the region between the curved lens surface and the tissue to be ablated needs to be completely filled with coupling material. Another disadvantage to such lens-based histotripsy endoscopes is that the ablation zone is limited by the fixed focus of the lens. This can limit the ablation rate since increasing the ablation zone requires relatively slow mechanical translation of the transducer.

SUMMARY

[0008] An ultrasound-based surgical system is provided for image guidance and mechanical ablation for minimally invasive procedures, particularly procedures which require the removal of tissue. The system includes a device having an elongate body portion that supports a therapeutic ultrasound transducer assembly containing a piezoelectric composite and an annular array of electrodes. The electrodes can be driven to generate focused ultrasound pulses for ablating tissue via cavitation. The device can be controlled to scan the focused ultrasound pulses within an elongate axial region for performing line ablation. An electrical isolation layer is formed over an annular array of electrodes to prevent arcing within a backing when high-voltage electrical pulses are delivered to the annular array of electrodes to generate ultrasound pulses for cavitation. The elongate body may support an imaging transducer assembly within a central aperture of the therapeutic ultrasound transducer assembly to facilitate image guidance during ablative procedures.

[0009] Accordingly, in a first aspect, there is provided a therapeutic ultrasound system for performing tissue ablation via cavitation, the therapeutic ultrasound system comprising:

a therapeutic ultrasound transducer assembly comprising:

a piezoelectric composite layer having a proximal surface and a distal surface;

an array of annular electrodes disposed on the proximal surface of the piezoelectric composite layer, the array of annular electrodes defining an array of annular ultrasound transducer elements;

a common electrode disposed on the distal surface of the piezoelectric composite layer;

an electrical isolation layer disposed on the array of annular electrodes on the proximal surface of the piezoelectric composite layer;

an elongate body, wherein the therapeutic ultrasound transducer assembly is supported at a location remote from a proximal end of the elongate body;

an electrical signal delivery assembly disposed along at least a portion of the elongate body, wherein the electrical signal delivery assembly is operatively connected to the therapeutic ultrasound transducer assembly such that electrodes of the array of annular electrodes are in electrical communication with respective electrical channels of the electrical signal delivery assembly, and such that the common electrode is in electrical communication with a common electrical channel of the electrical signal delivery assembly; and

control and processing circuitry operatively coupled to the therapeutic ultrasound transducer assembly through the electrical signal delivery assembly, the control and processing circuitry configured to generate electrical pulses that are delivered, through the electrical signal delivery assembly, to the array of annular electrodes for generating focused ultrasound pulses suitable for generating cavitation in water; and

wherein a thickness of the electrical isolation layer is less than a wavelength of the focused ultrasound pulses within the electrical isolation layer; and

wherein the thickness of the electrical isolation layer and a dielectric breakdown strength of the electrical isolation layer are sufficiently high to prevent arcing, within a backing of the therapeutic ultrasound transducer assembly, among adjacent electrodes of the array of annular electrodes, during generation of the focused ultrasound pulses for cavitation.

[0010] In some example implementations of the system, the piezoelectric composite layer is configured such that between at least one pair of adjacent electrodes of the annular array of electrodes, an annular kerf extends from the proximal surface into the piezoelectric composite layer, and wherein an electrical insulating material forming the electrical isolation layer resides within each annular kerf.

[0011] In some example implementations of the system, at least one annular kerf extends from the proximal surface to the distal surface. Each annular kerf may extend from the proximal surface to the distal surface. At least one annular kerf is may be a partial kerf that extends from the proximal surface into the piezoelectric composite layer without extending to the distal surface. Each annular kerf may be a partial kerf that extends from the proximal surface into the piezoelectric composite layer without extending to the distal surface. The partial kerf may have a depth between 5% and 95% of the thickness of the piezoelectric composite layer. The partial kerf may have a depth between 5% and 90% of the thickness of the piezoelectric composite layer. The partial kerf may have a depth between 5% and 75% of the thickness of the piezoelectric composite layer. The partial kerf may have a depth between 50% and 95% of the thickness of the piezoelectric composite layer. The partial kerf may have a depth between 50% and 90% of the thickness of the

piezoelectric composite layer. The partial kerf may have a depth between 50% and 75% of the thickness of the piezoelectric composite layer.

[0012] In some example implementations of the system, the thickness of the electrical isolation layer residing on each electrode of the annular array of electrodes exceeds a width of the annular kerf.

[0013] In some example implementations of the system, the piezoelectric composite layer comprises an array of piezoelectric pillars embedded in a matrix, the piezoelectric pillars extending from the proximal surface to the distal surface, and wherein the piezoelectric pillars are arranged in a segmented annular array comprising a plurality of concentric arrays of piezoelectric pillars, such that each electrode of the annular array of electrodes is capable of electrically actuating one or more radially consecutive arrays of piezoelectric pillars, and such that each annular kerf is aligned with, and extends into, an annular matrix region residing between a respective pair of radially adjacent concentric arrays of piezoelectric pillars.

[0014] In some example implementations of the system, the electrical isolation layer has a dielectric breakdown strength between 10 and 280 kV/mm.

[0015] In some example implementations of the system, the therapeutic ultrasound transducer assembly is air-backed.

[0016] In some example implementations of the system, the therapeutic ultrasound transducer assembly comprises a backing layer embedded with microballoons.

[0017] In some example implementations of the system, the annular array of electrodes are defined such that a lateral inter-electrode spacing is between 20 and 80 microns.

[0018] In some example implementations of the system, an outer diameter of the annular array of electrodes is between 10 and 25 mm, and a number of electrodes forming the annular array of electrodes is between 8 and 64.

[0019] In some example implementations of the system, the piezoelectric composite layer comprises an array of piezoelectric pillars embedded in a matrix, the piezoelectric pillars extending from the proximal surface to the distal surface, and wherein the piezoelectric pillars are arranged in a segmented annular array comprising a plurality of concentric arrays of piezoelectric pillars, such that each electrode of the annular array of electrodes is capable of electrically actuating one or more radially consecutive arrays of piezoelectric pillars, and such that and such that each annular inter-electrode gap is aligned with an annular matrix region residing between a respective pair of radially adjacent concentric arrays of piezoelectric pillars.

[0020] In some example implementations of the system, the electrical signal delivery assembly is operatively connected to the therapeutic ultrasound transducer assembly via a plurality of wire bonds. Each wire bond may electrically connect a respective electrode of the annular array of electrodes with a corresponding conductive channel of the electrical signal delivery assembly though an aperture formed in the electrical isolation layer.

[0021] In some example implementations of the system, the common electrode is electrically connected to the electrical signal delivery assembly via a ground ring extending along at least a portion of an outer circumferential edge of the piezoelectric composite layer.

[0022] In some example implementations of the system, the electrical signal delivery assembly comprises a flexible printed circuit board. The flexible printed

circuit board may be operatively connected to the therapeutic ultrasound transducer assembly via direct bonding of a distal region of the flexible printed circuit board to the therapeutic ultrasound transducer assembly though an aperture formed in the electrical isolation layer.

[0023] In some example implementations of the system, the thickness of the electrical isolation layer is equal to a quarter of the wavelength of the focused ultrasound pulses within the electrical isolation layer.

[0024] In some example implementations of the system, the thickness of the electrical isolation layer is equal to a half of the wavelength of the focused ultrasound pulses within the electrically isolation layer.

[0025] In some example implementations of the system, the therapeutic ultrasound transducer assembly further comprises a fixed acoustic lens.

[0026] In some example implementations of the system, the fixed acoustic lens has a f-number between 0.5 and 3.

[0027] In some example implementations of the system, the control and processing circuitry is configured to control the therapeutic ultrasound transducer assembly to scan the focused ultrasound pulses within an elongate axial region residing distalward from a distal energy emitting surface of the therapeutic ultrasound transducer assembly. The control and processing circuitry may be configured to unidirectionally scan the focused ultrasound pulses within the elongate axial region. The control and processing circuitry may be configured is configured to scan the focused ultrasound pulses at a scan rate between 0.3-1.3 m/s.

[0028] In some example implementations, the system further comprises an imaging transducer assembly supported by the elongate body such that a distal surface of the imaging transducer assembly resides within a central aperture defined

within the therapeutic ultrasound transducer assembly, and wherein the control and processing circuitry is operatively coupled to the imaging transducer assembly through the electrical signal delivery assembly, wherein the control and processing circuitry is configured to control the imaging transducer assembly to acquire ultrasound image data and to process the ultrasound image data to generate one or more ultrasound images characterizing an imaging region that spatially overlaps with the elongate axial region.

[0029] In some example implementations of the system, the control and processing circuitry is further configured to control the therapeutic ultrasound transducer assembly and the imaging transducer assembly such that scanning of the focused ultrasound pulses to perform line ablation is only initiated after detection of cavitation in the ultrasound images. The control and processing circuitry may be further configured to control the therapeutic ultrasound transducer assembly and the imaging transducer assembly such that collection of the ultrasound image data by the imaging transducer assembly is interleaved with delivery of the focused ultrasound pulses.

[0030] In some example implementations of the system, the control and processing circuitry is configured such that the ultrasound image data collected between successively generated focused ultrasound pulses represents a subset of a full image frame of a B-mode image. The control and processing circuitry may be configured such that ultrasound image data corresponding to a selected subset of a full B-mode image frame is collected before and after generation of a given focused ultrasound pulse, thereby obtaining first ultrasound image data and second ultrasound image data characterizing the selected subset of the full B-mode image frame, and wherein the control and processing circuitry is configured to process the

first ultrasound image data and the second ultrasound image data to generate a subtraction image characterizing a temporal change within the selected subset of the full B-mode image frame. The control and processing circuitry may be configured to display the full B-mode image frame and to annotate the full B-mode image frame based on the subtraction image.

[0031] In some example implementations of the system, the central aperture has a shape that results in segmentation of an inner electrode of the annular array of electrodes, and wherein the segmented portions of the inner electrode are electrically connected to facilitate actuation of the segmented portions by a single channel of the electrical signal delivery assembly.

[0032] In another example, there is provided a method of performing tissue ablation via cavitation, the method comprising:

bringing a distal, energy-emitting surface of a therapeutic ultrasound transducer assembly into acoustic contact with tissue, the therapeutic ultrasound transducer assembly comprising:

a piezoelectric composite layer having a proximal surface and a distal surface;

an annular array of electrodes disposed on the proximal surface of the piezoelectric composite layer;

a common electrode disposed on the distal surface of the piezoelectric composite layer;

an electrical isolation layer disposed on the annular array of electrodes on the proximal surface of the composite piezoelectric layer; and

generating and delivering electrical pulses to the annular array of electrodes to generating focused ultrasound pulses suitable for generating cavitation within a subsurface focal region;

wherein a thickness of the electrical isolation layer is less than a wavelength of the focused ultrasound pulses within the electrically isolation layer; and

wherein the thickness of the electrical isolation layer and a dielectric breakdown strength of the electrical isolation layer are sufficiently high to prevent arcing, within a backing of the therapeutic ultrasound transducer assembly, among adjacent electrodes of the annular array of electrodes, during generation of the focused ultrasound pulses for cavitation.

[0033] In some example implementations, the method further comprises controlling a delay between the electrical pulses delivered to the annular array of electrodes such the subsurface focal region is scanned to perform line ablation of the tissue.

[0034] In another aspect, there is provided a therapeutic ultrasound device for performing tissue ablation via cavitation, the therapeutic ultrasound device comprising:

a therapeutic ultrasound transducer assembly comprising:

a piezoelectric composite layer having a proximal surface and a distal surface;

an array of annular electrodes disposed on the proximal surface of the piezoelectric composite layer, the array of annular electrodes defining an array of annular ultrasound transducer elements;

a common electrode disposed on the distal surface of the piezoelectric composite layer;

an electrical isolation layer disposed on the array annular of electrodes on the proximal surface of the piezoelectric composite layer;

an elongate body, wherein the therapeutic ultrasound transducer assembly is supported at a location remote from a proximal end of the elongate body;

wherein the piezoelectric composite layer is configured such that between at least one pair of adjacent electrodes of the array of annular electrodes, an annular kerf extends from the proximal surface into the piezoelectric composite layer, and wherein an electrical isolation material forming the electrical isolation layer resides within each annular kerf.

[0035] In some example implementations of the device, at least one annular kerf is a partial kerf that extends from the proximal surface into the piezoelectric composite layer without extending to the distal surface.

[0036] A further understanding of the functional and advantageous aspects of the disclosure can be realized by reference to the following detailed description and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0037] Embodiments are described with reference to the accompanying drawings. In the drawings, like reference numbers can indicate identical or functionally similar elements.

[0038] **FIG. 1A** shows a non-limiting example embodiment of the imaging and therapy device for performing tissue ablation via cavitation.

[0039] **FIG. 1B** shows a cross-section view of the example embodiment in FIG. 1A to highlight internal details.