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(57) Abstract:

ABSTRACT CLAMP-MOUNTED APPARATUS AND METHOD FOR SOFT-TISSUE-COMPENSATED BONE-STIFFNESS ESTIMATION An apparatus for non-invasive estimation of a bone mechanical-stiffness parameter includes a rigid clamp body (1) configured to releasably engage opposing surfaces of a limb at a site where a long bone lies near the surface. A first jaw of the clamp body (1) carries a vibratory actuator (2), an in-line force transducer (3) disposed mechanically in series between the vibratory actuator (2) and a skin-contacting tip (4), and a drive-point accelerometer (5) co-located with the skin-contacting tip (4). A remote accelerometer (6) contacts the limb at a spacing along a long axis of the bone from the drive-point accelerometer (5). A preload mechanism (8) applies and varies a static compressive preload measured by a static load cell (9). A controller (10) drives the vibratory actuator (2) with a swept-frequency excitation, determines a complex frequency-dependent mechanical response at each of a plurality of measured static preload levels, extrapolates the response to a substantially preload-invariant bone-dominated component, and outputs a soft-tissue-compensated bone-stiffness proxy value. (FIG. 1)

FORM-2

**THE PATENTS ACT, 1970
(39 of 1970)**

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THE PATENTS RULES, 2003

**COMPLETE
SPECIFICATION**

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(See section 10 and rule 13)

TITLE OF INVENTION

15 **CLAMP-MOUNTED APPARATUS AND METHOD FOR SOFT-TISSUE-
COMPENSATED BONE-STIFFNESS ESTIMATION**

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**THE FOLLOWING SPECIFICATION PARTICULARLY DESCRIBES
THE INVENTION AND THE MANNER IN WHICH IT IS TO BE
PERFORMED**

CROSS-REFERENCE TO RELATED APPLICATIONS AND PRIORITY

[0001] The present application does not claim priority from any patent application.

PREAMBLE

5 [0002] The following specification particularly describes the invention and the manner in which it is to be performed.

FIELD OF INVENTION

[0003] The present disclosure relates to non-invasive musculoskeletal measurement instrumentation, and more particularly to a clamp-mounted apparatus
10 and method for estimating a bone mechanical-stiffness parameter using swept-frequency vibratory excitation with active soft-tissue damping compensation.

BACKGROUND

[0004] The following text of background art is provided for purposes of understanding and is not an admission that any cited document or technique forms
15 part of the prior art under applicable law.

[0005] Bone strength is fundamentally a mechanical property. The bending stiffness of a long bone is proportional to the product of the elastic modulus of the bone tissue and the cross-sectional second moment of area. Existing point-of-care tools, however, do not measure this property directly. Dual-energy X-ray
20 absorptiometry (DXA), the clinical reference, uses ionizing radiation, requires a large fixed clinic installation, is expensive, and measures areal mineral density, a mass quantity that is an imperfect surrogate for mechanical strength. Fracture healing is conventionally tracked with serial X-rays, which lag the underlying mechanical recovery and again involve radiation. There is presently no inexpensive,
25 portable, radiation-free instrument that quantitatively answers whether a bone is mechanically stiff, or whether a healing fracture is becoming stiffer over time.

[0006] Low-frequency mechanical excitation of a long bone to estimate stiffness is itself known. Mechanical Response Tissue Analysis (MRTA) applies low-frequency vibration in a range of approximately 40 Hz to 1000 Hz to a long
30 bone such as the ulna and measures a complex compliance or frequency response to extract bending stiffness. However, MRTA measurements are notoriously

corrupted by overlying soft tissue, leading to poor reproducibility, and the technique requires a bulky laboratory shaker, an impedance head, and a skilled operator. Quantitative Ultrasound (QUS) devices measure high-frequency speed-of-sound or attenuation, usually at the heel, but employ different physics and provide an indirect surrogate for strength. Vibration-based fracture-healing monitors track resonant-frequency or wave-transmission changes across a healing fracture as the callus stiffens, but a soft-tissue-rejected, low-cost, self-contained realization is not standard, and results remain operator- and coupling-dependent.

[0007] A persistent, unsolved limitation of all through-skin approaches is that the overlying soft tissue (skin, fat, muscle) lies mechanically in series and parallel with the bone. The soft tissue adds compliance, adds heavy damping that blurs the bone resonance, and couples in a manner that depends strongly on operator-applied contact pressure and probe placement. The resulting poor reproducibility is the principal reason such mechanical techniques have not become mainstream clinical tools. Existing methods treat soft tissue as noise to be minimized by careful technique, rather than as a quantity to be measured and actively rejected.

[0008] The present disclosure addresses the above shortcomings of the prior art.

OBJECT

[0009] In view of the foregoing, and without prejudice to the generality of the disclosure, it is to be understood that the foregoing objects are illustrative and non-limiting; additional objects will be apparent from the description, examples, and claims, and need not be achieved in every embodiment.

[0010] An object of the present disclosure is to provide an apparatus for non-invasively estimating a mechanical-stiffness parameter of a bone of a limb. A further object is to actively measure and reject the confounding effect of overlying soft tissue, thereby improving measurement reproducibility over prior mechanical-resonance approaches such as MRTA. Another object is to realize the measurement in a hand-portable, battery-operable, radiation-free device built from low-cost, off-the-shelf components. Yet another object is to output a physical, soft-tissue-compensated bone-stiffness proxy value representing a measurement, keeping clear

of diagnostic-method exclusions. A still further object is to support a longitudinal fracture-healing mode in which each subject is their own reference, tracking stiffness as a trend over time.

SUMMARY

5 **[0011]** The following summary is intended to introduce aspects of the present invention in a simplified form and does not identify all the features or the scope of the claimed invention. The summary is provided to assist in understanding the invention and is to be read in conjunction with the detailed description and accompanying drawings, claims, and abstract. One or more embodiments of the
10 present disclosure are set forth below solely for illustrative purposes and should not be construed as limiting.

[0012] According to an aspect of the present disclosure, an apparatus for non-invasive estimation of a bone mechanical-stiffness parameter is provided. The apparatus includes a rigid clamp body configured to releasably engage opposing
15 surfaces of a limb at a site where a long bone lies near the surface. A first jaw of the clamp body carries a vibratory actuator, an in-line force transducer disposed mechanically in series between the vibratory actuator and a skin-contacting tip, and a drive-point accelerometer co-located with the skin-contacting tip. A remote accelerometer is configured to contact the limb at a spacing along a long axis of the
20 bone from the drive-point accelerometer. An anvil pad is disposed on an opposing jaw of the clamp body to provide a mechanical reaction. A preload mechanism is operable to apply and to vary a static compressive preload between the clamp body and the limb. A static load cell is configured to measure the static compressive preload. A controller is configured to drive the vibratory actuator with a swept-
25 frequency excitation, determine from signals of the in-line force transducer and the drive-point accelerometer a complex frequency-dependent mechanical response at each of a plurality of measured static preload levels, extrapolate the complex frequency-dependent mechanical response across the plurality of measured static preload levels to a substantially preload-invariant bone-dominated component, and
30 output a soft-tissue-compensated bone-stiffness proxy value derived from the bone-dominated component.

[0013] The foregoing apparatus may provide a portable, radiation-free alternative to DXA for bone quality assessment. By measuring the complex frequency-dependent mechanical response at multiple preload levels and extrapolating to a bone-dominated component, the apparatus may actively reject the confounding compliance and damping introduced by overlying soft tissue, thereby improving measurement reproducibility compared to prior mechanical-resonance approaches.

[0014] According to other aspects of the present disclosure, the swept-frequency excitation may be a swept-sine signal over a frequency band in a range of 20 Hz to 2 kHz. The complex frequency-dependent mechanical response may comprise a complex accelerance or a driving-point mechanical impedance obtained by lock-in detection or transfer-function estimation.

[0015] The use of a swept-sine signal over the specified frequency band may excite both low-frequency bending modes and higher-frequency flexural-wave propagation in the bone. Lock-in detection or transfer-function estimation may provide accurate determination of magnitude and phase across the frequency band even in the presence of noise.

[0016] According to other aspects of the present disclosure, the controller may be further configured to fit, to the complex frequency-dependent mechanical response, a model comprising a high-quality-factor bone branch and a lower-quality-factor damped soft-tissue branch, and to read the bone-stiffness proxy value from the bone branch.

[0017] Fitting a model with separate bone and soft-tissue branches may allow the controller to distinguish the sharp resonance associated with the bone from the broad, heavily damped response of the soft tissue, thereby isolating the bone contribution even when the soft-tissue contribution is large.

[0018] According to other aspects of the present disclosure, the controller may be further configured to determine a differential flexural-wave phase between the drive-point accelerometer and the remote accelerometer over the spacing, such that common-mode soft-tissue coupling substantially cancels, and to refine the bone-stiffness proxy value based on the differential flexural-wave phase.

[0019] The differential flexural-wave phase measurement may exploit the fact that flexural waves propagate along the bone at a speed governed by the bone stiffness, while soft-tissue coupling affects both accelerometers similarly. Taking the phase difference may therefore cancel common-mode soft-tissue effects and provide an independent estimate of bone stiffness.

[0020] According to other aspects of the present disclosure, the apparatus may further comprise a non-volatile memory storing a per-subject baseline value of the bone-stiffness proxy value. The controller may be configured to compare a subsequently determined bone-stiffness proxy value to the per-subject baseline value and to output a trend of the bone-stiffness proxy value over time.

[0021] Storing a per-subject baseline and reporting a trend may allow fracture-healing progress to be monitored with each subject serving as their own reference, thereby neutralizing the absolute-calibration burden and improving sensitivity to changes in bone stiffness over time.

[0022] According to other aspects of the present disclosure, the clamp body may comprise a C-shaped or split-ring rigid frame. The vibratory actuator may comprise a voice-coil linear actuator or a piezoelectric stack driven by a power amplifier. The in-line force transducer may comprise a load washer or a strain-gauge load cell. The preload mechanism may comprise a calibrated spring and a lead-screw stage. The apparatus may further comprise a battery power supply and a data link to a host device.

[0023] The structural variations may allow the apparatus to be constructed from low-cost, off-the-shelf components while maintaining the mechanical stiffness and measurement accuracy required for reliable bone-stiffness estimation. Battery power and a data link may enable portable, point-of-care operation.

[0024] According to other aspects of the present disclosure, the apparatus may further comprise a third accelerometer configured to contact the limb at a further longitudinal position along the long axis of the bone. The controller may be configured to generate a graphical representation of a measured bone region with the bone-stiffness proxy value mapped thereon for display.

[0025] A third accelerometer and graphical mapping may allow the apparatus to provide spatially resolved information about bone stiffness along the length of the bone, which may be useful for identifying localized regions of reduced stiffness such as fracture sites.

5 **[0026]** According to another aspect of the present disclosure, a method for non-invasive estimation of a bone mechanical-stiffness parameter is provided. The method includes clamping an apparatus onto a limb at a site where a long bone lies near the surface, applying a measured static compressive preload between the apparatus and the limb, sweeping a vibratory excitation across a frequency band
10 while recording an applied dynamic force and acceleration at a first location and at a second location spaced along a long axis of the bone from the first location, computing a complex frequency-dependent mechanical response from the recorded dynamic force and acceleration, repeating the applying, sweeping, and computing at each of a plurality of different measured static preload levels, extrapolating the
15 complex frequency-dependent mechanical response across the plurality of different measured static preload levels to a substantially preload-invariant bone-dominated component, and outputting a soft-tissue-compensated bone-stiffness proxy value derived from the bone-dominated component.

[0027] The method may convert the principal source of measurement
20 variability, namely contact preload and soft-tissue coupling, into an additional controlled measurement dimension. By repeating measurements at multiple preload levels and extrapolating to a preload-invariant component, the method may actively reject soft-tissue effects and improve reproducibility.

[0028] According to other aspects of the present disclosure, the extrapolating
25 may further comprise fitting, to the complex frequency-dependent mechanical response, a model comprising a high-quality-factor bone branch and a damped soft-tissue branch to separate the bone-dominated component, and determining an inter-sensor differential phase between the first location and the second location.

[0029] Combining model fitting with inter-sensor differential phase
30 determination may provide multiple independent mechanisms for separating the

bone contribution from the soft-tissue contribution, thereby improving robustness of the soft-tissue rejection.

5 [0030] According to other aspects of the present disclosure, the method may further comprise storing a per-subject baseline value of the bone-stiffness proxy value at a first measurement, comparing subsequently determined bone-stiffness proxy values to the stored per-subject baseline value, and reporting a trend of the bone-stiffness proxy value over successive measurements.

10 [0031] Storing a baseline and reporting a trend may enable longitudinal monitoring of fracture healing without requiring absolute population-based calibration, with each subject serving as their own reference.

[0032] The foregoing general description of the illustrative embodiments and the following detailed description thereof are merely exemplary aspects of the teachings of this disclosure and are not restrictive.

BRIEF DESCRIPTION OF FIGURES

15 [0033] The drawings appended herein illustrate exemplary embodiments of the present invention and are provided to enhance understanding of the inventive features disclosed. These figures, when read in conjunction with the detailed description, depict the operational flow, component architecture, and other mechanisms.

20 [0034] The illustrations are schematic in nature and serve solely to clarify the principles and functionality of the present disclosure. While particular constructions and configurations are depicted for explanatory purposes, it will be understood that the invention is not limited to the precise implementations shown in the figures and may encompass variations without departing from the scope of protection.

25 [0035] FIG. 1 illustrates a cross-sectional schematic of an apparatus for non-invasive estimation of a bone mechanical-stiffness parameter clamped onto a limb, according to aspects of the present disclosure.

[0036] FIG. 2 illustrates a block diagram of a signal chain of the apparatus, according to aspects of the present disclosure.

[0037] FIG. 3 illustrates a flowchart of a method for non-invasive estimation of a bone mechanical-stiffness parameter, according to aspects of the present disclosure.

5 [0038] FIG. 4 illustrates a diagram of a soft-tissue-rejection scheme, according to aspects of the present disclosure.

[0039] FIG. 5 illustrates a plot of a longitudinal fracture-healing mode, according to aspects of the present disclosure.

[0040] FIG. 6 illustrates a diagram of a graphical bone-region representation, according to aspects of the present disclosure.

10 [0041] FIG. 7 illustrates a graph of a longitudinal fracture-healing mode showing bone-stiffness proxy measurements over time, according to aspects of the present disclosure.

[0042] Furthermore, in terms of the construction of the system, one or more components of the device may have been represented in the figures by conventional
15 symbols, and the figures may show only those specific details that are pertinent to understanding the embodiments of the present invention so as not to obscure the figures with details that will be readily apparent to those of ordinary skill in the art having benefit of the description herein.

DETAILED DESCRIPTION

20 [0043] The following detailed description is intended to provide an in-depth understanding of the invention and its various components, configurations, and operational aspects. While specific embodiments are described with reference to the accompanying drawings, the invention is not limited to the particular forms disclosed herein. The scope of the invention shall be interpreted broadly and in
25 accordance with the claims appended hereto.

[0044] The terms “comprises,” “comprising,” “includes,” “including,” and similar expressions used in this description are intended to be open-ended and should be interpreted to include, but not be limited to, the mentioned elements. Unless explicitly stated otherwise, singular terms may include their plural
30 equivalents and vice versa, depending on the context in which they appear.

[0045] Reference is now made to the accompanying figures, which illustrate example embodiments of the present invention. It should be appreciated that the figures are intended for illustration and explanatory purposes only and do not limit the scope of the invention. Similar reference numerals have been used to denote functionally similar components throughout the figures.

[0046] The embodiments described herein are presented for illustrative purposes and are subject to variations, modifications, and adaptations by those skilled in the art. Any equivalent implementations that perform substantially the same function in substantially the same manner are intended to fall within the scope of this disclosure and the claims appended hereto.

[0047] The use of the term “exemplary” in the description shall be understood to mean “serving as an example or illustration” and shall not be construed as limiting the invention to the preferred embodiments disclosed. Various other embodiments may be developed without departing from the spirit or essential characteristics of the invention. The technical principles and advantages outlined in the foregoing description should be read in conjunction with the figures and claims. It is expressly understood that while the detailed description sets out specific structural and operational aspects, the scope of protection is governed by the claims and includes all legal equivalents of the claimed subject matter. Embodiments of the disclosure are described in the following paragraphs with reference to Figures. In Figures, the same elements or elements that have the same functions are indicated by the same reference signs.

[0048] The present invention will now be described in detail with reference to the accompanying drawings illustrating exemplary embodiments.

[0049] FIG. 1 illustrates an apparatus for non-invasive estimation of a bone mechanical-stiffness parameter according to various embodiments. The apparatus includes a rigid clamp body 1 configured to releasably engage opposing surfaces of a limb at a site where a long bone lies near the surface. The clamp body 1 may comprise a C-shaped rigid frame machined from aluminium material. In some cases, the clamp body 1 may comprise a split-ring rigid frame fabricated from fibre-

reinforced 3D-printed material. The clamp body 1 provides a stiff mechanical ground for the measurement components.

[0050] A first jaw of the clamp body 1 carries a vibratory actuator 2. The vibratory actuator 2 may comprise a voice-coil linear actuator capable of operating in a frequency range of 20 Hz to 2 kHz. In some cases, the vibratory actuator 2 may comprise a piezoelectric stack actuator as an alternative to the voice-coil actuator. The vibratory actuator 2 may be driven by a power amplifier, such as an audio power amplifier.

[0051] An in-line force transducer 3 is disposed mechanically in series between the vibratory actuator 2 and a skin-contacting tip 4. The in-line force transducer 3 measures the dynamic force actually delivered to the limb. The in-line force transducer 3 may comprise a piezoelectric load washer or a strain-gauge load cell for measuring the dynamic force delivered to the skin.

[0052] A drive-point accelerometer 5 is co-located with the skin-contacting tip 4. The drive-point accelerometer 5 measures the vibratory response at the location where the excitation is applied. A remote accelerometer 6 is configured to contact the limb at a spacing along a long axis of the bone from the drive-point accelerometer 5. The drive-point accelerometer 5 and the remote accelerometer 6 may comprise micro-electro-mechanical systems (MEMS) accelerometers for measuring the vibratory response at the drive point and remote locations.

[0053] An anvil pad 7 is disposed on an opposing jaw of the clamp body 1 to provide a mechanical reaction. The anvil pad 7 supports the limb against the force applied by the vibratory actuator 2.

[0054] A preload mechanism 8 is operable to apply and to vary a static compressive preload between the clamp body 1 and the limb. The preload mechanism 8 may comprise a calibrated spring combined with a lead-screw stage for applying and varying the static compressive preload. In some cases, the preload mechanism 8 may be motorized to automatically vary the static compressive preload.

[0055] A static load cell 9 is configured to measure the static compressive preload. The static load cell 9 reports the instantaneous preload measurement. The

static load cell 9 may be coupled to an amplifier and analog-to-digital converter interface for reporting the instantaneous preload measurement to the controller 10.

[0056] A controller 10 is configured to drive the vibratory actuator 2 and process signals from the in-line force transducer 3, the drive-point accelerometer 5, the remote accelerometer 6, and the static load cell 9. The controller 10 is described in further detail below.

[0057] The apparatus is configured for use at sites where a long bone lies near the surface, such as the ulna site on the forearm or the tibial crest site on the shin. The apparatus may be battery-powered for portable operation without external power supply. The apparatus may include a wired or wireless data link to a host device for display and data storage.

[0058] FIG. 2 illustrates a signal chain of the apparatus according to various embodiments. The controller 10 synthesizes a swept-frequency drive signal. The swept-frequency excitation may comprise a swept-sine signal over a frequency band in a range of 20 Hz to 2 kHz. The controller 10 may comprise a microcontroller or system-on-chip with integrated digital-to-analog converter (DAC) and analog-to-digital converter (ADC) for synthesizing the swept-sine drive and sampling sensor channels.

[0059] A power amplifier 11 amplifies the swept-frequency drive signal from the controller 10 and applies the amplified signal to the vibratory actuator 2. The power amplifier 11 drives the vibratory actuator 2 to apply mechanical excitation to the limb, which comprises bone and soft tissue.

[0060] The in-line force transducer 3 senses the dynamic force applied to the limb. The drive-point accelerometer 5 and the remote accelerometer 6 sense the acceleration response at a drive-point location and at a remote location spaced along the long axis of the bone, respectively. The signals from the in-line force transducer 3, the drive-point accelerometer 5, and the remote accelerometer 6 are digitized by the ADC of the controller 10.

[0061] A signal-processing stage 12 receives the digitized signals and estimates the complex frequency-dependent mechanical response. The controller 10 may perform lock-in detection to estimate the complex frequency response from

the force and acceleration signals. In some cases, the controller 10 may perform transfer-function estimation to obtain the complex frequency response from the force and acceleration signals. The complex frequency-dependent mechanical response may comprise a complex accelerance or a driving-point mechanical impedance obtained by lock-in detection or transfer-function estimation.

5 [0062] A soft-tissue compensation stage 13 receives the complex frequency-dependent mechanical response from the signal-processing stage 12 and the measured preload from the static load cell 9. The soft-tissue compensation stage 13 processes the complex frequency-dependent mechanical response at each of a plurality of measured static preload levels to isolate a substantially preload-invariant bone-dominated component.

[0063] The soft-tissue compensation stage 13 outputs a bone-stiffness proxy value 14 derived from the bone-dominated component. The bone-stiffness proxy value 14 represents a soft-tissue-compensated estimate of the mechanical stiffness of the bone.

[0064] A baseline comparator 15 compares the bone-stiffness proxy value 14 against a stored per-subject baseline value. The baseline comparator 15 outputs a trend of the bone-stiffness proxy value 14 over time.

20 [0065] The apparatus may include a set of bone-surrogate calibration phantoms of known bending stiffness for calibrating the apparatus. The calibration phantoms may be jacketed in tissue-mimicking elastomer to simulate soft tissue overlying bone.

[0066] FIG. 3 illustrates a method 300 for non-invasive estimation of a bone mechanical-stiffness parameter according to various embodiments. The method 300 provides a radiation-free alternative to DXA for bone quality assessment. The method 300 measures a mechanical-stiffness proxy directly rather than measuring density as a surrogate for strength.

25 [0067] At a clamping step 302, the method 300 includes clamping an apparatus onto a limb at a site where a long bone lies near the surface. The apparatus may be clamped at the ulna site on the forearm or the tibial crest site on the shin.

[0068] At a preload application step 304, the method 300 includes applying a measured static compressive preload between the apparatus and the limb. The static load cell 9 measures the static compressive preload.

[0069] At an excitation sweep step 306, the method 300 includes sweeping a
5 vibratory excitation across a frequency band while recording an applied dynamic force and acceleration at a first location and at a second location spaced along a long axis of the bone from the first location. The in-line force transducer 3 records the applied dynamic force. The drive-point accelerometer 5 records the acceleration at the first location. The remote accelerometer 6 records the acceleration at the
10 second location.

[0070] At a response computation step 308, the method 300 includes computing a complex frequency-dependent mechanical response from the recorded dynamic force and acceleration. The complex frequency-dependent mechanical response may comprise a complex acceleration or a driving-point mechanical
15 impedance.

[0071] At a preload-level decision 310, the method 300 determines whether additional preload levels remain to be measured. If additional preload levels remain, the method 300 proceeds to a preload increment step 312, where the preload is increased. The method 300 then returns to the preload application step 304 to repeat
20 the applying, sweeping, and computing at the new preload level.

[0072] The method 300 repeats the applying, sweeping, and computing at each of a plurality of different measured static preload levels. By measuring the complex frequency-dependent mechanical response at multiple preload levels, the method 300 obtains data that allows separation of the bone contribution from the soft-tissue
25 contribution.

[0073] At an extrapolation step 314, the method 300 includes extrapolating the complex frequency-dependent mechanical response across the plurality of different measured static preload levels to a substantially preload-invariant bone-dominated component. The extrapolation exploits the fact that tissue coupling stiffens
30 nonlinearly with compression while bone stiffness remains substantially preload-invariant.

[0074] At a proxy output step 316, the method 300 includes outputting a soft-tissue-compensated bone-stiffness proxy value derived from the bone-dominated component. The bone-stiffness proxy value represents a physical measurement of the mechanical stiffness of the bone.

5 **[0075]** At a baseline comparison step 318, the method 300 may compare the bone-stiffness proxy value to a stored per-subject baseline value and report a trend of the bone-stiffness proxy value over successive measurements. The baseline comparison step 318 enables longitudinal monitoring of fracture healing with each subject serving as their own reference.

10 **[0076]** FIG. 4 illustrates a soft-tissue-rejection scheme 400 according to various embodiments. The soft-tissue-rejection scheme 400 receives a measured complex response 402 obtained at a plurality of static preloads. The measured complex response 402 comprises the complex frequency-dependent mechanical response determined from signals of the in-line force transducer 3 and the drive-point accelerometer 5.

15 **[0077]** The soft-tissue-rejection scheme 400 includes three cooperating rejection mechanisms that may be applied singly or in combination. A first mechanism is a preload-sweep extrapolation 404. The preload-sweep extrapolation 404 exploits the fact that tissue coupling stiffens nonlinearly with compression while bone stiffness remains preload-invariant. By measuring the complex frequency-dependent mechanical response at multiple preload levels and extrapolating to a preload-asymptotic value, the preload-sweep extrapolation 404 isolates the bone-dominated component.

20 **[0078]** A second mechanism is a branch model fit 406. The controller 10 may be configured to fit, to the complex frequency-dependent mechanical response, a model comprising a high-quality-factor bone branch and a lower-quality-factor damped soft-tissue branch. The high-quality-factor bone branch exhibits a sharp resonance peak compared to the broad damped soft-tissue branch. The controller 10 may read the bone-stiffness proxy value from the bone branch.

30 **[0079]** A third mechanism is a differential flexural-wave phase 408. The controller 10 may be configured to determine a differential flexural-wave phase

between the drive-point accelerometer 5 and the remote accelerometer 6 over the spacing. The inter-sensor differential flexural-wave phase is governed by the bone's flexural wave speed while common-mode soft-tissue coupling cancels in the difference. The controller 10 may refine the bone-stiffness proxy value based on the differential flexural-wave phase. The differential flexural-wave phase 408 determines an inter-sensor differential phase between the first location and the second location.

[0080] The three mechanisms converge to yield a compensated proxy value 410. The compensated proxy value 410 represents the soft-tissue-compensated bone-stiffness proxy value derived from the bone-dominated component. The mechanisms may be applied singly or in combination for robustness.

[0081] FIG. 5 illustrates a healing-trend plot 500 according to various embodiments. The healing-trend plot 500 illustrates a longitudinal fracture-healing mode in which the bone-stiffness proxy value is plotted against time relative to a stored per-subject baseline 502.

[0082] The apparatus may store a per-subject baseline value of the bone-stiffness proxy value in non-volatile memory at a first measurement. The per-subject baseline 502 represents the initial bone-stiffness proxy value for a particular subject. The controller 10 may compare subsequently determined bone-stiffness proxy values to the stored per-subject baseline value and output a trend of the bone-stiffness proxy value over time.

[0083] A progressing-union trajectory 504 represents a monotonically rising stiffness-proxy trajectory indicating healing. As a fracture callus mineralizes, the bone branch stiffens and the resonance shifts, resulting in an increasing bone-stiffness proxy value over time. The progressing-union trajectory 504 indicates that the fracture is healing properly.

[0084] A non-union trajectory 506 represents a substantially flat trajectory flagging delayed or non-union. The non-union trajectory 506 indicates that the bone-stiffness proxy value is not increasing over time, which may indicate that the fracture is not healing properly.

[0085] The method may further comprise storing a per-subject baseline value of the bone-stiffness proxy value at a first measurement, comparing subsequently determined bone-stiffness proxy values to the stored per-subject baseline value, and reporting a trend of the bone-stiffness proxy value over successive measurements.

5 **[0086]** FIG. 6 illustrates a graphical bone-region representation according to various embodiments. The drive-point accelerometer 5, the remote accelerometer 6, and a further accelerometer 16 contact the limb at spaced longitudinal positions along the long axis of the bone. The further accelerometer 16 is configured to contact the limb at a further longitudinal position along the long axis of the bone.

10 The controller 10 processes signals from the drive-point accelerometer 5, the remote accelerometer 6, and the further accelerometer 16. The controller 10 generates a bone-region map 17 for display. The bone-region map 17 comprises a graphical representation of a measured bone region with the bone-stiffness proxy value mapped along the length of the bone. The graphical representation may allow

15 visualization of spatially resolved bone-stiffness information.

[0087] FIG. 7 illustrates a graph of the longitudinal fracture-healing mode showing bone-stiffness proxy measurements over time according to various embodiments. The graph plots the bone-stiffness proxy value on the vertical axis against time in weeks after baseline on the horizontal axis. A horizontal dashed line

20 indicates the baseline measurement taken at week zero. A progressing-union trajectory, shown rising steeply during initial weeks and then levelling off, indicates successful fracture healing with increasing mechanical stiffness over time. A delayed or non-union trajectory, shown as substantially flat throughout the monitoring period, indicates minimal improvement in mechanical stiffness. The

25 graph demonstrates how the longitudinal monitoring mode can differentiate between successful bone healing and problematic non-union cases by tracking the stiffness-proxy trend relative to a stored per-subject baseline measurement.

[0088] The apparatus and method disclosed herein have industrial applicability in the field of medical instrumentation for musculoskeletal assessment. The

30 apparatus may be manufactured using off-the-shelf components including voice-coil or piezoelectric actuators, MEMS accelerometers, load cells, microcontrollers,

and 3D-printed or machined clamp bodies. The apparatus may be produced at low cost for deployment in clinics, hospitals, sports medicine facilities, and point-of-care settings. The method may be implemented in firmware or software running on the controller of the apparatus. The apparatus and method may be used by clinicians, physiotherapists, sports medicine practitioners, and researchers for assessing bone quality and monitoring fracture healing without ionizing radiation.

[0089] The apparatus and method disclosed herein may provide several technical effects. The apparatus may provide a portable, radiation-free alternative to DXA for bone quality assessment. The apparatus may measure a mechanical-stiffness proxy directly rather than measuring density as a surrogate for strength. The apparatus may actively reject the confounding compliance and damping introduced by overlying soft tissue by measuring the complex frequency-dependent mechanical response at multiple preload levels and extrapolating to a bone-dominated component. The apparatus may improve measurement reproducibility compared to prior mechanical-resonance approaches by converting contact preload, the principal source of measurement variability, into an additional controlled measurement dimension. The apparatus may enable longitudinal monitoring of fracture healing with each subject serving as their own reference, thereby neutralizing the absolute-calibration burden.

[0090] It will be appreciated that the above-detailed description, along with FIGs, is provided to illustrate the architecture and operation of exemplary embodiments of the present invention. Various modifications and enhancements can be made without departing from the scope of the invention. All such variations, as would be recognized by those skilled in the art, are intended to be within the scope of the present disclosure, which is defined by the claims that follow.

[0091] It will be appreciated by persons skilled in the art that while the invention has been described with reference to specific embodiments and accompanying drawings, numerous modifications, substitutions, variations, and equivalents are possible without departing from the spirit or scope of the present invention. The use of singular terms such as “a,” “an,” and “the” is not intended to limit the disclosed elements to a single instance unless explicitly stated, and such

terms should be interpreted to include plural forms as applicable. Likewise, the terms “comprises,” “comprising,” “includes,” “including,” “has,” “having,” and their grammatical variants are intended to be open-ended and non-limiting, and should be interpreted as meaning “including but not limited to.” Any enumerated
5 listing of components, features, or elements does not imply that the items are mutually exclusive unless expressly stated.

[0092] It is further understood that where features, characteristics, or elements are described in connection with a Markush group or a disjunctive phrase (e.g., “A or B”), the invention includes all possible combinations and sub-combinations
10 thereof unless explicitly excluded. Thus, a statement referring to “at least one of A, B, and C” should be interpreted to mean any one or more of A, B, and C, individually or in any combination. The language used in this specification is selected primarily for clarity and illustrative purposes and should not be construed to limit the inventive scope unless specifically recited in the claims. Accordingly,
15 the foregoing description of embodiments should be regarded as illustrative and not restrictive, with the scope of the invention being defined solely by the appended claims and their legal equivalents.

[0093] It will be recognized that various features, elements, and combinations thereof described herein may be desirably adapted for alternative implementations
20 or other applications. Many such modifications, substitutions, enhancements, or equivalents may become apparent to those skilled in the art upon reading this disclosure and are considered to fall within the scope and spirit of the present invention. The invention is not limited to the precise configurations or exemplary embodiments set forth in this specification, and various alternatives may be used
25 without departing from the intended objectives. The claims, and not the detailed description, shall define the legal scope of protection afforded by the present disclosure.

[0094] In interpreting the specification and claims, all terms should be construed in the broadest reasonable manner consistent with the context and the
30 understanding of those skilled in the art. The use of terms such as “comprises,” “comprising,” “includes,” “including,” or “has” should be interpreted to be non-

exclusive and not limited to the stated elements alone. Moreover, references to “one embodiment,” “an embodiment,” or “in certain embodiments” are not meant to imply that such features are required or exclusive, and any feature described in connection with one embodiment may be used in combination with other features or embodiments unless clearly prohibited or contextually inconsistent.

[0095] It should be further appreciated that reference throughout the specification to features, operations, or components using singular terms should not be construed as excluding a plurality thereof unless the context expressly indicates otherwise. Similarly, features described in the context of grouped or listed elements (e.g., A, B, and C) should be understood to encompass individual, multiple, or all combinations of said elements. Where ranges are given, all intermediate values and subranges are understood to be disclosed as if specifically recited. The scope of the invention should therefore be construed as inclusive of all such combinations and logical extensions as would be appreciated by a person of ordinary skill in the relevant technical field.

[0096] In another embodiment, the above disclosure is a description of the invention and is not intended to limit the scope of the invention. Other variations and modifications of the above-described embodiment shall be apparent to those skilled in the art and are intended to fall within the scope of the invention as defined in the following claims.

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(Kuldeep Singh)

Authorized Agent for the Applicant,

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CLAIMS

WE CLAIM:

1. An apparatus for non-invasive estimation of a bone mechanical-stiffness parameter, comprising:
 - 5 a rigid clamp body (1) configured to releasably engage opposing surfaces of a limb at a site where a long bone lies near the surface;
 - a first jaw of the clamp body (1) carrying:
 - a vibratory actuator (2),
 - an in-line force transducer (3) disposed mechanically in series
 - 10 between the vibratory actuator (2) and a skin-contacting tip (4), and
 - a drive-point accelerometer (5) co-located with the skin-contacting tip (4);
 - a remote accelerometer (6) configured to contact the limb at a spacing along a long axis of the bone from the drive-point accelerometer (5);
 - 15 an anvil pad (7) disposed on an opposing jaw of the clamp body (1) to provide a mechanical reaction;
 - a preload mechanism (8) operable to apply and to vary a static compressive preload between the clamp body (1) and the limb;
 - a static load cell (9) configured to measure the static compressive preload;
 - 20 and
 - a controller (10) configured to:
 - drive the vibratory actuator (2) with a swept-frequency excitation,
 - determine, from signals of the in-line force transducer (3) and the drive-point accelerometer (5), a complex frequency-dependent mechanical
 - 25 response at each of a plurality of measured static preload levels,
 - extrapolate the complex frequency-dependent mechanical response across the plurality of measured static preload levels to a substantially preload-invariant bone-dominated component, and
 - output a soft-tissue-compensated bone-stiffness proxy value
 - 30 derived from the bone-dominated component.

2. The apparatus of claim 1, wherein the swept-frequency excitation is a swept-sine signal over a frequency band in a range of 20 Hz to 2 kHz, and wherein the complex frequency-dependent mechanical response comprises a complex accelerance or a driving-point mechanical impedance obtained by lock-in detection or transfer-function estimation.

3. The apparatus of claim 1, wherein the controller (10) is further configured to fit, to the complex frequency-dependent mechanical response, a model comprising a high-quality-factor bone branch and a lower-quality-factor damped soft-tissue branch, and to read the bone-stiffness proxy value from the bone branch.

4. The apparatus of claim 1, wherein the controller (10) is further configured to determine a differential flexural-wave phase between the drive-point accelerometer (5) and the remote accelerometer (6) over the spacing, such that common-mode soft-tissue coupling substantially cancels, and to refine the bone-stiffness proxy value based on the differential flexural-wave phase.

5. The apparatus of claim 1, further comprising a non-volatile memory storing a per-subject baseline value of the bone-stiffness proxy value, wherein the controller (10) is configured to compare a subsequently determined bone-stiffness proxy value to the per-subject baseline value and to output a trend of the bone-stiffness proxy value over time.

6. The apparatus of claim 1, wherein:
the clamp body (1) comprises a C-shaped or split-ring rigid frame;
the vibratory actuator (2) comprises a voice-coil linear actuator or a piezoelectric stack driven by a power amplifier (11);
the in-line force transducer (3) comprises a load washer or a strain-gauge load cell;
the preload mechanism (8) comprises a calibrated spring and a lead-screw stage; and
the apparatus further comprises a battery power supply and a data link to a host device.

7. The apparatus of claim 1, further comprising a further accelerometer (16) configured to contact the limb at a further longitudinal position along the long axis of the bone, wherein the controller (10) is configured to generate a graphical representation of a measured bone region with the bone-stiffness proxy value mapped thereon for display.

8. A method for non-invasive estimation of a bone mechanical-stiffness parameter, comprising:

clamping an apparatus onto a limb at a site where a long bone lies near the surface;

10 applying a measured static compressive preload between the apparatus and the limb;

sweeping a vibratory excitation across a frequency band while recording an applied dynamic force at a drive point on the limb and recording acceleration at the drive point and at a remote location spaced along a long axis of the bone from

15 the drive point;

computing a complex frequency-dependent mechanical response from the recorded dynamic force and the recorded acceleration at the drive point;

repeating the applying, sweeping, and computing at each of a plurality of different measured static preload levels;

20 extrapolating the complex frequency-dependent mechanical response across the plurality of different measured static preload levels to a substantially preload-invariant bone-dominated component; and

outputting a soft-tissue-compensated bone-stiffness proxy value derived from the bone-dominated component.

25 9. The method of claim 8, wherein the extrapolating comprises fitting, to the complex frequency-dependent mechanical response, a model comprising a high-quality-factor bone branch and a lower-quality-factor damped soft-tissue branch to separate the bone-dominated component, and

wherein the method further comprises determining an inter-sensor

30 differential phase between the drive point and the remote location.

10. The method of claim 8, further comprising:

storing a per-subject baseline value of the bone-stiffness proxy
value at a first measurement;

comparing subsequently determined bone-stiffness proxy values to
the stored per-subject baseline value; and

5 reporting a trend of the bone-stiffness proxy value over successive
measurements.

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ABSTRACT

CLAMP-MOUNTED APPARATUS AND METHOD FOR SOFT-TISSUE- COMPENSATED BONE-STIFFNESS ESTIMATION

An apparatus for non-invasive estimation of a bone mechanical-stiffness parameter
5 includes a rigid clamp body (1) configured to releasably engage opposing surfaces
of a limb at a site where a long bone lies near the surface. A first jaw of the clamp
body (1) carries a vibratory actuator (2), an in-line force transducer (3) disposed
mechanically in series between the vibratory actuator (2) and a skin-contacting tip
(4), and a drive-point accelerometer (5) co-located with the skin-contacting tip (4).
10 A remote accelerometer (6) contacts the limb at a spacing along a long axis of the
bone from the drive-point accelerometer (5). A preload mechanism (8) applies and
varies a static compressive preload measured by a static load cell (9). A controller
(10) drives the vibratory actuator (2) with a swept-frequency excitation, determines
a complex frequency-dependent mechanical response at each of a plurality of
15 measured static preload levels, extrapolates the response to a substantially preload-
invariant bone-dominated component, and outputs a soft-tissue-compensated bone-
stiffness proxy value.

(FIG. 1)

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