IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KYPHON, INC., Plaintiff, v. DISC-O-TECH MEDICAL TECHNOLOGIES, LTD., and DISC ORTHOPAEDIC TECHNOLOGIES, INC., Defendant.	C.A. No. 04-204-JJF

KYPHON INC.'S MATERIALS PRESENTED AT THE CLAIM CONSTRUCTION AND SUMMARY JUDGMENT HEARING ON APRIL 19, 2005

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Attorneys for Plaintiff
KYPHON INCORPORATED

April 19, 2005

Kyphon v. DOT

Claim Construction
and Summary Judgment Hearing

April 19, 2005

OVERVIEW

I. CLAIM CONSTRUCTION

"Specifications teach. Claims claim."

II. INFRINGEMENT SJ's:

If "compacting" does not require balloon, DOT infringes – NO dispute.

III. VALIDITY SJ:

Neither Edeland or Olerud come close to invalidating '888 or '404, and fact issues abound.

I. CLAIM CONSTRUCTION

DOT's Flip-Flops

Patent:

- Problem addressed
- Best mode for solving

Claimed Invention:

- i. Forming passage
- ii. Compacting to enlarge said passage
- iii. Filling cavity

Rules of Construction

Key Issues

[I] DOT's Flip-Flops

"bone marrow"

was key to their case; now dropped

"forming a passage"

for non-infringement, was "passage in viscous liquid";

for invalidity, now is an "opening"

[I] DOT's Flip-Flops (more)

- **"compacting"**
  was focused on specification; now focus on prior art
  - both wrong
  - prior art does not, cannot, change plain meaning
  - details in specification are absent from claims

- **"flowable material"**
  was "bone filler"; now "non-solid material"

[I] Problem Addressed by Invention

- Long term, painful immobilization of patients recovering from fractures of the spine, known as “vertebral compression fractures”

- Kyphoplasty invention allowed for “instant fixation” (and allowed for reduction of fracture).

[I] What was patentee's best mode for practicing invention?

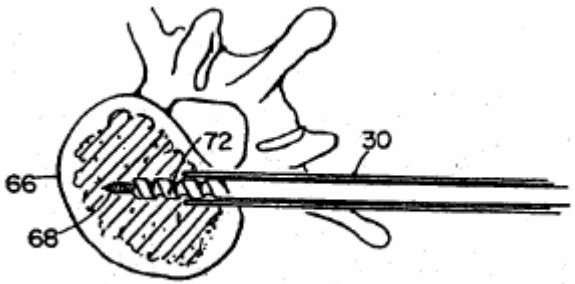


FIG.18

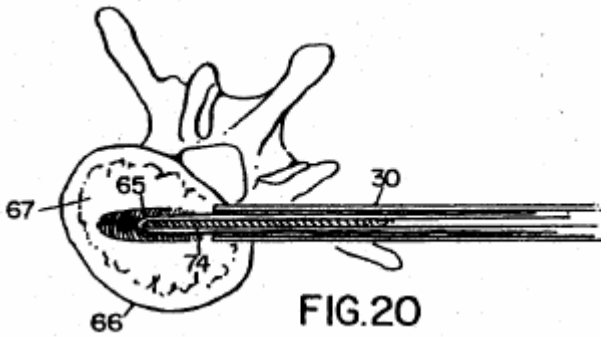


FIG.20

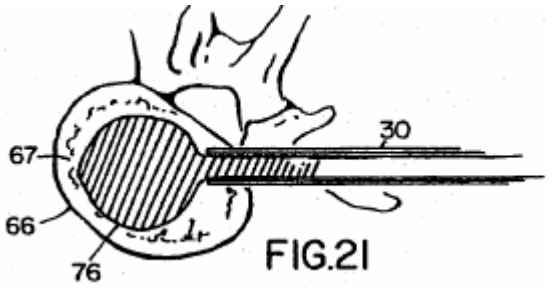


FIG.21

[I] What invention is claimed?

We claim: A method of fixation of a fracture or impending fracture of a bone having bone marrow therein comprising:

[1] forming a passage in the bone marrow;

[2] compacting the bone marrow to increase the volume of said passage; and

[3] filling the passage with a flowable material capable of setting to a hardened condition.

[I] Claim Construction Rules

"Specifications teach. Claims claim."

Two Steps:

1. Determine ***Plain Meaning*** of Claims

2. Examine Specification and Prosecution History to see if clear disclaimer/limitation.

[I] Claim Construction Rules (cont.)

Specification & Prosecution History (intrinsic evidence) provide context:

- Plain meaning of claim cannot contradict other intrinsic evidence.
- But, cannot limit claims to specification, absent:
  - "***explicit definition***";
  - "words or expressions of ***manifest exclusion*** or restriction, representing a ***clear disavowal*** of claim scope"; or
  - "***clear and unmistakable***" disclaimer.

[I] Claim Construction Rules (cont.)

Dictionary Rules of Use:

- Must be available as of date patent issued
- Cannot contradict intrinsic evidence
- Technical dictionaries okay where term:

  "has an established specialized meaning in technical dictionaries, encyclopedias, or treatises of the relevant field of art"
- But, where term has no such "specialized meaning":

  "standard dictionaries of the English language are the proper source of ordinary meaning of the phrase"

Inverness, 309 F.3d 1365, 1369-70 (Fed.Cir. 2002)

[I] Claim Construction Issues

1. "compacting the bone marrow to increase the volume of said passage"

2. "forming a **passage** in the bone marrow"

3. "a **flowable material** capable of setting to a hardened condition"

[I] 1.1 "compacting" step

"compacting the bone marrow to increase the volume of said passage"

=

compacting the bone marrow to increase the volume of the passage created by the surgeon, so that the resulting cavity can then be filled with a flowable material

[I] 1.2 "compacting" step

Plain Language:

- No mention of balloons;
- No mention of ***any*** type of device.

Prosecution History:

- References fail "to even remotely suggest the compacting of the bone marrow in the bone to increase the volume of a recess so that the recess can be filled with a flowable material capable of setting to a hardened condition" (Kyphon Response to PTO; D.I. 84, Ex. L at 4)
- Amended claim is allowable "because the claim recites the step of compacting the bone marrow in the bone to increase the volume of a recess formed in the bone so that the recess can be filled with a flowable material capable of setting to a hardened condition" (*Id.* at 6)

[I] 1.3 "compacting" step

Specification shows "a way of using the inventor's method and that he conceived that particular way described was the best one. But he is not confined to that particular mode of use since the ***claims*** of the patent, not its specifications, ***measure the invention***."

Smith v. Snow, 294 U.S. 1, 11 (1935) (emphasis added).

[I] 1.4.1 "compacting" step

Bard discussion regarding the specification was *dicta*:

"we need not decide in this case the precise relationship between ordinary and customary meaning, dictionary definitions, and the intrinsic record"

"both the specification and the prosecution history ***require*** that the plug in claim 20 be pleated"

388 F.3d at 863

[I] 1.4.2 "compacting" step

Bard concluded that:

> "the specification demonstrates that Bard ***clearly defined the terms*** 'implant' and 'plug' in claim 20 ***as requiring*** a pleated surface."

388 F.3d at 866 (emphasis added).

[I] 1.4.3 "compacting" step

- Claim, itself, in *Bard* limited nature of "plug" ("conformable" and "pliable")
- Specification then "required" plug to be "pleated"
- Pleating also used to distinguish prior art, to get Patent Office to issue patent

388 F.3d at 863-70.

[I] 1.5 "compacting" Step

1. Here, no unmistakable disclaimer during prosecution, and specification nowhere provides express definition of the claim term "compacting."
2. This Court's examination of entire specification resulted in finding that claims do ***not*** require use of an "Inflatable Device":

"***The Court finds*** that the patent does not state that an inflatable device is an essential element of the invention or that is the only possible embodiment for achieving the claimed invention of compacting the bone marrow." [PI Mem. Op., at 8-9.]

[I] 1.6 "compacting" step

- Court's finding concerned examination of patent – which has not changed at all.
- DOT: "evidence marshaled by DOT … is significantly greater." [DOT, CC Opp. at 13]
- Yet, ***no*** such "greater" evidence is cited – intrinsic evidence, which controls, is the same.

[I] 1.7 "compacting" step

Thus,

"compacting the bone marrow to increase the volume of said passage"

=

compacting the bone marrow to increase the volume of the passage created by the surgeon, so that the resulting cavity can then be filled with a flowable material

[I] 2.1 "passage" step

"forming a passage in the bone marrow"

=

forming a path or channel into the interior of the bone through the bone marrow

[I] 2.2 "passage" step

"Because words often have multiple dictionary definitions, some having no relation to the claimed invention, the intrinsic record must always be consulted to identify which of the different possible dictionary meanings of the claim terms in issue is most consistent with the use of the words by the inventor."

Texas Digital, 308 F.3d at 1203.

[I] 2.3 "passage" step

1. A "passage" IS NOT a mere "opening" as DOT *now* contends.

2. Dictionary definitions focus upon tunnel-like or tubular structures, such as channels, ducts, or paths, which are consistent with patents.

3. Specification:
   - Consistent with channel or path
   - ***Inconsistent*** with "opening"

[I] 2.4 "passage" step

- Passage: "a path, channel, or duct, through, over, or along which something may pass"

  [American Heritage, 1987]

- Passage: "a channel, duct, pore, or opening"

  [Stedman's, 2000]

- Passage: "a channel"

  [Sloane-Dorland Medical-Legal Dictionary, 1987]

[I] 2.5 "passage" step

Stedman's Medical Dictionary Definitions ***OMITTED*** by DOT:

- Duct: "a tubular structure giving exit to the secretion of a gland or organ, capable of conducting fluid"

- Channel: "a furrow, gutter, or groovelike passageway"

[I] 2.6.1 "passage" step

- "drill is tubular"

  ['888, 6:45 / '404, 6:55]

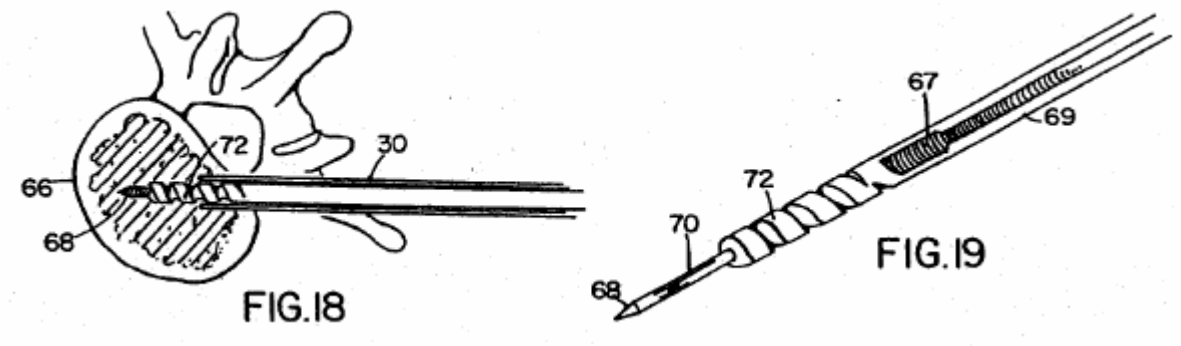
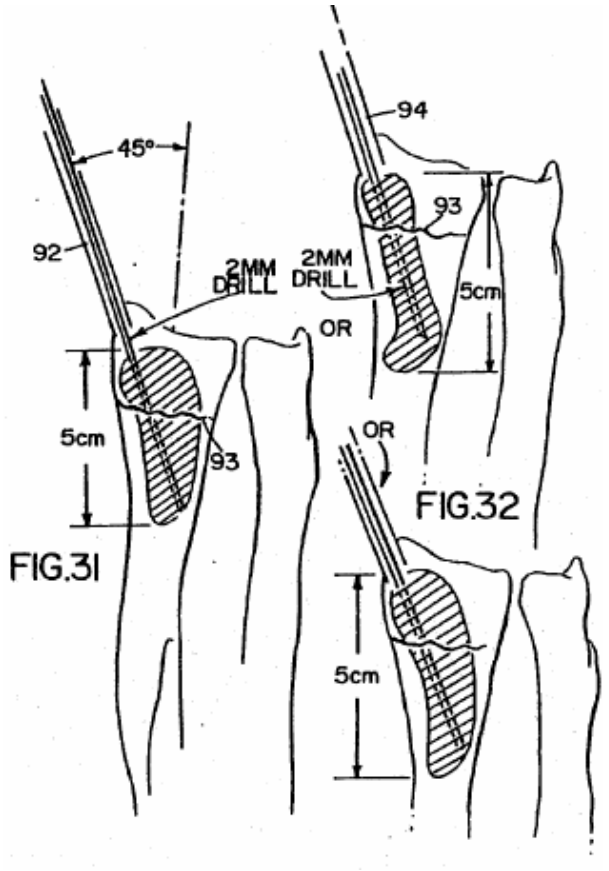


FIG.18 FIG.19

[I] 2.6.2 "passage" step

"drill is used to drill **a canal or passage** across the fracture"

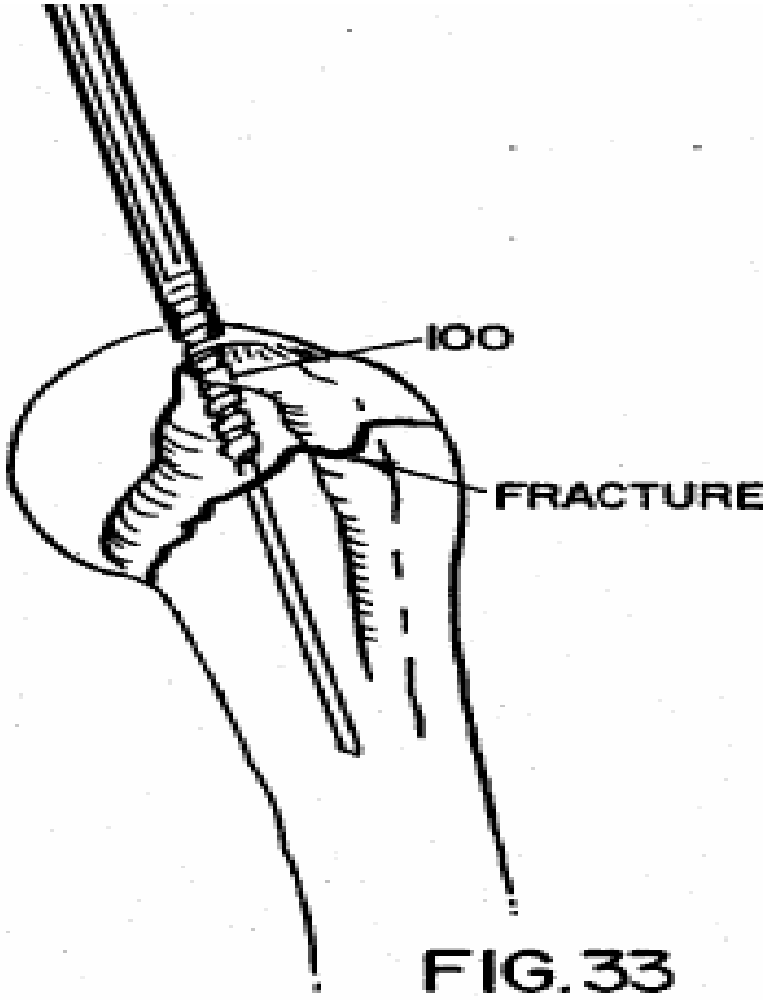
['888, 8:28-29 / '404, 8:38-39]



[I] 2.6.3 "passage" step

"[a] canal is drilled over the guide pin with a 3 mm drill"

['888, 8: 66-67 / '404, 9:8-9]



[I] 2.7 "passage step"

Canal: "a duct or channel; a tubular structure"

[Stedman's, 2000]

Canal: "a relatively narrow tubular passage or channel"

[Sloane-Dorland, 1987]

[I] 2.8 "passage step"

Thus,

"forming a passage in the bone marrow"

=

forming a path or channel into the interior of the bone through the bone marrow

Note: DOT's effort to include "opening" as part of construction of "drilling" step of claim 3, should also be rejected.

[I] 3.1 "flowable material" step

"a flowable material"

=

a material that is at some point in a fluid state (i.e., capable of flowing on its own)

[I] 3.2 "flowable material" step

- DOT is swimming upstream
  - to avoid Federal Circuit precedent requiring courts to hew close to the plain meaning; and
  - to get away from "fluid" plain meaning
- Flow = "characteristic of a fluid"

[I] 3.3 "flowable material" step

Neither of DOT's two attempts to define "flowable material" are supportable:

1. "bone filler" not plain meaning;

2. "nonsolid substance" definition, *now* offered

   - provides only DOT's favorite part of Stedman's definition of "fluid" while ignoring others, and

   - ignores Stedman's definition of "flow."

[I] 3.4 "flowable material" step

1. *Complete* Stedman's definition of "fluid" is:

   "nonsolid substance, such as a liquid or gas, that tends to flow or conform to the shape of the container"

2. DOT's *new* definition of "flowable material" deletes "liquid" from this definition:

   "a nonsolid substance that tends to conform to the shape of a container"

[I] 3.5 "flowable material" step

DOT completely ignores Stedman's definition of "flow" which repeatedly references the term "liquid":

"movement of a liquid or gas; specifically the volume of liquid or gas passing a given point per unit of time"

[I] 3.6 "flowable material" step

Thus,

"a flowable material"

=

a material that is at some point in a fluid state (i.e., capable of flowing on its own)

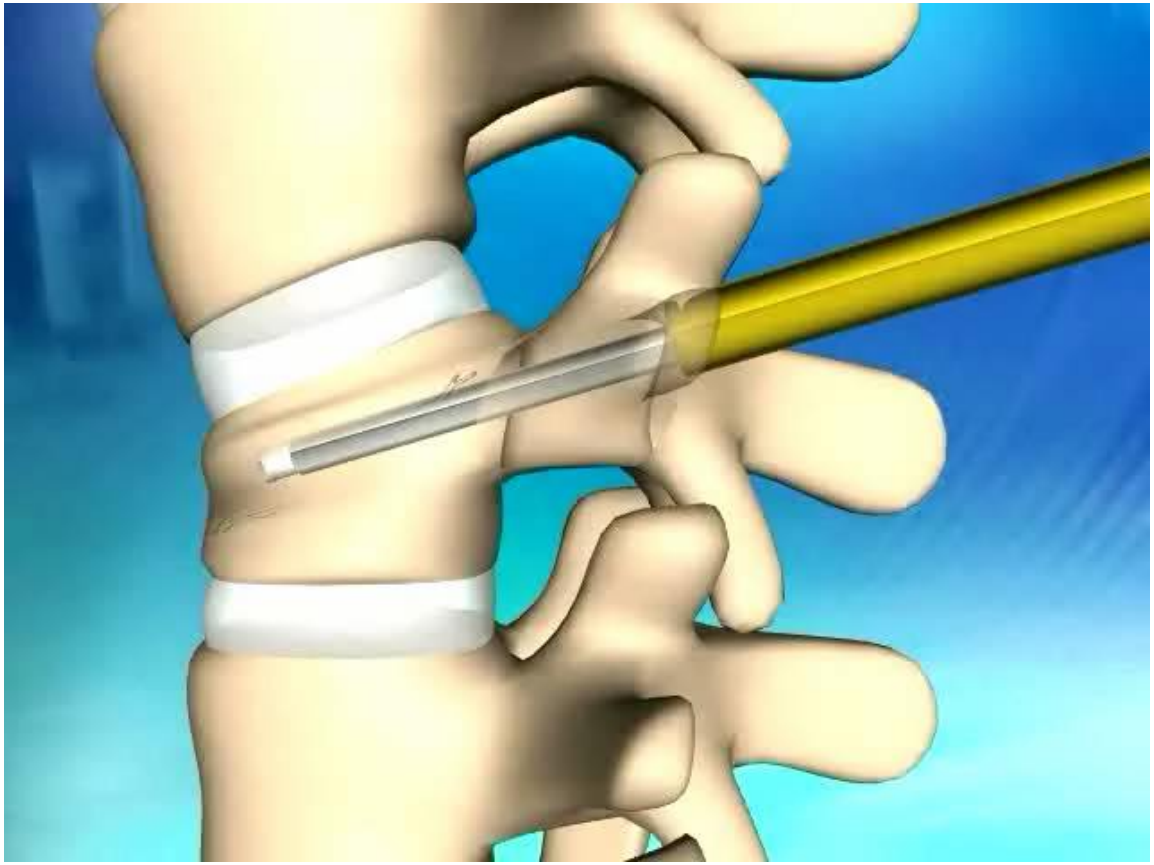
II. Infringement

1. "Compacting" does **not** require balloon;
2. Under this construction, there is no dispute that DOT infringes '888/'404 patents; and that
3. The Court must grant Kyphon's infringement SJ motion, and deny DOT's.

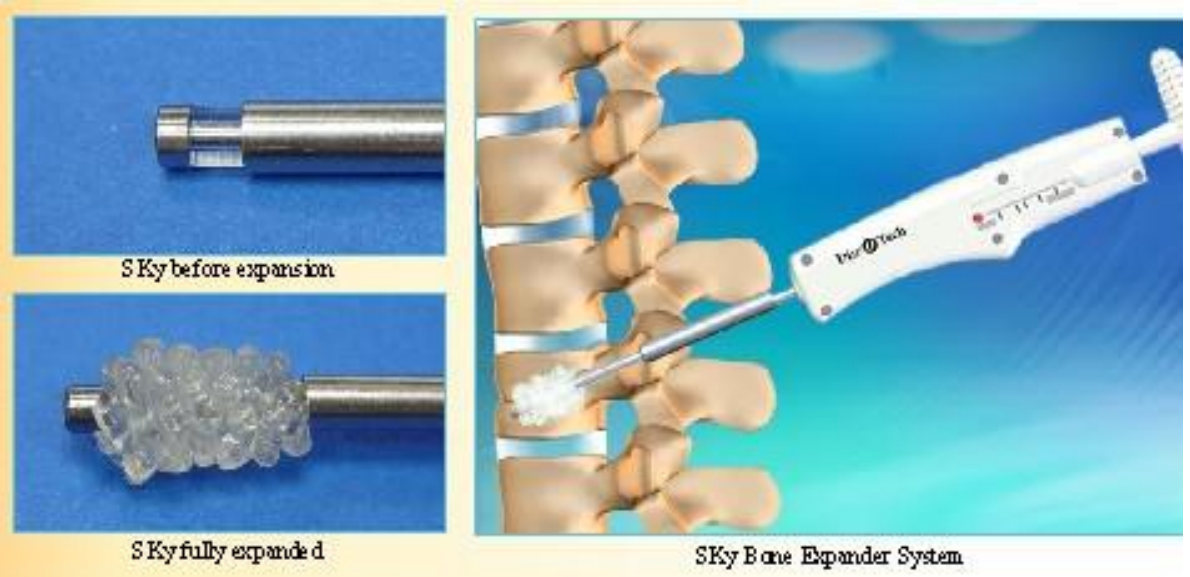
“forming a passage in the bone marrow”



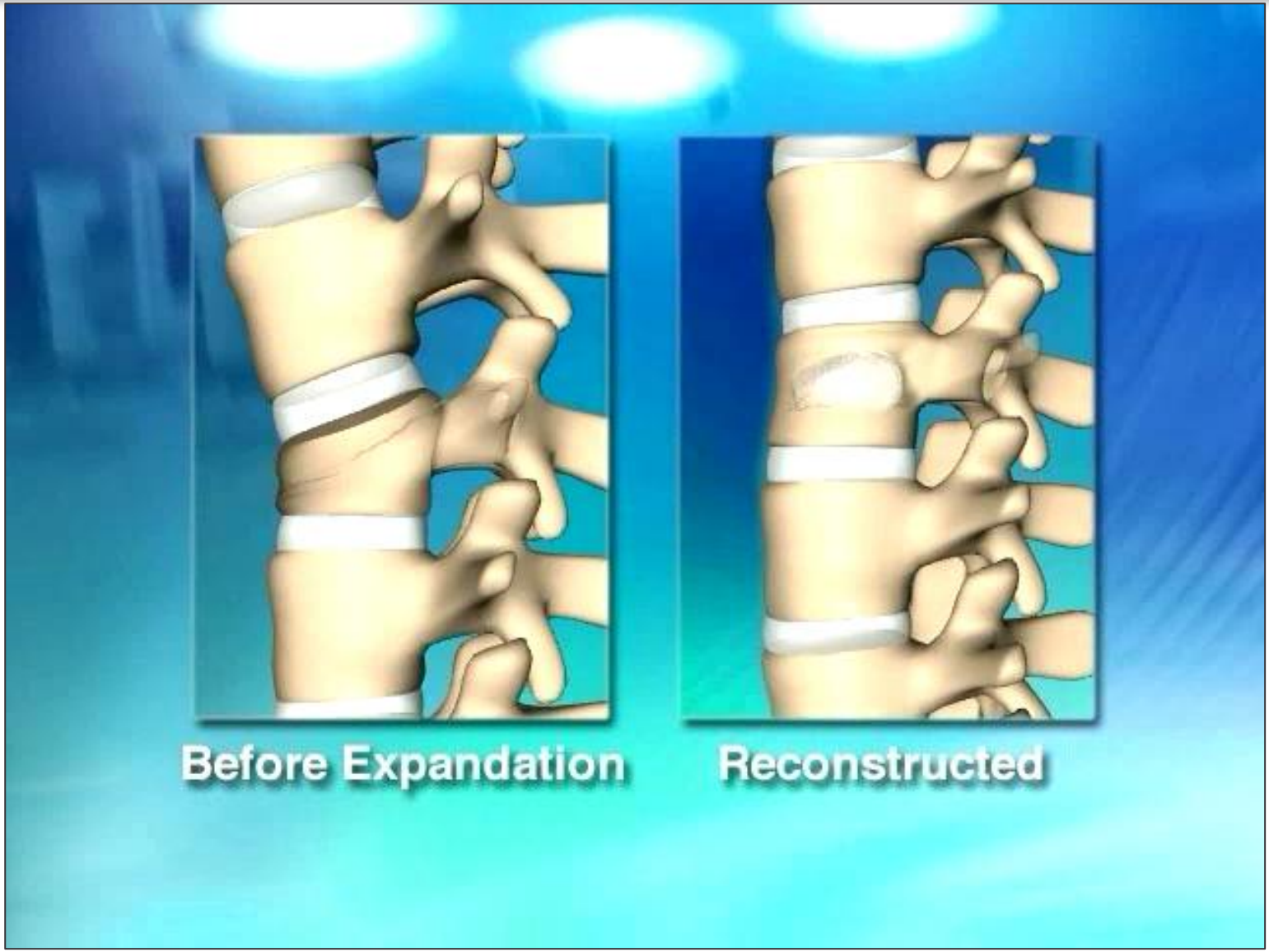
"compacting bone marrow to increase volume of said passage"



"compacting bone marrow to increase volume of said passage"



"filling the passage with a flowable material capable of setting to a hardened condition"



III. VALIDITY

1. Olerud and Edeland both fail to teach required steps in claims;

2. At minimum – fact issues abound:

   Drs. Mitchell and Marks plainly disagree regarding what these references would have taught to someone of ordinary skill in the art as of 1989; and

3. DOT ignores required consideration of objective factors of non-obviousness.

III. VALIDITY (CONT.)

- "compacting" step is not all-or-nothing
  - Not limited to requiring "balloon"
  - Not open-ended covering of ***any*** compacting

- Instead "compacting" step requires:
  - "compacting the bone marrow to increase the volume of **said** passage, so that the resulting cavity can then be filled with a flowable material"

III. VALIDITY (cont.)

Olerud and Edeland both fail to teach required steps in claims, including:

- "compacting the bone marrow to increase the volume of ***said*** passage"
- "filling the passage with a flowable material capable of setting to a hardened condition"

Edeland Reference

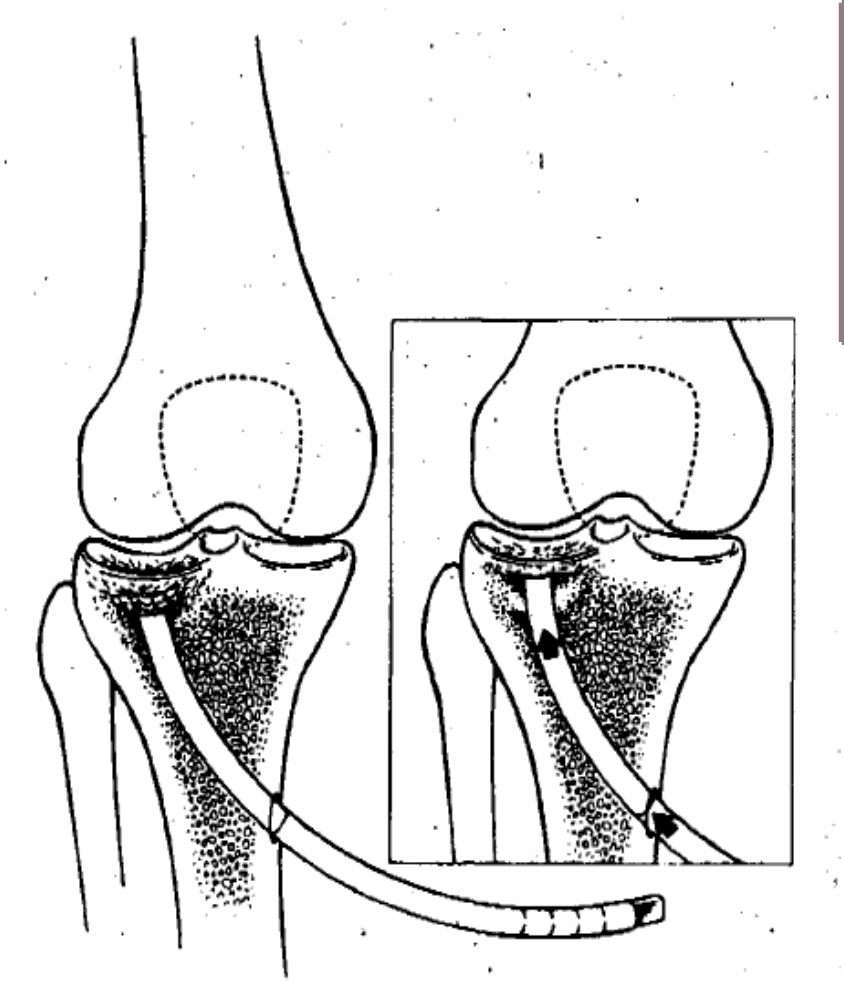


Figure 3. Principle of the fracture reduction and compaction procedure with a curved probe.

"compacting the bone marrow to increase the volume of said passage"

No teaching of forming a passage in bone marrow, followed by the separate step of increasing the volume of ***that*** passage.

EXHIBIT
D.I. 86
Ex. C

Edeland Reference

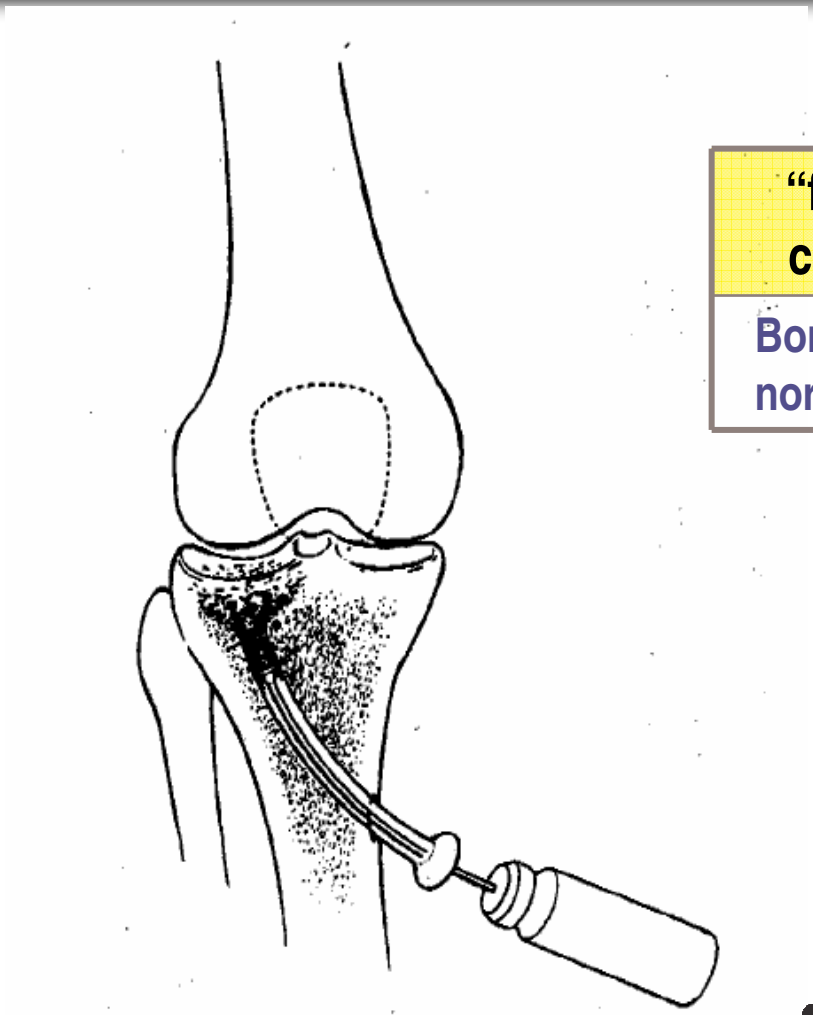


Figure 6. Principle of the use of the bone graft and/or ceramic "loaded" tube-and-plunger instrument set-up.

"filling the passage with a flowable material capable of setting to a hardened condition"

Bone graft and ceramic are not flowable material, nor do they set to a hardened condition.

EXHIBIT
D.I. 86
Ex. C

Edeland Reference

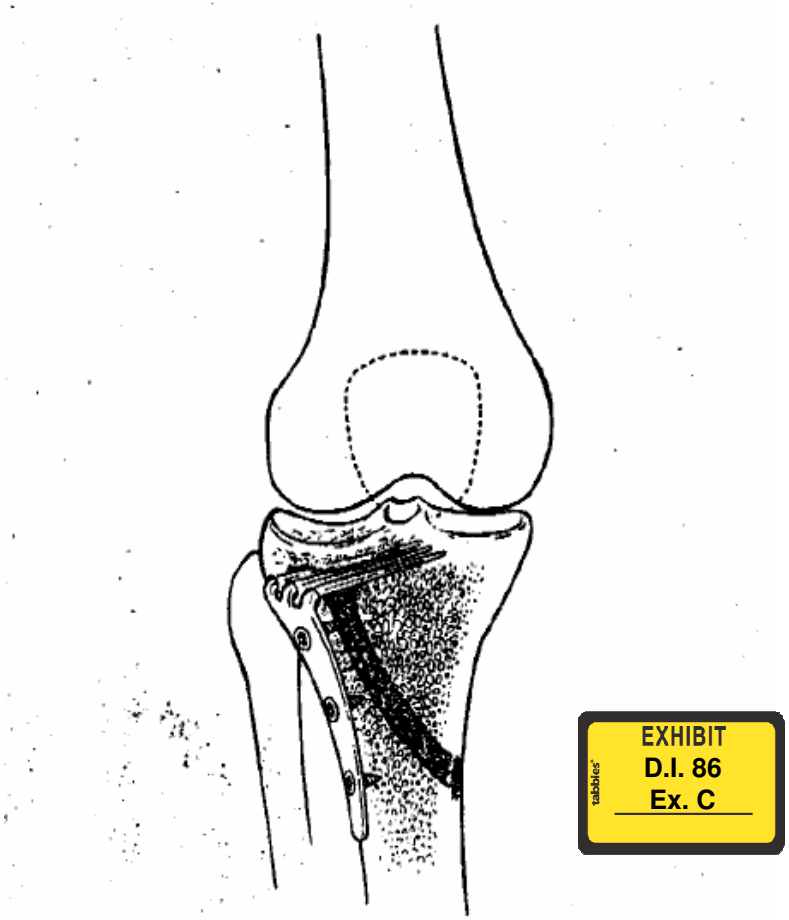


EXHIBIT
D.I. 86
Ex. C

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.

Olerud Reference

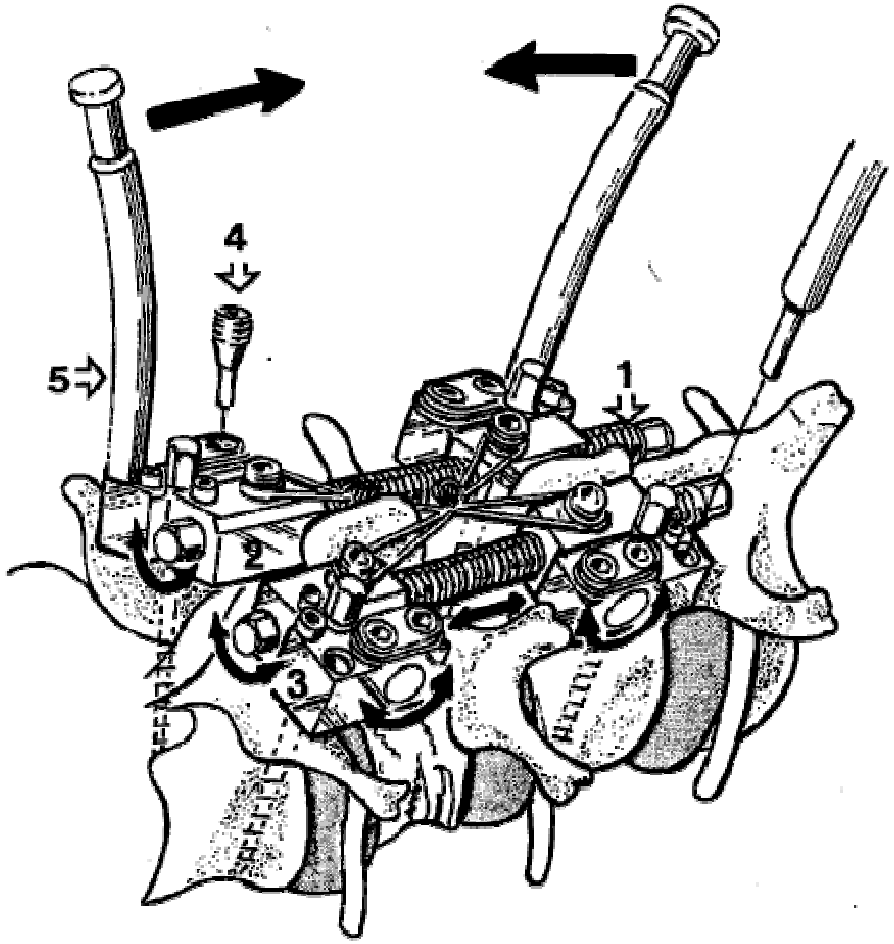


FIG. 1. The posterior segmental fixator (PSF). The device consists of two reversed units. Each unit is composed of one threaded rod (1). On this rod two bolt grips (2) are movable in relation to each other as well as to two screw grips (3) that surround the pedicular screws. The components are locked 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.

EXHIBIT
D.I. 86
Ex. A

Fixation of Fractures According to Goran Karlstrom, M.D., Reference

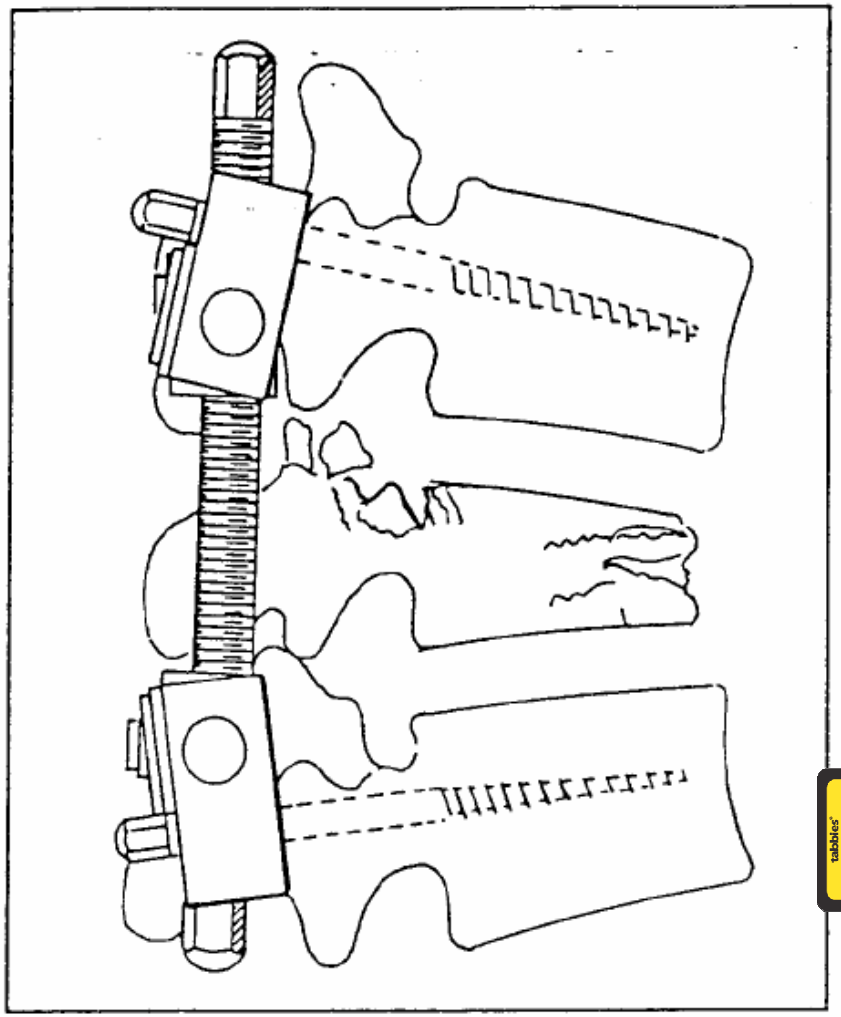


Fig. 4A Schematic drawing of the PSF device mounted but not locked.

Karlstrom/Olerud Teaching

Use of external hardware device in open procedure

EXHIBIT
D.I. X
KY4633

PSF = Posterior Segmental Fixator

Olerud Reference

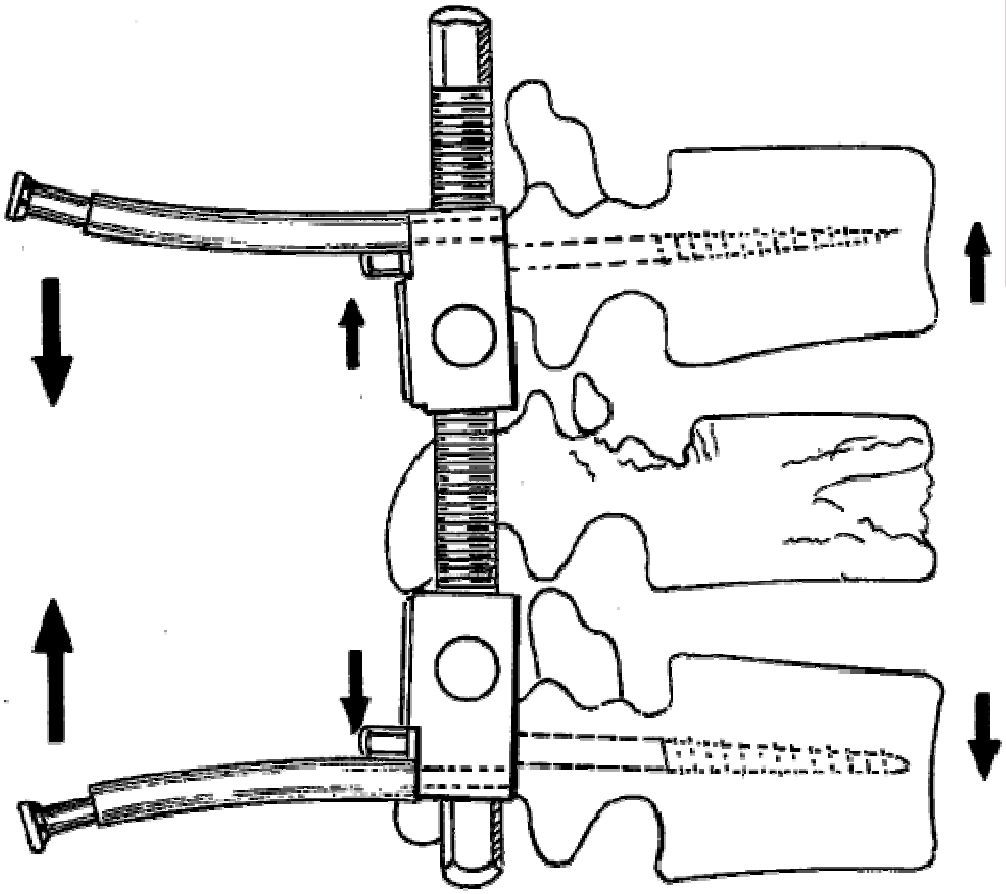


FIG. 2. The PSF allows reduction by extension as well as distraction. After reduction, the configuration and height of the fractured vertebra are normalized.

Operation of PSF

- Initial reduction will create "defects", or void, "within cancellous bone"
- THEN surgeon drills into vertebra and forms passage
- Inserts "curved punch" or probe

EXHIBIT
D.I. 86
Ex. A

PSF = Posterior Segmental Fixator

Olerud Reference

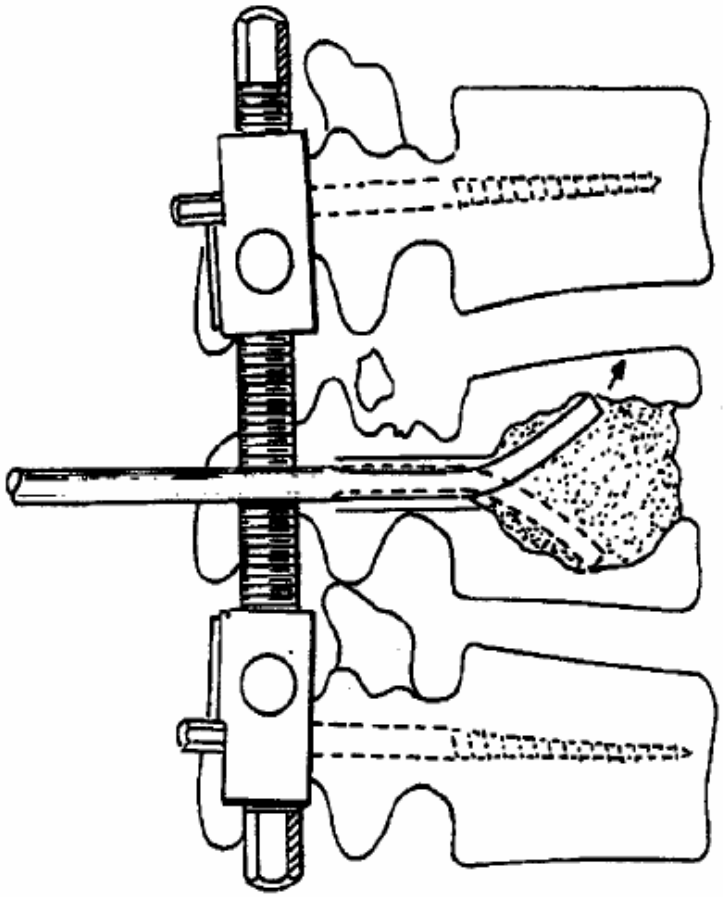


FIG. 3. With a transpedicularly introduced punch, further reduction of fragments in the vertebral body can be reduced. The defect in the vertebra is then filled with a graft in the form of bone paste.[8,13]

EXHIBIT
D.I. 137
Ex. A

"compacting the bone marrow to increase the volume of said passage"

- No disclosure of increasing volume of ***said*** passage
- Probe does NOT even appear to touch walls of said passage formed by surgeon

III. VALIDITY (CONT.)

Objective Factors of Non-Obviousness:

- Undisputed success of kyphoplasty;
- Long felt need;
- Initial skepticism & LOTS of praise –

Physician noting last patient, "arrived in a wheelchair due to back pain and walked out to go home 1 ½ hours later"

III. VALIDITY (CONT.)

At a minimum, numerous genuine issues of fact exist regarding, among other things:

1. What Olerud and Edeland would have taught to one of ordinary skill in the art; and
2. Whether there would have been any motivation to combine the teachings of these references.

SUMMARY

- Claim construction requires adoption of plain meanings ***consistent*** with specification's best mode of practicing the invention
  - not ***limited to only*** the best mode.

- If "compacting" step given plain meaning, then no dispute that DOT infringes
  - Essentially what Court found during Preliminary Injunction
  - GRANT Kyphon's SJ motion re infringement
  - DENY DOT's SJ motion

- Numerous fact issues preclude grant of DOT's validity summary judgment

BONE FILLER DEVICE PATENTS: Claim Construction

- No dispute; DOT infringes under Kyphon's proposed claim interpretations
- DOT's two tubes v. Best Mode of one tube
- Patents claim a device; not a method of use
- Plain meanings of "in," "into," and "through" control

BONE FILLER DEVICE PATENTS: Claim Construction (cont.)

"General use **dictionaries** define 'in' as 'used as a functional word to indicate location or position in space or in some materially bounded object.' *Webster's Third New International Dictionary* 1139 (1993)."

Gemstar, 383 F.3d 1352, 1372 (Fed.Cir. 2004)

BONE FILLER DEVICE PATENTS:
Summary Judgment

- No dispute, DOT's device has ***capability*** of tamping via one tube;
- No need to "alter" or change structure of DOT's device – DOT says nothing to contrary; and
- Thus, DOT infringes patents, even under DOT's claim construction which limits claims to tamping through only "one-tube."

END

Karlstrom Reference

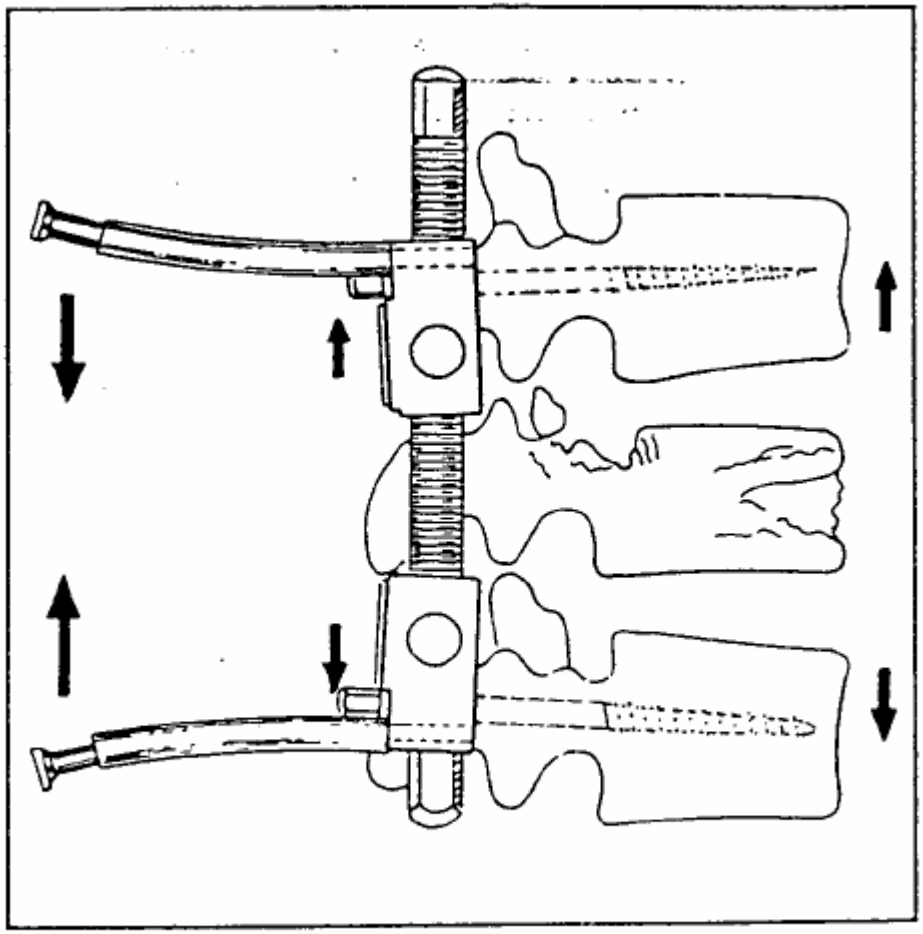


Fig. 4B The PSF device permits reduction both by extension to a lordotic correction and by distraction.

Operation of PSF

- Initial reduction creates "defect" or void

EXHIBIT
D.I. X
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Karlstrom Reference

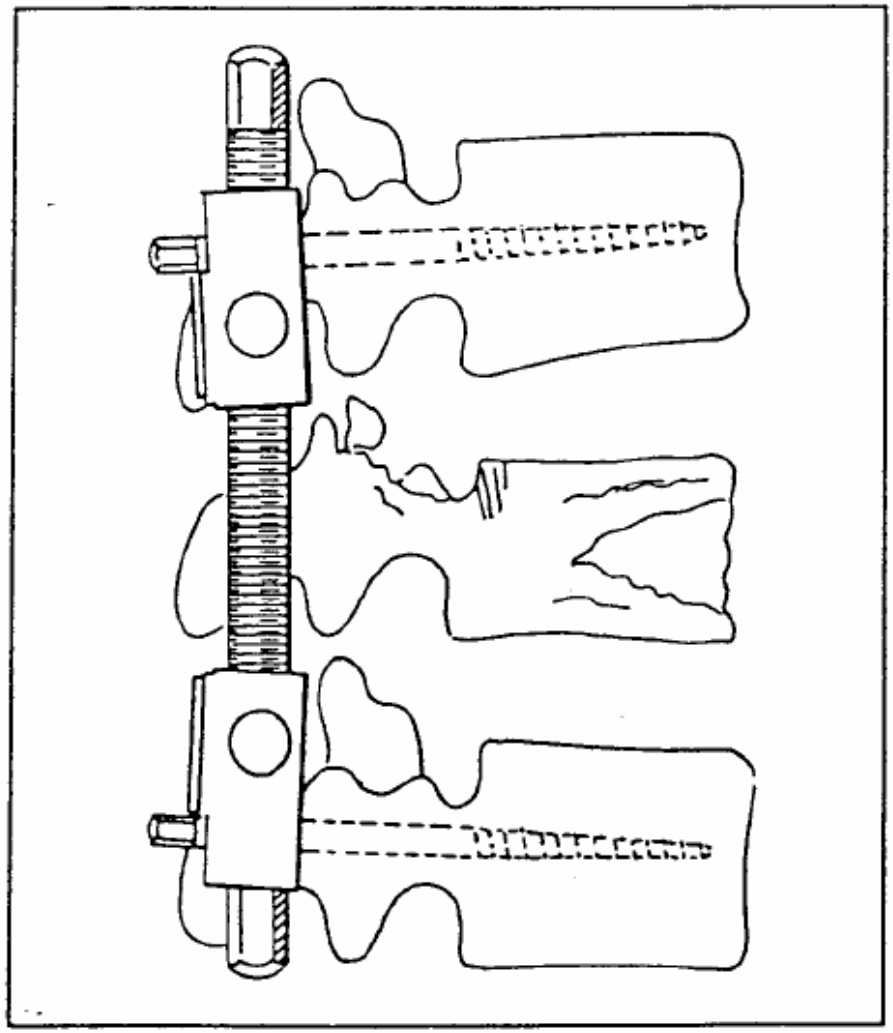


Fig. 4C After reduction, the configuration and height of the vertebral body are restored to normal.

Operation of PSF

- THEN surgeon drills into vertebra and forms passage
- Inserts "curved punch" or probe

EXHIBIT
D.I. X
KY4633

Karlstrom Reference

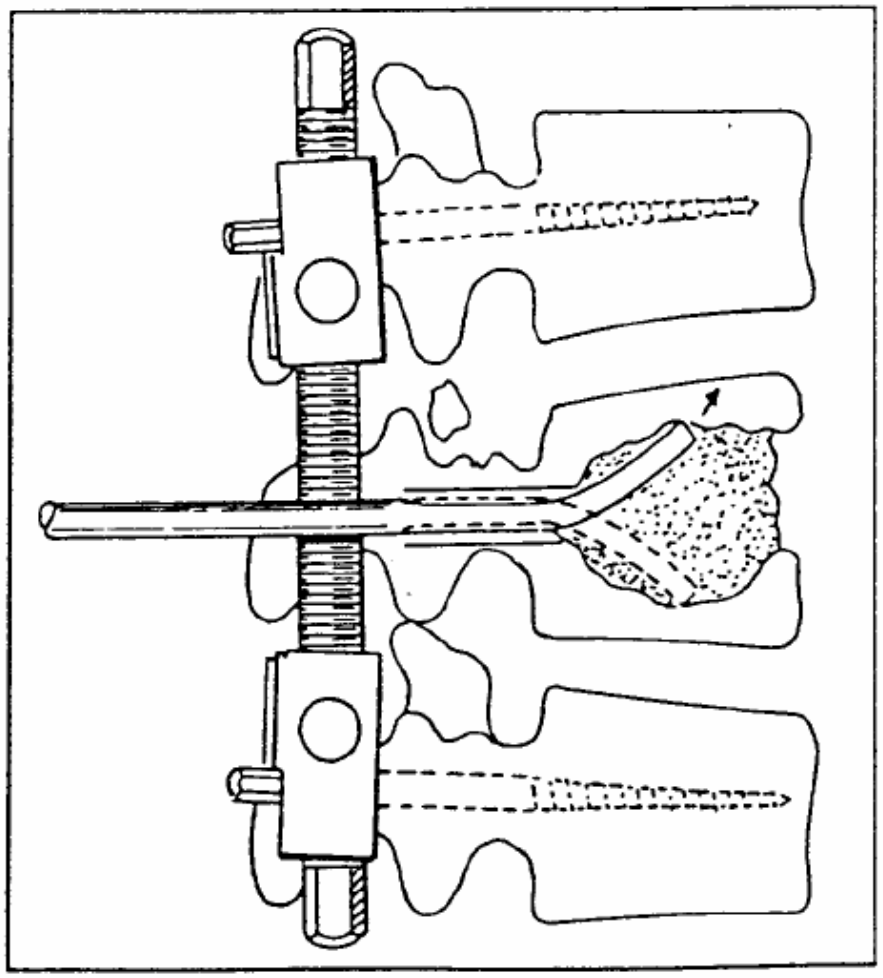


Fig. 4D Further reduction of vertebral body fragments can be achieved using a punch or elevator inserted through the pedicles. The defect that is created is then filled with a bone graft.

Operation of PSF

- Curved probe increases void
- Pushes top and bottom endplates
- Does NOT even touch walls of passage formed by surgeon
- Thus, probe CANNOT increase volume of ***said*** passage

EXHIBIT
D.I. X
KY4633

CERTIFICATE OF SERVICE

I hereby certify that on April 22, 2005, I electronically filed **KYPHON, INC.'S MATERIALS PRESENTED AT THE CLAIM CONSTRUCTION AND SUMMARY JUDGMENT HEARING ON APRIL 19, 2005** with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following:

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