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Olerud discloses the "vertebral fracture" limitation in Claim 12 of the '404 Patent

Transpedicular Fixation of Thoracolumbar Vertebral Fractures

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The most frequent surgical treatment of thoracolumbar fractures is still the Harrington rod system despite some adverse effects, the most serious being the locking of five to seven segments. The new pedicular fixation modifications suggested by Magerl and Dick lock only two segments and give far better stability of the fractures. Used internally, the system is convenient for the patient, permitting early mobilization, often without any external support. The instrument, called the "posterior segmental fixator" (PSF), is used both as a reduction device and as a fixation device. The injured vertebra is grafted through the pedicle, giving security against late collapse after device removal. Twenty patients treated with this method had an average follow-up period of ten months. The primary reduction attains 88% of the calculated height of the injured vertebra, with only a few percent loss during follow-up time. Clearance of fragments in the spinal canal, diagnosed with computed tomography scan in eight patients, was successfully accomplished in all but one, with only distraction or reduction of the fragment through a limited laminotomy. The instrumentation in these cases was lateral to the dura. Nine patients with neurologic deficits improved and could walk without support or with crutches within a few months. One patient with complete paraplegia remained unchanged.

The main goals of surgical treatment of thoracolumbar vertebral fractures are to achieve reduction, stability, and early, painless mobilization. It is assumed, though not proven, that stable fracture fixation and decompression of nerve structures facilitate the restoration of neurologic deficits.[4,5,16-19,22,24,25,27,33] A further aim is to avoid late malpositions and to preserve lumbar mobility and posture.[11,37,38,42]

Harrington instrumentation and similar methods are currently the most commonly used fixations for thoracolumbar fractures.[2,7,12,21,39,40,45] However, fracture treatment with the Harrington device has certain limitations. The main disadvantage is that this device fixates five to seven vertebrae, resulting in negative effects on mobility. This negative effect is greater the farther down in the lumbar spine the fracture is located. Furthermore, in the postoperative period a brace is needed for mobilization of the patient during healing time to avoid instrument failures.[21,39] Moreover, the patient is not allowed to sit for six months.

Instability, instrument failures, and correction losses have been reported.[1,5,15,23,32,41,45] Some loss of correction may occur after removal of the distraction devices, so that the end result is often roughly similar to the original deformation.[1,28,36]

Roy-Camille and co-workers' transpedicular screw fixations of plates[37,38] paved the way for Magerl's external fixation of vertebral fractures with the aid of transpedicular screws[30,31] and for posterior segmental fixation with an internal fixator.[1,13] This instrumentation, according to Dick, seems to have

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Olerud predates the effective filing date of the '404 and '888 Patents

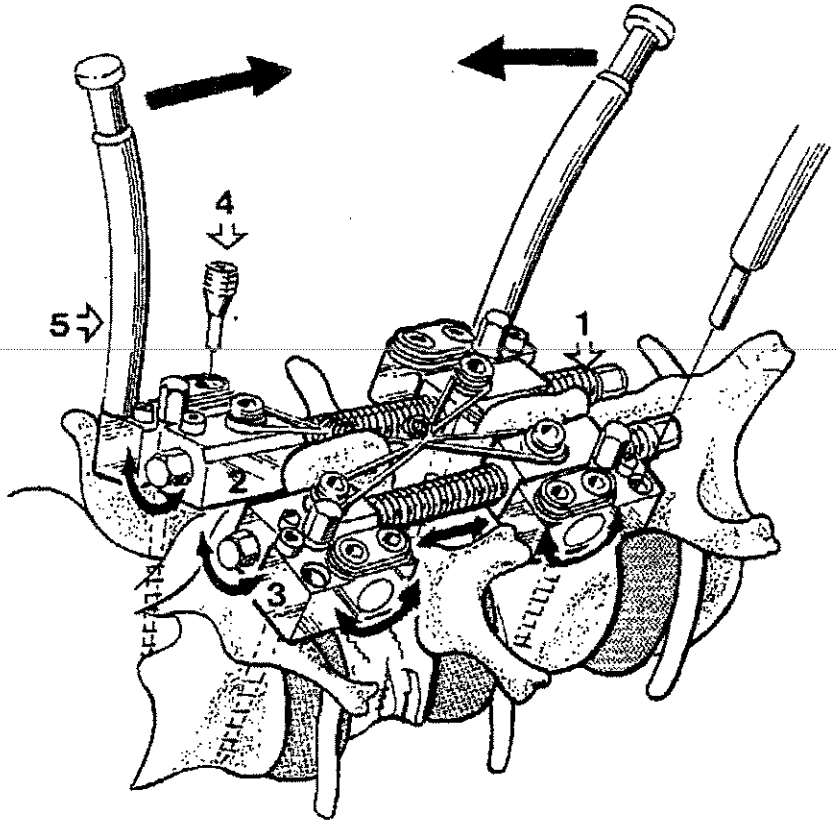


FIG. 1. The posterior segmental fixator (PSF). The device consists of two reversed units. Each unit is composed of one threaded rod (1). On this rod two bolt grips (2) are movable in relation to each other as well as to two screw grips (3) that surround the pedicular screws. The components are locked into each other by conical screws (4). With the special handles (5), the deformed vertebral body can be reduced to normal height and correct lordosis.

several advantages.[13] One is that only three vertebrae are immobilized, resulting in better preserved mobility.

Because transpedicular screws, used for reduction, are placed close to the injured vertebra, the possibility for anatomic reduction should be better, especially in the lower lumbar region. When this treatment is combined with a transpedicular bone graft[8] the risk for secondary deformities should be minimized.

This article reports the authors' early experiences with posterior segmental fixation using the Dick internal fixator[13] and a similar, modified instrument, the "posterior segmental fixator" (PSF).[35]

MATERIAL AND METHODS

The PSF (Fig. 1) consists of two identical but reversed units: a threaded rod against which two bolt grips can be moved in relation to each other and two screw grips that embrace the pedicle screws. The firm hold of the screws in the pedicles greatly facilitates reduction of the fractured vertebra to a correct height and to the correct degree of lordosis. The device is sufficiently stable to maintain the reduced position until healing is completed, without the need for a brace. If additional

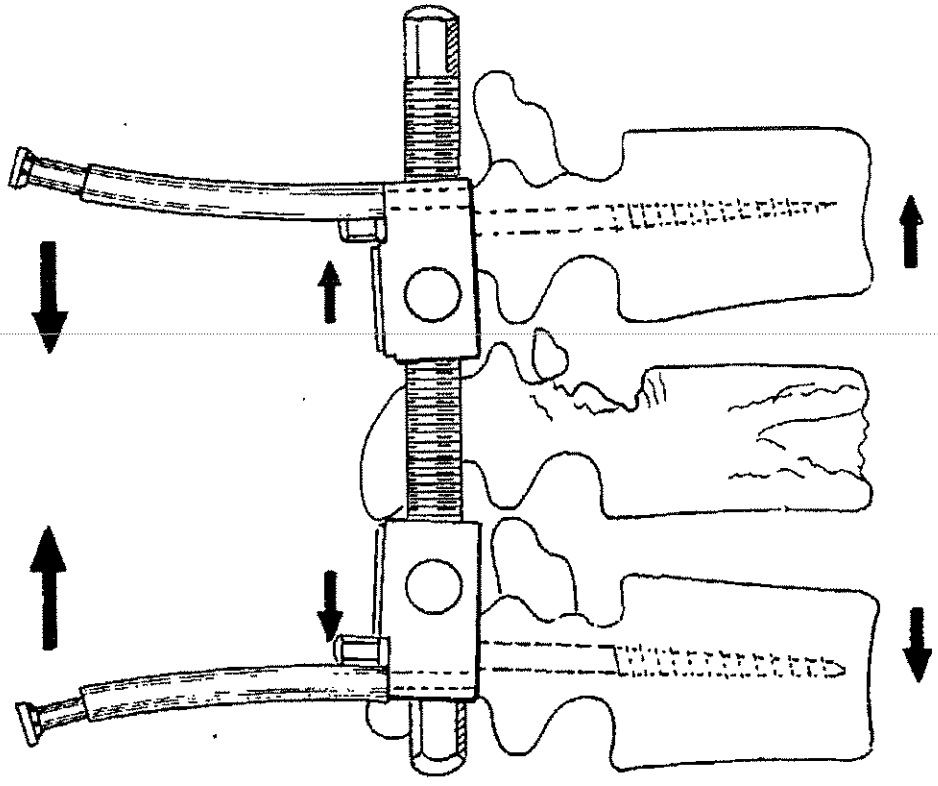


FIG. 2. The PSF allows reduction by extension as well as distraction. After reduction, the configuration and height of the fractured vertebra are normalized.

translatory stability is necessary, diagonal cerclage between the two halves of the instrument can also be used.

SURGICAL TECHNIQUE

The operation is performed with the patient in the prone position on two boards meeting at the level of the fracture site. An operating table suitable for fluoroscopy should be used, because an image intensifier with a C-arm is necessary for a correctly performed operation. The skin incision is made in the midline and should correspond to five spinous processes. The vertebral arches are dissected free subperiosteally to expose the facet joints. The sites of insertion of the screws are identified as described by Louis[29] and Roy-Camille *et al.*[37] The respective joint space and the middle of the transverse process are the most important reference points. A Kirschner wire is used at fluoroscopy to locate the correct place to insert the screw. An opening is then made in the pedicle with a drill or awl, and a self-threading screw is bored manually through the pedicle into the vertebral body. The screw is bored 3.5–4 cm, *i.e.*, almost to the anterior wall of the vertebral body. The position of the screw is checked most reliably in the lateral projection with the C-arm.

When all four screws have been inserted in the correct position, the threaded rod is attached to the screws by its clutches. With the aid of the image intensifier, the posterior wall of the vertebral body is reduced somewhat, but not completely; this will be done later, when the normal lordotic angulation is achieved. Lifting the head end and the foot end of the two boards on which the patient is lying also reduces the anterior wall of the vertebral body, with the fixator as a support; this is necessary if the vertebral arches and/or intervertebral joints do not provide stability.

Further lordosis is now achieved, if needed, by squeezing together the reduction pins that are fixed in the screw grips at the upper and lower vertebrae (Fig. 2). This can often be accomplished

relatively easily with a pair of tongs. The screw grips are then locked to the bolt grips by means of the conical screws. When the threaded rods are rotated, the fractured vertebra is distracted (Fig. 2) until the height of the vertebral body is restored to normal.

Subsequently, the threaded rods are locked to the bolt grips. If the posterior articular system is undamaged, the two segments around the fractured vertebra will be adequately stabilized. If any intervertebral joints or vertebral arches are fractured, however, some instability will remain in bending and in rotation. With the use of two diagonal cerclage wires between the two units of the instrument, adequate stability can be achieved.

On reduction of a compressed vertebral body, defects will occur in the cancellous bone (as in compression fractures in tibial condyles). Similarly, with the insertion of transpedicular screws, a hole can be made with a 5-mm drill through one of the pedicles of the fractured vertebra into the vertebral body. A slightly curved punch is brought through the pedicle into the vertebral body (Fig. 3); under fluoroscopic control with the image intensifier, the end plates and anterior wall of the vertebra are reduced, if possible. An aural speculum is inserted into the pedicular hole and a cancellous bone graft—bone paste obtained from the posterior aspect of the iliac crest with an acetabular reamer[14]—is pressed into the vertebra.[8]

Posterolateral fusions are only rarely performed, *i.e.*, in cases of facet fractures and after a laminectomy. Preoperative myelography or computed tomography (CT) scans will reveal any fragments that have been displaced into the spinal canal. If there is a burst fracture, the fragment can often be reduced with only distraction. Otherwise, with a minor laminectomy such a fragment can be identified by fluoroscopy with an image intensifier and with the aid of an elevator inserted at the side of the dura. Using the PSF, the fragment can then be pressed back into the vertebral body. If this is not possible, a limited laminectomy can be performed after removal of the threaded rod on one side. Any fracture fragments can then be reduced or any fragments present in the spinal canal extracted without any effect on the dura. The removed threaded rod is subsequently reinserted. The reduction usually is not jeopardized by short-term intraoperative dismantling of one of the device units, because the patient is in hyperextension. If desirable, intraoperative myelography can be performed as a check. After operation, the patients can often be mobilized immediately without any external support or, in a few cases, with a simple three-point brace.[13]

At follow-up examination, the reduction effect was measured by comparing the anterior height of the injured vertebra with the calculated height of the same vertebra (the mean value of the vertebra above and the one below the injured vertebra). The reduction effect was also estimated by comparing the Cobb angle.

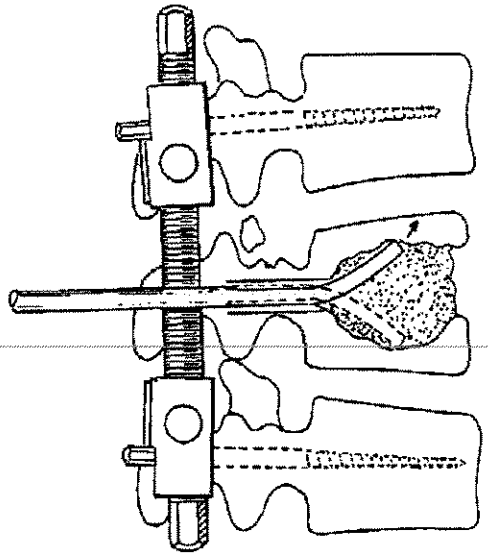


FIG. 3. With a transpedicularly introduced punch, further reduction of fragments in the vertebral body can be reduced. The defect in the vertebra is then filled with a graft in the form of bone paste.[8,13]

PATIENTS

This series consisted of 20 consecutive patients with thoracolumbar burst fractures (14 men and six women) aged 16–59 years (average, 35 years). All fractures had been caused by high-energy trauma, mainly traffic accidents (13 patients). Ten of the patients had neurologic symptoms on admission but only one had complete paraplegia. The injured vertebrae were T12 in three, L1 in five, L2 in four, L3 in two, and L4 in five patients (Table 1).

When classified according to Denis,[11] three fractures were of Type A, 14 of Type B, two of Type D, and one of Type E.

Two patients were treated at a relatively late stage (19 and 45 days, respectively) after injury, and the remaining 18 patients were treated within five days of injury. Of these, seven had surgery on the day of injury.

All were treated with open reduction and fixation with the PSF in the manner described above.

Olerud discloses the "forming the passage" step in Claims 1, 8-10 of the '404 Patent

Olerud discloses the "compacting" step in Claims 1 and 3 of the '404 Patent

Olerud discloses the "filling the passage" step in Claim 1 of the '404 Patent

Olerud discloses the "compacting" step in Claims 1 and 3 of the '404 Patent

Olerud discloses the "filling the passage" step in Claim 1 of the '404 Patent

TABLE 1. Kyphotic Deformities

Fractured Vertebra	No. of Patients	Cobb Angle (°)	
		Preoperative	Postoperative
T12	3	24	8
L1	6	18	7
L2	4	7	8 lordosis
L3	2	9	0
L4	5	10 lordosis	11 lordosis

Fifteen patients had transpedicular bone grafting (Fig. 4); in the other five patients the comminution of the vertebra was too severe for grafting to be worthwhile. For these and two other patients, a posterior fusion was done over the two immobilized segments. In 11 patients, minor laminotomies were carried out for inspection and/or additional repositioning of the anterior wall of the spinal canal. Later in the series, perioperative myelography was routinely carried out after reduction to check the repositioning of the anterior wall. This markedly decreased the need for laminotomy.

Eleven of the patients had other injuries, such as thoracic compression injuries or fractures of the lower extremities.

RESULTS

The average follow-up period was ten months (range, six to 17 months). The mean time for roentgenographic control is eight months.

When wound pain subsided, the patients were freely mobilized. They were discharged after two to three weeks if they had no other injury.

Two patients needed further operations. One had an anterior decompression and fusion because a postoperative CT scan showed that the neural decompression was not acceptable. The second patient had continuing radicular pain and was therefore treated with root decompression.

At follow-up examination, only the patient with complete paraplegia remained unchanged. Three patients who were classified before operation as "motor useless," *i.e.*, Frankel *et al.* Grade C,[20] were improved to Frankel Grade D. Six Frankel Grade D patients were improved, although none was entirely free from neurologic symptoms. All except the paraplegic patient are walking without support or with crutches. Six patients have returned to work, four are back at school, and two are being retrained. Eight are still on the sick list.

Two patients were regarded as technical failures. In one patient the lower grips of the fixator were insufficient, and he regained almost his original kyphotic deformity; however, he is pain-free and working again. This patient was the second in this series and the device was a prototype. Another patient had a translatory instability that was not recognized at the time of operation. This patient should have had diagonal cerclage wiring done to prevent a late lumbar scoliosis of minor degree.

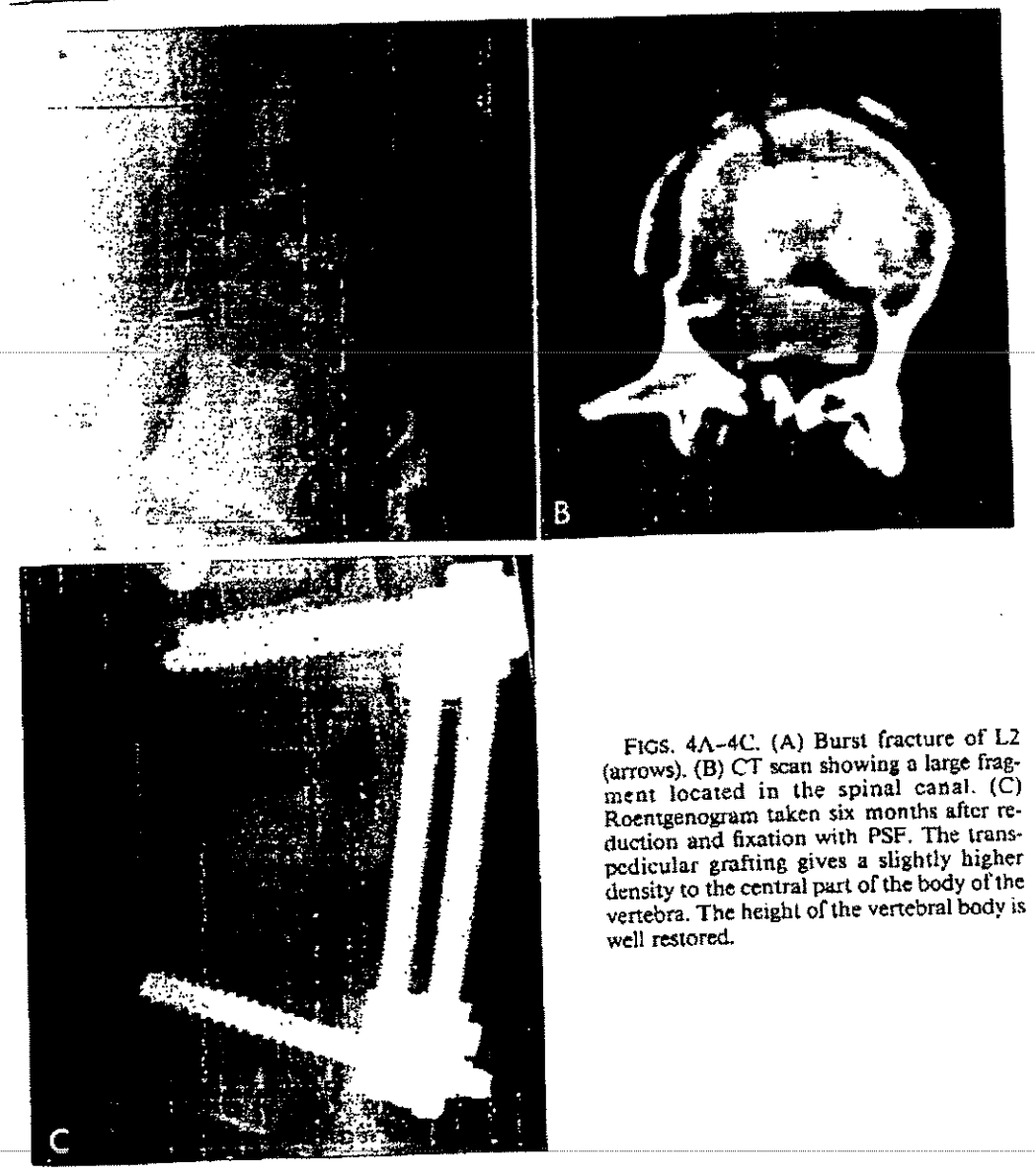
The preoperative and postoperative kyphotic deformities are listed in Table 1. In most of the fractures located in the middle and the lower lumbar spine, a local lordotic curve has been achieved.

The reduction effect, measured by comparing the anterior height of the injured vertebra before and after operation, was satisfying. The preoperative value showed a compression to 56% of the calculated height of the vertebra. At the first postoperative check, the height of the vertebra was raised to an average of 88% of the calculated value. After eight months, this value decreased to 83%. Roughly one-half of the total loss occurred in the two patients defined as technical failures. If these cases are excluded, the average postoperative height is 85% of normal.

The reduction effect, measured by calculating the Cobb angle, showed an average loss of 4° in the group of 20 patients. If the technical failures are excluded, the angulation loss during the eight-month period averaged only 2°.

DISCUSSION

With the PSF, the primary goals of the treatment are achieved: the patients are



FIGS. 4A–4C. (A) Burst fracture of L2 (arrows). (B) CT scan showing a large fragment located in the spinal canal. (C) Roentgenogram taken six months after reduction and fixation with PSF. The transpedicular grafting gives a slightly higher density to the central part of the body of the vertebra. The height of the vertebral body is well restored.

pain-free after a few days, mobilization is easier than after Harrington distraction operations since there are no sitting restrictions, and the brace, when required, is of a simple type.[13,35] The anatomic end results are comparable to or somewhat better than those achieved with the Harrington technique.[28]

Two principles of treatment are considered to promote regression of partial neurologic deficits in cases of unstable vertebral fractures. One is decompression of the spinal

cord and nerve roots; the other is elimination of instability.[5,16,24,25] The time factor is also important.[10]

Decompression of the contents of the spinal canal can be achieved with distraction procedures, laminectomy, or an anterior surgical approach. Laminectomies alone are currently considered to be of little value, because they increase instability[6,9,16] such that the neurologic deficit may even be aggravated.[34] Moreover, posterior decompression is usually an illogical choice of treatment since the pressure on the nerve structures is due, in most cases, to vertebral fragments or disc tissue that is forced into the spinal canal from the anterior direction.[1,27] This has been demonstrated in recent years with CT investigations.[43,44] Because distraction operations alone also do not guarantee adequate decompression,[27] especially in patients with a fracture more than three or four days old, anterior decompression operations combined with posterior or anterior fixation procedures have been used increasingly in recent years.[3,4,17,26,27,33]

Radical anterior decompression and stabilization, however, is in many cases a rather extensive procedure. Posterior reduction and internal fixation with the Dick device[13] or the PSF,[35] used in this series, are far less demanding procedures and give results equivalent to those of anterior operations.

The anatomic results in this series are comparable to or somewhat better than those achieved with the Harrington technique, the reduction having been close to anatomic (Fig. 4). The tolerance for flexion deformity should also be better than in Harrington-operated patients, since the possibility of compensating for such a deformity is better preserved when only two vertebral segments are immobilized. Several problems with Harrington-operated patients have been reported (*e.g.*, restricted lumbar mobility and loss of lordosis), notably after scoliosis surgery. The same is apparently true for traumatized patients treated the same way.[13]

The fractured and grafted vertebrae[8,13] are expected to heal after six months, although the device is not removed before at least one year. The loss of anterior vertebral height and increasing flexion deformity can to some extent be explained by the two technical failures in this series. For the rest of the patients, the loss of vertebral height is less than that described after Harrington fixation without technical failures.[28] The reason for the loss of correction in patients who do not show any signs of PSF failure is probably that the grip of the screws decreased somewhat in the cancellous bone of the vertebrae.

It is interesting that there is relatively more loss of flexion than of vertebral height. This is probably due to fact that an injured disc will collapse when the screw grip in the vertebra decreases somewhat.

The major advantage of this method seems to be that further deformation after device removal can be avoided, but this still has to be evaluated and confirmed.

REFERENCES

1. Acbi, M., Mohler, J., Zäch, G., and Morscher E.: Analysis of 75 operated thoracolumbar fractures and fracture dislocations with and without neurological deficit. Arch. Orthop. Trauma. Surg. 105:100, 1986.
2. Armstrong, G. W. D., and Johnston, D. H.: Stabilization of spinal injuries using Harrington instrumentation. J. Bone Joint Surg. 56B:590, 1974.
3. Bohlman, H. H.: Traumatic fractures of the upper thoracic spine with paralysis. J. Bone Joint Surg. 56A:1299, 1974.
4. Bohlman, H. H., and Eismont, F. J.: Surgical techniques of anterior decompression and fusion for spinal cord injuries. Clin. Orthop. 154:57, 1981.
5. Bradford, D. S., Akbarnia, B. A., Winter, R. B., and Seljeskog, E. L.: Surgical stabilization of fracture dislocation of the thoracic spine. Spine 2:185, 1977.
6. Clark, W. K.: Spinal cord decompression in spinal cord injury. Clin. Orthop. 154:9, 1981.
7. Convery, F. R., Minteer, M. A., Smith, R. W., and Emerson, S. M.: Fracture dislocation of the dorsolumbar spine. Acute operative stabilization by Harrington instrumentation. Spine 3:160, 1978.
8. Daniaux, H.: Teknik und erste Ergebnisse der transpedikulären Spongiosaplastik bei Kompressionsbrüchen im Lendenwirbelsäulenbereich. Acta Chir. Austriaca (Suppl.) 43:79, 1982.
9. Davies, W. E., Morris, J. H., and Hill, V.: An analysis of conservative (non-surgical) management of thoracolumbar fractures and fracture dislocations with neural damage. J. Bone Joint Surg. 62A:1324, 1980.
10. De la Torre, J. C.: Spinal cord injury: Review of basic and applied research. Spine 6:315, 1983.

11. Denis, F.: Spinal instability as defined by three-column spine concept in acute spinal trauma. Clin. Orthop. 189:65, 1984.
12. Denis, F., Armstrong, G. W. D., Searls, K., and Matta, L.: Acute thoracolumbar burst fractures in the absence of neurologic deficit. Clin. Orthop. 189:142, 1984.
13. Dick, W.: Innere Fixation von Brust- und Lendenwirbelfrakturen. Bern, Verlag Hans Huber, 1984.
14. Dick, W.: Use of the acetabular reamer to harvest autogenic bone graft material: A simple method for producing bone paste. Arch. Orthop. Trauma. Surg. 105:235, 1986.
15. Dickson, J. H., Harrington, P. R., and Erwin, W. D.: Results of reduction and stabilization of the severely fractured thoracic and lumbar spine. J. Bone Joint Surg. 60A:799, 1978.
16. Donovan, W. H., and Dwyer, A. P.: An update on the early management of traumatic paraplegia (nonoperative and operative management). Clin. Orthop. 189:12, 1984.
17. Dunn, H. K.: Anterior stabilization of thoracolumbar injuries. Clin. Orthop. 189:116, 1984.
18. Edwards, C. C., Simmons, S., Levine, A. M., Bands, R. E., and Campbell, S. E.: Primary rigid fixation of 135 thoracolumbar injuries: Analysis of results. Orthop. Trans. 9:479, 1985.
19. Erikson, D. L., Leider, L. L., and Brown, W. E.: One-stage decompression-stabilization for thoracolumbar fractures. Spine 2:53, 1977.
20. Frankel, H. L., Hancock, D. O., Hyslop, G., Melzak, J., Michaelis, L. S., Ungar, G. H., Vernon, J. D. S., and Walsh, J. J.: The value of postural reduction in the initial management of closed injuries of the spine with paraplegia and tetraplegia. Paraplegia 7:179, 1969.
21. Harrington, P. R.: Instrumentation in spine instability other than scoliosis. S. Afr. J. Surg. 5:7, 1967.
22. Jacobs, R. R., and Casey, M. P.: Surgical management of thoracolumbar spinal injuries: General principles and controversial considerations. Clin. Orthop. 189:22, 1984.
23. Jacobs, R. R., Nordwall, A., and Nachemson, A.: Reduction, stability, and strength provided by internal fixation systems for thoracolumbar spinal injuries. Clin. Orthop. 171:300, 1982.
24. Jelsma, R. K., Kirsch, P. T., Jelsma, L. F., Ramsey, W. C., and Rice, J. F.: Surgical treatment of thoracolumbar fractures. Surg. Neurol. 18:156, 1982.
25. Jelsma, R. K., Rice, J. F., Jelsma, L. F., and Kirsch, P. T.: The demonstration and significance of neural compression after spinal injury. Surg. Neurol. 18:79, 1982.
26. Johnson, J. R., Leatherman, K. D., and Holt, R. T.: Anterior decompression of the spinal cord for neurological deficit. Spine 8:396, 1983.
27. Kostuik, J. P.: Anterior fixation for fractures of the thoracic and lumbar spine with or without neurological involvement. Clin. Orthop. 189:103, 1984.
28. Lindahl, S., Willén, J., and Irstam, L.: Unstable thoracolumbar fractures: A comparative radiologic study of conservative treatment and Harrington instrumentation. Acta Radiol. [Diagn.] 26:67, 1985.
29. Louis, R.: Surgery of the Spine. Berlin, Springer Verlag, 1983.
30. Magerl, F.: External skeletal fixation of the lower thoracic and the lumbar spine. *In* Uhthoff, H. K. (ed.): Current Concepts of External Fixation of Fractures. Berlin, Springer Verlag, 1982, pp. 353–366.
31. Magerl, F. P.: Stabilization of the lower thoracic and lumbar spine with external skeletal fixation. Clin. Orthop. 189:125, 1984.
32. McAfee, P. C., and Bohlman, H. H.: Complications following Harrington instrumentation for fractures of the thoraco-lumbar spine. J. Bone Joint Surg. 67A:672, 1985.
33. McAfee, P. C., Bohlman, H. H., and Yuan, H. A.: Anterior decompression of traumatic thoraco-lumbar fractures with incomplete neurologic deficit using a retroperitoneal approach. J. Bone Joint Surg. 67A:89, 1985.
34. Morgan, T. H., Wharton, G. W., and Austin, G. N.: The results of laminectomy in patients with incomplete spinal cord injuries. Paraplegia 9:14, 1971.
35. Olerud, S., Karlström, G., and Sjöström, L.: A new principle in the treatment of fractures of the thoracolumbar spine: Transpedicular segmental fixation. Orthopedics (in press).
36. Osebold, W. R., Weinstein, S. L., and Sprague, B. L.: Thoracolumbar spine fractures: Results of treatment. Spine 6:13, 1981.
37. Roy-Camille, R., Saillant, G., Berteaux, D., and Marie-Anne, S.: Early management of spinal injuries. *In* McKibbin, B. (ed.): Recent Advances in Orthopaedics. Edinburgh, Churchill Livingstone, 1979, pp. 57–87.
38. Roy-Camille, R., Saillant, G., Marie-Anne, S., and Mamoudy, P.: Behandlung von Wirbelfrakturen und Luxationen am thorakolumbalen Übergang. Orthopäde 9:63, 1980.
39. Soreff, J., Axderph, G., Bylund, P., Odéen, I., and Olerud, S.: Treatment of patients with unstable fractures of the thoracic and lumbar spine. Acta Orthop. Scand. 53:369, 1982.
40. Svensson, A., Aaro, S., and Öhlén, G.: Harrington instrumentation for thoracic and lumbar vertebral fractures. Acta Orthop. Scand. 55:38, 1984.
41. Wenger, D. R., and Carollo, J. J.: The mechanics of thoracolumbar fractures stabilized by segmental fixation. Clin. Orthop. 189:89, 1984.
42. White, A. A. III, and Panjabi, M.: Clinical Biomechanics of the Spine. Philadelphia, J. B. Lippincott, 1978, pp. 223–224.
43. White, R. R., Newberg, A., and Seligson, D.: Computerized tomographic assessment of the traumatized dorsolumbar spine before and after Harrington instrumentation. Clin. Orthop. 146:150, 1980.
44. Willén, J., Lindahl, S., Irstam, L., and Nordwall, A.: Unstable thoracolumbar fractures: A study by CT and conventional roentgenology of the reduction effect of Harrington instrumentation. Spine 9:214, 1984.
45. Yosipovitch, Z., Robin, G. C., and Makin, M.: Open reduction of unstable thoracolumbar spinal injuries and fixation with Harrington rods. J. Bone Joint Surg. 59A:1003, 1977.

B

Edeland predates the effective filing date of the '404 and '888 Patents

Acta orthop. scand. 47, 686–689, 1976

OPEN REDUCTION OF CENTRAL COMPRESSION FRACTURES OF THE TIBIAL PLATEAU

Preliminary Report of a New Method and Device Arrangement

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Edeland discloses the "forming the passage" and "compacting" steps in Claims 1, 8-10 of the '404 Patent (See also text, p. 687 and Fig. 3, p. 688)

A new method of reduction and fixation of a uniformly depressed fracture of the tibial condyle is described. A curved steel probe, introduced through a cortical window in the uninjured condyle, is used to reduce the fracture fragments as well as to compact the fracture region (TV-monitored x-ray projectioning is desired). The instruments needed for the operative procedure are as follows: a probe for reduction and compaction, a tube and a plunger for deposition of bone transplants, and a forked plate. Five cases in which the curved probe reduction method has been used are reported.

Key words: ceramic material; fixation; fractures; tibial condylar fractures

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A fracture of one of the condyles of the tibia is not an uncommon injury, more often occurring laterally than medially, and mostly in the elderly osteoporotic patient (Rasmussen 1973). The uniformly depressed central condylar fracture with an intact cortical rim (Hohl Type I B) represents 26 per cent of the entire tibial condylar fracture group (Hohl 1967). Several of these fractures will benefit from the method of treatment outlined below.

Edeland discloses the "osteoporotic" limitation in the '888 Patent

In a forced valgus position of the knee, the lateral femoral condyle is wedged down upon the corresponding tibial condyle. In this way, the femoral condyle depresses and compresses the central parts of the tibial plateau thus fracturing the surface in a mosaic-like manner but often sparing the outer border of the condyle and the meniscus (Kennedy et al. 1968). (Figure 1.)

As stressed by several authors (Hohl 1967, Maquet et al. 1967, Rasmussen 1973), the fracture deformity produced by a central fracture of one of the tibial condyles, can only be tolerated for a short time, and it can only, to a limited extent, be compensated biomechanically by fibrous callus.

PATIENTS

Five patients have been operated on according to the method outlined below. In four patients the lateral condyle was fractured, in the fifth the medial condyle. In all cases the central compressions amounted to or exceeded one cm and the knee was unstable in the extended position. Three patients were women, two men. All patients were more than 55 years old. In

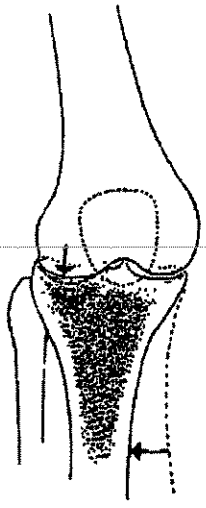


Figure 1. Forced valgus position of the knee, causing a central depression of the lateral tibial plateau.

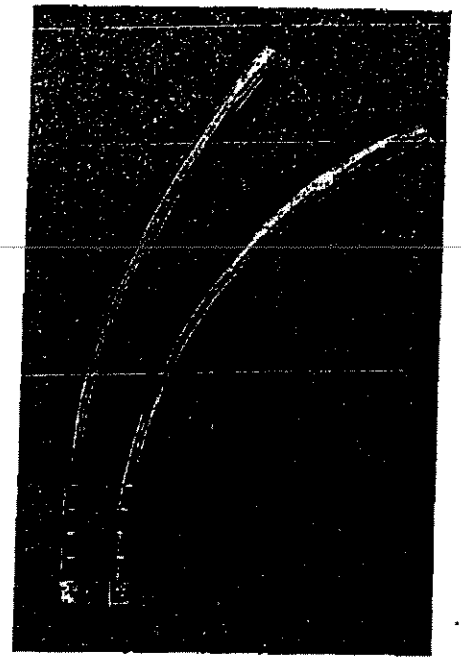


Figure 2. Two probes, with different curvatures.

one patient the fracture region was stabilized by two loops of wire, from the lateral to the medial side of the tibial condyle. Autologous bone transplantation was performed in two patients.

METHODS

The aim of the method described below is to re-establish in a simple way the all-important support of the femoral condyle and consequently the stability of the knee joint. This will prevent an otherwise unavoidable joint insufficiency due to increased load, with the forces converging on limited parts of the tibial condyle, resulting in gradually increasing strains on the ligaments.

The method requires a curved steel probe which has a diameter of 1.0–1.5 cm, a length of 20 cm, and a radius of the curve of approximately 25 cm. The "reduction end" of the probe is slightly concave. The instrument, with various curvatures, is illustrated in Figure 2.

The probe is introduced into the bone via a fenestration in the subcondylar cortex of the unfractured side of the tibial head, so that the probe will not affect the supporting cortical parts of the fractured condyle. The concave "reduction end" of the probe is placed in position beneath the compressed parts of the condyle, under TV-monitored x-ray control. The compressed fracture region is reduced by repeated careful pushes of the probe (Figure 3). On its way, the probe transfers and compacts considerable amounts of cancellous bone from the region beneath the depression. The curvature of the probe permits some "swing" and this makes some minor adjustments of the reduction possible and also compacts and forms transverse bone bridges immediately beneath the fracture parts. This stabilizes the reduced fracture parts. The reduction may, if necessary, be further stabilized by several methods of internal fixation, e.g., by a wire technique, described by Gottfries et al. (1971), or by a plate device especially designed for this purpose (Figure 4). Only a short skin incision is needed for the reduction procedure. The surgery should be performed with the fractured leg slightly extended. The pre-operative set-up is illustrated in Figure 5. A full-length circular knee-cast should be used for 4 to 6 weeks post-operatively in order to keep the fractured knee joint compartment protected.

Edeland discloses the "forming the passage" step in Claims 1, 8-10 of the '404 Patent (See also Abstract, p. 686)

Edeland discloses the "compacting" step in Claims 1 and 3 of the '404 Patent (See also Fig. 3, p. 688)

Edeland discloses the "compacting" step in Claims 1 and 3 of the '404 Patent
(See also text, p. 687)

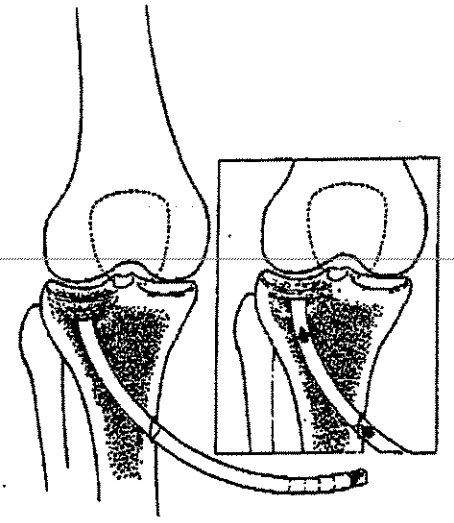


Figure 3. Principle of the fracture reduction and compaction procedure with a curved probe.

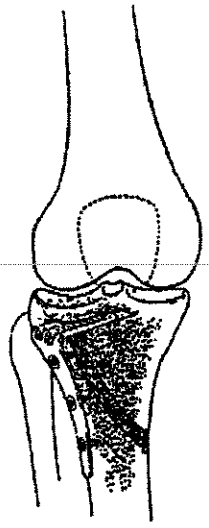


Figure 4. Outline of the support plate, applied to a reduced condylar fracture region, with bone grafts and/or ceramic material filling the bone defects.

RESULTS

All patients were followed up for at least six months, three for more than a year. A satisfactory joint function with an active flexion capacity of up to 90 degrees and with full or almost full extension capacity was noted in all cases.

A post-operative depression of 5 to 10 mm of the reduced area occurred in one case. This re-dislocation occurred within the first two months after surgery. Due to subjectively incapacitating valgus instability of the knee, this patient uses a walking stick and a short knee brace.

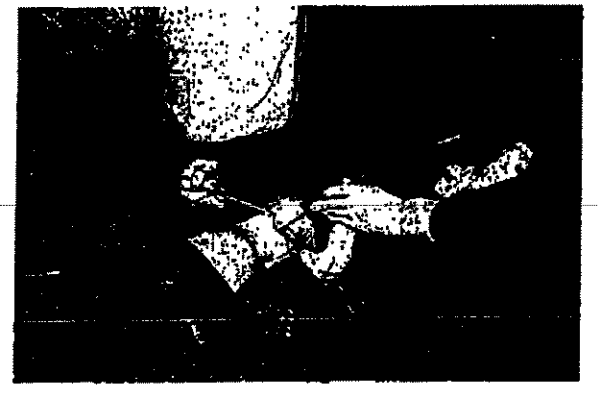


Figure 5. The per-operative set-up, with the C-bow x-ray apparatus in position for an A-P central beam projection of the knee joint space. This necessitates a free-hanging extremity, which should be slightly extended. Note that the probe is put into the slide of metaphysis contralateral to the fractured condyle.

Edeland discloses the "filling the passage" step in Claims 1 and 15 of the '404 Patent

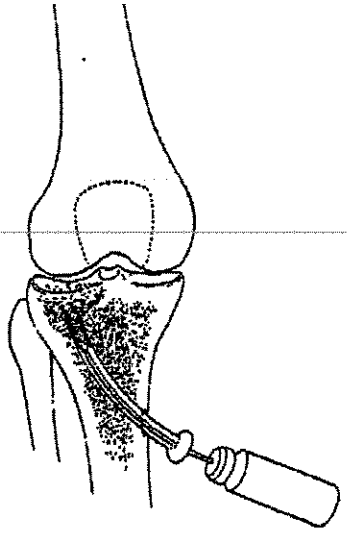


Figure 6. Principle of the use of the bone graft and/or ceramic "loaded" tube-and-plunger instrument set-up.

All patients had sagittal stability. Two patients (one mentioned above) had some valgus instability. All patients were able to use stairs. No-one was troubled by night pains. One patient had permanent joint swelling. There have been no infections or serious general complications, such as venous thrombosis or pulmonary embolism.

DISCUSSION

The method described is probably only suitable for the treatment of uniformly depressed central condylar fractures. The alternative to the selected method would have implied a wider approach to the fracture area. This would have decreased the support of the fracture region even if bone grafts had been used. This standard method usually includes visual control of the reduction through an arthrotomy. Meniscectomy would probably have been performed in order to facilitate the reduction of the fracture fragments, even if the meniscus was not ruptured primarily. It is suggested that by using the above method, arthrotomy, bone grafting, and meniscectomy could be avoided.

Instead of bone grafts to compensate for the bone defects, porous ceramic material could be used as suggested by Benum et al. (1976) and Cameron et al. (1976). The ceramic material (e.g. tricalcium phosphate) could be introduced into the bone defect region by the use of a cylinder-and-piston type of instrument arrangement, as shown in Figure 6.

ACKNOWLEDGEMENT

The drawings were made by Fredrik Johansson, Göteborg, Sweden.

REFERENCES

Benum, P., Lyng, Bø O., Hafn, I. & Haffner, J. D. W. (1976) Porous ceramics as a bone substitute in the medial condyle of the tibia. *Acta orthop. scand.* 47, 158–166.

Cameron, H. U., McNab, I. & Pilliar, R. M. (1976) Evaluation of a bio-degradable ceramic. Abstract, Program, 1976 Meeting, *American Society of Biomaterials*, p. 82.

Gotfries, A., Hagert, C.-G. & Sörensen, S. E. (1971) T- and Y-fractures of the tibial condyle. A follow-up study of cases treated by closed reduction and surgical fixation with a wire loop. *Injury* 3,1, 56–62.

Hohl, M. (1967) Tibial condylar fractures. *J. Bone Jt Surg.* 49-A, 1455–1467.

Kennedy, J. C. & Bailey, W. H. (1968) Experimental tibial-plateau fractures. Studies of the mechanism and a classification. *J. Bone Jt Surg.* 50-A, 1522–1534.

Maquet, P., Simonet, J. & de Marchin, P. (1967) Biomécanique du genou et gonarthrose. *Rev. Chir. orthop.* 53, 117–138.

Rasmussen, P. S. (1973) Tibial condylar fractures. Impairment of knee joint stability as an indication for surgical treatment. *J. Bone Jt Surg.* 55-A, 1331–1350.

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Fractures of the Tibial Condyles

A Preliminary Report on Supplementary Fixation With Methylmethacrylate

WILLIAM R. KENNEDY, M.D.*

Severely displaced fractures of the tibial condyles present a difficult problem in management. Surgical reconstruction of a significantly disrupted joint surface has been advocated by many authors,[4,6-12] however the technical problems associated with open reduction and internal fixation have frequently led to poor reductions, loss of fixation, and in turn, disappointing postoperative results.

A significantly depressed tibial condylar fracture in the osteoporotic elderly patient provides a most difficult problem for which many techniques have been developed. Bolts, screws, plates, tibial, iliac and patellar bone grafts plus combinations of the preceding have all been described in the literature and used with varying degrees of success. Since 1973 we have used methylmethacrylate in conjunction with metallic devices to treat these fractures. The following is the report based on 7 cases with follow-up ranging from 20 to 51 months.

CLASSIFICATION

For this review the modified classification system of Apley[1] described by Roberts[10] was used to classify which type of tibial condyle fractures were suitable for this method of treatment. All of the cases in this report were Type III displaced fractures, however a Type II fracture with significant displacement and instability would be an excellent candidate for this method of fixation if open reduction was elected to be used. Also, all of the cases in this report were lateral condyle fractures (Fig. 1).

MATERIALS AND METHODS

Surgical repair of the fracture was carried out under general anesthesia within 4 days of the date of injury. None of the cases were operated on as an emergency procedure. The routine was to follow admission with a medical evaluation and surgery to be performed on the second day of hospitalization. Upon admission to the hospital, the leg was placed in a splint, which was removed only for frequent Betadine® scrubs. Preoperative and postoperative antibiotics were given routinely.

The proximal tibia at the fracture site was exposed by a long lateral incision as described by Barr.[2] The capsule was incised 1 cm lateral to the patella and the joint was inspected. Removal of the lateral meniscus was usually necessary in order to provide maximal exposure of the joint surface. The capsular incision was continued distally over the lateral tibial condyle to the insertion of the iliotibial band. In 2 cases, the iliotibial band had avulsed a fragment of bone from the site of its attachment into the tibia.

Using a periosteal elevator the proximal origin of the anterior tibial muscle was elevated from the tibia hinging it on its posterior attachments. Care was taken to protect the anterior tibial artery and deep peroneal nerve as they pass under

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Kennedy has the same disclosure as Edeland, except methylmethacrylate bone cement fills the void instead of ceramic tri-calcium phosphate

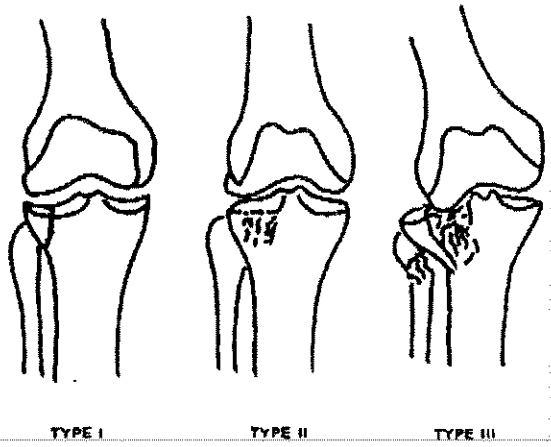


FIG. 1. The tibial plateau fracture classification of A. G. Apley modified by J. M. Roberts[10] is shown. Type I, nondisplaced. Type II, local compression of the lateral tibial plateau. Type III, displaced fracture of the tibial condyle with instability of the knee.



FIG. 2. The depression of the lateral tibial condyle is shown with an intact peripheral shell of tibial cortex.

the cover of the anterior tibial muscle. The bone exposed on the anterior tibia provided a site in which to fashion a window through which the depressed segments of the joint surface could be visualized and manipulated.

Through the window in the tibia, a blunt instrument could be inserted and used to push up the depressed bone fragments. By visualizing the interior of the joint through the capsular incision anatomical reduction was carried out. However, once the articular fragments had been put into their proper place an obvious cavity was present in the subarticular bone. The crushed cancellous bone beneath the articular surface usually left a space which we elected to fill with methylmethacrylate rather than a bone graft.

In the Type III fractures, a transverse fixation device was usually necessary. We used an ASIF cancellous screw in 6 cases but a bolt or other device could also be used. The surgeon must be aware that the methylmethacrylate filling the cavity has little strength in holding the split fragments together and its purpose is to maintain the articular fragments in their elevated position, thus providing support for the compressed articular surface. At the time of surgery, the methylmethacrylate filling the cavity beneath the articular surface provided some stability to the "split" or peripheral fragments, however lateral–medial fixation must also be used if early motion is to be instituted.

Once the methylmethacrylate had hardened the joint was then flexed and extended. At the time of surgery all of the repairs were felt to be stable enough to allow motion postoperatively and it was not necessary to cast any of our cases postoperatively until 90° of flexion had been achieved. The anterior tibial muscle was reattached anteriorly to its previous position covering the window in the tibia now filled with methylmethacrylate. Hemovac® tubes were usually inserted into the joint prior to closure and the leg was placed in a Jones compression bandage. Roentgenograms were taken in the surgical suite (Figs. 2–4).

POSTOPERATIVE CARE

After 48 hours the Hemovac® tubes were removed and on the third day following surgery the Jones bandage was removed. The leg was then carefully placed in a Thomas splint with a Pearson foot attachment. By means of pulleys and hand controls passive range of motion exercises were begun with the assistance of a registered physical therapist. When 90° of passive flexion had been accomplished with consistency

the leg was placed in a cylinder cast with the knee flexed 30°. A nonweight bearing gait was taught and the patient was allowed to ambulate.

RESULTS

The criteria used by Roberts[19] was adopted to rate our results. An acceptable result showed 90° of flexion from full extension, good strength and endurance for the patient's age, a normal gait pattern, good ligamentous stability and no more than mild intermittent symptoms after unusual exertion. If any one of these criteria was not fulfilled the result was rated not acceptable. Results were based only on the clinical evaluation (Table 1).

Six of our 7 cases achieved an acceptable result with a minimum follow-up of 21 months. Our one unacceptable result was a 71-year-old housewife who suffered 2 severe complications which compromised her result. Four days postoperatively she developed an acute anterior myocardial infarction. However, 26 days postoperatively she had gained a range of motion measuring 0–100°. She still did not fulfill our criteria for an acceptable result since strength was lacking. Three months after surgery she fell entering her mobile home and reinjured her knee necessitating another surgical procedure. This subsequent injury was not a result of failure of the methylmethacrylate.

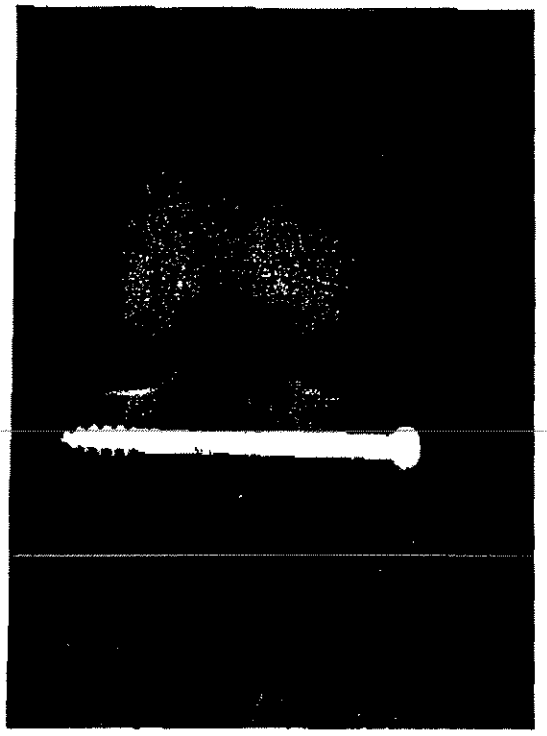


FIG. 3. Surgical elevation of the lateral tibial condyle has been secured with a screw. However, a residual space remains to be filled beneath the elevated condyle.

We have not noted any specific effects of the methylmethacrylate on the bone or joint surfaces. There has been no roentgenological evidence of necrosis of the articular sur-

TABLE 1.

Patient	*Age/Sex*	*Date of Injury*	*Postop Range of Motion*	*Complications*	*Rating*
E.H.*	49/F	5/20/73	0–130°	Myocardial infarction refracture lateral tibial condyle	Not Acceptable
G.M.	74/F	5/19/74	0–130°		Acceptable
E.M.*	74/F	10/17/74	5–100°		Acceptable
M.H.	20/F	10/24/74	0–130°		Acceptable
M.G.	90/M	12/ 9/74	0–130°		Acceptable
H.M.	70/F	5/29/75	5–120°		Acceptable
J.B.**	63/F	12/11/75	0–90°		Acceptable

* Case of Charles E. Boring, M.D.

** Case of Alfred P. Seminario, M.D.

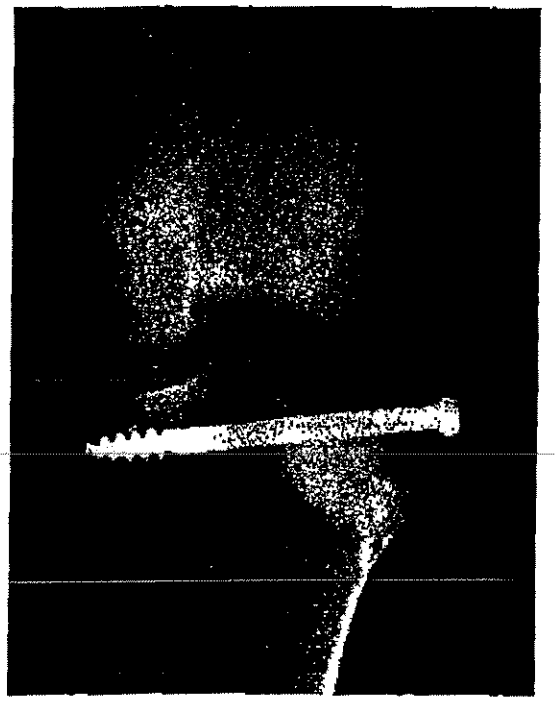


FIG. 4. The void is now filled with methylmethacrylate.

face bone in the repaired tibia nor has there been any specific sign of bone resorption. These findings were also noted by Harrington[3] in his study of intertrochanteric hip fractures using methylmethacrylate as an adjunct to fixation.

DISCUSSION

In the elderly a valgus producing force directed at the knee frequently produces a lateral tibial condyle fracture. The extent of damage to the joint surface is frequently more extensive than can be appreciated on the roentgenograms. In the Type III fractures, the significant displacement of the articular surface if left to heal in its displaced position can leave the knee joint unstable. The 7 such cases presented in this series were treated with open reduction and internal fixation using methylmethacrylate in conjunction with metallic devices.

Many authors have emphasized the importance of early mobilization of the knee joint following this injury.[1,4,5,7] In our experience open reduction with internal fixation has frequently yielded an excellent reduction of the fracture. However, the rigidity of the fixation may not be sufficient to allow the joint to be actively or even passively exercised in the immediate postoperative period. Furthermore, once mobilization of the knee was instituted the reduction obtained at surgery has been on occasion lost because of the fragility of the shell of the proximal tibial cortex.

In 1967, Dr. William Cassebaum and I recognized this problem and sought to improve the fixation then used for tibial condyle fractures by the addition of methylmethacrylate. Only cadaver surgery was performed at that time. Since then further experience with the use of methylmethacrylate in treating Type III tibial condylar fractures has confirmed the usefulness of the method.

SUMMARY

In severely displaced fractures of the tibial condyles, failure of the method of fixation may lead to disappointing results of open reduction operations. This problem may be successfully and safely treated by using methylmethacrylate (MMC) for internal fixation. In this series 6 of 7 cases achieved an acceptable result of fixation with MMC. This compares favorably to published series of fractures of this type treated by open reduction.

REFERENCES

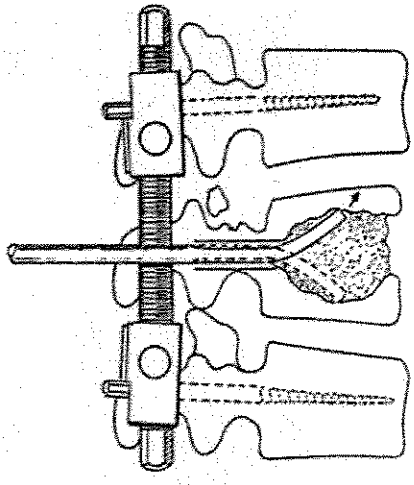
1. Apley, A. G.: Fractures of the lateral tibial condyle treated by skeletal traction and early mobilization. A review of sixty cases with special references to the long-term results, J. Bone Joint Surg. 38B:699, 1956.
2. Barr, J. S.: The treatment of fracture of the external tibial condyle (bumper fracture), JAMA 115:1683, 1940.
3. Harrington, K. D. : The use of methylmethacry-

late as an adjunct in the internal fixation of unstable comminuted intercrochanteric fractures in osteoporotic patients, J. Bone Joint Surg. 57A:744, 1975.

4. Hohl, M. and Luck, J. V.: Fracture of the tibial condyle,a clinical and experimental study, J. Bone Joint Surg. 38A:1001, 1956.
5. Hohl, M.: Tibial condylar fractures, J. Bone Joint Surg. 49A:1455, 1967.
6. Ledbetter, G. W. and Hand, F. M.: Fractures of the tibial plateau, J. Bone Joint Surg. 22:559, 1940.
7. Neal, E. G.: General principles in the management of the joints, Surg. Clin. North Am. 41:1607, 1961.
8. Palmer, I.: Compression fractures of the lateral tibial condyles and their treatment, J. Bone Joint Surg. 21:674, 1939.
9. ———: Fractures of the upper end of the tibia, J. Bone Joint Surg. 33B:160, 1951.
10. Roberts, J. M.: Fractures of the condyles of the tibia, J. Bone Joint Surg. 50A:1505, 1968.
11. Rombold, C. : Depressed fractures of the tibial plateau. Treatment with rigid internal fixation and early mobilization. A preliminary report, J. Bone Joint Surg. 42A:783, 1960.
12. Von Bahr, V.: Depressed and comminuted fractures of the lateral tibial tuberosity, Acta Chir. Scand. 92:139, 1945.

D

Claim of the '404 Patent	Anticipation by Olerud
1. A method of fixation of a fracture or impending fracture of a bone having bone marrow therein comprising:	As shown in Tab A hereto, Olerud discloses a procedure called "Transpedicular Fixation of Thoracolumbar Vertebral Fractures." The vertebral body contains both bone marrow and cancellous bone.
forming a passage in the bone marrow;	As shown in Tab A hereto, Olerud discloses that a slightly curved punch is brought through the pedicle into the vertebral body under fluoroscopic control, thereby forming a passage in the cancellous bone. (Fig. 3 and text, p. 47.) Olerud also discloses that "a hole can be made with a 5-mm drill through one of the pedicles of the fractured vertebrae into the vertebral body," thereby forming a passage in the cancellous bone. (Tab A, p. 47.)

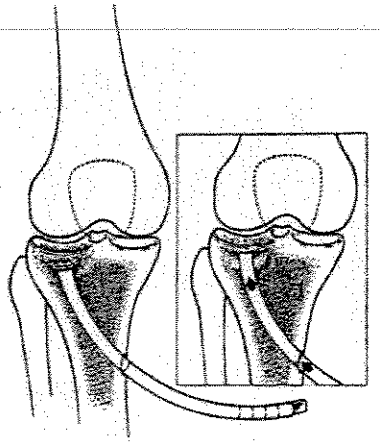
Claim of the '404 Patent	Anticipation by Olerud
compacting the bone marrow to increase the volume of said passage; and	As shown in Tab A hereto, Olerud discloses that a slightly curved punch is brought through the pedicle into the vertebral body in order to reduce fragments of the vertebral body, and further reduce the end plates and anterior wall of the vertebra. (Fig. 3 and text, p. 47.) Olerud discloses that defects (i.e. cavities) can be created by use of a transpedicularly introduced punch. Id. Fig. 3 depicts a single push of the punch that is repeated in different areas of the bone; Olerud discloses that the punch is moved in various directions, from the center to the outer portion of the bone, both upwards and downwards. (Id.; see also Exhibit E, Mitchell Decl. at ¶¶ 20-21.)  FIG. 3. With a transpedicularly introduced punch, further reduction of fragments in the vertebral body can be reduced. The defect in the vertebra is then filled with a graft in the form of bone paste.[2,13] The repeated movement of the punch in various directions compacts the cancellous bone on its way to, and in the process of, elevating the fracture, thereby increasing the volume of the passage. (See also Exhibit E, Mitchell Decl. at ¶¶ 20-21.)
filling the passage with a flowable material capable of setting to a hardened condition.	As shown in Tab A hereto, Olerud discloses that cancellous bone graft, described as "bone paste," is pressed into the defect (i.e. cavity) of the vertebra, thereby filling the passage with flowable material capable of setting to a hardened condition. (Fig. 3 and text, p. 47; see also Exhibit E, Mitchell Decl. at ¶ 18.)

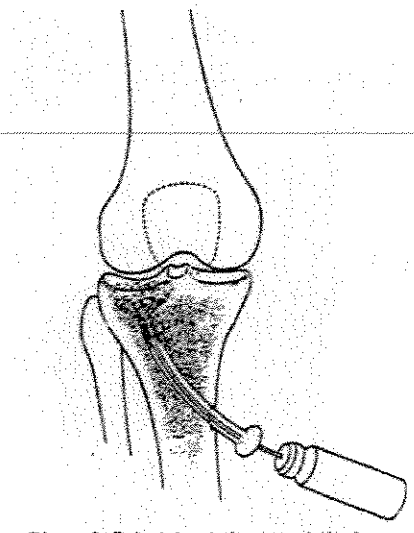
Claim of the '404 Patent	Anticipation by Olerud
3. A method as set forth in claim 1, wherein said compacting step includes forcing the bone marrow outwardly of the central portion of the bone.	See above at claim 1. As shown in Figure 3 of Tab A hereto, in Olerud, the transpedicularly introduced punch is moved in various directions, from the center to the outer portion of the bone, both upwards and downwards to reduce the vertebral fracture. (p. 47.) Fig. 3 depicts a single push of the punch; the repeated movement of the punch in various directions compacts the cancellous bone and creates cavities (i.e. increased passage volume) in the vertebral fracture, thereby forcing the cancellous bone outwardly of the central portion of the bone. (Tab A, Fig. 3 and text, p. 47; see also Exhibit E, Mitchell Decl. at ¶¶ 20-21.)
8. A method as set forth in claim 1, wherein said forming step includes drilling said bone marrow to form said passage.	See above at claim 1. As shown in Tab A hereto, Olerud discloses that "a hole can be made with a 5-mm drill through one of the pedicles of the fractured vertebrae into the vertebral body," thereby drilling through the cortical bone to form a passage in cancellous bone. (p. 47; see also Exhibit E, Mitchell Decl. at ¶¶ 6-7.)
9. A method as set forth in claim 8, wherein said drilling step includes guiding a drill through and into the proximate cortical bone marrow.	See above at claim 8. As shown in Tab A hereto, Olerud discloses that "a hole can be made with a 5-mm drill through one of the pedicles of the fractured vertebrae into the vertebral body." (p. 47) Olerud further discloses that a slightly curved punch is brought through the pedicle into the vertebral body under fluoroscopic control. Id. Olerud teaches guiding the 5-mm drill through the cortical bone and into the cancellous bone so that the punch can be positioned. (See also Exhibit E, Mitchell Decl. at ¶¶ 6-7.)

Claim of the '404 Patent	Anticipation by Olerud
10. A method as set forth in claim 8, wherein said forming step includes drilling the bone marrow to a predetermined depth.	See above at claim 8. As shown in Tab A hereto, Olerud discloses that "a hole can be made with a 5-mm drill through one of the pedicles of the fractured vertebrae into the vertebral body." (p. 47) Olerud further discloses that a slightly curved punch is brought through the pedicle into the vertebral body under fluoroscopic control. Id. Olerud teaches drilling through the cortical bone and into the cancellous bone to a predetermined depth so that the punch can be positioned. (See also Exhibit E, Mitchell Decl. at ¶¶ 6-7.)
12. A method as set forth in claim 1, wherein the fracture is a fracture of a vertebral body of the human spine.	See above at claim 1. As shown in Tab A hereto, Olerud discloses a procedure called "Transpedicular Fixation of Thoracolumbar Vertebral Fractures."
15. A method as set forth in claim 1, wherein said flowable material is selected from the group consisting of liquid synthetic bone and methyl methacrylate cement.	

E

Claim of the '404 Patent	Anticipation by Edeland
1. A method of fixation of a fracture or impending fracture of a bone having bone marrow therein comprising:	As shown in Tab B hereto, Edeland discloses a method of reduction and fixation of a fracture of the tibia, a bone that contains bone marrow and cancellous bone. (Abstract, p. 686.) Edeland refers to the "principle of the fracture reduction and compaction procedure with a curved probe." (See Tab B, Fig. 3, p. 688.)
forming a passage in the bone marrow;	As shown in Tab B hereto, Edeland discloses introducing a curved steel probe into the tibia bone via fenestration (i.e. an opening), thereby forming a passage in cancellous bone. (p. 687.) Edeland further discloses: "[t]he concave 'reduction end' of the probe is placed in position beneath the compressed parts of the condyle, under TV-monitored x-ray control." Id.

Claim of the '404 Patent	Anticipation by Edeland
compacting the bone marrow to increase the volume of said passage; and	As shown in Tab B hereto, Edeland discloses reduction of the compressed fracture site by "repeated careful pushes of the probe." (p. 687 and Fig. 3, p. 688.) "On its way, the probe transfers and compacts considerable amounts of cancellous bone from the region beneath the depression." Id. Figure 3 depicts a single push of the probe; this "push" is repeatedly performed, from the center to the outer portion of the bone, during the disclosed procedure in different areas of the bone.  *Figure 3. Principle of the fracture reduction and compaction procedure with a curved probe.* Each of the "repeated careful pushes of the probe" compacts the cancellous bone on the probe's way to, and in the process of, reducing the fracture, thereby increasing the volume of the passage. (See also Exhibit E, Mitchell Decl. at ¶¶ 4, 8.)

Claim of the '404 Patent	Anticipation by Edeland
filling the passage with a flowable material capable of setting to a hardened condition.	As shown in Tab B hereto, Edeland discloses that bone graft or ceramic material such as tri-calcium phosphate can be introduced via a tube-and-plunger instrument into the void, thereby filling the passage with a flowable material capable of setting to a hardened condition. (Text and Fig.6, p. 689; see also Exhibit E, Mitchell Decl. at ¶ 12.)  *Figure 6. Principle of the use of the bone graft and/or ceramic "loaded" tube-and-plunger instrument set-up.*
3. A method as set forth in claim 1, wherein said compacting step includes forcing the bone marrow outwardly of the central portion of the bone.	See above at claim 1. As shown in Tab B hereto, in Edeland, "repeated careful pushes" of the probe "transfers and compacts considerable amounts of cancellous bone from the region beneath the depression," thereby forcing the cancellous bone outwardly of the central portion of the bone. (p. 687) Figure 3 depicts a single push of the probe; this "push" is repeatedly performed from the center to the outer portion of the bone during the disclosed procedure in different areas of the bone. (See also Exhibit E, Mitchell Decl. at ¶¶ 4, 8.)
8. A method as set forth in claim 1, wherein said forming step includes drilling said bone marrow to form said passage.	See above at claim 1. As shown in Tab B hereto, Edeland discloses introducing a curved steel probe into the tibia bone via fenestration (i.e. an opening); fenestration involves drilling through the cortical bone to form a passage in cancellous bone. (p. 687; see also Exhibit E, Mitchell Decl. at ¶¶ 6-7.)

Claim of the '404 Patent	Anticipation by Edeland
9. A method as set forth in claim 8, wherein said drilling step includes guiding a drill through and into the proximate cortical bone marrow.	See above at claim 8. As shown in Tab B hereto, Edeland discloses introducing a curved steel probe into the tibia bone via fenestration (i.e. an opening); fenestration involves drilling through the cortical bone to form a passage in cancellous bone. (p. 687; see also Exhibit E, Mitchell Decl. at ¶¶ 6-7.) Edeland further discloses the use of TV-monitored x-ray projectioning and specific positioning of the probe: "[t]he concave 'reduction end' of the probe is placed in position beneath the compressed parts of the condyle, under TV-monitored x-ray control." (See Tab B, Abstract, p. 686-687.) Edeland discloses guiding a drill through the cortical bone and into cancellous bone so that the probe can be specifically positioned. (See also Exhibit E, Mitchell Decl. at ¶¶ 6-7.)
10. A method as set forth in claim 8, wherein said forming step includes drilling the bone marrow to a predetermined depth.	See above at claim 8. As shown in Tab B hereto, Edeland discloses introducing a curved steel probe into the tibia bone via fenestration (i.e. an opening); fenestration involves drilling through the cortical bone to form a passage in cancellous bone. (p. 687; see also Exhibit E, Mitchell Decl. at ¶¶ 6-7.) Edeland further discloses the use of TV-monitored x-ray projectioning and specific positioning of the probe: "[t]he concave 'reduction end' of the probe is placed in position beneath the compressed parts of the condyle, under TV-monitored x-ray control." (See Tab B, Abstract, pp. 686-687.) Edeland discloses drilling through the cortical bone to form a passage in cancellous bone to a predetermined depth so that the probe can be specifically positioned. (See also Exhibit E, Mitchell Decl. at ¶¶ 6-7.)
12. A method as set forth in claim 1, wherein the fracture is a fracture of a vertebral body of the human spine.	

Claim of the '404 Patent	Anticipation by Edeland
15. A method as set forth in claim 1, wherein said flowable material is selected from the group consisting of liquid synthetic bone and methyl methacrylate cement.	See above at claim 1. As shown in Tab B hereto, Edeland discloses that ceramic material such as tri-calcium phosphate can be introduced via a tube-and-plunger instrument into the void, thereby filling the passage with a flowable material capable of setting to a hardened condition. (Text and Fig. 6, p. 689; see also Exhibit E, Mitchell Decl. at ¶ 12.)

CERTIFICATE OF SERVICE

I, Maryellen Noreika, hereby certify that copies of the foregoing were caused to be served this 13h day of April, 2005 upon the following in the manner indicated:

BY HAND DELIVERY

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