Survivorship analysis of 150 consecutive patients with DIAMTM implantation for surgery of lumbar spinal stenosis and disc herniation

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Abstract Recently, the Device for Intervertebral Assisted Motion (DIAMTM) has been introduced for surgery of degenerative lumbar disc diseases. The authors performed the current study to determine the survivorship of DIAMTM implantation for degenerative lumbar disc diseases and risk factors for reoperation. One hundred and fifty consecutive patients underwent laminectomy or discectomy with DIAMTM implantation for primary lumbar spinal stenosis or disc herniation. The characteristics of the 150 patients included the following: 84 males and 66 females; mean age at the time of surgery, 46.5 years; median value of follow-up, 23 months (range 1–48 months); 96 spinal stenosis and 54 disc herniations; and 146 one-level (115, L4–5; 31, L5–6) and 4 two-level (L4–5 and L5–6). In the current study, due to lumbosacral transitional vertebra (LSTV) L6 meant lumbarization of S1 and this had a prominent spinous process so that the DIAMTM was implanted at L5–6. Reoperations due to any reasons of the DIAMTM implantation level or adjacent levels were defined as a failure and used as the end point for determining survivorship. The cumulative reoperation rate and survival time were determined via Kaplan–Meier analysis. The log-rank test and Cox regression model were used to evaluate the effect of age, gender, diagnosis, location, and level of DIAMTM implantation on the reoperation rate. During a 4-year follow-up, seven patients (two males and five female) underwent reoperation at the DIAMTM implantation level,

giving a reoperation rate of 4.7%. However, no patients underwent reoperation for adjacent level complications. The causes of reoperation were recurrent spinal stenosis ($n = 3$), recurrent disc herniation ($n = 2$), post-laminectomy spondylolisthesis ($n = 1$), and delayed deep wound infection ($n = 1$). The mean time between primary operation and reoperation was 13.4 months (range 2–29 months). Kaplan–Meier analysis predicted an 8% cumulative reoperation rate 4 years post-operatively. Survival time was predicted to be 45.6 ± 0.9 months (mean $\pm$ standard deviation). Based on the log-rank test, the reoperation rate was higher at L5–6 ($p = 0.002$) and two-level ($p = 0.01$) DIAMTM implantation compared with L4–5 and one-level DIAMTM implantation. However, gender ($p = 0.16$), age ($p = 0.41$), and diagnosis ($p = 0.67$) did not significantly affect the reoperation rate of DIAMTM implantation. Based on a Cox regression model, L5–6 [hazard ratio (HR), 10.3; 95% CI, 1.7–63.0; $p = 0.01$] and two-level (HR, 10.4; 95% CI, 1.2–90.2; $p = 0.04$) DIAMTM implantation were also significant variables associated with a higher reoperation rate. Survival time was significantly lower in L5–6 (47 vs. 22 months, $p = 0.002$) and two-level DIAMTM implantation (46 vs. 18 months, $p = 0.01$) compared with L4–5 and one-level DIAMTM implantation. The current results suggest that 8% of the patients who have a DIAMTM implantation for primary lumbar spinal stenosis or disc herniation are expected to undergo reoperation at the same level within 4 years after surgery. Based on the limited data set, DIAMTM implantation at L5–6 and two-level in patients with LSTV are significant risk factors for reoperation.

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vertebra

Introduction

Decompressive surgery, with and without fusion, is the standard of care for degenerative lumbar disc diseases [24]. Decompressive surgery has been shown to be a successful treatment in relieving symptoms of lumbar spinal stenosis and disc herniation without instability [2, 12]. However, previous studies have noted deterioration of the early favourable results of decompressive surgery over time due to post-operative instability or recurrent spinal stenosis or disc herniation [10, 11, 28]. Therefore, addition of fusion surgery has been performed to reduce the failure or reoperation rate at the level of decompressive surgery [19, 20]. However, fusion surgery has been reported to increase biomechanical stresses, such as motion and intradiscal pressure, on the adjacent levels leading to transitional diseases [16, 17, 21]. These issues have led some investigators to develop novel approaches to dynamically stabilize the lumbar spine so as to avoid adjacent level complications, as well as complications related to decompressive surgery alone.

Recently, interspinous spacers have been introduced for surgery of degenerative lumbar disc diseases as a concept of dynamic stabilization [4, 22, 23]. The device for intervertebral assisted motion (DIAMTM) is a relatively new interspinous spacer consisting of silicone core, polyester mesh, fixation cables, and titanium crimps [26]. The DIAMTM is known to restrict segmental motion, such as extension and flexion, but allow full range of axial rotation and lateral bending at the level of implantation. Therefore, the DIAMTM does not increase motion and intradiscal pressure at the adjacent levels, which can theoretically avoid the development of adjacent level complications [3, 5]. To date, few studies have reported the biomechanical, clinical, or radiological outcomes of the DIAMTM used for degenerative lumbar disc diseases [7, 13, 23, 26]. However, there have been no studies to determine the survivorship of the DIAMTM as used for degenerative lumbar disc diseases.

If a patient has a normal S1, it is not technically possible at the present time to implant any type of interspinous spacers, including the DIAMTM at L5–S1. In some patients of the current study, however, S1 is lumbarized to become L6 due to a lumbosacral transitional vertebra (LSTV) [8, 9, 26]. Compared with a normal S1, L6 has a prominent spinous process so that the DIAMTM can be implanted at L5–6 (Fig. 1). L6 is linked to the sacrum by several types of articulation, and this leads to a relatively stable lumbosacral junction-like fusion. Therefore, it has been reported that pathologic changes, including disc degeneration, disc herniation, or spinal stenosis, occur more frequently at the disc level above LSTV, especially L5–6 [1, 15, 18, 27].

In general, the reoperation rate has been used as a measure of clinical outcomes of surgery for lumbar spinal stenosis and disc herniation. However, the use of simple percentages without considering the effect of the time course or the follow-up losses has a potential drawback that cannot reflect a true reoperation rate. On the contrary, survivorship analysis is considered to be a more appropriate method to provide accurate assessment of the true reoperation rate [6, 14]. We therefore performed the current study to determine the survivorship of the DIAMTM implantation for primary lumbar spinal stenosis and disc herniation as well as risk factors for reoperation.

Materials and methods

One hundred and fifty consecutive patients underwent either laminectomy or discectomy with the DIAMTM implantation for one- or two-level lumbar spinal stenosis or disc herniation between 2005 and 2009 (Figs. 2, 3, 4, 5). All patients had back pain and intractable leg or buttock pain associated with positive radiological findings without response to conservative treatment for a minimum of 6 weeks. All of the operations were performed by one surgeon at one institute with the same operative techniques. Eighty-four patients were males and 66 were females, with a mean age at the time of surgery of 46.5 years (range 20–73 years). Ninety-six patients had lumbar spinal stenosis and 54 patients had lumbar disc herniation. One hundred and forty-six patients were implanted at one-level (115, L4–5; 31, L5–6) and four patients were implanted at two-levels (L4–5 and L5–6). All patients, in whom the DIAMTM was implanted at L5–6 for one- or two-level surgery, had L6 with a prominent spinous process due to LSTV. Patients with degenerative spondylolisthesis, degenerative scoliosis, flexion angular instability, and a history of previous lumbar surgeries were not included in this study.

Reoperation due to any reasons at the DIAMTM implantation level or adjacent levels was defined as a failure and used as the end point for determining survivorship. Survival time for analysis of 150 patients with the DIAM[®] implantation was calculated from the date of primary surgery to the date of reoperation, the date of death, loss to follow-up, or 30 June 2009, whichever came first. The median value of follow up time for patients known to have survived at the end of the study was 23 months (range 1–48 months). Of 150 patients, 105 (70%) were seen at the last follow-up (30 June 2009) and 45 (30%) patients had dropped out by the last follow-up: 43 (28.7%) patients were lost to follow-up and 2 (1.3%) patients died from unrelated causes of surgery, 6 and 22 months after surgery.

Fig. 1 Anteroposterior and lateral radiographs of lumbar spine shows that S1 is lumbarized to become L6 due to a lumbosacral transitional vertebra (LSTV). Compared with a normal S1, L6 has a prominent spinous process (*asterisk*) so that the DIAMTM can be implanted at L5–6. L6 is linked to the sacrum by several types of articulation, and this leads to a relatively stable lumbosacral junction-like fusion (*white arrows*)

Fig. 2 Intraoperative clinical photographs show laminectomy (*black arrows*) and nerve root (*asterisk*) (a) and DIAMTM implantation (b) at L4–5 and L5–6

The cumulative reoperation rate (i.e. 100% less the cumulative survival rate) and survival time were determined via Kaplan–Meier analysis. The variables for univariate and multivariate analyses were age (<50 vs. ≥50 years), gender (male vs. female), diagnosis (disc vs. stenosis), location (L4–5 vs. L5–6), and level (one-level vs. two-level) of the DIAMTM implantation. The log-rank test and Cox regression proportional hazard model were used to evaluate the effect of age, gender, diagnosis, location, and the level of DIAMTM implantation on the reoperation rate. A *p* value < 0.05 was considered as statistically significant.

Results

During a 4-year follow-up, seven patients (two males and five females) underwent revision surgery at the DIAMTM implantation level, giving a reoperation rate of 4.7%. However, no patients underwent revision surgery for adjacent level complications. The mean time between primary surgery and reoperation was 13.4 months (range 2–29 months). The causes of reoperation were recurrent spinal stenosis (*n* = 3; 2 one-level at L4–5 and 1 two-level), recurrent disc herniation at L5–6 (*n* = 2, 1 ipsilateral side

Fig. 3 38-year-old male patient complained of severe low back pain and both buttock and leg radiating pain for 8 years. Neutral lateral radiograph of lumbar spine (a) shows that degenerative changes and disc space narrowing of L4–5 with segmental hyperlordosis. Magnetic resonance image (b) shows that severe degenerative changes and herniated disc at L4–5. After DIAM™ implantation after discectomy (c), segmental angle of L4–5 was normalized

Fig. 4 34-year-old female patient complained of severe low back pain and both buttock and leg radiating pain for 10 years. Neutral lateral radiograph of lumbar spine (a) shows that degenerative changes and disc space narrowing of L4–5 and L5–6 with segmental hyperlordosis. Magnetic resonance image (b) shows that inferiorly migrated herniated disc at L5–6 and herniated disc at L4–5. After DIAM™ implantation after discectomy (c), segmental angle of L4–5 and L5–6 was normalized

Fig. 5 62-year-old male patient complained of low back pain and both buttock and leg radiating pain for 5 years. Neutral lateral radiograph of lumbar spine (a) shows that degenerative changes and disc space narrowing of L4–5 with segmental hyperlordosis. Magnetic resonance image (b) shows that moderate spinal stenosis at L4–5. After DIAM™ implantation after laminectomy (c), segmental angle of L4–5 was normalized

and 1 contralateral side), post-laminectomy spondylolisthesis at L4–5 ($n = 1$), and delayed deep wound infection at L5–6 ($n = 1$). The reoperation was performed based on the

development of new symptoms and magnetic resonance imaging findings showing a compatible lesion in the same segment as the initial diagnosis. Two patients who had

one-level recurrent spinal stenosis underwent laminectomy again after removal of the DIAMTM. Two patients who had one-level recurrent disc herniation also underwent discectomy again after removal of the DIAMTM. One diabetic patient, who had a delayed deep wound infection secondary to urinary tract and bladder infections 6 months post-operatively, underwent thorough debridement of the wound after removal of the DIAMTM. One patient who had recurrent foraminal stenosis at two-levels (L4–5 and L5–6) had a laminectomy and foraminotomy after removal of the DIAMTM; however, the clinical symptoms were not improved after reoperation. Therefore, 2 weeks after reoperation, he underwent a second reoperation consisting of a total laminectomy, facetectomy, foraminotomy, and posterolateral fusion with pedicular screw fixation. After the second reoperation, the clinical symptoms were resolved.

Kaplan–Meier analysis predicted that the cumulative survival rate of the DIAMTM implantation was 97% at 1 year, 94% at 2 years, and 92% at 4 years after surgery (Fig. 6). In other words, the cumulative reoperation rate of the DIAMTM implantation was 3% at 1 year, 6% at 2 years, and 8% at 4 years after surgery. In addition, Kaplan–Meier analysis expected that mean survival time was 45.6 months (standard deviation 0.9). The results of analysis for survival time were summarized in Table 1. Survival time was significantly lower in L5–6 (47 months vs. 22 months, $p = 0.002$) and two-level DIAMTM implantation (46 months vs. 18 months, $p = 0.01$) compared with L4–5 and one-level DIAMTM implantation. However, gender ($p = 0.16$), age ($p = 0.41$), and diagnosis ($p = 0.67$) did not significantly affect the survival time of DIAMTM implantation.

Fig. 6 Kaplan–Meier analysis predicted that the cumulative survival rate of the DIAMTM implantation was 97% at 1 year, 94% at 2 years, and 92% at 4 years after surgery. In other words, the cumulative reoperation rate of the DIAMTM implantation was 3% at 1 year, 6% at 2 years, and 8% at 4 years after surgery

Table 1 Analysis of survival time of 150 patients with DIAMTM implantation for primary lumbar spinal stenosis or disc herniation

Variables	Survival time	Standard error	95% CI	<i>p</i> value
Age				0.40
<50	46.1	1.1	44.0–48.2	
≥50	44.9	1.5	42.0–47.8	
Gender				0.16
Male	46.6	1.0	44.8–48.5	
Female	44.5	1.5	41.4–47.4	
Diagnosis				0.67
Stenosis	46.1	1.3	43.6–48.7	
Disc	45.2	1.2	42.8–47.6	
Location				0.002*
L4–5	46.7	0.7	45.3–48.1	
L5–6	22.0	1.2	19.8–24.3	
Level				0.01*
One	45.8	0.9	44.1–47.5	
Two	18.3	4.1	10.2–26.3	

* Statistically significant by the log-rank test

Table 2 Univariate analysis of 150 patients with DIAMTM implantation for primary lumbar spinal stenosis or disc herniation

Variables	Total number	Number of reoperation	4-year reoperation (%)	Chi-square	<i>p</i> value
Age				0.70	0.40
<50	90	3	3.3		
≥50	60	4	6.7		
Gender				1.93	0.16
Male	84	2	2.4		
Female	66	5	7.6		
Diagnosis				0.18	0.67
Stenosis	96	5	5.2		
Disc	54	2	3.7		
Location				9.43	0.002*
L4–5	115	3	2.6		
L5–6	31	3	9.7		
Level				6.70	0.01*
One	146	6	4.1		
Two	4	1	25.0		

* Statistically significant by the log-rank test

The log-rank test and Cox regression proportional hazard model were used to analyse risk factors for reoperation of the DIAMTM implantation. The results of univariate survival analysis by the log-rank test were summarized in Table 2. The reoperation rate of the DIAMTM implantation at L5–6 was significantly higher compared with the DIAMTM implantation at L4–5 (9.7 vs. 2.6%, $p = 0.002$;

Fig. 7 Log-rank test showed that the reoperation rate of the DIAM™ implantation at L5–6 was significantly higher compared with the DIAM™ implantation at L4–5 (9.7 vs. 2.6%, $p = 0.002$)

Fig. 9 Log-rank test showed that patient age (<50 vs. ≥50) did not significantly affect the reoperation rate of the DIAM™ implantation (3.3 vs. 6.7%, $p = 0.40$)

Fig. 8 Log-rank test showed that the reoperation rate of the two-level DIAM™ implantation was significantly higher compared with the one-level DIAM™ implantation (25.0 vs. 4.1%, $p = 0.01$)

Fig. 10 Log-rank test showed that gender (male vs. female) did not significantly affect the reoperation rate of the DIAM™ implantation (2.4 vs. 7.6%, $p = 0.16$)

Fig. 7). The reoperation rate of the two-level DIAM™ implantation was significantly higher compared with the one-level DIAM™ implantation (25.0 vs. 4.1%, $p = 0.01$; Fig. 8). However, patient age ($p = 0.40$), gender ($p = 0.16$), and diagnosis ($p = 0.67$) did not significantly affect the reoperation rate of the DIAM™ implantation (Figs. 9, 10, 11). The results of multivariate survival analysis by the Cox regression proportional hazard model were summarized in Table 3. The L5–6 [hazard ratio (HR), 10.3; 95% confidential interval (CI), 1.7–63.0; $p = 0.01$] and two-level (HR, 10.4; 95% CI, 1.2–90.2; $p = 0.04$) DIAM™ implantation were significant variables associated with a higher reoperation rate. However, age (HR,

1.05; 95% CI, 0.17–6.27; $p = 0.96$), gender (HR, 0.33; 95% CI, 0.06–1.71; $p = 0.19$), and diagnosis (HR, 0.70; 95% CI, 0.14–3.61; $p = 0.67$) were not significant variables associated with a higher reoperation rate.

Discussion

In the current study, for the first time, we have determined the survivorship of the DIAM™ implantation used for surgery of degenerative lumbar disc diseases and found that 8% of the patients who had DIAM™ implantation for primary lumbar spinal stenosis or disc herniation are

Fig. 11 Log-rank test showed that diagnosis (stenosis vs. disc) did not significantly affect the reoperation rate of the DIAMTM implantation (5.2 vs. 3.7%, $p = 0.67$)

Table 3 Multiple stepwise regression analysis with Cox proportional hazard model

Variables	Hazard ratio	95% CI	p value
Age	1.05	0.17–6.27	0.96
Gender	0.33	0.06–1.71	0.19
Diagnosis	0.70	0.14–3.61	0.67
Location	10.25	1.67–62.96	0.01*
Level	10.35	1.15–90.22	0.04*

* Statistically significant

expected to undergo reoperation at the same level within 4 years following surgery. The causes of reoperations were recurrent stenosis or disc herniations, post-operative spondylolisthesis, and delayed deep wound infections. None of the patients underwent reoperation for adjacent level complications. The DIAMTM implantation at L5–6 and two-levels in patients with LSTV is a significant risk factor for reoperation.

According to univariate and multivariate analyses, the reoperation rate of DIAMTM implantation at L5–6 was 3.7 times greater than DIAMTM implantation at L4–5. In the current study, all patients, in whom the DIAMTM was implanted at L5–6, had L6 with a prominent spinous process due to LSTV. Previous studies have reported a higher incidence of back pain as well as disc degeneration and herniation at the disc level above the LSTV [1, 15, 18, 27]. The LSTV would result in greater biomechanical stresses imparted to the disc level above the LSTV, and potentially more translation and rotation occurring with movement at the above disc level. Biomechanical loading conditions are thought to be similar between a LSTV and a surgical fusion, with both placing more biomechanical stresses on

the upper disc level. Except for delayed deep wound infections, most of the causes of reoperations are thought to be related to altered biomechanical conditions of the index surgery level caused by the DIAMTM implantation in conditions with LSTV. Therefore, we speculate two possible reasons for higher reoperation rates in DIAMTM implantation at L5–6 compared to DIAMTM implantation at L4–5. First, similar to the motion segment immediately cephalad to a fusion, LSTV may cause more biomechanical stress concentration at L5–6, which accentuates development of recurrence of spinal stenosis or disc herniation and post-laminectomy spondylolisthesis compared with L4–5. Second, although it is possible to implant DIAMTM at L5–6 due to a prominent spinous process of L6, the implant DIAMTM may not be deeply seated in the L5–6 interspinous space, leading to an inappropriate action of DIAMTM at L5–6.

Univariate and multivariate analyses also demonstrated that the reoperation rate of two-level DIAMTM implantation was 6.1 times greater compared with one-level DIAMTM implantation. This result was consistent with our general expectation that the greater the level of surgery, the higher the reoperation rate. In addition, all patients who underwent DIAMTM implantation for two-level surgery (L4–5 and L5–6) had L6 with a prominent spinous process due to LSTV. Therefore, two possible reasons for a higher reoperation rate in DIAMTM implantation at L5–6 can also be applied to explain a higher reoperation rate of two-level DIAMTM implantation (L4–5 and L5–6). However, in the current study, we should be cautious in interpreting the effect of the level of DIAMTM implantation on the reoperation rate in the current study because there was a significant difference in the number of one- and two-level DIAMTM implantation cases (4 two-level and 146 one-level cases). We cannot definitely exclude the possibility of statistical error caused by a significant difference in the number of one-level and two-level DIAMTM implantation cases. Therefore, additional two-level patient data should be collected to correctly identify the risk of reoperation of two-level DIAMTM implantation surgery. However, age, gender, and diagnosis were not significant risk factors for reoperation of DIAMTM implantation surgery.

Decompressive surgery such as laminectomy or discectomy is the most common operation procedure for lumbar spinal stenosis or disc herniation without instability, which results in early favourable outcome [2, 11]. However, the outcome usually deteriorates over time due to recurrent stenosis or disc herniation or instability. Reoperation rates after decompressive surgical procedures are reported to range from 6 to 23% depending on duration of follow-up and type of disease [6, 10, 12, 17, 19, 20, 29]. In the current study, reoperation rate after DIAMTM implantation for lumbar spinal stenosis or disc herniation was

4.7% (spinal stenosis 5.2% and disc herniation 3.7%) and cumulative reoperation rate by Kaplan–Meier analysis was predicted to be 8% at 4 years after surgery. The authors think that actual reoperation rate of 4.7% after DIAMTM implantation for lumbar spinal stenosis or disc, even though considering 8% cumulative reoperation rate calculated by survivorship analysis, was favourable or similar to the results of 17% of Katz et al's study, 11% of Jansson et al's study, and 6% of Davis et al's study [6, 10, 12].

Another important point of the current study was that all of the reoperations were performed at the DIAMTM implantation level. None of the patients underwent reoperation for adjacent level complications. Previous biomechanical studies have reported that DIAMTM causes a significant reduction in the range of motion, especially extension and flexion, whereas at the adjacent levels, no significant changes were predicted [7, 13, 23]. Moreover, the DIAMTM does not increase the intradiscal pressure at adjacent levels [3, 5]. These biomechanical advantages of DIAMTM are expected to avoid development of adjacent level problems caused by fusion. However, there have been no clinical studies to directly investigate this issue. Therefore, the current study was the first to support the use of DIAMTM implantation in avoiding the development of adjacent level complications in degenerative lumbar disc diseases.

As with any investigation, our study had several limitations. First, the percentage of dropouts at the final follow-up was relatively high. However, we believe that the use of survivorship analysis can minimize the potential risk of statistical error due to high percentage of dropouts. Second, the number of two-level DIAMTM implantation cases was significantly small compared with one-level DIAMTM implantations. To accurately address the reoperation risk of two-level DIAMTM implantation, we need to collect a larger number of two-level DIAMTM implantation cases. Third, only reoperation was used as the end point for survivorship analysis. This definition did not consider patients who refused reoperation in spite of the presence of recurrent spinal stenosis and disc herniation. Therefore, we believe that it is important to consider the recurrence of symptoms irrespective of the requirement of reoperation in the following survivorship study.

In conclusion, the current results suggest that 8% of the patients who has DIAMTM implantation for primary lumbar spinal stenosis or disc herniation are expected to undergo reoperation at the same level within 4 years after surgery. Based on the limited data set, DIAMTM implantation at L5–6 and two-levels in patients with LSTV are significant risk factors for reoperation. More analyses of DIAMTM implantation with different study designs are necessary to identify appropriate patient indications and understand significant reoperation risk factors. This is the

first study to determine reoperation of DIAMTM implantation used for surgery of lumbar spinal stenosis and disc herniation using survivorship analysis.

Conflict of interest None.

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