

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
8 August 2002 (08.08.2002)

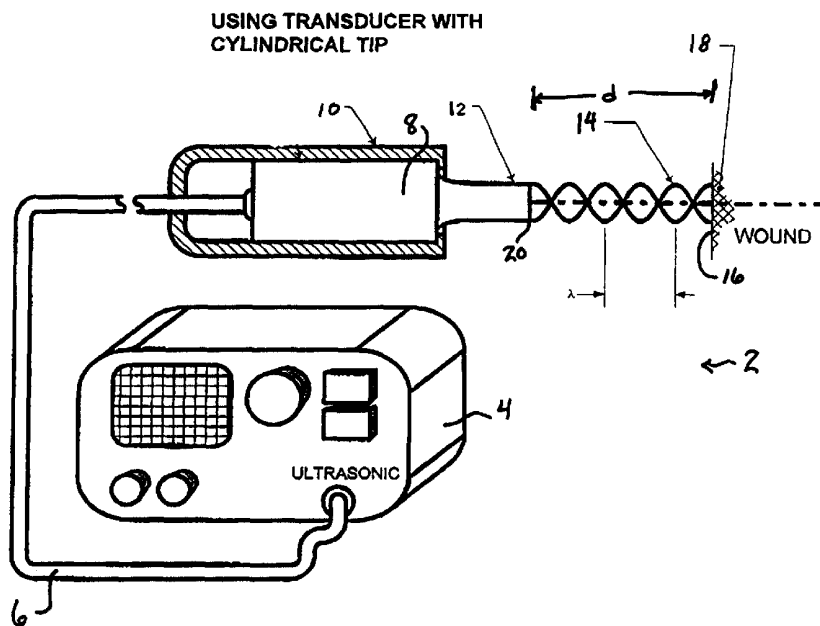
PCT

(10) International Publication Number
WO 02/060525 A2

- (51) International Patent Classification⁷: **A61N**
 - (21) International Application Number: PCT/US02/02724
 - (22) International Filing Date: 30 January 2002 (30.01.2002)
 - (25) Filing Language: English
 - (26) Publication Language: English
 - (30) Priority Data:
09/774,145 30 January 2001 (30.01.2001) US
 - (71) Applicant (for all designated States except US): **ADVANCED MEDICAL APPLICATIONS, INC.** [US/US];
6570 Edenvale Boulevard, Eden Prairie, MN 55346 (US).
 - (72) Inventor; and
 - (75) Inventor/Applicant (for US only): **BABAEV, Eilaz** [US/US]; 5564 Bimini Drive, Minnetonka, MN 55343 (US).
 - (74) Agents: **LIKOUREZOS, George** et al.; Carter, Deluca, Farrell and Schmidt LLP, 445 Broad Hollow Road, Suite 225, Melville, NY 11747 (US).
 - (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
 - (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
- Published:**
— without international search report and to be republished upon receipt of that report

[Continued on next page]

(54) Title: ULTRASOUND WOUND TREATMENT METHOD AND DEVICE USING STANDING WAVES



(57) Abstract: The method and device of the present invention for wound treatment with ultrasound standing waves includes a transducer probe to produce ultrasonic waves. The ultrasonic transducer has a tip with a distal radiation surface that radiates ultrasound energy toward the surface of a wound. Ultrasound standing waves occurring as a result of incident and reflected waves from the wound surface create ultrasonic radiation pressure. ultrasound radiation pressure increases the blood flow in wound area, and ultrasound waves kill bacteria, stimulate healthy tissue cell and treat wounds.

WO 02/060525 A2



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

ULTRASOUND WOUND TREATMENT METHOD AND DEVICE

USING STANDING WAVES

FIELD OF INVENTION

5 The present invention relates to the treatment of wounds using ultrasound standing waves. In particular, the present invention relates to a method and device of creating ultrasonic standing waves in air and directing them to a wound for delivering aerodynamic forces as ultrasonic radiation pressure and ultrasonic waves as well. Ultrasound radiation pressure increases the blood flow in the wound area, and ultrasound waves kill bacteria, stimulate healthy tissue cells, and treat the wound.

10

BACKGROUND OF THE INVENTION

Ultrasonic waves have been widely used in medical applications, including diagnostics and therapy as well as many industrial applications, e.g., welding, cutting, fiber optics technology, speed meters, etc. Diagnostic use of ultrasound waves
15 includes using ultrasonic waves to detect underlying structures in an object or human tissue. In this method, an ultrasonic transducer is placed in contact with the tissue or object via a coupling medium, and high frequency (1-10 MHz) ultrasonic waves are directed into the tissue. Upon contact with the various underlying structures, the waves are reflected back to a receiver adjacent the transducer. By comparison of the
20 signals of the ultrasonic waves sent with the reflected ultrasonic wave as received, an image of the underlying structure can be produced. This technique is particularly useful for identifying boundaries between components of tissue and can be used to detect irregular masses, tumors, etc.

Three therapeutic medical uses of ultrasound waves include aerosol mist
25 production, contact physiotherapy, and soft tissue ablation. The ultrasound contact physiotherapy procedure may cause a patient significant discomfort and/or pain, and skin may appear raw and damaged. Aerosol mist production makes use of a nebulizer

or inhaler to produce an aerosol mist for creating a humid environment and delivering drugs to the lungs.

5 Ultrasonic nebulizers operate by passing ultrasound waves of sufficient intensity through a liquid, the waves being directed at an air-liquid interface of the liquid from a point underneath or within the liquid. Liquid particles are ejected from the surface of the liquid into the surrounding air following the disintegration of capillary waves produced by the ultrasound. This technique can produce a very fine dense fog or mist.

10 Aerosol mists produced by ultrasound are preferred because a smaller particle size of the aerosol can be obtained with the ultrasonic waves. One of the major shortcomings of ultrasonic inhalers and nebulizers is that there is no directed aerosol to the target. An air stream is then required to direct the aerosol to the target, but this decreases the efficiency of ultrasound.

15 Ultrasonic sprayers (Sonic and Materials Inc., Misonix Inc., Sono-Tek Inc., Zevex International, Inc., operate by passing liquid through central orifice of ultrasound instrument-tip. See, for example, U.S. Patents Nos. 3,765,606; 4,659,014; 5,104,042; 4,930,700; 4,153,201; 4,655,393; 5,516,043; 5,835,678; 5,879,364; and 5,843,139.

20 Ultrasonic inhalers and drug delivery systems from Medisonic USA, Inc., 3M, Siemens Gmb, The Procter & Gamble Company, Sheffield Pharmaceuticals, Aradigm, Inc., operate by atomizing liquid using piezoceramic film. See, for example, U.S. Patents Nos. 4,294,407; 5,347,998; 5,520,166; 5,960,792; 6,095,141; 6,102,298; 6,098,620; 6,026,808; and 6,106,547.

OBJECT OF THE INVENTION

It is an object of the invention to provide an improved method and device for treating wounds.

It is also an object of this invention to provide an improved method and device
5 for treating wounds using ultrasound standing waves.

It is a further object of the invention to provide a method and device for increasing blood flow, killing bacteria, and stimulating healthy tissue cell growth.

These and other objects of the invention will become more apparent from the discussion below.

10

SUMMARY OF INVENTION

The present invention is a method and device for using ultrasonic standing waves to treat wounds. Ultrasound standing waves occur as a result of incident and reflected waves from a reflective surface that are traveling in opposite directions. The
15 resultant superposition of the two waves forms standing waves, which create ultrasonic radiation pressure. The standing waves, actually ultrasound radiation pressure, occur when the distance between (a) the distal end of a transducer (as a radiant of ultrasound waves) and (b) the reflected surface (e.g., a wound surface) is: $n \times \lambda/2$, where λ is the wave length and n is a positive integer. The standing waves are more effective in
20 limited space or area as a tube.

According to the invention ultrasound waves are created, directed, and delivered to a wound surface through the air to increase blood flow, kill bacteria, stimulate healthy tissue cells and treat wounds with ultrasound energy. The method of treating wounds involves the use of ultrasound standing waves of a continuous or
25 pulsed ultrasound.

More particularly, the method of the invention comprises producing ultrasound standing waves using a free end surface of an ultrasonic transducer and wound surface.

According to the method of the present invention, the radiation pressure of ultrasonic standing waves increase blood flow in wound area and destroy the surface bacteria to result in a higher disinfecting property of ultrasound. Additionally, the ultrasound also stimulates healthy cell growth to aid in granulation and epithelization of the healing tissue. Other applications of the method can be directed to non-medical uses such as cleansing, drying, sterilizing and coating surfaces of objects and food.

The method of the present invention offers an approach that may re-establish use of some traditional ultrasound and establish a method of treating wound and fighting bacteria without antibiotics when necessary.

The overall concept of the present invention relates in method and apparatus for wound treatment using ultrasonic standing waves through air with no drug. This wound treatment method is possible with combination of different energy sources as an ultrasound, laser, electric current, magnetic field, ultraviolet, microwaves, radio frequency, etc.

15

BRIEF DESCRIPTION OF DRAWINGS:

Fig. 1 is a perspective view of an ultrasound wound treatment system with standing waves, according to the present invention;

Fig. 2 is a schematic, lateral cross-sectional view of another transducer useful with the system of Fig. 1.

Fig. 3 is a schematic, lateral cross-sectional view of a transducer having a bushing;

Fig. 4 is a schematic, lateral cross-sectional view of a transducer of Fig. 3 where the distal tip has been modified to provide a focussed beam; and

Fig. 5 is a schematic, lateral cross-sectional view of an embodiment of the invention intended to facilitate dissolution of blood clots.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is a method and system, which uses ultrasound standing wave energy to treat wounds. The system comprises a generator of electrical signals and a handpiece having an ultrasound transducer and tip.

The invention can perhaps be better appreciated from the drawings. A system for wound treatment according to present invention is illustrated in Fig. 1. The system comprises a signal generator 4 operatively or electrically connected through cable 6 to a transducer 8 in a housing 10. Transducer 8 has an ultrasound tip 12 that generates standing ultrasound waves 14. Standing ultrasound waves 14 are directed to the surface 16 of a wound 18.

Standing ultrasound waves 14 occur when activated ultrasound tip 12 is directed through the air to a wound surface 16 as a result of incident and reflected waves from wound surface 16, which creates ultrasonic radiation pressure. The distal end 20 of transducer tip 12 (as a radiant of ultrasound waves) is preferably a distance d from wound surface 16 (a source of reflected waves). Distance d is related to the wavelength λ of the ultrasound wave or signal by the formula

$$d = n \times \lambda/2$$

where n is a positive integer. To reach this preferred distance and therefore effect wound treatment practice, ultrasound transducer 8 or tip 12 must frequently be moved back and forward toward wound surface 16 by an operator.

The waveform of the ultrasound waves generated by transducer 8 preferably corresponds to the waveform of the electrical signals generated by signal generator 4. For example, electrical signals from signal generator 4 with rectangular, sinusoidal, trapezoidal, or triangular waveforms will cause transducer 8 to produce respective similarly shaped ultrasound waveforms.

The standing waves are more effective in limited space or area such as a tube. In each of Figs. 3 to 5 a bushing 26 increases ultrasound radiation pressure. Bushing 26 may or may not be disposable part on the distal end 28 of housing 10.

In the embodiment of the invention set forth in Fig. 4 the distal end 28 of ultrasonic tip 12 has been modified to a concave shape to focus ultrasound waves 14.

One of the possible applications of the method of present invention is the facilitation of dissolution of blood clots by using ultrasound energy. In Fig. 5
5 ultrasound tip 12 is directed to a blood vessel 30 with clot or clots 32. In this case ultrasound standing waves 34 create cavitation inside blood vessel 30 and dissolve clot or clots 32.

In another embodiment of the present invention a wound can also be treated with a gel or drug. After the gel or drug is applied to the wound surface, ultrasound
10 standing waves would be directed to the wound. The drug would be activated and penetrate into tissue under ultrasound radiation pressure.

Additional possible application of method using ultrasound standing waves is for the diffusion of grafts to a wound with radiation pressure gently.

The preceding specific embodiments are illustrative of the practice of the
15 invention. It is to be understood, however, that other expedients known to those skilled in the art or disclosed herein may be employed without departing from the spirit of the invention or the scope of the appended claims.

I CLAIM:

1. A method of treating a wound, comprising the step of positioning an ultrasound transducer having a distal radiation surface to direct an ultrasound standing wave at a surface of a wound, wherein the distance d between distal radiation surface and the wound surface is determined by the formula

$$d = n \times \lambda / 2$$

wherein λ is the wavelength of the ultrasound standing wave and n is a positive integer.

2. The method of Claim 1, wherein the ultrasound transducer operates at a frequency of from about 10kHz to 10^3 MHz.

3. The method of Claim 1, wherein d is at least 0.1 in.

4. The method of Claim 1, wherein the ultrasound transducer is frequently moved back and forth in a longitudinal direction by an operator to reach a preferred distance to create a standing wave.

5. The method of Claim 1, wherein the ultrasound standing wave creates radiation and/or pressure that energizes the wound.

6. The method of Claim 1, wherein in a prior step a gel, drug, or other medicant is applied to the wound surface.

7. The method of Claim 6, wherein any medical effect of the gel, drug, or other medicant is energized by the ultrasound standing wave.

8. The method of Claim 1, wherein the ultrasound standing wave has an ultrasound radiation, pressure, massage, and/or sterilization effect.

9. A system for treating a wound with ultrasound standing waves, comprising

a generator for generating ultrasound waves,

an ultrasound transducer operatively connected to said generator and having a distal radiation surface, and

means for adjusting the distance between the distal radiation surface and a surface of a wound to create ultrasound standing waves.

10. The system of Claim 9, wherein the ultrasound transducer operates at a frequency of from about 10KHz to 10^3 MHz.

5 11. The system of claim 9, wherein the distal end of the ultrasound transducer comprises a bushing.

12. The system of Claim 9, wherein the ultrasound frequency is modulated.

13. The system of claim 9, wherein the ultrasound frequency is pulsed.

14. The system of Claim 9 wherein the waveform of the ultrasound wave is
10 sinusoidal.

15. The system of Claim 9, wherein the wave form of the ultrasound wave is rectangular.

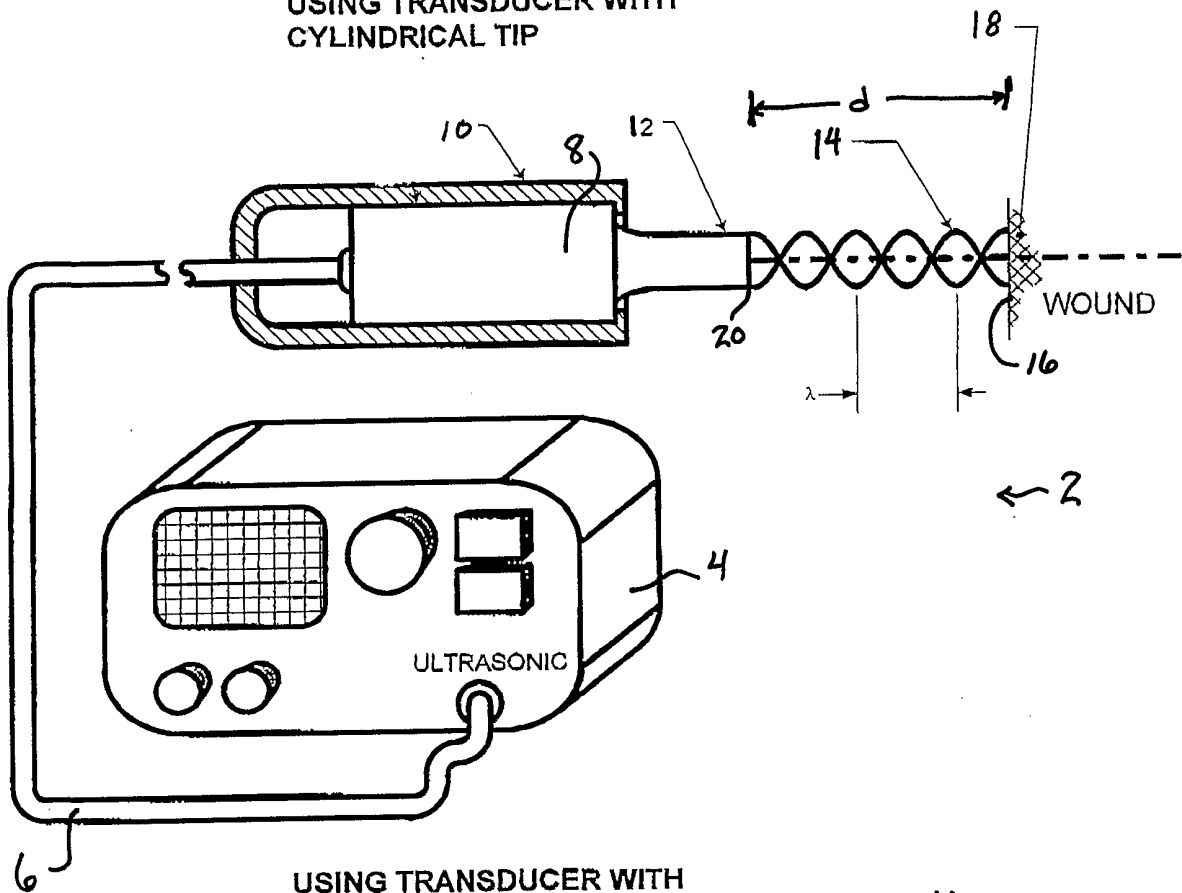
16. The system of Claim 9, wherein the wave form of the ultrasound wave is trapezoidal.

15 17. The system of Claim 9, wherein the waveform of the ultrasound wave is triangular.

18. The system of Claim 9, wherein the ultrasound beam is focussed.

FIGURE 1

USING TRANSDUCER WITH
CYLINDRICAL TIP



USING TRANSDUCER WITH
INCREASED RADIATION SURFACE

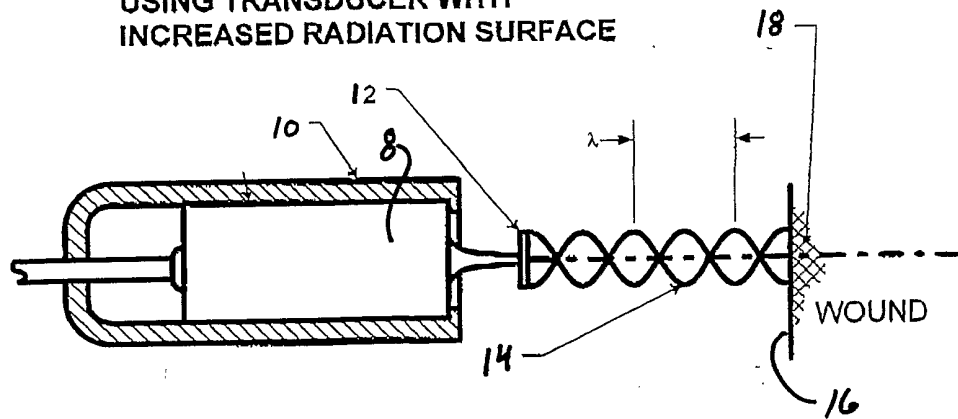


Fig. 2

FIGURE 3

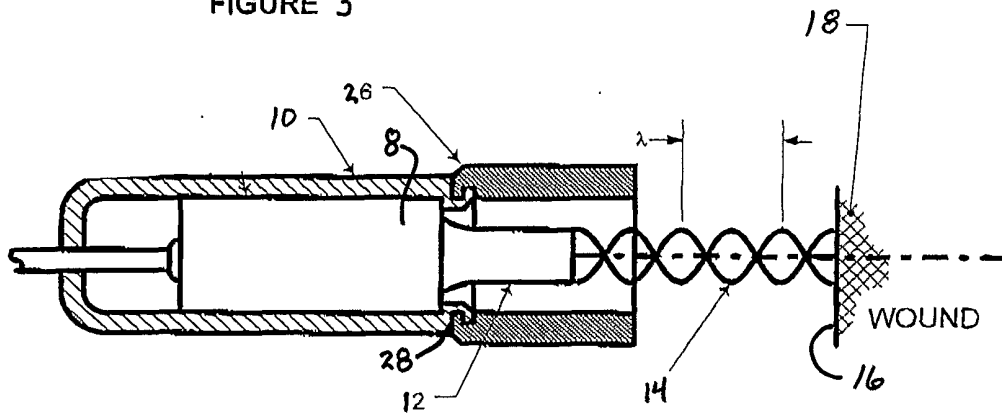


FIGURE 4

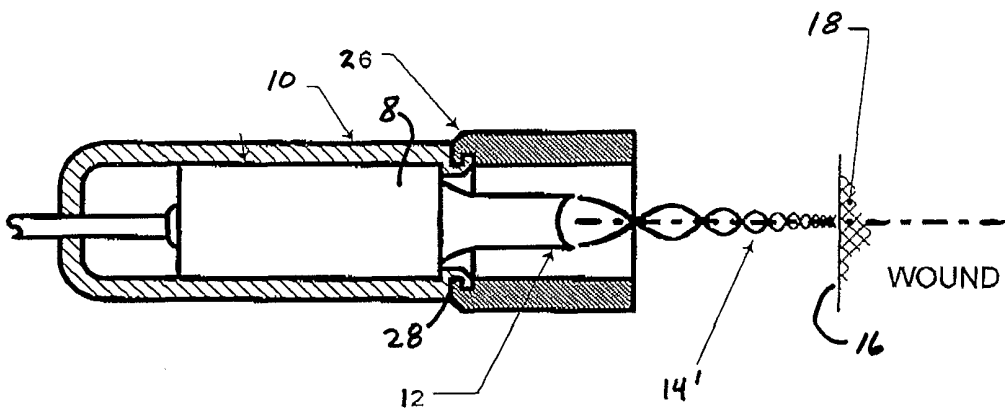


FIGURE 5

