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Graf ligamentoplasty: a 7-year follow-up

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seen as a means of stabilising and reducing the mobility of one or more severely symptomatic motion segments associated with degenerative disc disease. It is a less invasive procedure than fusion and appears to have a similar or slightly better success rate. Some studies have reported mixed results at early follow up; generally, they have suffered from poorly defined indications for the procedure, which are now much clearer. Reports on the first 50 patients undergoing Graf stabilisation in 1990/1991 were published in the European Spine Journal in 1995, with a 2-year follow-up. In the present study, the results of which were independently reviewed by the second author (K.C.P.), a spinal research fellow from an unrelated centre, we were able to establish postal contact with 40 of those patients, of whom 31 still had Graf instrumentation in situ. Examination of the clinical records of the ten non-responders when last seen indicated no particular bias of the results. The average age at surgery and average follow-up were 41.8 years (range 17.2-60 years)

Abstract Graf ligamentoplasty is

and 7.4 years (range 5.6–8.5 years) respectively. Excellent and good subjective results were reported in 62% of patients; 61% reported significant or total relief of low-back pain and 77% never or occasionally used analgesics. Patients were evaluated using the Oswestry Disability Score and the MSPQ (Modified Somatic Perception Questionnaire) and Zung Depression Index with the DRAM (Disability and Risk Assessment Method). Additional information was obtained from the clinical notes and radiographs at last review. The mean Oswestry Disability Score was 59± 10% pre-operatively and 37.7±14% after 7 years. There was a statistically significant correlation between the Oswestry scores and the subjective outcome (P=0.009). The results of this study suggest that the beneficial effects of Graf ligamentoplasty are sustained in the longer term in spite of the presence of an established degenerative process.

Keywords Graf ligamentoplasty · Flexible stabilisation · Low-back pain · Disc degeneration

Introduction

The mechanical model of the pathogenesis of discogenic back pain predicts that if the motion segment is immobilised then there will be no further stimulation of nociceptive receptors. All of us with any extensive experience of the surgical treatment of low-back pain will know that things are not that simple. Firstly, fully rigid fixation is probably not achieved by posterior or intertransverse fusion alone -360° fusion is necessary.

Secondly, the causes of pain in degenerative disc disease are not well understood and are difficult to investigate. Laboratory testing, with demonstration of various



Fig. 1 Graf pedicle screws and polyester bands. The optional diabolo on the left protects the band from chafing against the facet joint

modes of mechanical instability, is suggestive and provides circumstantial evidence; however, the main complaint of pain, being a symptom, is not amenable to verification in the laboratory or in an animal model.

We are all aware that over the past 20 years the biopsycho-social model of back pain and its associated disability has gained much greater appreciation and is better understood [13]. A great array of psychometric tools has been described, along with a variety of educational, physical and therapeutic management programmes designed to reorientate the individual's attitude to their pain and to lessen their disability.

We strongly believe, however, that a proper understanding of back pain and its consequences must include both the mechanical and bio-psycho-social models. Neither has a monopoly of wisdom, as some would have us believe. We have no doubt that either surgery or rehabilitation programmes or both, when applied to well-selected patients without undue delay, will provide the key for the great majority of back sufferers and enable them to live a reasonably fulfilling life. However, there are those who slip through the net and receive either delayed or inappropriate treatment, and also those who are psychologically vulnerable, who make their own lives a misery and challenge the resources of those who try to help them.

This article describes the Graf technique which, like all stabilising back pain surgery, is applicable only to a small percentage of back sufferers who are psychologically robust and have a demonstrable pain source verified, so far as is possible, by clinical assessment, plain radiography, magnetic resonance imaging (MRI) and discography, where necessary.

Graf ligamentoplasty (Fig. 1) may be described as a stabilising and splinting procedure, designed to substantially immobilise a symptomatic and presumably damaged motion segment made vulnerable by the degenerative process or injury.

The prime clinical indication for Graf ligamentoplasty may be described as "the lumbar instability syndrome."



Fig. 2 Characteristic spasm of lumbar instability syndrome. The lumbar spine is immobilised in extension, the position of maximum stability, as in the Graf operation. This man had no leg pain and his symptoms resolved with time with no surgery being necessary

The important word here is "syndrome," meaning a collection of symptoms. Frequently patients are highly symptomatic, with pain sources that are difficult to demonstrate objectively. The surgeon has to decide on the relative importance of the mechanical model and the bio-psycho-social model. Surgeons and physicians have to become expert at resolving this conflict and assessing the correct balance, so that they can recommend the treatment mode most likely to help that individual.

The lumbar instability syndrome (Fig. 2) is often characterised by recurrent or chronic low-back pain with disabling episodes of acute muscle spasm. The longer the history and the more intense the back pain, the more likely it is to be referred down one or both legs, sometimes to the feet.

The pain is often described as a vague, dead, heavy ache with tingling into the feet and toes in a non-dermatomal distribution. Objective neurological signs are absent unless there is associated lumbar nerve root involvement.

Needless to say, patients do not become candidates for surgery unless they have been through a thorough course of non-operative treatment. A pre-operative functional restoration or self-management programme is often helpful anyway, because of its educational content and instruction in physical therapy.

Indications

The indications for Graf ligamentoplasty may be summarised as follows:

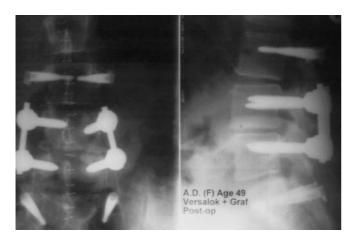
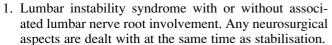


Fig. 3 Hybrid stabilisation. L4/5 fusion with L3/4 and L5/S1 Graf. This school-teacher, who was about to retire because of her back, was able to return to full duties 4 months after surgery and rehabilitation



- Stabilisation of degenerate and symptomatic discs above or below an existing fusion. Fusing yet another level with its invasiveness and biomechanical consequences is often undesirable and unnecessary.
- 3. Stabilisation of a symptomatic adjacent disc to a spondylolysis which is repaired at the same time, as an alternative to fusion.
- 4. Stabilisation of three-level disc degeneration as a more successful alternative to three-level fusion. We have found that ligamentoplasty up to three levels is as successful as one-level stabilisation, provided the correct levels are stabilised. Four-level stabilisations have been disappointing.
- 5. "Hybrid" stabilisation (Fig. 3). Graf stabilisation in combination with fusion of an adjacent severely degenerate disc or spondylolisthesis not suitable for Graf stabilisation. In these cases the Graf bands are placed deep to the pedicle screw-rod junction. A slightly longer screw (5 mm) may be necessary to allow for the thickness of the band. Allowance should also be made for the difference in band length, because of any difference in screw diameter from that of the Graf screw (6.5 or 7.5 mm).

Contra-indications

The contra-indications for Graf ligamentoplasty are as follows:

1. Isthmic or degenerative spondylolisthesis greater than grade 1. Such cases are better treated by fusion if necessary.



Fig. 4 The arrows indicate where nerve root compression can occur

- 2. Severe degenerative disc disease. It seems illogical to preserve movement of a severely degenerate disc, and fusion is probably preferable. However, good results have been reported in some such cases. When marked disc narrowing is present, the risk of lateral recess and foraminal compression is much greater, as the motion segment is immobilised in lordosis with Graf bands. It is often not possible to carry out an adequate decompression without excessive partial facetectomy in these cases.
- 3. Tumours, infection or trauma, where rigid stabilisation is required.
- 4. Patients with prolonged and severe disability for more than 1 year and those with unsatisfactory psycho-social profiles. In this group, stabilising surgery may produce some benefits, but a good or excellent result is not to be expected.

As a general consideration, it is necessary to appreciate that application of appropriate Graf bands immobilises the motion segment in lordosis with the facet joints in a position of full extension, in which position they are very stable. As a consequence, the lateral recess and the exit foramen will be narrowed to some extent.

If significant disc narrowing is present or there is a constitutional tendency to stenosis, then nerve root compression may result if ligamentum flavum removal or partial facetectomy is not carried out as a precaution (Fig. 4).

The clinical history and the MRI scan will give some guidance as to the need for decompression, but the exit foramen should always be probed to ensure there is adequate space if there is any doubt. In the experience of the first author, around 60% of operated levels need bilateral decompression, but some surgeons will decompress all levels.

In our report [5] of the first 50 Graf stabilisation patients, new post-operative lumbar nerve root compression

symptoms were the commonest complication and, although the majority resolved with time, epidural injections etc., a small number did not. Lessons were learnt.

All these matters are reviewed in greater detail in other publications [2, 3, 4].

Materials and methods

The first 50 patients operated upon by the first author (A.G.) were independently reviewed and reported in the *European Spine Journal* in 1995 [6]. For the purposes of the present study, as many as possible of these patients, who had undergone surgery between August 1990 and December 1991, were subject to a further independent review conducted by the second author (K.C.P.), an orthopaedic surgeon from another, unrelated, centre.

The objective was to assess the long-term outcome of patients with the Graf implant in situ. Patients were evaluated using a postal questionnaire, which included the Oswestry Disability Score [1], the MSPQ (Modified Somatic Perception Questionnaire) [9] and the Zung Depression Index [14]. This enabled calculation of the DRAM (Disability and Risk Assessment Method) score [10]. Additional information was obtained from the clinical notes and radiographs at last review.

Results

Data were available on 40 patients (ten non-responders). For the final analysis, 31 patients with the Graf implant in situ were considered after excluding patients who had undergone subsequent fusion or removal of the Graf implant. Four had undergone fusion, with indifferent results. They probably represented errors of case selection. Three patients had had screws removed for late loosening, with symptomatic relief. One patient had had the implant removed because of persistent pain with no relief, and one patient, a 35-year-old policeman, had developed an acute infection 8 weeks after surgery; the implant was removed, with an excellent long-term outcome and return to full duties. The combination of surgical stabilisation and infection seemed to cure his "instability".

The clinical records of the ten non-responders were reviewed and the spread of results showed no particular bias compared with the responders.

The average age at the time of surgery was 41.8 years (range 17.2–60 years). No significant difference in the subjective result was seen between patients below and those above the age of 40 years.

The average follow up was 7.4 years (range 5.6–8.6 years).

Twenty-two patients had undergone single-level instrumentation and nine had had more than one level instrumented. Patients instrumented at more than one level appeared to have better results, although this difference did not reach statistical significance (P=0.06).

Additional information was obtained from the clinical notes and radiographs at last review.

The results of the questionnaire are given in Fig. 5. Sixty-one percent of patients were still rated as good or

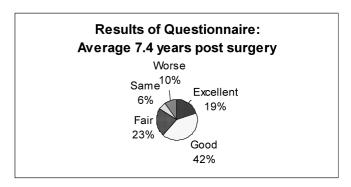


Fig. 5 Results of questionnaire assessing the outcome of surgery at an average of 7.4 years after the operation

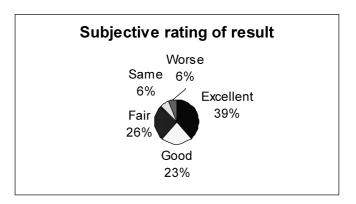


Fig. 6 Subjective rating of the results

excellent 7.4 years after surgery, but 10% were rated worse than their preoperative condition.

This is always a cause for concern, but there was no particular pattern to this group of patients. It has been a noticeable, but anecdotal, feature that patients who are worse after Graf stabilisation do not seem to be severely worse; they have simply gone on deteriorating, in contrast to those who are worse after fusion, who seem to be a great deal worse and complain bitterly. The first author's telephone has been very much quieter since Graf stabilisation replaced the majority of fusions for degenerative disc disease.

The subjective ratings of the result by the patients when asked to place themselves in one of five categories was, as usual, somewhat optimistic (Fig. 6). The percentage of good and excellent results, at 62%, remained much the same as the doctor's grading in Fig. 5, but within this group, the percentage who considered themselves excellent was doubled.

In the questionnaire, patients were asked whether, if they had the choice again, they would be willing to undergo the same surgery (Fig. 7). Sixty-eight percent responded in the positive, with none responding that they would not have made that decision. This was understandable, as nobody likes to be proved wrong. It was encouraging that nobody admitted to being misled or misinformed.

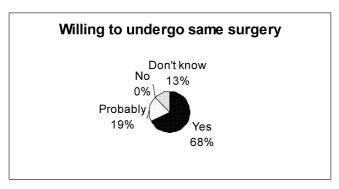


Fig. 7 Responses to item on whether patient would be willing to undergo the same surgery

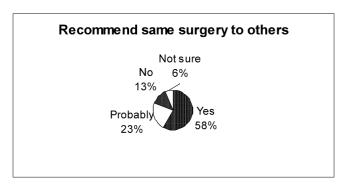


Fig.8 Responses to item on whether the patient would recommend the same surgery to others

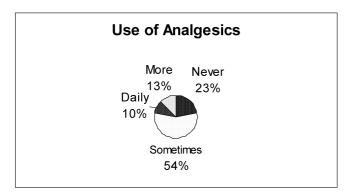


Fig. 9 Use of analgesics

The question as to whether patients would recommend the same surgery to others (Fig. 8) was less encouraging, with only 58% being sure and 13% (four patients) responding in the negative.

Patients were also asked about their analgesic consumption (Fig. 9). One-quarter said they never used analgesics, and 54% said they sometimes used them, with 13% using them more than daily. Given that the average Oswestry score prior to surgery was 59%, it was considered reasonably satisfactory that 77% of patients (24 out of 31) used analgesics sometimes or never.

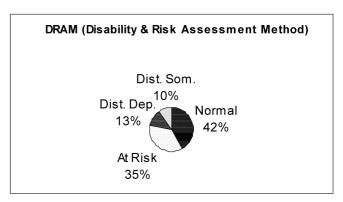


Fig. 10 Results of the Disability and Risk Assessment Method (DRAM)

Finally, the DRAM category (Fig. 10) of each patient was calculated using the MSPQ and Zung scores to establish the psychological profile. Seventy-seven percent of patients were considered to be normal or at risk, with 23 being rated as distressed. This series was too small to obtain any statistical correlation between psychological category and outcome. However, it is worth making the point that while the first author has operated on distressed depressive patients with good or excellent results, the outcomes for distressed somatic patients have been generally disappointing.

Discussion

A previous series of 268 patients, independently reviewed (K.C.P.), produced results sufficiently encouraging to maintain that Graf stabilisation for patients experiencing intolerable symptoms from degenerative disc disease is a useful procedure [4]. The results were considered to be as good as, if not better than, those obtained by spinal fusion for this condition.

The above assertion will no doubt be challenged by many with an equal lack of objective information. There is an undoubted need for more carefully structured clinical trials to answer the following questions, to which we have partial answers only:

- 1. What precisely is the place for surgical stabilisation, either fusion or ligamentoplasty, in degenerative disc disease? Some maintain that there is no place, and they are probably wrong, as is usual with a dogmatic point of view. On the other hand, many surgeons, including the first author, have probably over-operated in the past, before the bio-psycho-social model of back pain and its associated treatment options became appreciated. The mechanical model of back pain remains important in many patients.
- Flexible or soft stabilisation appears to be a more physiological and less mechanically disruptive procedure than fusion, particularly for three-level instrumentations. It is also a less invasive procedure. The

- Graf and Dynesys methods appear to be the most popular. Is one method more effective than the other in both the short and the long terms?
- 3. Which patients and which spinal levels should undergo fusion and which flexible stabilisation? Severe degeneration and bone problems should be fused and soft tissue problems need soft tissue surgery, i.e. Graf.
- 4. Do patients undergoing flexible stabilisation benefit from reduced symptomatic disc degeneration at adjacent levels compared with those undergoing fusion? This remains to be established, but it is probably the case.
- 5. Should MRI dehydrated discs, which are thought to be asymptomatic and are adjacent to a symptomatic disc, be stabilised? The first author, prior to the advent of MRI around 15 years ago, generally fused the lower two lumbar discs if either was symptomatic, whether or not they were both degenerate. Since MRI, it has been easier to discriminate. The first author has generally advised extending Graf stabilisation to cover degenerate discs that are thought to be asymptomatic and are adjacent to symptomatic degenerate discs up to a maximum of three levels. Failure to do this has resulted in secondary surgery in some patients. It has to be admitted that this information is anecdotal, but at present there is little other information.
- 6. Finally, we come to the largely philosophical question as to whether we should advise major surgery for which the main indication is pain a symptom that is difficult to measure and whose sources we do not fully understand. Perhaps the best that can be said on this is that spinal surgeons with experience in this field can probably produce a majority of patients who are grateful for their surgery, although there are some who are undoubtedly worse as a result.

Increasingly, we in the UK, and also surgeons in many other countries, are being advised and often instructed by administrators that we should use only evidence-based medical and surgical techniques. However, unfortunately, in many cases they fail to supply the resources and infrastructure to enable clinicians to collect that evidence. Meanwhile, is it not unethical to deny substantially disabled patients a probable route back to a more satisfactory and productive life? Clinical experience should not be ignored. It was many years before clinical trials established the efficacy of antibiotics and decades before their mode of action was understood.

Conclusions

The first author now has experience of over a thousand Graf stabilisations carried out between 1990 and 2000. In-

dependent reviews have been conducted by Michael Grevitt reporting on a 2-year follow-up of the first 50 cases in 1995 [6], and the second author (K.C.P), who conducted the subsequent follow-up reported in this article. In addition, he also reviewed results of a further 268 patients reported elsewhere [3, 4]. Grevitt and Pande were Spinal Fellows from the University of Nottingham, with no medical or administrative connection to the Essex Spine Centre. It is considered reasonable to draw the following conclusions.

- Graf ligamentoplasty has proved successful in the majority of patients undergoing stabilisation of up to three motion segments for highly symptomatic degenerative disc disease not responding to non-operative management. It is of course essential to establish which discs are symptomatic by clinical examination, plain radiology, MRI scanning and discography, where necessary. (Discography is particularly valuable in younger patients under the age of 25, who may have normal MRI scans but highly symptomatic discs.)
- 2. Graf ligamentoplasty is quicker, less invasive and, in experienced hands, less prone to complications than spinal fusion, being a simpler procedure with less to go wrong. Pseudarthrosis and donor site pain, in particular, are avoided. Since it is a less invasive procedure than a posterior or posterolateral fusion, and since there is no bone graft to worry about, recovery and rehabilitation can proceed more quickly and the majority of patients are back to light work within 6–8 weeks.
- 3. It has been suggested that Graf stabilisation either has inferior results to fusion [7] or that the results are not sustained. Neither criticism has been substantiated on independent review of the above series, and it is clear that some studies have had major structural defects [5] and others errors of case selection. Other studies [8, 11, 12] have had satisfactory results, similar to those reported in the present series.

The concept of flexible stabilisation is a soft tissue solution to what is essentially a soft tissue problem. Significant spondylolisthesis and severe degenerative disc disease with secondary bone changes are bone problems requiring a bone solution such as spinal fusion. The overkill of spinal fusion for most symptomatic degenerate discs is unnecessary and over-elaborate. Flexible stabilisation merits serious consideration in psychologically stable individuals when the symptomatic disc or discs can be identified with reasonable certainty and the response to nonoperative treatment has been poor.

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