Edeland Discloses the "Filling the Passage" Step of Claim 1



- Dr. Mitchell filled void created by conventional bone tamp with ceramic calcium phosphate compound (flowable slurry) (Mitchell Decl., ¶ 9).

- Dr. Mitchell could have opted to fill void created by conventional bone tamp with methyl methacrylate bone cement. (Mitchell Decl., ¶ 9).

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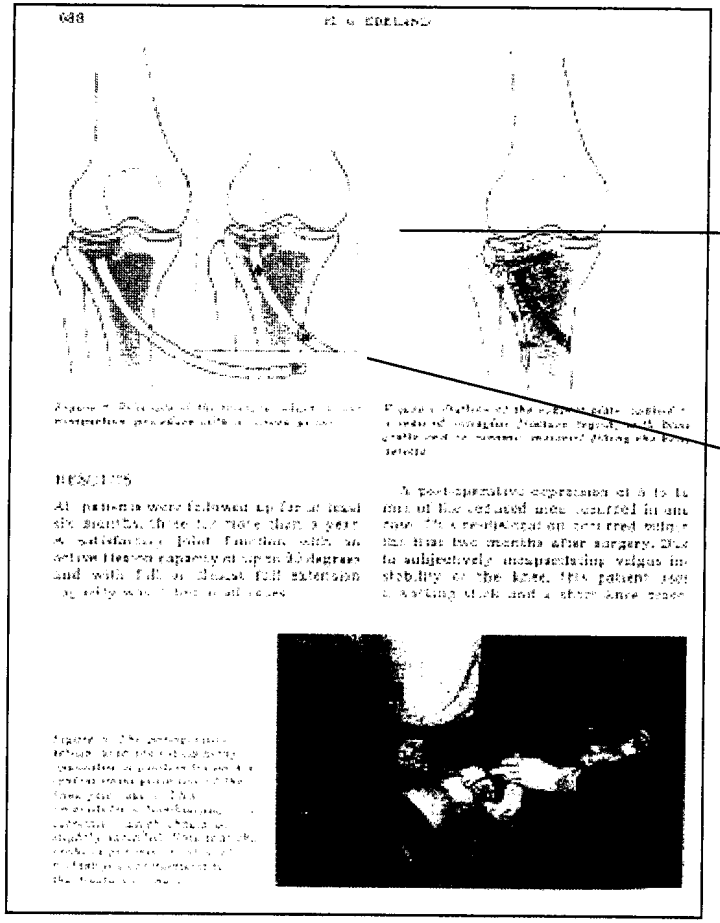
Edeland Discloses the Claim 3 Limitation: "compacting step includes forcing the bone marrow outwardly of the central portion of the bone"



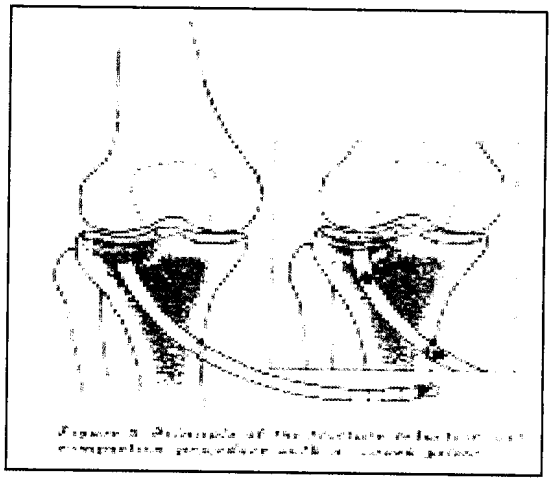


Fig. 3 provides a snapshot of a push of probe that is repeated in different areas of the bone, from the center to the outer portion of bone.

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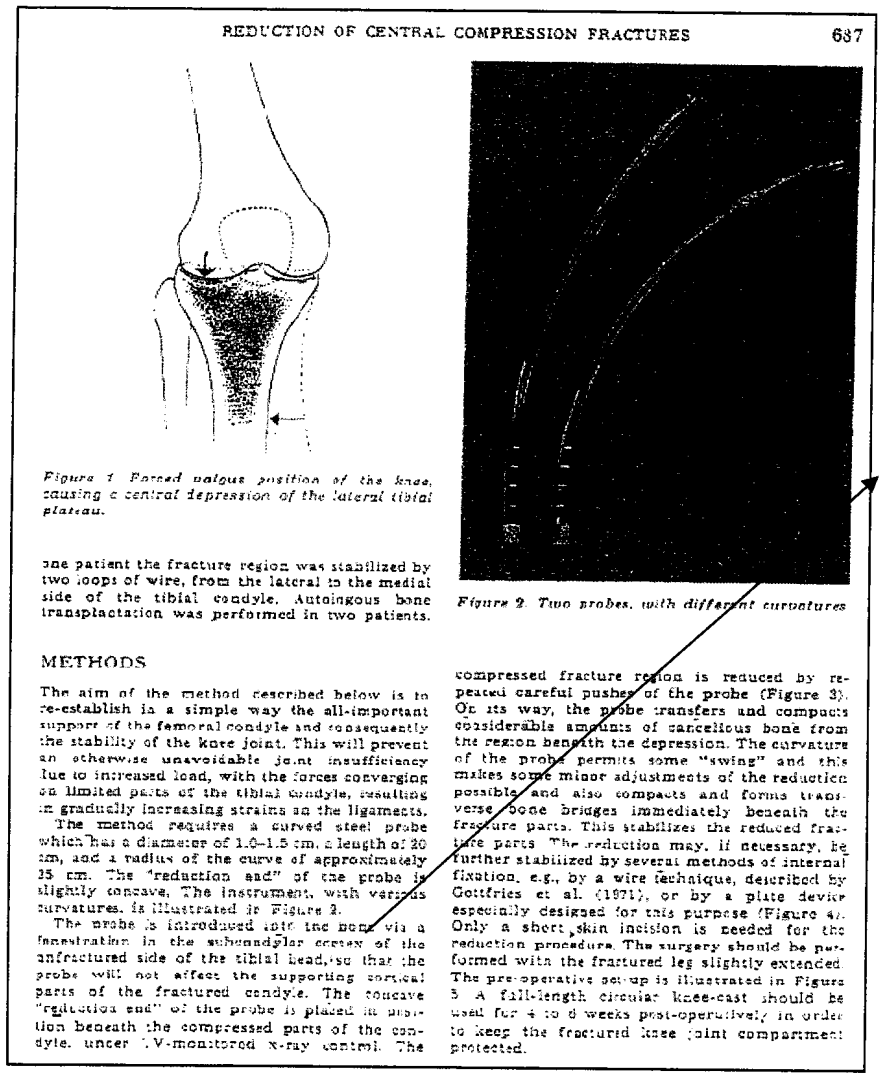
Edeland Discloses the Drilling Limitations of Claims 8, 9 and 10 (drilling into bone marrow, under guidance, to a predetermined depth)



REDUCTION OF CENTRAL COMPRESSION FRACTURES 687

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 35 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 subchondylar 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.

"The probe is introduced into the bone via a fenestration . . . . The concave "reduction end" of the probe is placed in position beneath the compressed parts of the condyle, under TV-monitored x-ray control."

Fenestration involves drilling through the cortical bone to create an opening, hole or perforation in the bone marrow; the drill goes through and into the bone marrow. (See Mitchell Decl., ¶¶ 6, 24.)

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Obviousness

- Knowledge of a reference in the same field is presumed (In re Dance, 160 F.3d 1339, 1343 (Fed. Cir. 1998))
- What else can we use to fill the void that is flowable and capable of setting to a hardened condition?
  - Edeland plus Kennedy (1978) (same procedure as Edeland, using methylmethacrylate)
  - Edeland plus Brown and Chow (1983 filing date; calcium phosphate hardening material)
  - Olerud plus Kennedy
  - Olerud plus Brown and Chow
- Secondary considerations – praise was for the balloon.
  - DOT is not arguing that balloon aspect was obvious
  - Kyphon can't have it both ways; claims are limited to balloon;
    - if not, they are anticipated and rendered obvious by the prior art

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CLAIM CONSTRUCTION &

NON-INFRINGEMENT -

BONE FILLER PATENTS
('734 and '054)

PRESENTATION ON BEHALF OF DISC-O-TECH MEDICAL TECHNOLOGIES, LTD. and DISC ORTHOPAEDIC TECHNOLOGIES, INC.

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CLAIM CONSTRUCTION

OF

BONE FILLER PATENTS

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