Purpose: To determine why A.D.R.’s fail by examining results of 91 patients in F.D.A. studies performed at a single I.D.E. site with minimum two-year follow-up.

Methods: To minimize variables, every patient undergoing A.D.R. at one I.D.E. site by two surgeons were evaluated for clinical success. Failure was defined as less than 50% improvement in O.D.I. and V.A.S. or any additional surgery at index or adjacent spine motion segment. This criterion for success was more stringent than F.D.A. guidelines, which require only a 25% improvement in O.D.I. and V.A.S. for clinical success.

Three A.D.R.’s were evaluated: Maverick™ (M) 25 patients, Charité™ (C) 31 patients, Kineflex™ (K) 35 patients. All procedures were one level performed at L4-5 or L5-S1. Demographics and inclusion/exclusion criteria were similar and will be discussed. Facet pain was diagnosed by facet block and significant clinical improvement after facet rhizotomy.

Results: Overall clinical failure occurred in 26%, (24 of 91 patients) at two-year follow up. Clinical failure occurred in: (M) 28%, (7 of 25 patients); (C) 39%, (12 of 31 patients); (K) 14%, (5 of 35 patients). The type of A.D.R. makes a difference. Causes of failure included: facet pathology 46% of failure patients,( 11 of 24). Implant complications occurred in 6% of the total patients and 25% of the failure patients, (6 of 24). Patients with additional orthopedic or medical pathology or disability/narcotic issues making them unable or unwilling to fill out follow-up forms specific to their A.D.R. occurred in 29% (7 of 24), of the failure group. Despite the fact these patients were considered failures based on O.D.I. and V.A.S., they reported a 92% satisfaction with the A.D.R. and would repeat the surgery for the same result. Interestingly, A.D.R. patients are often either a clinical success at three-month follow-up (home run) or a possible failure (strike out). Only five patients went from a success to failure after three months. One was an infection one year after A.D.R. and four patients developed additional pathology unrelated to their A.D.R. Only one patient went from a failure to success after a facet rhizotomy one year after A.D.R.

Conclusions: Seventy-four percent of patients after A.D.R. met strict clinical success after two-year follow-up. The clinical success versus failure rate did not change from their three-month follow-up in 85 of the 91 patients (93%). Home run versus strike out can be determined early. Failures occurred due to: facet pain, 46% of the time; implant complications in 25%; and additional unrelated pathology or disability/narcotic issues resulting in form filling not specific to their A.D.R in 29% of patients. Implant type appears to impact clinical success. These results indicate overall clinical success can be improved most by patient selection and implant type. Patients with a B.M.I. over 34, multiple orthopedic and/or medical pathology, facet pain, or disability/narcotic issues have a higher failure rate with A.D.R.