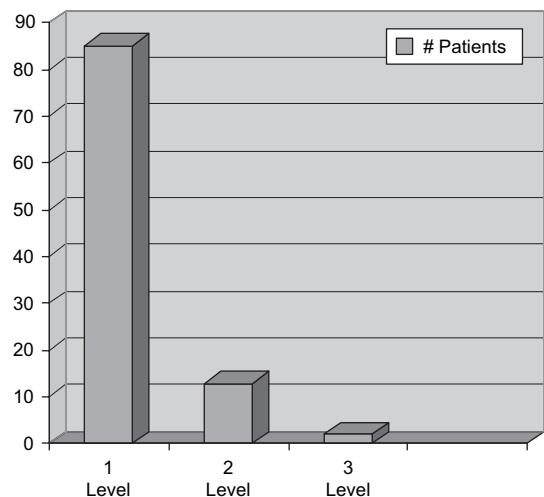


Fig. 3. Numbers of levels fused in 100 patients. The vast majority of patients in our cohort (85/100) had a single-level fusion. There were two levels fused in 13 patients and three segments fused in two patients.

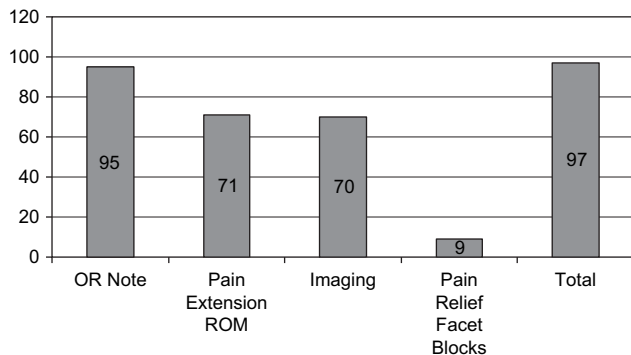


Fig. 4. Facet arthritis: frequency of criteria for diagnosis. Patients may have more than one criterion for the diagnosis of facet arthritis. Of the 97 patients felt to have facet disease, the pathology was documented most often on operating room (OR) notes (95/100). Pain with extension range of motion (ROM) was the next most frequent indication found (71/100). Imaging reports suggested facet problems in 70/100. Nine patients had facet blocks with more than 50% relief of their back pain.

frequency of this decisive clinical circumstance in the population in general and even in the cohort of patients undergoing lumbar spinal fusion appears extremely indefinite. There has been great enthusiasm in some quarters that TDA would obviate spinal fusion in a large percentage of the patients presently undergoing a fusion procedure. Cammissa's study [10] directly contradicts this supposition on the basis that patients undergoing spinal fusion at the Hospital for Special Surgery generally have a multifactorial symptom complex that may include discogenic pain, but very often incorporates other diagnoses which represent contraindications to TDA. The senior author (DAW) was extremely surprised at the incidence of contraindications to TDA reported in the Hospital for Special Surgery population. The present study was undertaken to compare and contrast a similar cohort of spinal fusion patients at our institution in an effort to see if the data supported or contradicted the Hospital for Special Surgery study.

Interestingly, our data were almost identical with Cammissa's in terms of overall frequency of contraindications in this population (100% of all spinal fusion patients having one or more contraindication to TDA in both studies). The relative incidence of contraindication per patient was also closely mirrored (average of 3.25 contraindications per patient in the Hospital for Special Surgery study and 3.69 in ours).

The spine surgeons at our institution generally consider themselves fairly conservative in terms of their overall view of the indications for spinal fusion. This mind-set would account for the high incidence in our patient population of diagnoses such as spondylolisthesis (75%), central spinal stenosis (72%), lateral recess stenosis (33%), and HNP (31%). The frequency of these diagnoses in our fusion patients indicates a clear surgeon bias away from fusion for the degenerative disc. Fusion for "black disc disease" is uncommon in the cohort of patients presently undergoing lumbar fusion at our medical center. The characteristics

of fusion patients at other institutions may be quite different. The present study population was not specifically chosen for consideration of a TDA. Nevertheless, our patients and those in the Hospital for Special Surgery review do represent a definite segment of the lumbar fusion population and should be viewed as at least accounting for a portion of the whole. In this context, the universal presence of contraindications to TDA at our two spine surgery services suggests that the premise held by Wall Street analysts [27,28] that many patients presently undergoing lumbar spinal fusion would likely shift to a TDA may be overstated. Recent articles in the popular press [29] and in journals [30] have referenced the controversy over the role of spinal fusion for degenerative disc disease. TDA adds another layer of controversy to this situation.

The similarity of results between Hospital for Special Surgery and our five-surgeon series (including both orthopedic and neurosurgeons), suggests that the relative frequency of contraindications is fairly consistent across multiple practices, different surgical subspecialties, and different practice settings (academic vs. private medical center).

With respect to "hard" (eg, spondylolisthesis, spinal stenosis) versus "soft" (eg, facet arthritis) contraindications to TDA, clinical decision making would be easier if there were a low incidence of the relatively soft contraindication of facet arthritis. The number of instances when a "soft" contraindication had to be considered in surgical decision making would thus be limited. Unfortunately, it appears that the incidence of facet arthritis (the "soft" contraindication) is quite frequent (97/100 patients in our series).

A major challenge facing physicians evaluating potential candidates for TDA will be the identification of the subgroup of patients who have clinically significant facet pathology. Almost all our patients (97/100) had some degree of facet disease identified; conversely, only three patients had no identified facet disease (and all three patients had at least one other contraindication to TDA). A small subgroup of nine patients does appear to have definite facet contraindications to TDA. These were the set with facet problems identified in all three clinical categories: facet injection procedures (>50% pain reduction facet blocks), physical examination (pain on extension), and records documentation (facet disease on operating room or imaging reports).

Therefore, the facet issue is in question in the residual cohort of patients. This group, in fact, represents the majority (76/100) of the total patient group (100 total patients–3 normals–12 with asymptomatic facet disease–9 definite symptomatic facets=76). This still represents the controversial area in the choice of the appropriate candidate for TDA.

It also appears that the degenerative process cannot be considered as an isolated occurrence involving either the disc or the facet to the exclusion of other structures making up the motion segment. Degenerative pathology tends to

involve the motion segment as a whole. This observation is supported by our statistical analysis which identified four other statistically significant factors associated with the presence of facet arthritis (age, numbers of contraindications to TDA present, presence of lateral recess stenosis, and numbers of levels fused).

Conclusions

Significant contraindications to TDA appear to exist in some patient populations presently having lumbar spinal fusion surgery. Both the present study and the original similar review at the Hospital for Special Surgery [10] found that 100% of the patients having fusion surgery at our two institutions have one or more recognized contraindications to TDA.

Careful analysis of pain generators will be necessary to define appropriate candidates for TDA.

The role of clinically significant facet disease is still controversial and seems to be a significant issue in the majority of our patients (76/100) having fusion surgery. Classification systems are limited in their utility at this point. It will likely take long-term follow-ups of series of TDAs with evaluation of the degree of clinical and radiographic pathology before selection criteria can be refined.

Kirkaldy-Willis has outlined the “degenerative cascade” [22]. The cascade details interconnected degenerative processes in multiple anatomic areas of the spinal motion segment (including the disc and facets) versus time. It has been postulated that the interval in the cascade where traditional fusion surgery is performed would correlate with the interval that would be appropriate for TDA. In this circumstance, TDA could potentially replace the majority of fusions. In fact, the high incidence of contraindications to TDA found in two similar studies may suggest that the actual “ideal” patient for lumbar disc arthroplasty may be found at an earlier time frame and at a less serious level of degeneration in the cascade.

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