Doctor Jacques SAMANI
ORTHOPAEDIC SURGERY

Spinal surgery, child orthopaedics
1707

1, rue Burdeau
69001 LYON

Tel : 0033 478 27 99 94
Fax : 0033 478 27 12 95

STUDY OF A SEMI-RIGID INTERSPINOUS "U" FIXATION SYSTEM
106 patients over six years
J. SAMANI – LYON 2000

The interspinous « U » belongs to the flexible systems used for spinal stabilization. It is positioned in the interspinous space and substantially restricts mobility of the vertebral level, but not completely. It reduces stresses at the posterior joints, partially modifying lordosis. It opens up the foramena.

It is not a new idea and was widely developed by Doctor SENEGAS. On the other hand, the type of implant, its material and insertion technique are different.

OBJECTIVES

It offers an alternative to arthrodesis, is quick to perform and risk-free. It may be used either as a transition area above or below an arthrodesis in order to prevent a hinge effect and the formation of a secondary lumbar spinal stenosis, or it may be used alone at one, even two and more unusually three segments.

In this case it may solve the problem of painful interfacet arthropathy without having recourse to vertebral fusion.

DESCRIPTION OF THE IMPLANT

It is a metallic « U » shaped device in titanium, available in heights of 10, 12 and 14 mm ending in two thin clips, one upper and one lower, which surround the spinous processes.

After its first use in 1994, the implant has undergone little change. The first « U »s were associated with figure-of-8 ligament tying, but this was soon found to be

unnecessary as sufficient stability was provided by the clips and automatic placing under compression of the « U » provided by lordosis.

The upper clips of the « U » are staggered relative to the lower clips so that two "U"s can be superimposed.

We have recently added surface embossing to the two limbs of the "U", more for the purpose of reassuring some users.

BIOMECHANICAL STUDY

Two types of test were conducted : static and dynamic machine and spinal tests.

A/ Machine testing

a) static tests were used to determine yield strength : using a stretching/compression machine, forces were applied perpendicular to the "U" axis. The test was continued to determine the maximum force tolerated before plastic deformation occurred.

For a size 10 "U ", this was 28 daNewtons

For a size 12 "U" it was 20.2 daNewtons.

b) dynamic endurance tests were performed on a size 12 "U" with forces of 1 to 5 daNewtons and a frequency of 5 hertz. No breakage occurred after 1 200 000 cycles.

Torsion tests were also conducted, even though in individuals these forces are minimal. We found that even with an excursion of over 5 mm between one limb and another, no breakage occurred. Moreover it proved impossible to break the implant under torsion.

B) Spinal tests

Tests were conducted on the lumbar vertebrae of a female patient.

We endeavoured to determine stiffness under compression on a spine fitted either with a "U" at L4-L5, or with two "U"s at L3-L4 and L4-L5. In this way, it was possible to determine height reduction of the "U" at its two ends in relation to the forces applied.

At L4-L5, for a single "U" with 415 Newtons, the reduction in height was 0.115 mm; with 700 Newtons 0.292; with 1000 Newtons 0.451.

When two "Us" were superimposed, the deformation of each of the "U"s was scarcely different.

IMPLANT TECHNIQUE

Patient position is of importance: it should be in slight delordosis. The "U" must not distend the space too excessively. When being placed in position it should fit tightly. The rounded part stops at 5 mm from the dural sheath. The clips prevent any protrusion of the material inside the canal, and lordosis prevents backward displacement maintaining the implant under load. The two thin, malleable clips are tightened around the spinous processes, blocking rotation.

Contrary to other types of implant, the support zone is not located solely on the finer part of the spinous process, but also on its base which offers greater resistance.

The implanting technique is simple. Using a conventional median approach, the spinous processes are sparingly resected either side of the ligamentum flavum; endo-canal procedure is performed : decompression, release of the foramena, possible curettage of herniated intervertebral disc. The "U" size is chosen using templates. The "U" is then inserted. The clips are tightened around the spinous processes. The same procedure can be performed at another level. There is no superimposition of the clips since they are staggered.

CLINICAL TRIAL

This trial involved 106 patients (63 women and 43 men) who underwent surgery between 1994 and 1999; mean age was 54.2 years (range 21 to 81 years).

Mean follow-up was 3 years 3 months (6 months to 6 years).

It is to be noted that out of the 106 patients, 58.5% underwent surgery for the first time and 41.5% had received anterior surgery.

The total number of implants used on the 106 patients was 117. Implant sites were as follows:

* at L1 L2: 5
* at L2 L3: 17
* at L3 L4: 35
* at L4 L5: 49
* at L5 S1: 11

i.e.

* 76 implants at one level (71.6%)

* 28 implants at two levels (26.4%)
* 2 implants at three levels (2%).

INDICATIONS

The "U" was used for two very distinct indications:

- either associated with another type of material
- or used alone

A) Associated with another type of material

The purpose was to achieve a transition area above or below an arthrodesis to prevent a hinge effect and painful hypermobility, or a secondary lumbar spinal stenosis.

26 patients underwent surgery in this group, i.e. 24.5%:

- 22 patients above the arthrodesis
- 1 patient below the arthrodesis
- 2 patients above and below the arthrodesis
- 1 patient with two "U"s above the arthrodesis.

"U" implant above the arthrodesis:

- at L1 L2: 4 patients
- at L2-L3: 9 patients
- at L3-L4: 5 patients
- at L4-L5: 3 cases

B) "U" with no other material:

This group series involved 80 patients. The "U" positioning sites were as follows:

- at L1-L2: 1 patient
- at L2-L3: 4 patients
- at L3-L4: 8 patients
- at L4-L5: 39 patients
- at L5-S1: 4 patients.

Therefore:

* 54 patients with a single "U"
* 24 patients with two "U"s
  - at L2-L3 L3-L4: 1 patient
  - at L3-L4 L4-L5: 19 patients
  - at L4-L5 L5-S1: 4 patients

Three "U"s: 2 patients:

- from L3 to S1: 1 patient
- from L1 to L4: 1 patient.

SURGICAL INDICATIONS

A) In 24.5% of cases, the "U" was associated with an arthrodesis and used as a hinge area: i.e. 24 patients.

- in 22 patients above the arthrodesis
- in 2 patients below the arthrodesis.

This made it possible to limit the graft by sparing a level for which there was doubt, and to form a transition area between the free spine and fixed spine; the objective being to avoid further lumbar spinal stenosis above the arthrodesis.

Indications were quite varied:

- 3 scolioses
- 18 lumbar spinal stenoses + herniated disc
- 3 vertebral instabilities with disc bulging.

B) In 75.5% of cases, the "U" was used alone with no other type of material, i.e. 80 patients, 42 % had already undergone anterior surgery:

- lumbar spinal stenosis with or without herniated intervertebral disc: 63 patients
- isolated herniated disk: 2 patients
- herniated disc + vertebral instability: 9 patients
- recurrent herniated disc: 14 patients.

RESULTS

A) In respect of the implant

No fracture was noted. In two patients, both with a follow-up of more than 5 years, slight slippage of the two limbs of the "U" was noted with no symptomatology. In both cases the "U"s had been implanted alone at L4-L5, and in both cases this finding was related to a considerable weight gain since surgery.

B) Functional results:

As noted above, there were two types of clearly precise indications:

- isolated "U" implant
- "U" implant in association with another type of material as transition area.

In the second case, patient improvement during the early or later postoperative period cannot be attributed to the "U" as, in this case, the purpose of the implant was to prevent possible secondary complications and to reduce possible low back pain above or below the assembly.

For the review of these patients, who represent 26% of the series, no improvement or deterioration in symptomatology can be attributed to the implant.

In these patients, for whom details are given above, the combined procedure mainly involved arthrodeses generally reaching L4, with a "U" positioned above. At functional level, and using the Beaujon scale, a total of 79% excellent and good results were obtained; and one failure which underwent revision. But these results relate more to the problems connected with the arthrodesis than with the "U". In respect of pain above the assembly, results are even better and at the present time there has been no recurrence of lumbar spinal stenosis above the arthrodesis zone after "U" implanting.

In the second series which represents 80 cases, in which "U"s were implanted with no other type of material: 54 of the 80 patients received a single "U"; the main site was L4-L5 ; 24 patients received two "U"s chiefly at L3-L4 and L4-L5; two patients received three "U" implants.

Results were as follows:

- 74% excellent and good results
- 16% average results with persisting low back pain and sciatica
- 10% failures which underwent revision.

Failures had two causes:

- related to a poor indication, in severe lumbar spinal stenosis requiring wider laminectomy; this is not compatible with sparing of the spinous processes. Release had been insufficient to provide for good implant stability and the sciatica picture persisted.

Therefore this technique must not be used in severe lumbar spinal stenosis for which complete laminectomy is sometime preferable to simple decompression.

- the two cases of dislodgement: these both occurred at L5 S1. The sacral spinous process does not provide good support. Use of the "U" should therefore be avoided at this level.

- the superimposition of more than two "U"s was a failure in the two cases in which it was performed. In both cases the patients were relatively young with congenital multilevel lumbar spinal stenosis. It was wished to avoid an extensive arthrodesis, but this had to be performed secondarily on account of insufficient release leading to persistent postoperative sciatica

During revision surgery the excellent stability of the implants was noted with the onset of fibrosis surrounding the implants, and the presence of ossification areas at the stabilizing clips in contact with the spinous process. Revision surgery in these patients brought to light the excellent tolerance of the material with bone mineralization in contact with the implant, which was also confirmed by CT scanning.

The majority of failures were related to indications.

Therefore no more than two "U"s should be superimposed, the L5 S1 space should be avoided especially if the spinous process is of poor quality at S1; and evidently this surgery is not compatible with wide release procedure.

These results are more connected with arthrodesis-related problems than with the "U" implant.

C) Overall conclusion on these isolated "U" implants:

The best indication is a single "U" preferably positioned at L4 L5. These are the indications that are most frequently encountered. No difference in results was observed if two "U"s are placed one above the other. These two "U"s are well tolerated. On the other hand, we take the view that implanting should be limited to two "U"s and three superimposed "U"s should be avoided.

COMPLICATIONS IN THE SERIES

Two deaths occurred:

- one patient died from an intracranial aneurysmal rupture one month after surgery
- the other patient died from a massive pulmonary embolism, also after a time interval of one month.

In both cases the patients were fairly elderly, being aged over 70 years.

COMPLICATIONS DIRECTLY RELATED TO THE IMPLANT

Intraoperatively: none

There were cases when the "U" could not be inserted due to extensive weakness of the spinous process during release of the lumbar spinal stenosis. In these cases, patients were unable to benefit from the technique and conventional fusion with pedicular screws was performed.

There were no late neurological complications related to the "U", and no cases of "U" penetration inside the canal, in particular no dural injury etc..

DISCUSSION

This series generally demonstrated: **two precise indications:**

A) **"U" above an arthrodesis:** plays a useful role, with reference to statistics for recurrence of lumbar spinal stenosis above arthrodeses, especially when they stop at an angled disc. Also, the "U" may contribute to limiting the extent of an arthrodesis, the "U" possibly being positioned on one of the pathological levels if compression does not require wide laminectomy.

Therefore the results in this type of patient are good. Follow-up remains insufficient at the present time to assure that this implant prevents any risk of recurrence above the assembly.

B) in respect of "U"s with no arthrodesis: the major indication is a single "U" positioned at L4-L5 to treat instability, lumbar spinal stenosis and recurrent disc herniation. In these cases, the implant gives good results. It leaves adequate remaining mobility of the space even after several years. Two superimposed "U"s may also be used, and here again the statistics are perfectly satisfactory. On the other hand, three superimposed "U"s should be avoided, since results are not good even though this series is extremely limited.

PREOPERATIVE EXAMINATIONS PERFORMED ON PATIENTS

57.7% of patients underwent CT - myelography.

28 patients, i.e. 26.5% received a CT scan.

17 patients i.e. 16% underwent nuclear magnetic resonance imaging.

POSTOPERATIVE EXAMINATIONS PERFORMED ON PATIENTS

We performed follow-up postoperative scanning, in particular of the space concerned, to determine whether there was recurrence of lumbar spinal stenosis at the site of the "U", and to ascertain bone response in contact with the implant. Not all patients evidently were able to benefit from this examination.

Out of the patients examined, mineralization of the spinous process in contact with the implant was found, in particular at its base which appears to absorb high stresses.

It would appear that the implanting of the "U" when disc curettage is performed, partly prevents subsidence of the space. In most cases a relatively substantial disc height persists, but above all it is found that over time the "U" adapts to lordosis. If stresses become major, especially due to excessive weight gain, the "U" compresses slightly to act as shock absorber.