

HIGH INTENSITY FOCUSED ULTRASOUND (HIFU) PROBE

FIELD OF THE INVENTION

[0001] The present disclosure relates to probe for use in tissue ablation having a transducer which can be changed in shape between two orientations. Preferably, the probe is a high intensity focused ultrasound (HIFU) probe. The present disclosure further provides a therapy process utilising a probe for tissue ablation.

BACKGROUND TO THE INVENTION

[0002] Ultrasonic devices commonly include ultrasound imaging devices. Ultrasound signals can be attenuated partly via the conversion of mechanical wave energy to thermal energy. This known property of mechanical wave energy being converted to heat energy has led to the development of other medical applications which harness the heat of such a process. For example, intensified ultrasound energy has been used to heat and kill cells within a subject and in particular to ablate tumour tissue through a process called coagulative necrosis. Probes have been developed for insertion into a patient having a transducer to generate ultrasound waves that are focused onto an individual focal region of tissue to be ablated. The probe can be manipulated/manoeuvred to adjust the focal region to ensure ablation and formation of lesions on all of the required tissue.

[0003] This type of therapy is referred to as High Intensity Focused Ultrasound (HIFU). Typically tissue is generally heated to somewhere in the region of 65°C to 100°C. Temperatures generated at the upper end of this range and higher may cause boiling of liquids in the body tissue.

[0004] An alternative to thermal tissue destruction via HIFU is mechanical HIFU ablation. In some situations tissue emulsification caused by mechanical HIFU damage may be preferable to thermal tissue damage as the resulting liquefied volumes may be absorbed or removed more easily compared to coagulative

tissue caused by thermal damage. A mechanical disruption may be achieved by exposing tissue to repeated short duration pulses of high-intensity ultrasound. High intensity pulses may form bubbles that mechanically disrupt tissue. Such pulses are typically, of microsecond to millisecond duration. These treatments may reduce the undesirable effects on surrounding tissue that may be caused by thermal HIFU damage.

[0005] US Patent No. 9,700,742 describes methods and systems for HIFU therapy utilising mechanical damage of tissue. Such HIFU system is configured such that the duration of each pulse is at least equivalent to the time necessary to induce tissue boiling at approximately 100° C. Each pulse may create one or more boiling bubble having a cross-sectional dimension of 2-4mm. This treatment method can emulsify tissue. US 9,700,742 utilises an imaging system to monitor temperature and boiling activity during HIFU treatments. It would be desirable to improve on the methods and/or systems described in this document.

[0006] US Patent No. 6,461,314 discloses to a HIFU applicator for applying sonic energy within the body of a living subject. The apparatus includes a probe with a distally located 'spatially-distributed sonic transducer', which can emit sound from a plurality of spaced apart transducer elements. The transducer can be deformable to move one portion of the transducer relative to another. It is desired to provide a probe which provides an alternative to the spatially-distributed transducer of US 6,461,314.

[0007] It would be desirable to provide a probe or method of use of a probe which is improved in some aspect or which solves at least one problem associated with the prior art.

SUMMARY OF THE INVENTION

[0008] An aspect of the present invention provides a probe for use in targeted ablation of tissue within a subject, comprising a transducer, and first and second

control lines, the transducer having a plurality of distinct shape elements, wherein each shape element is shaped to correspond to at least one other shape element, wherein the transducer has a first orientation in which the shape elements are aligned in a substantially elongate manner adapted for insertion into a subject, and the transducer has a second orientation in which the corresponding shapes of the shape elements are combined together to form a focusing arrangement adapted to focus ultrasound waves onto an area of tissue of the subject to be ablated, wherein the control lines are configured such that tensioning of the first control line causes the transducer to change from the first to the second orientation, and tensioning of the second control line causes the transducer to change from the second to the first orientation.

[0009] According to embodiments, the probe comprises at least one hinge. Each hinge may connect adjacent shape elements.

[0010] According to embodiments, the probe includes more than two control lines. Each control line may attach to one or more of the shape elements. Preferably, the control lines attach to at least two shape elements. The control lines may function by being pulled or released from a proximal end such that the distal end of the control line moves towards or away from the proximal end of the probe. The control lines may be controlled manually or via mechanical or electrical motion means.

[0011] The probe may comprise at least one biasing element and each biasing element biases the transducer to one of the first orientation or the second orientation. The biasing element is preferably a spring. One or each hinge may be a biasing element. The biasing element may be in the form of a torsion spring. According to embodiments, one of the control lines is the biasing element.

[0012] The selective tensioning of the first and second control lines may be utilised to control the motion of the shape elements between the orientations. In other words, both control lines may be controlled by either being tensioned or

released simultaneously to more accurately control the movement of the transducer between the first and second or between the second and first orientations.

[0013] According to another aspect of the invention, there is provided a probe for use in targeted ablation of tissue within a subject, comprising: a transducer having a plurality of distinct shape elements, wherein each shape element is shaped to correspond to at least one other shape element, wherein the transducer has a first orientation in which the shape elements are aligned in a substantially elongate manner adapted for insertion into a subject, and the transducer has a second orientation in which the corresponding shapes of the shape elements are combined together to form a focusing arrangement adapted to focus ultrasound waves onto an area of tissue of the subject to be ablated; at least one hinge connecting adjacent shape elements; at least one biasing element positioned between adjacent shape elements, said biasing element being configured to bias the transducer towards one of the first and second orientations; and a control mechanism configured, when activated, to act against the bias of the biasing element to change the transducer from the first to the second orientation or from the second orientation to the first orientation.

[0014] According to embodiments, the control mechanism includes at least one motor.

[0015] According to embodiments, the at least one hinge comprises said at least one biasing element. In embodiments where the probe comprises a number of hinges, each hinge may comprise at least one biasing element. The at least one biasing element may be a spring. According to embodiments, the at least one biasing element is a torsion spring.

[0016] The probe according to any of the aspects or embodiments may resemble a dish when in the second orientation. For example, the transducer may be substantially circular when view from one direction when in the second

orientation. Each shape element may be an individual part of the dish shaped transducer, for example each shape element may include at least one concave and/or partially concave face or surface. Alternatively, the transducer may be another shape which provides the ability to focus soundwaves onto a target area of tissue within a subject.

[0017] According to embodiments of any of the described aspects, the plurality of shape elements are connected together by at least one hinge which extends in the longitudinal direction of the probe. The transducer may comprise a plurality of part-circular shape elements connected together by at least one hinge.

[0018] According to embodiments of any of the described aspects, the plurality of shape elements are connected together by at least one hinge which extends in the lateral direction of the probe. Optionally, the plurality of shape elements are connected together in such a manner as to form an elongate arrangement of shape elements in the first orientation, and, in the second orientation, the plurality of shape elements form a substantially circular focusing arrangement.

[0019] The shape elements may be polygonal in one cross-section. In embodiments, the shape elements are hexagonal in the cross-section and the transducer in the second orientation is in the form of a hexagonal ring.

[0020] Another aspect of the present invention provides a probe for use in targeted ablation of tissue within a subject, comprising a transducer, the transducer having a plurality of distinct shape elements, wherein each shape element is shaped to correspond to at least one other shape element, and wherein each shape element comprises a magnetic element, wherein the transducer has a first orientation in which the shape elements are aligned in a substantially elongate manner adapted for insertion into a subject, and the transducer has a second orientation in which the corresponding shapes of the shape elements are combined together to form a focusing arrangement adapted to focus ultrasound waves onto an area of tissue of the subject to be ablated,

wherein the magnetic elements are configured to change the transducer from the first orientation to the second orientation by bringing together opposed magnetic poles of adjacent shape elements.

[0021] Each magnetic element may be an electromagnet which can be energised to change the transducer from the first orientation to the second orientation. The shape elements may be connected to a distinct power line which supplies energy to energise the magnetic element. Alternatively, the shape elements may share a common power line. According to embodiments, the shape elements are selectively energised in a sequence to progressively change from the first orientation of the transducer to the second orientation. Alternatively, the shape elements may be energised simultaneously.

[0022] The shape elements may be elongate members that are adapted to be inserted into the subject one after the other. According to embodiments, the shape elements are distinct elongate members that are adapted to be inserted into the subject individually.

[0023] According to embodiments of a probe, the transducer is formed from a plurality of transducer elements. Each shape element may be a transducer element.

[0024] According to embodiments, the transducer includes at least one transducer element adapted to generate image ultrasound waves and configured to determine one or more of: an orientation state of the probe, a location of the probe, a relative position of the probe, an orientation state of a shape element, a location of a shape element or a relative position of a shape element, and/or configured for use in guiding the probe during insertion into the subject. Optionally, at least one said shape element comprises at least one said transducer element.

[0025] The probe according to any of the above aspects or embodiments may comprise at least one sensor which is adapted to send signals representative of the orientation of the transducer. The at least one sensor may be adapted to additionally or alternatively send signals representative of the position and/or location of the transducer within the subject. According to embodiments, each shape element includes one of the sensors.

[0026] According to exemplary embodiments, the probe is a high intensity focused ultrasound (HIFU) probe and the transducer is adapted to emit a focused ultrasound waves when in the second orientation.

[0027] It is understood that any of the individual features provided above or described below or shown in the accompanying figures may themselves be the subject of independent or dependent claims. The features as described herein may be utilised in any combination as would provide a beneficial outcome and no single embodiment is considered on its own to be limiting to the scope of the invention. Accordingly, the present disclosure may contain a plurality of inventions.

[0028] Another aspect of the present invention provides a method of use of an ultrasonic probe, comprising the following steps:

A) providing a probe having a head adapted to generate a focused beam of ultrasonic waves;

B) generating and focusing ultrasonic waves onto a first target region for a predetermined period of time;

C) generating and focusing ultrasonic waves onto a plurality of other target regions in turn for the predetermined period of time until each of the first target region and other target regions has been partially ablated for the predetermined period of time to complete a cycle; and

D) repeating steps B and C until a predetermined number of cycles has been completed.

[0029] Optionally, step A comprises providing the probe according to any one of the aspects or embodiments described above. According to embodiments, the method includes a pause period between each predetermined period of time in which the respective target region receives the ultrasonic waves, each pause period being a period of time where no ultrasonic waves are generated.

[0030] According to embodiments, the first target region and other target regions form a first portion of a target volume, and wherein the target volume comprises a second portion having a plurality of second target regions, and wherein the method further comprises:

E) generating and focusing ultrasonic waves onto the plurality of second target regions in turn for a predetermined period of time until each of the first target region and other target regions has been partially ablated for the predetermined period of time to complete a cycle; and

D) repeating step E until a predetermined number of cycles has been completed.

[0031] The method may further comprise a pause period between each predetermined period of time in which the respective second target region receives the ultrasonic waves, each pause period being a period of time where no ultrasonic waves are generated.

BRIEF DESCRIPTION OF THE DRAWINGS

[0032] Embodiments of the present invention will now be described, by way of non-limiting example, with reference to the accompanying drawings, in which:

[0033] Figure 1A shows an isometric view of a probe according to a first embodiment in a first orientation;

[0034] Figure 1B shows an isometric view of the probe of the first embodiment in a second orientation;

[0035] Figure 2A shows an isometric view of a probe according to a second embodiment in a first orientation;

[0036] Figure 2B shows an isometric view of the probe of the second embodiment in a second orientation;

[0037] Figure 3A shows an isometric view of a probe according to a third embodiment in a first orientation;

[0038] Figure 3B shows an isometric view of the probe of the third embodiment in a second orientation;

[0039] Figure 4A shows an isometric view of a probe according to a fourth embodiment in a first orientation;

[0040] Figure 4B shows an isometric view of the probe of the fourth embodiment in a second orientation;

[0041] Figure 4C shows a longitudinal cross-section the probe of the fourth embodiment in the first orientation;

[0042] Figure 5A shows an isometric view of a probe according to a fifth embodiment;

[0043] Figure 5B shows an isometric view of the probe of the fifth embodiment in a second orientation;

[0044] Figure 5C shows a front view of the probe of the fifth embodiment in the second orientation;

[0045] Figure 6 shows an ablation technique using the probe of the second embodiment;

[0046] Figures 7A and 7B show prior art ultrasound pulse methods used to ablate tissue; and

[0047] Figure 8A and 8B show an embodiment of an ultrasound pulse method that may be utilised with a HIFU probe as described herein.

DESCRIPTION OF PREFERRED EMBODIMENTS

[0048] Described herein and shown in the accompanying figures 1 to 5 are embodiments of a probe for use in the targeted ablation of tissue within a living subject. Each embodiment of a probe according to the present disclosure includes two orientations between which the probe can be changed to suit its purpose. For example, in a first orientation, the probe may be substantially elongate in overall shape with the purpose of delivery into the body of a subject. In a second orientation, the probe includes a fully formed transducer surface which may be utilised for the targeted ablation of tissue of a subject. Various methods of changing between the first and second orientations are contemplated within the scope of the present disclosure.

[0049] Within the present disclosure, the discussion relating to a transducer and transducer elements relates to use of these terms as known in the art. For example, in the present disclosure, a transducer is utilised to emit soundwaves and may include piezoelectric substrates and elements, and electrodes. A transducer element may include the piezoelectric substrate and electrodes and a number of transducer elements may be combined to form one larger transducer. The transducer being utilised for the purpose of emitting soundwaves, and in particular ultrasound waves, which are focused onto a target point or area for ablation of target tissue.

[0050] Figures 1A and 1B show a first embodiment of a (high intensity focused ultrasound) HIFU probe 10. The probe 10 is intended for use at a distal end of an apparatus for insertion into a subject's body. The probe 10 is attached to a flexible cable 11 via the cable sleeve 12. The flexible cable 11 is utilised to deliver energy and/or signals to and from the probe. For example, the signals may be control signals to control the orientation of the probe 10, alternatively the signals may be sensor signals which are sent to another location from one or more sensors within the probe 10.

[0051] The probe 10 is formed from two transducer halves 15, 16 in the form of shape elements which are each substantially shaped as semi-circular prisms. The transducer halves are connected to one another via hinges 14A, 14B. The hinges 14A, 14B permit the transducer halves 15, 16 to be positioned in a first orientation (figure 1A) in which the width of the probe is reduced and the transducer halves are folded back onto each other. By pivoting the second transducer half 16 relative to the first half 15 about the hinges 14A, 14B the probe may be transformed to its second orientation (figure 1B) when the transducer halves 15, 16 combine to form a complete transducer. In the second orientation the transducer halves of the probe 10 may be used for the purpose of focusing ultrasound waves onto a target location. To aid the ultrasound focusing purpose of the probe's second orientation, each of the transducer halves 15, 16 includes an at least partially concave surface 17, 18. The transducer halves 15, 16 generate and emit an ablation ultrasound which may be used to ablate target tissue.

[0052] The transducer element 13 of the probe 10 is also adapted to generate and emit the ultrasound waves. The transducer element 13 may emit image ultrasound waves to create a visual image to assist in guiding the probe 10 when being inserted into the subject. Additionally or alternatively, the ultrasound waves generated by the transducer element 13 may be used to monitor the therapy process being carried out. The transducer element 13 may optionally be omitted in other embodiments should its features not be desired.

[0053] Figures 2A and 2B show a second embodiment of a HIFU probe 20 according to the present disclosure. In some respects, the probe 20 is similar that that shown in figures 1A and 1B. The probe 20 is intended for use at a distal end of an apparatus for insertion into a subject's body. The probe 20 is attached to a flexible cable 21 via the cable sleeve 22. The flexible cable 21 is utilised to deliver energy and/or signals to and from the probe. For example, the signals may be control signals to control the orientation of the probe 20, alternatively the signals may be sensor signals which are sent to another location from one or more sensors within the probe 20.

[0054] The probe 20 is formed from three transducer shape elements 25, 26, 27 which are movable relative to one another via hinges 24 (note: a hinge between first and second shape elements 25, 26 is not shown in figures, but will function similarly to first hinge 24 between the first and third elements 25, 27). The first shape element 25 is located centrally of the second and third shape elements 26, 27. Figure 2A shows the probe 20 in a first orientation of reduced width which is adapted for delivery of probe 20 into a subject, such as through an incision in the subject's skin and/or within a catheter. Figure 2B shows the probe 20 in a second orientation where the second and third shape elements 26, 27 are pivoted via the hinges 24 to join the central shape element 25 and to form a substantially circular transducer head. The transducer head is substantially or at least partially dish shaped, in other words, the shape elements 25, 26, 27 each include at least partially concave front surfaces 285, 286, 287. The shape elements 25, 26, 27 generate the ultrasound waves that are used for ablation of target tissue.

[0055] The transducer element 23 of the probe 20 is also adapted to generate and emit the ultrasound waves. The transducer element 23 may emit image ultrasound waves that are used to create a visual image to assist in guiding the probe 20 when being inserted into a subject. Additionally or alternatively, the ultrasound waves generated by the transducer element 23 may be used to monitor the therapy and ablation process as it is being carried out. According to other embodiments the transducer element 23 could be omitted if its guiding or

monitoring uses are not desired, however in many embodiments these are desirable features.

[0056] Figures 3A and 3B show a third embodiment of a probe 30 according to the present disclosure. The figures 3A, 3B omit the cable and cable sleeve depicted in the figures 1 and 2, however it is understood that the fully assembled probe 30 would in use be connected to a similar cable to convey any required energy or signal lines.

[0057] The probe 30 is formed from twelve transducer shape elements 35A:35L. The shape elements 35 being shaped to correspond to each adjacent shape element 35, such that when the probe 30 is in a second orientation (figure 3B) the shape elements 35 combine to form a focusing transducer head of the probe 30. Each of the shape elements 35 is connected to an adjacent shape element 35 via a pivot 34. The pivots 34 may be in the form of hinges.

[0058] In the first orientation as shown in figure 3A, the shape elements 35 are arranged in an elongate pattern. Specifically, in this embodiment, the shape elements 35 are arranged in pairs spaced apart longitudinally along the rear member 39. The rear member 39 is adapted to substantially rigidly maintain the elongate alignment of the shape elements 35 in the first orientation. In the second orientation shown in figure 3B, the shape elements have been pivoted on their respective pivots 34 to form the transducer head. Each shape element 35 includes a concave surface 38A:38L which together may create a dish/concave shaped head that is adapted to focus ultrasound waves for tissue ablation. In addition, any one or more of the shape elements 35A:35L may be configured to emit an image ultrasound for use in delivery guidance or monitoring. The shape element(s) 35 that generates image ultrasound may be utilised in a similar manner as the transducer elements 13, 23 discussed above in relation to the first and second embodiments.

[0059] Figures 4A to 4C show a fourth embodiment of a probe 40 according to the present disclosure. The probe 40 is intended for use at a distal end of an apparatus for insertion into a subject's body. The probe 40 is attached to a flexible cable 41 via the cable sleeve 42. The flexible cable 41 is utilised to deliver energy and/or signals to and from the probe. For example, the signals may be control signals to control the orientation of the probe 40, alternatively the signals may be sensor signals which are sent to another location from one or more sensors within the probe 40.

[0060] The probe 40 includes six shape elements 45A:45F. Each shape element 45 is a hexagonal prism with hexagonal front face. The hexagonal front face of each shape element 45 preferably includes a concave surface such that when the shape elements 45 are combined in the second orientation of the probe 40 (figure 4B) the probe 40 is in the form of a hexagonal ring shaped transducer which can focus ultrasound waves on a target as desired. Each shape element 45 is connected to an adjacent shape element 45 via a pivot 44. The first shape element 45A and last shape element 45F (proximally to distally) each include an end point 49 which are adapted to connect to one another when the probe 40 is in its second orientation as shown in figure 4B.

[0061] In the first orientation shown in figure 4A, the shape elements 45 are arranged in an elongate pattern with reduced overall width compared to the second orientation. In other words, the shape elements 45 are arranged one after the other in a line. The components of the probe 40 may be adapted such that the elongate orientation of the shape elements 45 can be controlled or held in place firmly to assist with ease of deployment of the probe 40 within the body of a subject. To change shape from the first orientation (figure 4A) to the second orientation (figure 4B) the shape elements 45 pivot about the pivots 44 such that a side face of each shape element 45 contacts a like side face of an adjacent shape element 45.

[0062] According to the fourth embodiment of figures 4A and 4B, the shape elements 45 could be pivoted in either direction by pivots 44, such that the second orientation of the probe 40 could be formed by rotating the shape elements 45 downwardly or upwardly from the elongate position shown in figure 4A. In addition, the movement of the shape elements 45 upwardly and/or downwardly may be controlled during insertion into a subject to guide the probe 40 during insertion to a target site. The movement and pivoting of the shape elements may be controlled via the first and second control lines 46, 47 shown in figure 4C.

[0063] Figure 4B shows the probe 40 in the second orientation where the shape elements 45 have been rotated about the pivots downwardly. This ability of moving between the first and second orientations of the probe 40 may be of use in situations where the rotation in one direction is hindered when the probe is positioned within a subject and rotation in the opposite direction provides a backup movement to achieve the second orientation. However, the embodiments shown in figures 4A to 4C do not permit this ability to rotate in either direction since the cable 41 and cable sleeve 42 connected to the first shape element 45A will hinder any connection with the sixth shape element 45F when the shape elements 45 are rotated upwardly. In addition, the concave nature of the front face of each shape element 45 in the embodiment shown in figures 4A to 4C would mean that the ability to focus ultrasound waves in the second orientation requires the specific arrangement of figure 45B. In order to allow upward as well as downward rotation of the shape elements 45 to achieve the second orientation, the front face of the shape elements 45 would be configured to focus the ultrasound waves after having been rotated in either rotation direction or alternatively, the focusing effect or concave face of the shape elements 45 would be configured to be altered to suit the second orientation in use.

[0064] All of the first, second, third and fourth embodiment discussed require the ability to change from a first orientation, in which the width of the probe 10, 20, 30, 40 is minimised, and a second orientation, in which the shape elements of the

probe 10, 20, 30, 40 combine to form a transducer head which can focus ultrasound energy onto a target area of tissue. Various manners of achieving the change of orientation are envisaged within the scope of the present disclosure.

[0065] One manner of changing the probe 10, 20, 30, 40 from the first orientation to the second orientation involves the use of control lines. As an example, figure 4C shows an embodiment with two control lines 46, 47. However, it is envisaged that alternative embodiments may be possible within the scope of the present disclosure which utilise any other number of control lines. For example, a probe may include one control line, additionally or alternatively a probe may have three or more control lines.

[0066] Figure 4C shows a longitudinal cross-sectional view of the probe 40 according to the fourth embodiment. The first control line 46 and second control line 47 may be either manually, mechanically, electronically controlled or controlled via any other means. The control lines 46, 47 run the length of the cable 41 (not shown) to a proximal end which provides a control input. The control lines 46, 47 pass through the cable sleeve/collar 42 into the first shape element 45A and then through each of the intermediate shape elements 45B, 45C, 45D, 45E to the end shape element 45F. The distal end of the control lines 46, 47 are attached to the distal shape element 45F. The control lines 46, 47 preferably pass through narrow apertures through each of the shape elements 45, such that the alignment of the control lines through and relative to each of the shape elements 45 may be maintained.

[0067] In operation the control lines 46, 47 are both held substantially without any movement in order to maintain the orientation of the probe 40 shown in figures 4A and 4C. A small amount of give, flexibility of longitudinal movement may be allowed in the control lines 46, 47 when in the first orientation to permit a degree of flexing of the elongate shape of the probe 40 to allow for easier insertion of the elongate probe into a subject. To change the probe 40 from the first orientation to the second orientation requires tightening of the first control line

46 while allowing a degree of loosening of the second control line 47. In other words, the first line 46 is pulled proximally while the second line 47 may be permitted to length slightly distally. In order to control the motion of the shape elements 45 of the probe 40 between the first and second orientations the tightening or loosening of the first and second control lines 46, 47 may be precisely controlled. Once the probe 40 is in its second orientation, the tightening of the first control line 46 is stopped. The tightness of the first control line 46 in the second orientation is maintained to prevent the probe 40 from unwantedly moving out of the alignment of the second orientation when in use.

[0068] To change the probe 40 back from the second orientation to the first orientation the second control line 47 is tightened and the first control line 46 is loosened. A similar control over the respective tightening and loosening of the second and first control lines 47, 46 may be maintained to ensure a controlled motion of the shape elements 45. Once the probe 40 has returned to its first orientation the control of the control lines 46, 47 is stopped. For example, the probe 40 may be removed from the body of the subject after it has been returned to its first orientation.

[0069] Optionally or alternatively, the pivots 44 may be biased in some way towards the first orientation of the probe 40. For example, the pivots 40 may be utilised to resiliently retain the shape elements 45 in the alignment of the first orientation. In that case, to move from the second orientation back to the first orientation would require merely loosening the first control line and 46 allowing the bias of the pivots 44 to move the shape elements 45.

[0070] Within the scope of the present disclosure, it is conceived that the embodiments shown in figures 1, 2 and 3 can also include control lines similar to those shown in figure 4C. For example, the movement of the shape elements of the first, second and third embodiments may be controlled via a respective tightening and/or loosening of one or more respective control lines.

[0071] Another manner of motion between the first and second orientations requires the use of biasing elements. The biasing elements have an in-built resilience. The biasing elements may be in the form of spring, such as torsion springs. For example, according to the first, second, third and fourth embodiments, the hinges/pivots 14, 24, 34, 44 may themselves be biasing elements which are biased towards one of the first and second orientations. Alternatively, the biasing elements may be separate from the hinges/pivots. In any case, the biasing elements bias the probe 10, 20, 30, 40 towards one of the first and second orientations. The probe 10, 20, 30, 40 may therefore also include means for moving the shape elements against the bias of biasing element, such as at least one motor (not shown) or a control line. The control line may be controlled by a motor.

[0072] In order to manoeuvre between the first and second orientations, the movement means will be activated to cause the shape elements to pivot about their respective pivot(s)/hinge(s) 14, 24, 34, 44. To then manoeuvre back to the original orientation, the action of the movement means will be relaxed to allow the bias of the biasing elements to takeover and return the probe 10, 20, 30, 40 to its initial orientation.

[0073] In alternative embodiments of the present disclosure, the probe 10, 20, 30, 40 may include any combination of control lines, biasing elements and motors which enables the ability to efficiently, and preferably simply, change between the first and second orientations.

[0074] Figures 5A to 5C show a probe 50 according to a fifth embodiment of the present disclosure. The probe 50 includes a number of transducer sections / shape elements 51, 52, 53, 54. Each shape element 51, 52, 53, 54 is an elongate structure which is adapted for easy insertion/deployment into a subject. The shape elements 51, 52, 53, 54 each include a respective cable/line 55, 56, 57, 58. According to the embodiment shown in figures 5A to 5C, the shape elements 51, 52, 53, 54 are each separate from one another. In this

embodiment, the shape elements 51, 52, 53, 54 are adapted to be inserted either individually or in line one after the other. Each shape element 51, 52, 53, 54 includes an internal magnetic element and the lines 55, 56, 57, 58 are adapted to provide energy/control signals for the magnetic elements. Preferably, the magnetic elements are electromagnets and the lines 55, 56, 57, 58 provide an electrical current to energise the magnetic elements.

[0075] When the shape elements 51, 52, 53, 54 are ready to be changed from a first orientation, where they are separate from one another, to a second orientation, where they are connected together, the magnetic elements may be activated. Preferably, the magnetic elements of each of the shape elements 51, 52, 53, 54 will be activated/energised in a specified order such that the probe will form the second orientation progressively. For example, the first shape element 51 may be inserted first, followed by the second shape element 52 and once both are in the same vicinity the first shape element may be energised followed by the second shape element such that the opposed poles of each magnetic element attract one another and the two shape elements 51, 52 connect together. Next, the third shape element 53 may be inserted into the subject and energised to connect to the other side of the second shape element 52. Finally, the fourth shape element 54 may be inserted into the subject and energised to connect to the other side of the third shape element 53 and to complete the probe 50 being placed into its second orientation. Alternatively, each of the shape elements 51, 52, 53, 54 may be inserted into a subject together or following each other and energisation may only occur once all of the shape elements 51, 52, 53, 54 have been deployed into the subject.

[0076] According to other embodiments, not shown, the shape elements 51, 52, 53, 54 may be pivotally connected to one another, such as in a similar manner to the connections between shape elements in any of the first to fourth embodiments. In that case, the energisation of the shape elements may act against a bias of the pivot to form the second orientation of the probe. Furthermore, the use of magnetic elements within the shape elements may be

utilised in conjunction with the general shape and arrangement of any of the embodiments shown in figures 1 to 4.

[0077] As noted in figures 5A to 5C, the second line 56 is larger/thicker than the other lines 55, 57, 58. The reason for this is that the second line 56 includes energisation and signalling lines, where necessary, to energise the transducer element of the probe and/or to send sensor signals, similar to the flexible cable of any of the other embodiments. In other words, in the embodiment shown, the second shape element 52 is intended to include the transducer element which emits/generates ultrasound waves to be focused by the probe. Further, a surface of the probe 50 in the second orientation preferably includes a concave section to focus the generated ultrasound waves onto a target tissue location.

[0078] In embodiments, each of the shape elements of any of the embodiments may include one or more transducer elements which generate ultrasound waves in order to create the desired focused ultrasound waves onto a target tissue location. Furthermore, the shape elements of any of the embodiments may be formed in any desired shape which achieves the desired goal of providing a focused ultrasound probe, where there is a first and second orientation.

[0079] According to other embodiments, not shown, the probe may include a sensor which is adapted to send signals determinative of the orientation state of the probe. In addition or alternatively, the sensor of the probe may send signals representative of the location or position of the probe within the body of the subject (when deployed). Further, in preferred embodiments, each of the shape elements may include a sensor, such that the location and/or orientation of each of the shape elements and/or the probe as a whole may be known. According to embodiments, the probe and/or each shape element includes a transducer element which generates imaging ultrasound waves which are utilised to determine an orientation state, location and/or relative position of the probe and/or each shape element.

[0080] To utilise the HIFU probe effectively, it is desirable to utilise a method of operation of the probe which achieves the desired tissue ablation, ensures safety for the subject in which the probe is deployed and/or in particular is time/energy efficient.

[0081] In relation to thermal ablation techniques, one method of use is referred to as an 'always on' ablation method which focuses on ablating a specific region of tissue for a predetermined time until the specific tissue region is fully ablated. The ultrasound beam is then focused onto an adjacent region until that region is fully ablated, and so on until all of the specific regions making up a target area have been ablated. A possible outcome of this method is that tissue which is not part of the target area, but is adjacent to the target area, can be ablated unintentionally.

[0082] It is preferred that a method of use of the presently described ultrasound probe utilises a mechanical damage of tissue instead of the thermal tissue damage. For example, as previously referred to, US patent 9,700,742 utilises mechanical HIFU damage of tissue rather than thermal tissue damage.

[0083] Figure 6 shows an overview of tissue in a target area 70 being ablated with the probe 20 of the second embodiment of figures 2A, 2B. The target area 70 includes a plurality of target regions 71, 72, 73, 74. As shown in figure 6, the transducer of the probe 20 has its ultrasound beam 78 focused onto focal point 79 within a second target region 72.

[0084] Prior art methods of ablating tissue using a mechanical HIFU damage are as shown in figures 7A and 7B. In these methods a pulse 81 of ultrasound energy is focused onto a target region, such as any one of regions 71, 72, 73, 74 in figure 6. To ensure that a thermal damage of the target region or surround tissue is prevented, the pulse 81 is a short on period D. The on period D is then followed by an off period in which no ultrasound energy is emitted that allows the target region to cool. The time of one cycle P is equal to the sum of the on period

and the off period. The duty cycle for this sequence is therefore D/P . To ablate the target region of tissue utilising the mechanical damage, the on and off periods are repeated for a number M of times. Referring to figure 7A, the total time T_s to ablate one target region utilising pulses 81 to provide mechanical damage of the tissue is the multiple of P and M , in other words: $T_s = P \times M$.

[0085] Therefore, in the prior art, the total time to ablate a target area 70 using mechanical HIFU damage requires the same process to be followed a number of times N to cover each target region within the total area 70 in turn. As shown in figure 7B, where there are N target regions, a first series of pulses 81 is applied to a first target region for total time T_s . Then a second series of pulses 82 is applied to a second target region for total time T_s . And so on, until an N^{th} target region has been applied with an N^{th} series of pulses 83 for total time T_s . Thus, the total time T_{total} to ablate the target area 70 is the multiple of the cycle time P , the number M of cycles required to ablate each region and the number N of target regions to be ablated. In other words: $T_{\text{total}} = P \times M \times N$.

[0086] According to the present disclosure it is desired to provide an improved method compared to the prior art method shown in figures 7A and 7B. As noted above, it is desired to utilise a method of operation of the probe which achieves the desired tissue ablation, ensures safety for the subject in which the probe is deployed and/or is more time/energy efficient than existing methods. The proposed method may be termed 'cyclic ablation', which can perform ablation of a target area through ablating specific target regions therein in a new cyclical manner. This new method which also utilises mechanical ultrasound ablation is shown in figures 8A and 8B.

[0087] The cyclic ablation technique is described in reference to figure 6 which shows the probe 20 of the second embodiment of figures 2A, 2B, although could be used with any of the presently described probes or other probes not described herein. The cyclic ablation method utilises pulses 91, 92, 93, 94 of ablation of the target regions 71, 72, 73, 74 in the target area 70 and cycles through ablating

each one in turn for the shortened period. Once all target regions 71, 72, 73, 74 have been ablated by the pulses 91, 92, 93, 94, the focus of the probe 20 is returned to the first target region 71 and each of the target regions 71, 72, 73, 74 is ablated again in turn each by a pulse 91, 92, 93, 94. This process is repeated for a number of times until each of the target regions 71, 72, 73, 74 is fully ablated. The focus may then be turned to new target regions in another location 77 of interest within the target area 70 and the same process may be undertaken to cyclically and gradually ablate each target region within that location 77 using further respective pulses 95-98. This process can be repeated until all regions within the target location have been ablated. This overall process is then repeated until all target regions within the target area 70 have been ablated.

[0088] It is understood that the target area 70 within a subject may be a 3-dimensional volume of tissue, such as a tumour. Thus, the figure 6 is a 2-dimensional representation showing x and y axis distances, however the z axis direction may also be utilised when focusing ultrasound on target regions within a target volume. According to the present cyclic ablation technique, damage to tissue adjacent to a target region is reduced or prevented to ensure that ablation of target tissue within a target area 70 can be carried out in a safe manner.

[0089] The cyclic ablation method is adaptable to the required purpose and the number of location of target regions being ablated in each cycle can be chosen to suit the size of the target region. For example, one cycle location of ablation can be performed along one plane, such as the target regions 71, 72, 73, 74 shown in figure 6. Once the first cycle location has been ablated fully through a number of cycles, a second cycle location can be ablated such as the adjacent location 77. Alternatively, size of target area permitting, all target regions within an entire target area 70 could be ablated in each cycle and the cycles repeated until the entire target area 70 is fully ablated.

[0090] As shown in figure 8A, according to the method of one example there are four target regions 71, 72, 73, 74 in each cycle. Ultrasound waves are focused

on the first target region 71 for duration D, the probe is then focused on the second target region 72 on which the ultrasound waves are focused following a brief pause. In a similar manner the probe then focuses ultrasound waves onto the third region 73 for duration D following a brief pause period and next the probe focuses ultrasound waves onto the fourth region 74 for duration D following another brief pause period. Another brief pause period will follow the ultrasound waves being focused onto the further region 74 to complete one cycle P before repeating the same steps again in a second cycle P.

[0091] The pulses 91, 92, 93, 94 each have the same pulse duration D. The cycle duration P is the time for each pulse 91, 92, 93, 94 duration D with a pause period between each pulse 91, 92, 93, 94. The cycle duration P to apply pulses 91, 92, 93, 94 to four target regions 71, 72, 73, 74 of the example of figure 8A is the same as the cycle duration P to apply a single pulse 81. The duty cycle of the example in figure 8A is equal to four times the duration D divided by cycle period P, in other words duty cycle = $4D / P$. The pulses 91, 92, 93, 94 are repeated in the cycles as shown in figure 8A for number M of cycles. The number M of cycles being the number of applications of pulsed ultrasound waves required to ablate each target region 71, 72, 73, 74. Thus, completion of the above cyclic process M time will ablate each of the four target regions 71, 72, 73, 74. Therefore, the time T_s to ablate the four target region 71, 72, 73, 74 is the number M of cycles multiplied by the duration P of each cycle. In other words, for this example: $T_s = P \times M$. Hence, according to this example, four target regions 71, 72, 73, 74 can be ablated using this method in the same time as was required to ablate a single target region 71 in the above described prior art method.

[0092] In the new method shown in figure 8A, the cooling period between allowed to each target region following receiving a pulse remains the same as in the prior art method. Therefore, the described new method permits the safety of the cooling period provided to each target region while at the same time allowing a number of target regions to be ablated during the same overall time period. Hence, the new method is more efficient. According to the example of figures 8A,

8B, the method is four times quicker to complete than the prior art method previously described. Of course, the number of target regions to be included in each cycle duration P can be selected as appropriate to provide the desired cooling period for each and to allow the probe to correctly be manoeuvred to focus onto each target region in turn. For example, each cycle may include 2, 3, 4, 5, 6, 7, 8, 9, 10 or more target regions that receive a pulse of ultrasound waves with duration P .

[0093] As shown in figure 8B, a similar process for ablating all of the target regions within a target area 70 may use this cyclic method. This example maintains four target regions receiving mechanical ultrasound damage per cycle. Here, pulses 91 to 94 are applied to the first four target regions for a number M of times until they have each been ablated. Next, pulses 95 to 98 are applied to a second four target regions for the number M of times until they are each ablated. The sequence is repeated $N/4$ number of times until the final four target regions are ablated with pulses 9A-9N/4 (the value A being $N/4 - 4$). Thus, the total time T_{total} to ablate the target area 70 is the multiple of the cycle duration P , the number M of cycles required to ablate each region and the number N of target regions to be ablated divided by four. In other words: $T_{\text{total}} = (P \times M \times N) / 4$. Hence, again this shows that this example would be four times faster to complete the ablation of a target area than the previous prior art method.

[0094] To describe this idea more broadly, we take an amount G of target regions being ablated in each cycle duration P . Where G is an integer. Thus, a time T_G to ablate G regions will be: $T_G = P \times M$. Averaged out, this means the time to ablate a single region averaged is $T_s = P \times M / G$. Where there are N target regions in total ($N \geq G$), then the total time to ablate an entire target area will be $T_{\text{total}} = T_s \times N = T_G \times N / G = (P \times M \times N) / G$. Hence, it is clear to see that the total ablation time T_{total} provided by this method may be reduced compared to the prior art method by G times.

[0095] This new method can thus significantly reduce the treatment time for a patient to undergo ablation while providing the same ablation outcome.

[0096] As an example, take each duration D in one cycle to be 0.25 seconds and the pause period between ablating one target region to the next target region is also 0.25 seconds. Now for this example take the value of $G = 4$. Therefore, the period P of each cycle would be $0.25 \times 4 + 0.25 \times 4 = 2$ seconds. Thus, if example is taken as being shown in figure 6, ablating each of the target regions 71, 72, 73, 74 in one cycle will take 2 seconds. Next, according to this example, say it takes four cycles for each target region to become fully ablated, in other words taken $M = 4$. Therefore, the total time required to fully ablate the target regions 71, 72, 73, 74 over four cycles of 0.25 seconds per individual ablation period would be 8 seconds. In the example where the target area 70 includes twelve target regions, in other words $N = 12$. Thus, according to this example, the total time T_{total} to ablate all twelve target regions will be $T_{\text{total}} = 2 \times 4 \times 12 / 4 = 24$ seconds. This is merely an example, and it is understood that the time required to ablate each target region, all of the regions in each cycle location and the entire target area/volume is dependent on a number of factors including the type of tissue to be ablated, the power supplied to the probe transducer and the heat generated at each target region.

[0097] According to preferred embodiments, tissue will be ablated using a method having the following steps:

1. provide a probe having a head adapted to generate a focused beam of ultrasonic waves;
2. deliver the probe head to a desired location within a patient, optionally the probe has a first delivery orientation where it has a reduced width for insertion into the patient and a second orientation where the transducer head is in an assembled state to deliver the ultrasonic waves;
3. focus ultrasonic waves onto a first target region for a predetermined period;
4. focus ultrasonic waves onto a plurality of other target regions, in turn, each for the same predetermined period, optionally with pause periods between the

ultrasound focusing period on each target region, until each of the target regions have been partially ablated for the predetermined period in one cycle;

5. focus ultrasonic waves onto the first target region for another predetermined period;

6. focus ultrasonic waves onto each of the plurality of other target regions for the predetermined period, optionally with pause periods of between the ultrasound focusing period on each target region;

7. Repeat steps 5 and 6, as necessary, until all of the target regions have been fully ablated.

[0098] Optionally, the method may further include focusing the ultrasonic waves onto other target regions within a target area and following the same steps 3 to 7 until the other target regions are fully ablated. The method may be performed over a plurality of locations within a target volume until the tissue within the target volume has been ablated.

[0099] In interpreting the disclosure, all terms should be interpreted in the broadest reasonable manner consistent with the context. For example, comprises/comprising and grammatical variations thereof when used in this specification are to be taken to specify the presence of stated features, integers, steps or components or groups thereof, but do not preclude the presence or addition of one or more other features, integers, steps, components or groups thereof.

[00100] The preceding description relates to features of preferred embodiments of a deformable probe according to the present disclosure. It is contemplated that one or more features may be replaced with equivalent or alternative features. It is therefore to be understood that numerous modifications may be made to the illustrative examples and that other arrangements may be devised without departing from the spirit and scope of the technology. The invention according to the following claims in its broadest sense is not to be limited to the specific

features as shown in the accompanying figures or described in the present description.

CLAIMS:

1. A probe for use in targeted ablation of tissue within a subject, comprising a transducer, and first and second control lines,

the transducer having a plurality of distinct shape elements, wherein each shape element is shaped to correspond to at least one other shape element,

wherein the transducer has a first orientation in which the shape elements are aligned in a substantially elongate manner adapted for insertion into the subject, and the transducer has a second orientation in which the corresponding shapes of the shape elements are combined together to form a focusing arrangement adapted to focus ultrasound waves onto an area of tissue of the subject to be ablated,

wherein the control lines are configured such that tensioning of the first control line causes the transducer to change from the first to the second orientation, and tensioning of the second control line causes the transducer to change from the second to the first orientation.

2. The probe according to claim 1, wherein selective tensioning of the first and second control lines is utilised to control the motion of the shape elements between the orientations.

3. The probe according to claim 1 or claim 2, further comprising at least one hinge, wherein said at least one hinge connects adjacent shape elements.

4. The probe according to claim 3, further comprising at least one biasing element, preferably in the form of a spring, wherein said at least one biasing element biases the transducer to one of the first orientation or the second orientation.

5. The probe according to claim 4, wherein said at least one hinge is a biasing element in the form of a torsion spring.

6. The probe according to claim 5, wherein one of said control lines is the biasing element.
7. A probe for use in targeted ablation of tissue within a subject, comprising:
 - a transducer having a plurality of distinct shape elements, wherein each shape element is shaped to correspond to at least one other shape element, wherein the transducer has a first orientation in which the shape elements are aligned in a substantially elongate manner adapted for insertion into a subject, and the transducer has a second orientation in which the corresponding shapes of the shape elements are combined together to form a focusing arrangement adapted to focus ultrasound waves onto an area of tissue of the subject to be ablated;
 - at least one hinge connecting adjacent shape elements;
 - at least one biasing element positioned between adjacent shape elements, said biasing element being configured to bias the transducer towards one of the first and second orientations; and
 - a control mechanism configured, when activated, to act against the bias of the biasing element to change the transducer from the first to the second orientation or from the second orientation to the first orientation.
8. The probe according to claim 7, wherein the control mechanism includes at least one motor.
9. The probe according to claim 7 or claim 8, wherein said at least one hinge comprises said at least one biasing element.
10. The probe according to any one of claims 7 to 9 wherein said at least one biasing element is a spring.
11. The probe according to claim 10, wherein the spring is a torsion spring.

12. The probe according to any one of the preceding claims, wherein each shape element includes a concave front surface, and in the second orientation the transducer resembles a dish.
13. The probe according to any one of claims 3 to 12, wherein the plurality of shape elements are connected together by at least one hinge which extends in the longitudinal direction of the probe.
14. The probe according to claim 12 or claim 13, wherein the transducer comprises a plurality of part-circular shape elements connected together by said at least one hinge.
15. The probe according to any one of claims 3 to 12, wherein the plurality of shape elements are connected together by at least one hinge which extends in the lateral direction of the probe.
16. The probe according to claim 15, wherein the plurality of shape elements are connected together in such a manner as to form an elongate arrangement of shape elements in the first orientation, and wherein, in the second orientation, the plurality of shape elements form a substantially circular focusing arrangement.
17. The probe according to any one of the preceding claims, wherein the shape elements are each polygonal in one cross-section.
18. The probe according to claim 17, wherein the shape elements are hexagonal in said cross-section, and the transducer in the second orientation is in the form of a hexagonal ring.
19. A probe for use in targeted ablation of tissue within a subject, comprising a transducer, the transducer having a plurality of distinct shape elements, wherein each shape element is shaped to correspond to at least one other shape element, and wherein each shape element comprises a magnetic element,
wherein the transducer has a first orientation in which the shape elements are aligned in a substantially elongate manner adapted for insertion into a

subject, and the transducer has a second orientation in which the corresponding shapes of the shape elements are combined together to form a focusing arrangement adapted to focus ultrasound waves onto an area of tissue of the subject to be ablated,

wherein the magnetic elements are configured to change the transducer from the first orientation to the second orientation by bringing together opposed magnetic poles of adjacent shape elements.

20. The probe according to claim 19, wherein each magnetic element is an electromagnet which can be energised to change the transducer from the first orientation to the second orientation.

21. The probe according to claim 20, wherein each shape element is connected to a distinct power line which supplies energy to energise the magnetic element.

22. The probe according to claim 20 or 21, wherein the shape elements are selectively energised in a sequence to progressively change from the first orientation of the transducer to the second orientation.

23. The probe according to any one of claims 19 to 22, wherein the shape elements are elongate members and are adapted to be inserted into the subject one after the other or individually.

24. The probe according to any one of the preceding claims, wherein the transducer includes at least one transducer element adapted to generate image ultrasound waves and configured to determine one or more of: an orientation state of the probe, a location of the probe, a relative position of the probe, an orientation state of a shape element, a location of a shape element or a relative position of a shape element, and/or configured for use in guiding the probe during insertion into the subject.

25. The probe according to claim 24, wherein at least one said shape element comprises at least one said transducer element.
26. The probe according to any one of the preceding claims, further comprising at least one sensor which is adapted to send signals representative of the orientation of the transducer.
27. The probe according to claim 26, wherein the at least one sensor is further adapted to send signals representative of the position and/or location of the transducer within the subject.
28. The probe according to claim 26 or 27, wherein each shape element includes one of the sensors.
29. The probe according to any one of the preceding claims, wherein the probe is a high intensity focused ultrasound (HIFU) probe and the transducer is adapted to emit a focused ultrasound waves when in the second orientation.
30. A method of use of an ultrasonic probe, comprising the following steps:
- A) providing a probe having a head adapted to generate a focused beam of ultrasonic waves;
 - B) generating and focusing ultrasonic waves onto a first target region for a predetermined period of time;
 - C) generating and focusing ultrasonic waves onto a plurality of other target regions in turn for the predetermined period of time until each of the first target region and other target regions has been partially ablated for the predetermined period of time to complete a cycle; and
 - D) repeating steps B and C until a predetermined number of cycles has been completed.
31. The method according to claim 30, wherein step A comprises providing the probe according any one of claim 1 to 29.

32. The method according to claim 30 or 31, comprising a pause period between each predetermined period of time in which the respective target region receives the ultrasonic waves, each pause period being a period of time where no ultrasonic waves are generated.

33. The method according to any one of claims 30 to 32, wherein the first target region and other target regions form a first portion of a target volume, and wherein the target volume comprises a second portion having a plurality of second target regions, and wherein the method further comprises:

E) generating and focusing ultrasonic waves onto the plurality of second target regions in turn for a predetermined period of time until each of the first target region and other target regions has been partially ablated for the predetermined period of time to complete a cycle; and

D) repeating step E until a predetermined number of cycles has been completed.

34. The method according to claim 33, comprising a pause period between each predetermined period of time in which the respective second target region receives the ultrasonic waves, each pause period being a period of time where no ultrasonic waves are generated.