To evaluate the clinical and radiographic outcomes of patients undergoing lumbar total disc replacement (LTDR) with M6-L and make comment about its effectiveness and durability.

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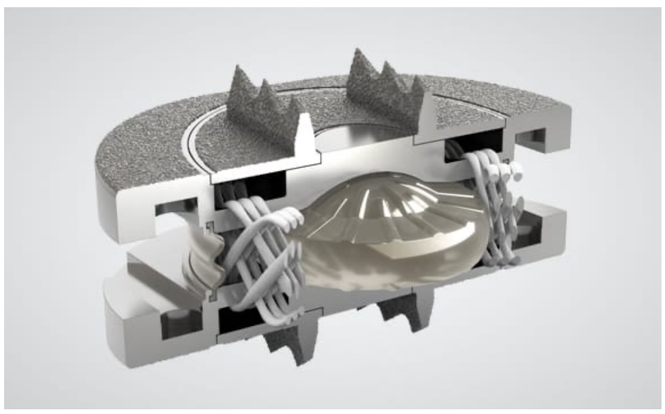

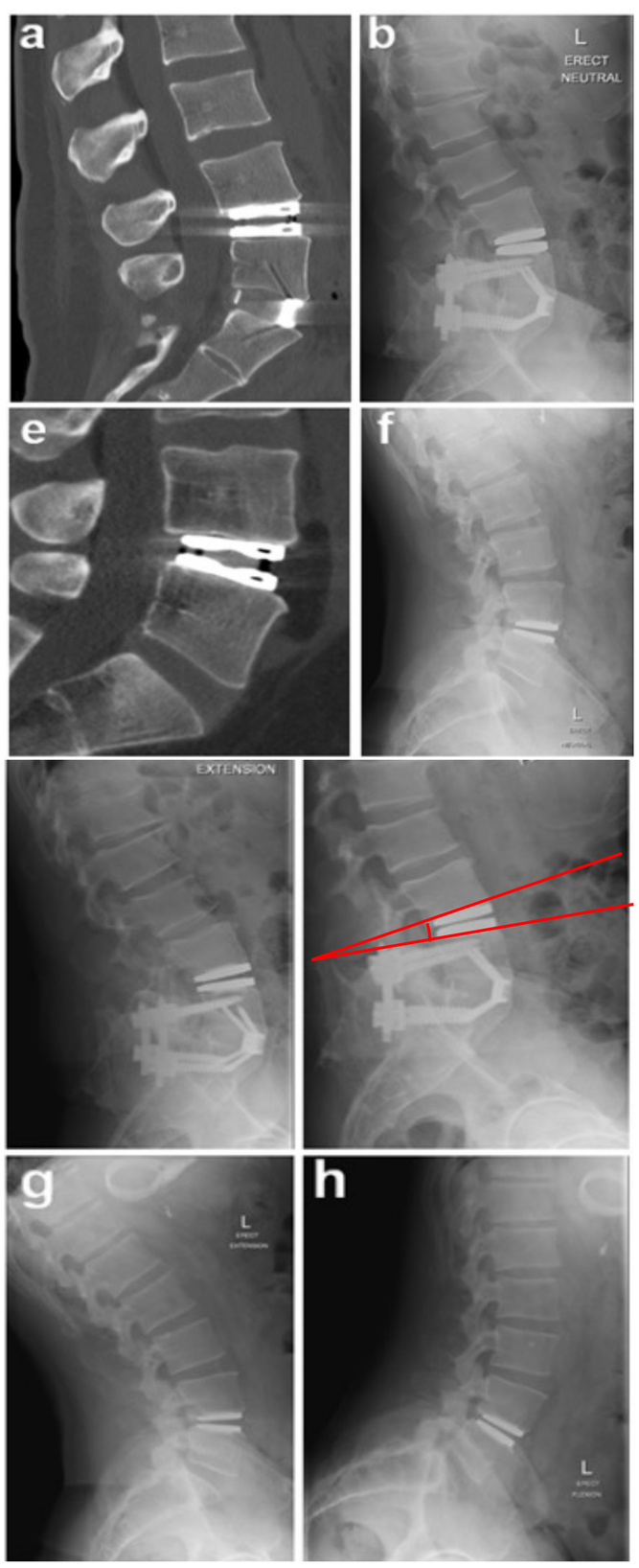

Purpose

To evaluate the clinical and radiographic outcomes of patients undergoing lumbar total disc replacement (LTDR) with M6-L and make comment about its effectiveness and durability.

Study design

A retrospective single center chart review was performed of all patients who underwent LTDR with M6-L between January 1, 2011, and January 1, 2021, either as standalone device or combined with a caudal anterior lumbar interbody fusion (hybrid procedure). Preoperative, postoperative, and final follow-up patient reported outcome measures (PROMs) (VAS back, VAS leg, ODI, and SF-12) and patient satisfaction were recorded prospectively. Device range of motion (ROM), adjacent segment degeneration/disease and heterotopic ossification (HO) were obtained from flexion and extension lumbar radiographs at most recent follow-up.

Results

Sixty patients underwent LTDR with the M6-L device. Mean age was 41 (16-71) years and 38 (63%) were male. Sixteen (27%) underwent standalone LTDR, 42 (70%) a hybrid procedure, and 2 (3%) a 3-level procedure. Twenty-three (38%) patients were lost to follow-up. Thirty-seven (62%) were followed for a mean of 4.3 (1-10) years with 36/37 reviewed at a minimum of 2-years and 13/37 followed for over 5 -years. Only one patient with osteopenia needed index level revision LTDR surgery for subsidence requiring supplemental posterior instrumentation. There were no osteolysis induced device related failures. Thirty patients obtained long-term follow-up radiographic data. Six patients had adjacent segment degeneration; none required surgery for adjacent segment disease. Three patients presented with clinically significant HO (2 with McAfee class III, 1 with class IV). The average M6-L ROM was 8.6 degrees. Mean preoperative baseline PROMs demonstrated statistically significant improvements postoperatively and were sustained at last follow-up ($p<0.05$).

KEY FINDING

TDR with M6-L showed clinically significant improvement in PROMs that were sustained at long-term follow-up. There were no osteolysis induced device related failures. The device ROM was maintained and showed a downward trend over the 10-year study follow-up period. This paper demonstrated that the M6-L was an effective and durable arthroplasty device in this series.