

[54] **METHOD OF TREATING BONE
FRACTURES AND NON-UNIONS**

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[56] **References Cited**

UNITED STATES PATENTS

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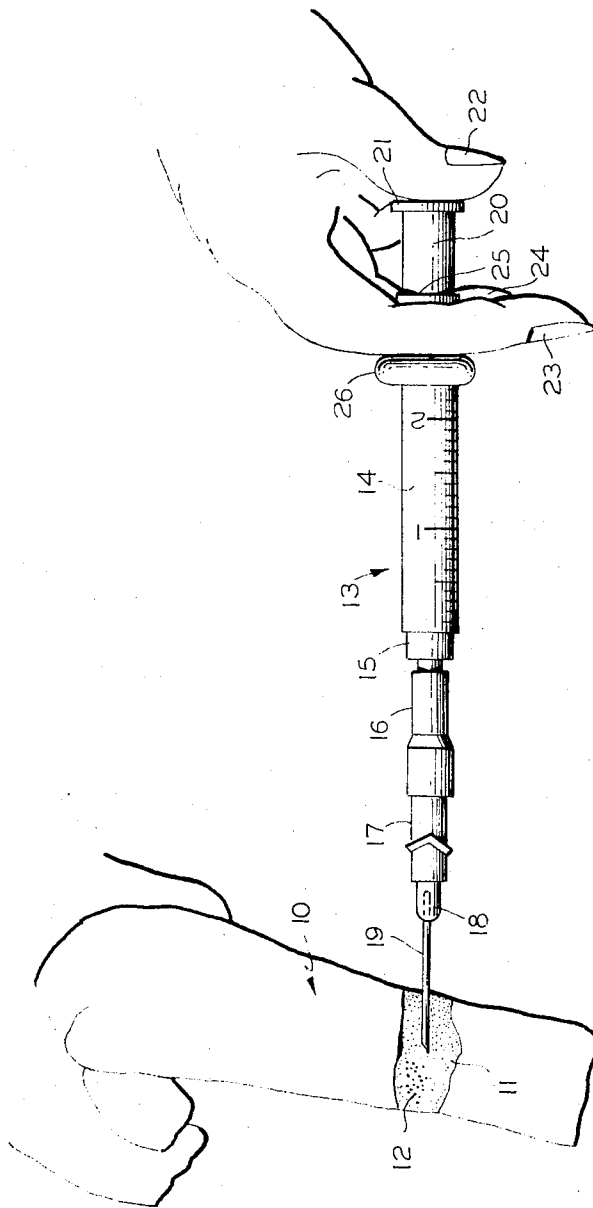
[57] **ABSTRACT**

Fractures and nonunions of bones are more readily
healed without muscle atrophy, etc., by injecting a liq-
uefied composition containing a non-necrotic vascular
sclerosing agent into the site of the fracture or non-
union. No cast is used. The preferred non-necrotic vas-
cular sclerosing agent is sodium morrhuate.

14 Claims, 1 Drawing Figure

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METHOD OF TREATING BONE FRACTURES AND NON-UNIONS

PRIOR ART

Known vascular sclerosing agents include phenol, zinc, sulphate, glucose, strong sodium chloride solution, tannic acid and extracts containing tannins, urea, quinine, resins and extracts containing them, mineral acids, the salts or soaps of the fatty acids of various oils, particularly cod liver oil, and psyllium seed oil, amine soaps of fatty acids, ethanol, dextrose and invert sugar.

U.S. Pat. No. 1,621,118 teaches producing serum by treating bacteria and/or their toxins with soluble salts of higher fatty acids, and injecting the resultant antigens into the system of man or animal. U.S. Pat. No. 1,936,456 discloses the use of sodium ricinoleate and a fluid vehicle to treat internal body surfaces which can only be reached through body orifices.

BROAD DESCRIPTION OF THE INVENTION

This invention involves a process of treating bone fractures breaks and nonunions of man and animal. The process includes: aligning (only when necessary) the bone parts to position for setting; and then injecting at least one dosage of a liquefied composition comprised of a non-necrotic vascular sclerosing agent and a liquid carrier into the site of the fracture, break or nonunion area of the bone until there is a substantially complete bone union. Preferably another dosage is injected a week or two after the first dosage and then every week or two thereafter, as needed, until there is a substantially complete bone union. Preferably each dosage of the liquefied composition is injected into the site of the fracture, break or nonunion at its axis.

The non-necrotic vascular sclerosing agent can be, among other things, a fatty acid compound, e.g., a fatty acid salt or a fatty acid soap. The preferred non-necrotic vascular sclerosing agent is sodium morrhuate. The preferred liquid carrier is water.

The preferred liquefied composition is comprised of sodium morrhuate, enough sodium hydroxide to obtain a pH between about 9 and about 10 and water. It is also desirable to place up to 5 weight percent of benzyl alcohol in that liquefied composition.

Reduction of a fracture, heretofore, must be accomplished by immobilization of a cast as compression is put into effect. Compression, per se, can only increase the mass, it cannot align. My theory is that a cast leading to compression and atrophy of muscle is not only undesirable, but in the case of the equine reduction in many bones is impossible. I have proven that by injecting a non-necrotic vascular sclerosing agent at the axis of the fracture, I chemically introduce "struts," giving rise to shear, and thus alignment. The lack of the cast not only eliminates atrophy of muscles, the complication of "lipping," but the movement of bone against the tension of muscle insertion helps to promote the flow blood to and from the damaged area.

The novel process of this invention can be used to heal (treat) simple, compound, comminuted, linear, green-stick, multiple, distracted and partial fractures as well as non-unions which have been in existence as long as 1 year. This invention can also be used for splints, diffused splints, and fusion of meta-carpals and/or meta-tarsals in regards to the three bone weight bearing complex or any boney material.

The use of the liquefied composition of this invention allows the healing of bone fractures, breaks and non-unions to be reduced from as long as 18 months to 8 to 10 weeks, sometimes less.

The accepted four stages of the healing of fractures to date are: (1) Stage of haematoma formation, (2) Stage of Callus formation, (3) Stage of Consolidation, and (4) Remodelling of Callus.

DETAILED DESCRIPTION OF THE INVENTION

In the FIGURE, the bone is illustrated at 10, the locus of the fracture being indicated at 11 and a blood clot 12 (hematoma in periosteum). A syringe entity is indicated at 13 and includes graduated cylinder 14, which cylinder converges toward one end and is in communication with a polyvinyl tube 15 through sleeve 16. Tube 15, in turn, is in communication with nylon adapter 17, the latter emptying into a hypodermic needle socket 18, the needle being indicated at 19. The point of needle 19 is engaged in the interstice of fracture 11, as illustrated. Cylinder 14 is adapted for the reception of a fluid composition containing a non-necrotic vascular sclerosing agent. The fluid composition is forced from cylinder 14 by plunger 20, which has finger-engaging head 21. The heads are operated by thumb 22 of the user. Two of the fingers of the user, 23 and 24, are interposed between terminal flange 25 of cylinder 14 and clamp 26 as shown in the FIGURE.

The term liquefied composition includes slurries, suspensions, solutions, etc.

All of the components of the liquefied composition must be substantially non-toxic in the amounts and under the conditions of use.

The pH of the liquefied composition should be between about 8 and about 11, and preferably between 9 and about 10. Each non-necrotic vascular sclerosing agent will produce a different pH at different concentration levels so non-toxic agents may be added to adjust the pH level, e.g., sodium hydroxide can be used when sodium morrhuate is used.

Natural or synthetic fatty acids can be used to form the fatty acid compound. Mixtures of fatty acids can be used.

Useful fatty acids for forming the fatty acid compounds may be saturated or unsaturated. The useful saturated fatty acids are represented by the general formula: RCOOH , where R can be H, an alkyl group, branched or straight chain. Examples of useful saturated fatty acids are formic acid, acetic acid, propionic acid, n-butyric acid, isobutyric acid, N-valeric acid, n-caproic acid, n-heptoic acid, caprylic acid, n-nonylic acid, capric acid, undecylic acid, lauric acid, tridecylic acid, myristic acid, pentadecylic acid, palmitic acid, margaric acid, stearic acid, nonadecanoic acid, heneicosanoic acid, triosanic acid, lignoceric acid, pentacosanoic acid, cerotic acid, arachidic acid and behenic acid. Example of useful unsaturated fatty acids are oleic acid, linoleic acid, linolenic acid, licanic acid, eleostearic acid, ricinoleic acid, clupanodonic acid and palmitoleic acid. The useful unsaturated fatty acids can be those containing one double bond, e.g., oleic acid, two double bonds, e.g., linoleic acid, three double bonds, e.g., eleostearic, etc.

Useful fatty acids for forming the fatty acid salts which contain one or more hydroxyl groups are, e.g., dihydroxystearic acid. Useful hydrogenated fatty acids are cod liver oil fatty acids, tallow fat fatty acids, caster

oil fatty acids, rape oil fatty acids, peanut oil fatty acids, cottonseed oil fatty acids, corn oil fatty acids, soybean oil fatty acids, linseed oil fatty acids, tung oil fatty acids, oiticia oil fatty acids, lard oil fatty acids, neat's foot oil fatty acids, whale oil fatty acids, olive oil fatty acids, coconut fat fatty acids, palm fat fatty acids, butter fat fatty acids, lard fat fatty acids and fish oil fatty acids. The useful hydrogenated fatty acids can be obtained from vegetable oils and fats, and animal oils and fats. Polymeric fatty acids can be used.

The fatty acid compound can be a fatty acid salt. The fatty acid salts can be those prepared from metals, such as, aluminum and alkaline earth metals, e.g., calcium, but are preferably those prepared by alkali metals, e.g., sodium (preferred) lithium, potassium, caesium and rubidium. (Ionic fatty acid compounds such as, sodium morrhuate are preferred, even though the potassium salts are usually more soluble.) The metals are used as compounds such as hydroxides, carbonates, etc. The fatty acid salts can be prepared from ammonia and similar non-metallic inorganic bases. The fatty acid compounds can be esterified fatty acids, e.g., methyl formate, ethyl propionate and n-amyl acetate. The fatty acid compounds can be soaps such as the reaction products of the fatty acids and organic bases, e.g., methylamine, triethanolamine, monoethanolamine, diethanolamine, phenyl ethanol amine, ephedrine and pseudoephedrine. Fatty acid soaps of mono-, di- and tri-alkyl amines and aryl amines can be used.

U.S. Pat. No. 2,115,491 teaches a method of preparing the sodium salts or soaps of the fatty acids of psyllium seed oil. Amine soaps of the fatty acids can be prepared by the method taught by U.S. Pat. No. 2,090,456. U.S. Pat. No. 1,767,041 discloses a method of making the product of alkali metals and fatty acids. The other fatty acid compounds can be made by methods readily known by those ordinarily skilled in the art.

The liquefied solutions should contain between about 0.5 and about 10 percent by weight of the fatty acid compound, and preferably contain between about 1 and about 5 percent by weight of the fatty acid compound.

Examples of specific useful compounds of fatty acids which can be used as non-necrotic vascular sclerosing agents are: sodium morrhuate (a mixture of the sodium salts of the fatty acids of cod liver oil); sodium psyllate (a mixture of the sodium salts of psyllium oil liquid fatty acids); sodium ricinoleate; ethylamine oleate; monoethanolamine oleate; sodium formate; sodium acetate; and calcium propionate. Salts of fatty acids are preferred, particularly those formed from alkali metals, and the preferred fatty acid salt is sodium morrhuate.

Examples of other useful non-necrotic sclerosing agents are dextrose and invert sugar. (Invert sugar is a mixture of dextrose and levulose obtained by the inversion of sucrose.) Solutions containing, for example, dextrose (25 wt. percent) and sodium chloride (15 wt. percent), or invert sugar (30 wt. percent) and sodium chloride (10 wt. percent) can be used. Solutions containing about 50 percent by weight of dextrose are preferred. Solutions containing about 60 to about 75 percent by weight of invert sugar are preferred.

The fatty acid compounds (preparations) are preferred over the other useful non-necrotic vascular sclerosing agents because, for among several reasons, less of the liquefied composition (dosage) is needed. This means the less concentrated fatty acid compound

preparations are needed than the more concentrated preparations such as those containing dextrose or invert sugar.

Solutions of dextrose or invert sugar or salts of fatty acids are not very irritating and do not produce necrosis.

Examples of the liquid carrier for the non-necrotic vascular sclerosing agent are water; monoglycerides; diglycerides; etc. Water is the preferred liquid carrier, and salt (NaCl) can be added to make an isotonic aqueous solution as the liquid carrier.

The useful vascular sclerosing agents must be non-necrotic in effect or operation. Sclerosing agents' to be useful must not cause the pathologic death of one or more cells, or a portion of tissue or organ, resulting from irreversible damage to the nucleus.

Anodynes in amounts of up to and including about 5 percent by weight may be added. An anodyne is an agent which has the power to relieve pain. An example of a useful anodyne is benzyl alcohol. In general small amounts of antiseptics or anaesthetics can be used.

Suitable preservations can be added in an amount not to exceed 0.5 percent by weight.

In some instances it may be necessary to use traction, but a cast as such is not used.

Unless otherwise stated or indicated, in the following examples, all percentages and proportions are expressed on a weight basis.

The following examples further illustrate, but do not limit, this invention.

EXAMPLE 1

A liquefied composition containing 5 weight percent of sodium morrhuate, 3 weight percent of ethanol, enough NaOH to obtain a pH of 9.5 and the remainder water. The liquefied composition was placed in several 2 c.c. ampoules. One of the ampoules was used to fill a hypodermic needle syringe of the type shown in the Figure. The liquefied solution was injected into the axis or plane of a fresh break of the coffin bone of a horse, the ends being held manually in alignment during the injection. No cast was used and the horse was not suspended. The treatment was not painful. X-rays indicated that "struts" were produced, giving rise to shear and thus alignment. The horse was able to "test out" the leg and successfully put minor weight on the foot after about 10 days. Another injection was made on the tenth day, and about every 10 days thereafter until the fracture was substantially cured after about 3 months.

EXAMPLE 2

Example 1 was repeated, except that the liquefied composition containing the non-necrotic vascular sclerosing agent of Example 1 was replaced with an aqueous solution (5 c.c. vial) containing 5 percent of sodium psyllate and 2 percent by weight of benzyl alcohol. That aqueous solution had a pH of 8.9 (enough 10 percent NaOH solution was added to achieve that level). The fracture was substantially cured in about 3 months after repeated injections.

EXAMPLE 3

Example 1 was repeated, except that the liquefied composition containing the non-necrotic vascular sclerosing agent of Example 1 was replaced with an aqueous solution (2 c.c. vial) containing 5 percent of sodium psyllate. A NaOH solution was added to ob-

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tain a pH level of 8.7 The fracture was substantially cured in about 3 months after repeated injections.

EXAMPLE 4

Example 1 was repeated, except that the liquefied composition containing the non-necrotic vascular sclerosing agent of Example 1 was replaced with an aqueous solution (2 c.c. vial) containing 2 percent of sodium ricinoleate. That solution has a pH between 8.2 and 8.5. The fracture was substantially cured in about 3 months after repeated injections.

EXAMPLE 5

Example 1 was repeated, except that the liquefied composition containing the non-necrotic vascular sclerosing agent of Example 1 was replaced with an aqueous solution (2 c.c.) containing 50 percent dextrose. The fracture was substantially cured in about 3 months after repeated injections.

EXAMPLE 6

Example 1 was repeated, except that the liquefied composition containing the non-necrotic vascular sclerosing agent of Example 1 was replaced with an aqueous solution (2 c.c. ampul) containing 65 percent of invert sugar. The fracture was substantially cured in about 3 months after repeated injections.

EXAMPLE 7

Example 1 was repeated, except that the liquefied composition containing the non-necrotic vascular sclerosing agent of Example 1 was replaced with an aqueous solution (2 c.c. ampul) containing 5 percent ethylamine oleate and 2 percent benzyl alcohol. The fracture was substantially cured in about 3 months after repeated injections.

EXAMPLE 8

Example 1 was repeated, except that the liquefied composition containing the non-necrotic vascular sclerosing agent of Example 1 was replaced with an aqueous solution (2 c.c. ampul) containing 5 percent ethylamine oleate. The fracture was substantially cured in about 3 months after repeated injections.

EXAMPLE 9

Example 1 was repeated, except that the liquefied composition containing the non-necrotic vascular sclerosing agent of Example 1 was replaced with an aqueous solution (2 c.c. ampul) containing 5 percent of sodium morrhuate, 3 percent of benzyl alcohol, and enough N_2O to bring the pH up to 9.5. The fracture was substantially cured in about 3 months after repeated injections.

EXAMPLE 10

Example 1 was repeated, except that the liquefied composition containing the non-necrotic vascular sclerosing agent of Example 1 was replaced with an aqueous solution (2 c.c. ampoule) containing 5 percent of sodium morrhuate and enough N_2O to bring the pH up to 9.5. The fracture was substantially cured in about 3 months after repeated injections.

EXAMPLE 11

Example 1 was repeated, except that the liquefied composition containing the non-necrotic vascular

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sclerosing agent of Example 1 was replaced with an aqueous solution (2 c.c. ampoule) of 1 percent of sodium morrhuate and enough N_2O to bring the pH up to 9.1. The fracture was substantially cured in about 3 months after repeated injections.

EXAMPLE 12

Example 1 was repeated, except that the liquefied composition containing the non-necrotic vascular sclerosing agent of Example 1 was replaced with an aqueous solution (2 c.c. ampoule) of a 3 percent solution of sodium morrhuate and enough KOH to bring the pH up to 9.3. The fracture was substantially cured in about 3 months after repeated injections.

EXAMPLE 13

Example 1 was repeated except that the treatment was done to an apex sesamoid fracture of a horse. The fracture was substantially cured in about 3 months after repeated injections.

EXAMPLE 14

Example 1 was repeated except that the treatment was done to a distal sesamoid fracture of a horse. The fracture was substantially cured in about 3 months after repeated injections.

EXAMPLE 15

Example 1 was repeated except that the treatment was done to a chip fracture in the carpus of a horse. The fracture was substantially cured in about 3 months after repeated injections.

What is claimed is:

1. A process of treating bone fractures, breaks and nonunions which comprises injecting at least one dosage in an effective amount of a liquefied composition comprised of a non-necrotic vascular sclerosing agent of a fatty acid compound and a liquid carrier into the site of the fracture, break or nonunion area of the bone, said process being repeated until there is a substantially complete bone union.
2. A process as described in claim 1 wherein said fatty acid compound is a fatty acid salt or a fatty acid soap.
3. A process as described in claim 1 wherein said liquid carrier is water.
4. A process as described in claim 1 wherein a dosage of said liquefied composition is injected into the site of said fracture, break or nonunion every week or two until there is a substantially complete bone union.
5. A process as described in claim 1 wherein said dosage of said liquefied composition are injected into the site of said fracture, break or nonunion at its axis.
6. A process as described in claim 1 wherein the bone parts are aligned into position for setting.
7. A process as described in claim 1 wherein said liquefied composition has a pH between about 8 and about 11.
8. A process as described in claim 1 wherein said fatty acid compound is a salt of an alkali metal and a fatty acid.
9. A process as described in claim 8 wherein said alkali metal is sodium.
10. A process as described in claim 8 wherein said fatty acid is oleic acid.
11. A process as described in claim 8 wherein said alkali metal is sodium, wherein said fatty acid is oleic

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acid, wherein said liquefied carrier is water, wherein said liquefied composition is a solution, wherein said liquefied composition has a pH between 9 and 10, and wherein said fatty acid compound is present in an amount between about 1 and about 5 percent.

12. A process as described in claim 8 wherein said fatty acid is an unsaturated fatty acid.

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13. A process as described in claim 8 where said fatty acid compound is present in an amount between about 0.5 and about 10 percent.

14. A process as described in claim 8 wherein said liquefied composition also contains ethanol.

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