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Graf ligament stabilisation: mid- to long-term follow-up

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Abstract Previous studies have looked at early follow-up of the Graf ligament stabilisation system. We present mid- to long-term results of this procedure. A retrospective review of Graf ligaments inserted since 1993 was undertaken. A total of 51 patients were reviewed. Pre-operative Oswestry Disability Index scores were compared to post-operative scores recorded via a postal questionnaire. There were 28 men and 23 women. The average age was 41 years (range, 22–67 years). The mean pre-operative score was 46 (range, 22–78), the mean follow-up time was 51 months

(range, 23–84 months) and the mean post-operative score was 40 (range, 0–82). There were 12 complications (4 requiring further surgery), and seven patients went on to require bony fusion procedures. Forty one per cent of the group would choose not to have the operation again. Longer-term results of this technique are not as encouraging as earlier studies. The continued use of this procedure should be viewed with caution.

Keywords Graf ligament · Spinal stabilisation

Introduction

Mechanical instability in the lumbar spine is a term often used to describe an altered pattern of segmental movement causing pain. This is usually due to degenerative disease. Historically, symptoms of mechanical instability have been treated surgically with spinal fusion.

In an attempt to modify the movement pattern of an abnormal motion segment, the Graf ligament system was introduced. It consists of modified titanium pedicle screws inter-connected with bands of braided polypropylene. This arrangement attempts to recreate the lumbar lordosis and allows limited movement to occur, hence the concept of 'flexible intervertebral stabilisation'. The operation is quicker, less destructive and requires less rehabilitation than a definitive spinal fusion.

Previous authors [3, 4, 7] have reviewed early results of the system, which have been encouraging. We reviewed over 50 patients who underwent this procedure with an average follow-up time of over 5 years.

Patients and methods

We retrospectively reviewed 69 patients who underwent Graf ligament stabilisation between 1993 and 1997. Of these, 51 patients were available for follow-up. There were 23 women and 28 men. The mean age was 41 years (range, 22–67 years). All patients had chronic low back pain. Eight patients had had previous spinal surgery in the form of discectomy. Conservative management of back pain had failed in all the patients. This included physiotherapy, epidurals and facet joint injection. All patients were assessed pre-operatively with an Oswestry Disability Index for low back pain. Our indication for stabilisation with the Graf ligament was intractable low back pain for which conservative measures of treatment had failed. All patients had magnetic resonance imaging (MRI) or computed tomography (CT) scans. Abnormal degenerative discs, end-plate changes or marked facet degeneration were targeted for stabilisation. Patients with equivocal scans were further investigated using discography. The surgery was performed by the two senior authors (M.A.F. and A.J.B.F.) exclusively. Fifteen patients had significant leg pain with clinical and radiological signs of nerve root entrapment and consequently underwent nerve root decompression at the same time as the spinal stabilisation. The majority of patients ($n=31$) had single-level stabilisation, while 17 had two-level and 3 had three-level stabilisation.

Patient notes were examined. Previous history and details of surgery were recorded. Post-operative complications and length of

hospital stay were also documented. The patients were contacted via a postal questionnaire. A few patients who did not respond were telephoned. In this manner, post-operative Oswestry Disability Index scores were obtained for 51 patients. Patients were asked to grade the success of their surgery on a visual analogue scale (0=worst outcome, 10=best outcome), and they were specifically asked whether they would consider undergoing the same surgery again.

Results

The mean follow-up time was 51.7 months (range, 23–84 months). The mean pre-operative Oswestry Disability Index was 46 (range, 22–78), and the mean post-operative score 40 (range, 0–82). A Wilcoxon test comparing the pre- and post-operative back scores produced a *P* value of 0.128, showing that there is no significant difference between the groups. The mean length of hospital stay was 9 days (range, 4–19 days). The mean patient rating was 5 (range, 0–10), and 21 patients would not choose to have the same operation again.

There were 12 complications: three superficial wound infections (which resolved with antibiotic therapy) and one deep surgical infection requiring removal of the implant. There was one dural tear, which was treated conservatively with no long-term sequelae. Two pedicle screws were malpositioned despite the use of intra-operative fluoroscopy, and one required revision at a later date. Three patients had post-operative radicular pain and foot drop; these were not related to screw malposition. One of these patients has now recovered following removal of the Graf ligament and formal bony fusion. Two ligaments failed, one ruptured and one slipped off the pedicle screw. Both required further surgery.

The overall re-operation rate was 21% (11 out of 51). Included in these are seven patients who required bony fusion procedures.

Discussion

Early results of the Graf ligament 'soft stabilisation system' have been encouraging [7]. Our mid- to long-term results, however, do not confirm these early results. Post-operative Oswestry Disability Index scores clearly show no appreciable improvement when compared with the pre-operative scores. Re-operation rates are high, and patient satisfaction scores are low. In the first clinical series of Graf ligament stabilisations documented by Gelosi [3], good or excellent results were reported in 85% of patients. However, follow-up was less than 1 year. Markwalder and Dubach [7] and subsequently Brechbuhler and Markwalder [1] reviewed 27 patients following Graf ligament stabilisation. Their preliminary results in 1995 showed good or excellent results in 77.5% of patients. Longer-term results were published in 1998 with an average follow-up of 50 months. Two of the original 27 patients were

excluded as they had undergone further surgery, one for L5/S1 translaminar screw fixation and one for removal of the implants. Of the remaining 25, 74% had good or excellent results, with only two further patients requiring subsequent bony fusion procedures. The authors accredited their results to their strict indications for surgery.

Hadlow et al. [5] have recently published results of a retrospective, non-randomised case-control comparison between the Graf ligamentoplasty procedure and instrumented posterolateral fusion. The patients were able to choose which procedure to have following discussion with the surgeon. They found that the Graf procedure was associated with a worse outcome and a significantly higher re-operation rate at 1 and 2 years follow-up, respectively.

We feel that our results are inferior to spinal fusion. West et al. [8] reviewed 64 patients after pedicle screw-plate spinal fusion. Their results show that pain and disability scores are halved, at an average follow-up of 2 years. They show a re-operation rate of 16%, all for pseudarthrosis. Enker and Steffe [2] also show similarly high rates of fusion (91.6%) and patient satisfaction (80.2%) in their series of 169 patients following spinal fusion.

In the largest series to date of Graf ligament stabilisation, Grevitt et al. [4] report on 50 patients at an average follow-up of 24 months. The results showed a downward trend in Oswestry Disability Index scores after surgery; however, this is not demonstrated as significant. It is noteworthy that the most common complication that they report is post-operative radicular pain (24%). They hypothesise that the increase in lumbar lordosis due to insertion of the ligaments causes narrowing of the lateral recess, and hence nerve root entrapment. We would agree with this hypothesis and feel that this is the cause of the post-operative radiculopathies and persistent foot drop experienced in three of our patients. One of these patients who has now had the Graf ligaments removed and undergone formal bony fusion has now recovered, adding weight to this argument.

Overall, previous reports on the Graf ligament stabilisation system are good. They report early results. We feel that the system fails to maintain the stabilisation, possibly as the Dacron stretches with time. The stabilisation has then effectively failed although the components may remain intact. Instability then returns with resultant symptoms. If the ligaments do maintain their integrity, increased pressure on the facet joints caused by the forced lordosis may lead to accelerated degeneration and hence pain.

Pedicle screw malpositioning is a recognised complication of their use. We have documented two cases. In a recent review of nearly 5000 pedicle screws, Lonstein et al. [6] showed malpositioning in 2.8% of screws inserted. Only 0.2% of the total screws inserted caused nerve root irritation requiring screw revision or removal. Pedicle screw insertion is obviously common to both spinal fusion with screw-plate systems and Graf ligament stabilisation.

In conclusion, our mid- to long-term experience with the Graf ligament stabilisation system has yielded disappointing results when compared to published data on spinal fusion. While the idea of a soft stabilisation system

may be attractive, with less destructive surgery and faster rehabilitation, it appears to produce an inferior long-term clinical outcome. We have viewed the continued use of this system with caution.

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