

METHOD AND SYSTEM FOR DETECTING EARLY KNEE OSTEOARTHRITIS

RELATED APPLICATION

[0001] This application claims the benefit of priority to the Singapore application no. 10202301985Y filed July 12, 2023, the contents of which are hereby incorporated herein by reference in their entirety for all purposes.

TECHNICAL FIELD

[0002] The present disclosure relates to the detection of specific knee osteoarthritis conditions and in particular to a computer-implemented method and system for detection of early knee osteoarthritis.

BACKGROUND

[0003] Knee osteoarthritis (OA) is likely to be increasingly prevalent in aging populations worldwide. People who have developed advanced stages of knee OA have relatively distinctive symptoms. For example, it is possible to identify a case of advanced stage knee OA based on an x-ray image of the lower limb and using the Kellgren-Lawrence (KL) grading scale. The lower limb with an advanced stage knee OA may also show the knee laterally displaced from a force vector (e.g., extending vertically through the foot in contact with the ground), i.e., the force vector is outside of the knee joint center. Often times, surgery is the only option by the time the knee OA has developed to an advanced stage.

[0004] Detection of early onset or early intervention of knee OA is not well understood. One of the challenges is that the x-ray of a subject with an early stage knee OA and the x-ray of a healthy subject may appear indistinguishable. Studies using other conventional diagnostic tools such as questionnaires can return highly subjective and variable responses.

SUMMARY

[0005] In one aspect, a system to detect knee OA includes a processor configured to perform a method according to instructions stored in a computer-readable memory. The method includes: using a data set, the data set including

measured pressure values associated with a plurality of selected sectors of a plantar pressure distribution, the data set excluding pressure values of advanced knee OA; and for each one of the plurality of selected sectors: calculating a change from a reference pressure value for a selected sector to the measured pressure value for the plurality of selected sector; and determining a result based on one or more sets of conditions. Each of the one or more sets of conditions includes any one or more of: the change in at least one of the plurality of selected sectors being a positive change; and the change in at least one other of the plurality of selected sectors being a negative change. The processor is configured to identify a presence of early knee OA as the result if a first set of conditions are met, and to identify an absence of early knee OA as the result if the first set of conditions are not met.

[0006] The processor may be configured to identify the presence of early knee OA: (i) based on static measured pressure values, the change is determined to be positive in one or more first selected lateral sectors; (ii) based on the static measured pressure values, the change is determined to be negative in one or more first selected medial sectors; and (iii) based on dynamic measured pressure values, another of the change is determined to be negative in one or more second selected medial sectors.

[0007] The processor may be configured to calculate the change based on normalized pressure values, in which the normalized pressure values are based on the respective measured pressure values and/or the reference pressure values normalized to a body weight area.

[0008] The measured pressure values may include data from dynamic tests and/or static tests.

[0009] The processor may be configured to identify the presence of early knee OA responsive to: an absolute value of the change in each of the plurality of selected sectors being greater than or less than a respective threshold value.

[0010] In another aspect, the proposed method may further include: making a determination to classify a case under one of three categories of an early knee OA category, a high-risk category, and a normal category.

[0011] In another aspect, the processor may be configured to plot a development of the knee OA over a period of time, in which the development includes a stage of

early knee OA, the stage of early knee OA being distinguishable from a normal stage and/or an advanced knee OA stage.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] Various embodiments of the present disclosure will be described with reference to the following figures:

[0013] **FIG. 1A** is a schematic diagram illustrating a case of advanced knee OA;

[0014] **FIG. 1B** is a schematic diagram illustrating a case where knee OA is not apparent;

[0015] **FIG. 2** is a schematic diagram of a system according to embodiments of the present disclosure;

[0016] **FIG. 3** is an exploded view of a schematic diagram of a footwear with a sensor array according to one embodiment;

[0017] **FIG. 4** is an exploded view of a schematic diagram of a footwear with a sensor array according to another embodiment;

[0018] **FIG. 5A** is a schematic diagram of a pressure mat;

[0019] **FIG. 5B** is an example of a plantar pressure distribution obtainable from the pressure mat;

[0020] **FIG. 6A** is a schematic diagram showing one example of a distribution of sectors;

[0021] **FIG. 6B** is a schematic diagram showing another example of a distribution of sectors;

[0022] **FIG. 6C** is a schematic diagram showing yet another example of a distribution of sectors;

[0023] **FIG. 7** shows box plots of KOOS scores for participants with normal knees, participants at high risk of knee OA, and participants with early knee OA;

[0024] **FIG. 8A** shows box plots of pressure values measured by one or more sensors in sector S1 in static tests, normalized by weight area of the participants;

[0025] **FIG. 8B** shows box plots of pressure values measured by one or more sensors in sector S2 in static tests, normalized by weight area of the participants;

[0026] **FIG. 8C** shows box plots of pressure values measured by one or more sensors in sector S3 in static tests, normalized by weight area of the participants;

[0027] **FIG. 8D** shows box plots of pressure values measured by one or more sensors in sector S4 in static tests, normalized by weight area of the participants;

[0028] **FIG. 8E** shows box plots of pressure values measured by one or more sensors in sector S6 in static tests, normalized by weight area of the participants;

[0029] **FIG. 8F** shows box plots of pressure values measured by one or more sensors in sector S8 in static tests, normalized by weight area of the participants;

[0030] **FIG. 8G** shows box plots of pressure values measured by one or more sensors in sector S13 in static tests, normalized by weight area of the participants;

[0031] **FIG. 9A** shows box plots of peak pressure values measured by one or more sensors in sector S10 in dynamic tests, normalized by weight area of the participants;

[0032] **FIG. 9B** shows box plots of peak pressure values measured by one or more sensors in sector S14 in dynamic tests, normalized by weight area of the participants;

[0033] **FIG. 10A** shows box plots of average pressure values measured by one or more sensors in sector S10 in dynamic tests, normalized by weight area of the participants;

[0034] **FIG. 10B** shows box plots of average pressure values measured by one or more sensors in sector S14 in dynamic tests, normalized by weight area of the participants;

[0035] **FIG. 11A** shows box plots of another pressure-based variable derived from one or more sensors in sector S1 in dynamic tests, normalized by weight area of the participants;

[0036] **FIG. 11B** shows box plots of the pressure-based variable derived from one or more sensors in sector S2 in dynamic tests, normalized by weight area of the participants;

[0037] **FIG. 11C** shows box plots of the pressure-based variable derived from one or more sensors in sector S10 in dynamic tests, normalized by weight area of the participants;

[0038] **FIG. 11D** shows box plots of the pressure-based variable derived from one or more sensors in sector S11 in dynamic tests, normalized by weight area of the participants;

[0039] **FIG. 11E** shows box plots of the pressure-based variable derived from one or more sensors in sector S14 in dynamic tests, normalized by weight area of the participants;

[0040] **FIG. 12A** to **FIG. 12C** show an example of a distribution of changes in normalized peak pressure values across a plurality of sectors, the pressure values being obtained from static tests;

[0041] **FIG. 13A** to **FIG. 13C** show an example of the distribution of changes in normalized peak pressure values across a plurality of sectors, the pressure values being obtained from dynamic tests;

[0042] **FIG. 14A** to **FIG. 14C** show another example of the distribution of changes in normalized dynamic pressure values across a plurality of sectors, the pressure values being obtained from dynamic tests;

[0043] **FIG. 15A** to **FIG. 15C** show an example of the distribution of changes in the pressure-based variable across a plurality of sectors, the pressure-based variable normalized pressure values derived from dynamic tests;

[0044] **FIG. 16** is a schematic diagram illustrating a method to detect early knee OA according to some embodiments of the present disclosure; and

[0045] **FIG. 17** is a schematic diagram illustrating the method according to another embodiment of the present disclosure.

DETAILED DESCRIPTION

[0046] The following detailed description is made with reference to the accompanying drawings, showing details and embodiments of the present disclosure for the purposes of illustration and to aid understanding, and not to be limiting. Features that are described in the context of an embodiment may correspondingly be applicable to the same or similar features in the other embodiments, even if not explicitly described in these other embodiments. Additions and/or combinations and/or alternatives as described for a feature in the context of an embodiment may correspondingly be applicable to the same or similar feature in the other embodiments.

[0047] As used herein, the term “and/or” includes any and all combinations of one or more of the associated listed items.

[0048] The word “exemplary” is used herein to mean “serving as an example, instance, or illustration.” Any embodiment described herein as “exemplary” is not necessarily to be construed as preferred or advantageous over other embodiments.

[0049] As used herein, the singular ‘a’ and ‘an’ may be construed as including the plural “one or more” unless apparent from the context to be otherwise.

[0050] The terms “about” and “approximately” as applied to a stated numeric value encompasses the exact value and a reasonable variance as will be understood by one of ordinary skill in the art, and the terms “generally” and “substantially” are to be understood in a comparable manner, unless otherwise specified.

[0051] Some processes may be described in terms of steps merely to aid understanding and/or for convenient reference. The delineation between one step and another step may be described as such merely for convenient reference in the present disclosure. It will be understood that in actual implementation there may not be a clear division or transition from one step to another subsequent step. There may be a certain amount of overlap among the steps and/or more than one step may occur or be performed concurrently in time, etc.

[0052] As used herein, the term “concurrent”, or “concurrently”, is used loosely to refer to two or more occurrences (or events) that at least partially overlap in time. The occurrences may or may not start at the same time instant and/or end at the same time instant.

[0053] Terms such as “first” and “second” are used in the description and claims only for the sake of brevity and clarity, and do not necessarily imply a priority or order, unless required by the context.

[0054] For the purpose of the present disclosure, an advanced stage knee OA refers generally to a case where the symptoms of knee OA are clearly identifiable, and in particular, to a condition that is clearly distinguishable from that of a healthy subject who is not afflicted with knee OA. Advanced stage knee OA may be identified based on an x-ray image, with a KL grading of 3 and 4 or with a clinical assessment, including a physical display of a lower limb 111 (schematically represented based on the skeletal structure of a thigh 112, a shin 113, and a foot 114).

[0055] To illustrate, consider, for example, a subject who may appear “bow-legged” to a casual observer. As schematically illustrated in **FIG. 1A**, the knee 125 is afflicted with advanced stage knee OA 120. The knee 125 is laterally displaced (e.g., offset sideways) relative to a vertical force vector 101. For example, the vertical force vector 101 extending through the foot (e.g., when the foot is bearing weight on the ground 102 as a result of standing or walking) would extend along a vertical axis spaced apart a center of the afflicted knee (knee center). A relatively objective and evidence-based determination of a case of advanced stage knee OA can be obtained, independently of various subjective factors such as the pain tolerance level of the subject. For the purpose of the present disclosure, the terms “advanced stage knee OA” and “advanced knee OA” may be used interchangeably to refer to the presence of knee OA that is clearly distinguishable from a case where there is no knee OA.

[0056] **FIG. 1B** schematically illustrates another possible type of people. In this example, the vertical force vector 101 extending through the foot on the ground 102 also extends through the knee 135. Conventionally, such a case would be deemed a healthy knee (e.g., a knee that does not have knee OA), unless there is reason to believe otherwise, e.g., walking is too painful. It was found that the interpretation of x-rays can be somewhat subjective especially when, to all appearances, the knee seems to be a healthy knee. In other words, there is an absence of clearly visible symptoms that can be relied upon consistently to determine if a knee is healthy or if the knee has early onset of knee OA symptoms.

[0057] In general, conventional methods of determining knee OA refer to advanced stage knee OA. In general, early stage knee OA does not seem to be the focus of studies in the technical field. There seems to be a general lack of understanding of the biomechanical factors in early stage knee OA. A knee afflicted with early knee OA may appear similar to a completely healthy knee. There is a general lack of information on early knee OA such that the brief description provided herein should not be taken to provide a definitive scope of what constitutes early knee OA. Rather, the lack of a definitive list of symptoms and/or causes associated with early knee OA highlights the urgent need for a more reliable method to detect

the condition, and a pressing need for a way to distinguish a knee with early knee OA from a healthy knee without knee OA.

[0058] It can be appreciated that relying on the subject's feedback (e.g., degree of pain felt, etc.) is less than ideal. Some people may have a relatively high level of tolerance for pain, and some others may simply downplay their condition from a desire to avoid surgery, etc. In some cases, wrongly concluding that the knee is healthy meant a missed opportunity for an early intervention or to address the knee OA condition before invasive surgery becomes necessary. In some cases, people put up with years of unnecessary pain because conventional diagnostic tools fail to distinguish early stage knee OA from a healthy knee.

[0059] In a study originally designed to screen for participants who are healthy but are at risk of developing knee OA, surprising results were obtained that showed the inadequacy of conventional screening methods. For the study, participants meeting all of the following conditions were assumed to be "normal" or without knee OA: (i) a body mass index (BMI) lower than 23; (ii) a waist circumference of less than 80cm (for female participants) and a waist circumference of less than 90cm (for male participants); (iii) had no pain in the past six months; (iv) no occupational history of high-risk activities involving prolonged loading of the knees; and (v) no family history of knee OA.

[0060] The remaining candidates were sent for X-rays and graded using the Kellgren/Lawrence (KL) method. Based on the KL scoring system, a KL grading above 2 is indicative of advanced knee OA. Candidates with advanced knee OA were deemed not relevant to the particular study and therefore not included in the study. Only candidates with a KL grading of 2 or below were recruited.

[0061] Based on the above process, thirty-nine participants were eventually recruited for the study. The thirty-nine participants were evaluated by a doctor to categorize these participants into "normal", "high-risk" of developing OA (but are still normal), or "early OA". Responses based on the Knee injury and Osteoarthritis Outcome Scoring (KOOS) system were also collected. Based on the doctor's assessment, twenty-one of the thirty-nine participants were classified as "normal". Thirteen of the thirty-nine participants were classified as "high-risk". Five of the thirty-nine participants were classified as "early knee OA". Overall average KOOS

score was 97 (SD 4), 95 (SD 5) and 84 (SD 13) for normal, high-risk and early OA participants respectively. The study was subsequently expanded and the demographic data / statistics of the participants are summarized in Table 1 below.

Table 1. Participants' Statistics.

Groups (Count)	Age (years)		Height (m)		Weight (kg)		KOOS	
	Mean	Std. Dev.	Mean	Std. Dev.	Mean	Std. Dev.	Mean	Std. Dev.
Normal (27)	50.2	12.1	1.59	0.11	52.5	9.44	97	4
High-Risk (18)	50.5	14.6	1.63	0.1	64.7	15	96	5
Early Knee OA (33)	59.3	8.24	1.61	0.07	63.3	10.1	87	9

[0062] The plantar pressure and centre of pressure (COP) was collected as each of the participants walked and stepped up or stepped down. Each of the recruited participants walked at a self-selected fastest velocity over a flat 10 m (meters) walkway. In the initial study, plantar pressure was collected using insole sensors (Moticon ReGo, available from Moticon, Germany). Heel-drop neutral shoes may be worn by the participants during the tests. To standardize, the studies were conducted with all the participants wearing the same brand and model of aquashoes (Adults Aquashoes 100, available from Decathlon) to mimic natural barefoot walking while ensuring that sensors placed on the insole remain in place throughout the tests.

[0063] The conventional methods for identifying participants with knee OA work well for participants with advanced knee OA. In the course of the study, it was noted that differentiating between normal participants and participants with early knee OA was a challenge without the doctor's diagnosis.

[0064] One possible reason was because most or all signs of the early knee OA might have escaped the notice of the questionnaire respondents. This was the case even when using culturally adapted and translated versions of the KOOS questionnaire (Singapore English and Chinese versions based on version LK 1.0), which is a well-accepted test to supplement knee OA diagnosis. The KOOS

questionnaire included questions such as the degree of severity of knee stiffness after sitting, lying or resting later in the day. Another question relates to the amount of knee pain experienced by the respondent in the last week in the course of activities such as straightening the knee fully. The questionnaire also asked about the extent to which the respondent is troubled with a lack of confidence in the knee, etc. Responses were expected to be selected from the following choices: “none”, “mild”, “moderate”, “severe”, and “extreme”. The trend of the average 5 composite KOOS score also supports the doctor’s categories of “normal” (closest to 100 for a healthy individual), “high-risk” and “early OA” (furthest from an ideal score of ‘100’). However, analysis showed that categorizing participants purely by KOOS resulted in a less sensitive identification of early knee OA participants.

[0065] For non-advanced knee OA cases, some participants might not even be aware of an occasional low level of pain or discomfort. It was further observed that the participants’ responses to the KOOS questionnaire may be affected by the individual’s tolerance for pain or the level of comfort in talking about a possible deterioration in personal health and well-being. It was found that the pain reported by the participants did not correlate well with the clinical assessment of the severity of knee OA.

[0066] **FIG. 2** is a schematic diagram of a system 300, according to embodiments of the present disclosure, configured to perform a method 600 to determine a presence (or an absence) of knee OA. More particularly, the system 300 enables performance of the method 600 to detect early stage knee OA. The terms “early stage knee OA” or “early knee OA” are used interchangeably in the present disclosure and describes an unhealthy condition of a knee related to an onset of knee OA. As mentioned, there is insufficient understanding of early knee OA and further studies may be required for an authoritative definition of early knee OA. For the purpose of the present disclosure, the term “early knee OA” may be understood to refer to a knee OA condition that is early or very mild, e.g., knee OA that to all appearances seem similar to a normal or healthy knee.

[0067] The system 300 includes a processor 310. The processor 310 is configured to execute instructions stored in a computer-readable memory 320. In operation, the processor 310 is in signal communication with a sensor array 350 to

acquire, store, and/or process data corresponding to signals received from the sensor array 350. In some embodiments, the sensor array 350 may include a plurality of sensors 352 distributed in an array, e.g., across the entire sole of a foot or at specific regions/points at the sole of the foot, to acquire biomechanics-related sensed data 343.

[0068] The computer-readable memory 320 may be a local memory (e.g., on a mobile device, a smart wearable, a laptop, etc.) or a remote memory (e.g., remote server, other cloud storage, etc.). The system 300 may include a wireless module 330 (e.g., to enable data transmission via Wi-Fi, Bluetooth, cellular communications, etc.) to enable signal communication between the processor and other devices.

[0069] The system 300 may include a user interface 340 to acquire input (e.g., demographic data, user feedback, etc.) from a subject 390 and/or provide output 345 (e.g., display a result from executing the method of determining if the subject 390 has early knee OA, etc.).

[0070] The data acquired from the sensor array 350 and/or via the user interface 340 may also be stored to build a library of training data for training a machine learning module, plot a subject's health state over time, or for use in remote clinical consultations. Optionally, the data may be linked to a medical team or to biomechanics specialists to provide clinical advice and/or implement early intervention measures, e.g., gait correction.

[0071] According to embodiments of the present disclosure, the sensor array 350 is distributed over a plantar area 400.

[0072] **FIG. 3** schematically illustrates an example according to embodiments of the present disclosure in which a sensor array 350 is integrated with circuit components 332 (e.g., wires, etc.) and a base to form a sensor plate 210. The circuit components 332 connect the sensor array 350 with the wireless module 330. The wireless module may include a data-logger and/or a battery to power the wireless module 330. The sensor plate 210 may further include an adjustable hook 214 or another form of a connector to couple the wireless module 330 to the footwear article 220.

[0073] The sensor plate 210 may be shaped and dimensioned differently to suit the individual foot. The sensor plate 210 may be disposed on/in a footwear article 220. The footwear article 220 may be a shoe, a cast, or a partial shoe. In some examples, the footwear article 220 includes an insole 222, a midsole 224, and an outsole 226. The insole 222 may include customized arch support and inserts. In some examples, the sensor plate 210 is detachable from the footwear article 220 or interchangeably replaceable relative to the footwear article 220.

[0074] **FIG. 4** schematically illustrates another embodiment of the present disclosure in which the sensor array 350 and circuit components 332 (e.g., wires, etc.) are embedded in the insole 222 to form a “smart insole” 230. The circuit components 332 connect the sensor array 350 with the wireless module 330. The wireless module may include a data-logger and/or a battery to power the wireless module 330. The smart insole 230 may further include an adjustable hook 214 or another form of a connector to couple the wireless module 330 to the footwear article 220.

[0075] The smart insole 230 may be disposed on the midsole 224 of the footwear article 220. The footwear article 220 may be a shoe, a cast, or a partial shoe. In some examples, the footwear article 220 includes the smart insole 230, the midsole 224, and an outsole 226. In other embodiments, the smart insole 230 and the midsole 224 may be formed as one integrated article.

[0076] In other embodiments, the sensor array 350 may include one or more sensing device 354. For example, the sensing device 354 may include a fabric-like sensor. In some examples, the sensing device 354 may be wearable, e.g., in the form of a sock. In some examples, the sensing device 354 may be a pressure sensing mat. **FIG. 5A** shows a schematic diagram of a mat-like sensing device 354. The subject may stand or walk on the mat-like sensing device 354 as the sensing device 354 acquire sensed data from the whole plantar area 400.

[0077] The sensor array 350 may employ electrical sensing, mechanical sensing, or a combination of both. For example, the sensor array 350 may include one or more of the any combination of the following types of devices: a resistive sensor, a capacitive sensor, a strain gauge, a piezoelectric gauge, etc. The sensor array 350 may be formed of a material that changes color when subjected to a force or a load.

[0078] The sensed data may be communicated via a wireless module 330 or otherwise communicated to the processor 310 to be stored and/or processed. As schematically represented in **FIG. 5B**, the processor 310 may be configured to obtain a pressure distribution 450 based on the sensed data. In some examples, the processor 310 is configured to train a machine learning model based on the data acquired from the sensor array 350. In some examples, the processor 310 may be configured to build a library of data based on input including, but not limited to, the sensed data, metadata, and demographic data. In some examples, the processor 310 is configured to select a collection of training data from the library of data, and to use the selected collection of training data to train a classification machine learning model based on, for example, a support vector machine algorithm.

[0079] **FIG. 6A** illustrates an example of a sector distribution 490 used in some experiments. In this non-limiting example, the plantar area 400 corresponding to one foot was divided into multiple sectors 410 and respective pressure values were measured in each sector. For example, a plurality of sectors 410, e.g., sectors S1 to S16, may be defined in the plantar area 400. For example, the plantar area 400 may be divided into rows of sectors, with various numbers of sectors per row. For example, each row 406 of sectors may range from two sectors per row to five sectors per row. The sectors 410 are present on the medial side 404 (inner side of the foot) and on the lateral side 405 (outer side of the foot). For the sake of brevity, sectors such as S1, S3, S10, and S14 may be referred to as medial sectors. For the sake of brevity, sectors such as S2, S4, S6, S8, and S13 may be referred to as lateral sectors.

[0080] **FIG. 6B** illustrates another example of a sector distribution 490 across a plantar area 400. One or more sectors 410 may be defined in a toe zone 401. One or more sectors may be defined in a metatarsal heads zone 407 (corresponding to the location of the metatarsal heads of the toes). One or more sectors 410 may be defined in a midfoot zone 402. For convenience, the metatarsal heads zone 407 and the midfoot zone 402 may be collectively referred to herein as a central zone 408. One or more sectors may be defined in a heel zone 403. In some examples, the sensor array 350 includes a plurality of sensors distributed across one or more

of the following: the medial heel zone, the lateral midfoot zone, the lateral metatarsal heads zone, the medial metatarsal heads zone, and the medial toe zone.

[0081] According to various embodiments of the present disclosure, the sensor array 350 may be disposed or attached according to the sector distribution 490. For example, at least one sensor in a plurality of sensors may be assigned to sense or measure pressure corresponding to each of a plurality of selected sectors 410.

[0082] In some embodiments, the sensor array 350 includes a plurality of sensors in all of the following sectors: sectors S1 to S4, sector S6, sector S8, sector S10, sector 13 and sector 14. The sensor array 350 may be configured to acquire static pressure values at each of sectors S1 to S4, sector S6, sector S8, and sector S13. The static pressure value may be a pressure value measured as the participant is standing (also referred to as a static test). The sensor array 350 may be configured to acquire dynamic pressure values at each of sector S10 and sector S14. The dynamic pressure value may be a peak pressure value or an average pressure value measured over time as the participant is walking (also referred to as a dynamic test).

[0083] The sector distribution 490 may be implemented in various configurations. To further illustrate, and not to be limiting, **FIG. 6C** shows a schematic diagram of yet another example of a sector distribution 490 and a sensor array 350. In this example, six sectors 410 (e.g., sector S1-S4, sector S6, sector S8, sector S13, sector S10, and sector S14) are defined in a sector distribution 490 across one plantar area 400. The sensor array is correspondingly distributed with at least one sensor 352 in each of the sectors 410 defined.

[0084] In some examples, one sensor 352 may measure pressure values corresponding to any one or more of multiple sectors 410 (e.g., S1 to S4). In some examples, one sensor 352 may be positioned in one sector (e.g., S10). In some examples, multiple sensors 352 may be positioned in one sector (e.g., S8). In some examples, different numbers of sensors 352 may be positioned in a sector (e.g., S6 / S8 / S14). In some examples, sensors 352 of different shapes and/sizes (e.g., sensors 352 shown in S1-S4 / S6 / S13) may be defined for one plantar area 400.

[0085] In some examples, at least one sector 410 is defined in each of the toe zone 401, midfoot zone 402, metatarsal heads zone 407, and heel zone 403. In

some examples, the sensor array 350 includes at least one sensor 352 configured and/or positioned to measure pressure values in one or more of the following: the medial heel zone 403, the lateral midfoot zone, the lateral metatarsal heads zone, the medial metatarsal heads zone, and the medial toe zone.

[0086] In various embodiments of the present disclosure, the total number of sectors defined in one plantar area may vary from embodiment to embodiment. The respective area, size, and shape of each sector may vary from embodiment to embodiment. The total number of sensors configured to be concurrently in operation may vary from embodiment to embodiment.

[0087] In some examples, the total number of sensors provided may be greater than the number of sensors from which pressure data is collected and used in the method proposed herein.

[0088] Referring to the study described above, at the beginning of the study, participants without knee OA but possibly at risk of eventually developing knee OA were categorized as high-risk. The high-risk knee OA participants were therefore expected to have more in common with normal people as they were essentially healthy in the sense that they have not developed knee OA (as determined by conventional methods). Further studies were subsequently conducted involving more participants. **FIG. 7** shows the box plots of KOOS scores of the participants with normal knees, participants at high risk of knee OA, and participants with early knee OA.

[0089] Based on data collected from 78 participants and processed according to the method proposed herein, the findings from insole sensor readings are similar to the observations noted above, as shown in **FIG. 8A** to **FIG. 10B**. In the box plots, the label “normal” refer to data derived from participants with normal knees, “high-risk” refer to data derived from participants at risk of developing knee OA, and “early OA” refer to data derived from participants with early stage knee OA.

[0090] The plantar pressure data were normalized to eliminate the effect of the body weight of the participant on the pressure sensed so that meaningful analysis could be carried out. The pressure data were also normalized to sensing area. For the sake of brevity, the term “normalized” as used herein refers to values that have been normalized by the body weight and the sensing area (e.g., normalized by the

weight area). The term “static” describes data obtained and/or derived from static tests in which the participant is standing when measurements are taken. The term “dynamic” describes data obtained and/or derived from dynamic tests in which the participant is walking when pressure measurements are taken. For example, dynamic pressure may be measured as the participants walked over a 10 metre walkway.

[0091] In various embodiments of the present disclosure, the pressure values at the selected sectors can be processed to produce a determination of a presence or an absence of early knee OA. According to various embodiments of the present disclosure, the normalized pressure values are based on one or more selected from either or both static tests and dynamic tests. This is supported by the data derived and presented in the box plots of **FIG. 8A** to **FIG. 10B**.

[0092] For example, **FIG. 8A** shows box plots of normalized static pressure values corresponding to one or more sensors in sector S1. **FIG. 8B** shows box plots of normalized static pressure values corresponding to one or more sensors in sector S2. **FIG. 8C** shows box plots of normalized static pressure values corresponding to one or more sensors in sector S3. **FIG. 8D** shows box plots of normalized static pressure values corresponding to one or more sensors in sector S4. **FIG. 8E** shows box plots of normalized static pressure values corresponding to one or more sensors in sector S6. **FIG. 8F** shows box plots of normalized static pressure values corresponding to one or more sensors in sector S8. **FIG. 8G** shows box plots of normalized static pressure values corresponding to one or more sensors in sector S13.

[0093] **FIG. 9A** shows box plots of normalized dynamic peak pressure values corresponding to one or more sensors in sector S10. **FIG. 9B** shows box plots of normalized dynamic peak pressure values corresponding to one or more sensors in sector S14. **FIG. 10A** shows box plots of normalized dynamic peak pressure of average pressure curves corresponding to one or more sensors in sector S10. **FIG. 10B** shows box plots of normalized dynamic peak pressure of average pressure curves corresponding to one or more sensors in sector S14.

[0094] In various embodiments of the present disclosure, the normalized peak values and the normalized average values may be interchangeably used. This is

verified by the data derived. As shown in **FIG. 9A** to **FIG. 10B**, the outcomes based on normalized peak values are consistent with those based on normalized average values.

[0095] In some other embodiments, other pressure-based variables may be derived from the static and/or dynamic tests and normalized. **FIG. 11A** to **FIG. 11E** show box plots of a new pressure variable (which may also be referred to as “dynamic average pressure”) derived from taking the maximum of average pressure readings, normalized by the weight area, for sectors S1, S2, S10, S14, and S11, respectively. Comparing with box plots of **FIG. 10A** and **FIG. 10B**, it can be seen that the trends are consistent in showing a statistically meaningful difference between a presence of early knee OA and an absence of knee OA (e.g., normal and/or high-risk), with the values for the normal knees being higher. This validates the robustness of the proposed method 600 for detecting early knee OA, e.g., the normalized pressure values may be calculated in various different ways.

[0096] **FIG. 12A** to **FIG. 15C** present the pressure values in the form of plantar pressure distribution diagrams 500. **FIG. 12A** to **FIG. 12C** show an example of a distribution of changes in normalized peak pressure values across a plurality of sectors, the pressure values being obtained from static tests. **FIG. 13A** to **FIG. 13C** show an example of the distribution of changes in normalized peak pressure values across a plurality of sectors, the pressure values being obtained from dynamic tests. **FIG. 14A** to **FIG. 14C** show another example of the distribution of changes in normalized dynamic pressure values across a plurality of sectors, the pressure values being obtained from dynamic tests. **FIG. 15A** to **FIG. 15C** show an example of the distribution of changes in the new pressure-based variable across a plurality of sectors, in which the new pressure-based variable normalized pressure values are derived from dynamic tests.

[0097] There is a significantly higher plantar pressure at the lateral midfoot for the early knee OA participants, as compared to the normal participants with a p-value of less than 0.05 in a standing position. The results are indicative that participants with early knee OA were adapting their gait and stance, even if they were doing so subconsciously or that the level of discomfort experienced was not deemed relevant or significant enough to mention. Conversely, significantly higher

plantar pressure was found at the heel region for normal participants, as compared to early knee OA participants. As shown by the dynamic pressure data, significantly higher plantar pressure was found at the big toe and second metatarsal head region.

[0098] **FIG. 16** is a schematic flow chart showing one example of a method 600 to detect early knee OA, according to embodiments of the present disclosure.

[0099] The method 600 includes using a data set that excludes data from known cases of advanced knee OA (e.g., step 608). In some embodiments, the method 600 may include excluding advanced knee OA data from the training data for a machine learning module. In some embodiments, the method 600 may include filtering and discarding data from known advanced knee OA participants. In some embodiments, the method may include building a data set including data from various participants over time (e.g., participants with or without knee OA, known or unknown knee OA at various stages, etc.) with the respective data tagged to enable data of advanced knee OA to be disregarded.

[00100] The data acquired includes demographic data (e.g., weight and footprint area or sensing area, etc.) and pressure values. In various embodiments of the present disclosure, the pressure values (whether sensed using discrete sensors or by a pressure mat) are each associated with the respective sector (e.g., S1, S14, etc.) where the pressure is measured.

[00101] The method 600 includes processing the sectorized plantar pressure data based on static tests and dynamic tests (610). Static tests refer to tests in which the subject is standing. Dynamic tests refer to tests in which the subject is walking. The plantar pressure data acquired may include retrieving plantar pressure data from a data storage and/or a library of previously acquired measurements. The plantar pressure data may be acquired in real-time, e.g., via a sensor array 350 (**FIG. 3** or **FIG. 4**) or a pressure mat 354 (**FIG. 5**). For example, dynamic tests may involve the subject walking over ground wearing a shoe 220 with the sensor array 350 disposed on the insole of the shoe). For example, static tests may involve the subject standing on the pressure mat 354. As used herein, the term 'sectorized plantar pressure data' refers to the plantar pressure measurements acquired for a plurality of sectors.

[00102] According to various embodiments of the present disclosure, the method 600 includes normalizing (step 615) the pressure data of a person (e.g., participant) by the body weight of the person and by the sensing area (e.g., area sensed by the relevant sensor). The measurements for each of selected sectors may be processed (608/610/615/620/640) separately by the processor 310. According to various embodiments, processing the data includes normalizing the selected pressure data (e.g., pressure data of selected sectors) to remove the effect of weight. Data were also normalized to the sensing area. According to various embodiments, for each selected sector, a peak pressure value or an average pressure value of each participant is obtained. According to various embodiments, a normal peak pressure value or an average pressure value is determined for each of the selected sectors, the normal peak pressure value or average pressure value being based on normalized pressure data of normal participants. For the sake of brevity, the terms "pressure value" and "measured pressure value" may refer to peak pressure value and/or average pressure value. The terms "maximum", "max", and "peak" may be understood to be interchangeable, and to refer to a largest value among multiple values. The terms "average" and "mean" may be understood to be interchangeable, and to refer to a total of multiple values divided by the number of multiple values.

[00103] According to various embodiments of the present disclosure, the method 600 includes selecting pressure data of selected sectors and processing the selected pressure data (620/640) to obtain a determination of a presence of early knee OA (630) or an absence of early knee OA (635).

[00104] According to various embodiments of the present disclosure, the method 600 includes determining a combination of a reduction in the plantar pressure in at least one other of the selected sectors and an increase in the plantar pressure in at least one of the selected sectors. For each of the plurality of selected sectors, a change from the normal peak or average pressure value to the combined peak or average pressure value is calculated. The change is calculated by subtracting the normal peak or average pressure value from the combined peak or average pressure value. A positive change corresponds to a combined peak (or average) pressure that is higher than the normal peak (or average) pressure. A negative

change corresponds to a combined peak (or average) pressure that is lower than the normal peak (or average) pressure.

[00105] In various embodiments, the processor 310 is configured to identify the subject as one with early knee OA, if all of the following conditions of a first set of conditions are fulfilled (620, 630). For example, the first set of conditions may be defined to include: (i) in the static tests, at least one of first selected sectors S6, S8, and S13 showing a positive change and S1, S2, S3 and S4 show a negative change with an absolute value of the change being less than a second threshold value; and/or (ii) in the dynamic tests, at least one of second selected sectors S10 and S14 showing a negative change.

[00106] In some embodiments, the first selected sectors include any one or more selected from the group consisting of sectors S1 to S4, sector S6, sector S8, and sector S13.

[00107] In some embodiments, the first selected sectors include one or more sectors in the lateral midfoot region.

[00108] In some embodiments, the second selected sectors include any one or more selected from the group consisting of sector S10 and sector S14.

[00109] In some embodiments, the second selected sectors include one or more sectors in forefoot region.

[00110] In some embodiments, the second selected sectors include one or more sectors corresponding to one or both of a second metatarsal and a first phalanx.

[00111] The processor 310 may be configured to identify the participants as a normal participants if the first set of conditions are not fulfilled and if the second set of conditions are fulfilled (640, 650).

[00112] The processor 310 may be configured to identify the subject as a high-risk case if the case does not fall produce a positive answer to either query. For example, the processor 310 may be configured to identify the subject as being at a high risk of developing knee OA if the subject does not fall within either the early knee OA category or the normal category.

[00113] The terms "first set of conditions" and "second set of conditions" are used merely for convenient reference and does not reflect the sequence of the queries. In some embodiments, the processor 310 may be configured to execute a first query

based on only the first set of conditions.

[00114] In some embodiments, the processor 310 may be configured to store the result in a memory and/or output the result to the user interface following the query based on the first set of conditions.

[00115] In some embodiments, the processor 310 may be configured to continue to execute a query based on the second set of conditions. In some embodiments, the processor 310 may be configured to store the result in a memory and/or output the result to the user interface following the query based on the second set of conditions.

[00116] In some embodiments, the processor 310 may be configured to store the results in a memory and/or output the results to the user interface following a first query based on the first set of conditions and the second query based on second set of conditions.

[00117] In some embodiments, as schematically illustrated in **FIG. 17**, the method 600 may include a two-way determination involving classifying (622) a person (e.g., a participant) under one of two categories of “presence of early knee OA” (630) and “absence of early knee OA” (635). In some embodiments, the method 600 may include a three-way determination involving classifying a participant in one of the three categories of early knee OA (630), normal (650), and high-risk (660). In some embodiments, the method 600 may include a two-way determination involving classifying a participant under one of two categories of early knee OA (630) and absence of early knee OA. In some embodiments, the method may include classifying a participant under one of two categories of early knee OA (630) and indeterminate (635) (e.g., indeterminate whether the participant is a normal case or a case at high risk of knee OA).

[00118] In some embodiments, one or more predetermined sectors are selected (e.g., one or more selected sectors) and the method 600 of determining early knee OA is based on pressure data derived from the one or more selected sectors instead of from the entire plantar area.

[00119] Table 2 shows threshold values for selected sectors which may be used to define one or more sets of conditions used in the method 600 of **FIG. 16** or **FIG. 17**. It should be understood that the normalized pressure values shown in Table 2

are merely to illustrate and are not limiting.

[00120] For example, a first set of conditions may be defined as in terms of whether a change of the normalized pressure value of one or more selected sectors is a positive change or a negative change, relative to a normalized reference pressure value (e.g., the normalized pressure value derived from normal participants) and whether the absolute value of the change is greater than or less than the early knee OA limit.

[00121] For example, according to one embodiment of the present disclosure, a participant with a normalized static pressure value of 0.00360 at sector S8 may be taken as indicative of the participant having early knee OA.

[00122] For example, according to another embodiment of the present disclosure, a participant may be taken as indicative of the participant having early knee OA only if the participant has a normalized static pressure value of 0.00360 at sector S8, a normalized dynamic pressure value of 0.03500 at sector S10, and a normalized dynamic pressure value of 0.05010 at sector S14.

[00123] For example, according to one example of the present disclosure, a participant having a normalized dynamic pressure value of 0.03600 at sector S10 and a normalized static pressure value of 0.00288 at sector S8 may be determined as having normal.

Table 2. Threshold Values or Ranges for Selected Sectors

Pressure Measurements	Sensor / Sector	Normalized Pressure to Body Weight Area		
		Normal Limit ($\geq$ threshold)	Early OA Limit ($\leq$ threshold)	High Risk Limit
Static	S1	0.01080	0.01070	In between
Static	S2	0.00891	0.00841	In between
Static	S3	0.00953	0.00944	In between
Static	S4	0.00794	0.00738	In between
Pressure Measurements	Sensor / Sector	Normal Limit ($\leq$ threshold)	Early OA Limit ($\geq$ threshold)	High Risk Limit
Static	S6	0.00646	0.00676	In between

Static	S8	0.00298	0.00354	In between
Static	S13	0.00153	0.00178	In between
Pressure Measurements	Sensor / Sector	Normal Limit ($\geq$ threshold)	Early OA Limit ($\leq$ threshold)	High Risk Limit
Dynamic peak pressure	S10	0.03550	0.03519	In between
Dynamic peak pressure	S14	0.05269	0.05038	In between
Dynamic peak pressure of average pressure curves	S10	0.03456	0.03430	In between
Dynamic peak pressure of average pressure curves	S14	0.05166	0.04938	In between
Dynamic average pressure	S1	0.01526	0.01486	In between
Dynamic average pressure	S2	0.01477	0.01466	In between
Dynamic average pressure	S10	0.01719	0.01638	In between
Dynamic average pressure	S11	0.01919	0.01891	In between
Dynamic average pressure	S14	0.02231	0.02167	In between

[00124] As illustrated in the example above, threshold values may be defined in a way that provides for data with overlapping confidence intervals. In this example, a ‘high-risk’ determination may be concluded if the normalized pressure value falls between the threshold limits of early knee OA and normal. Table 2 also indicates whether the respective threshold limits refer to upper limits or lower limits.

[00125] For example, a participant may be determined to have early knee OA if the normalized static pressure value at sector S8 is greater than or equal to

0.00354, if the normalized dynamic pressure value at sector S10 is less than or equal to 0.01638, and if the normalized dynamic pressure value at sector S14 is less than or equal to 0.02167. Correspondingly, a determination of an absence of early knee OA may be obtained if none of the conditions for early knee OA are met.

[00126] With respect to Table 2, the term “static” refers to an average value taken over the time of standing. The term “dynamic” refers to the pressure data of each participant taken over several steps (e.g., stance phases of gait cycles). The term “dynamic peak pressure” refers to generating a curve for each step, taking the maximum value of each step, and taking the average over all maximum values. The term “dynamic peak pressure of average pressure curves” refers to: normalizing data of each step (i.e., data curve) into a fixed number of time points (e.g., 101 time points), taking an average of all curves pointwisely to get an averaged curve, and taking the maximum value of the averaged curve. The term “dynamic average pressure” refers to taking an average value of each step (averaged over time) and taking the maximum value of all averaged values.

[00127] As illustrated in the examples above, the method 600 does not necessarily need to use pressure data from all available sensors. For example, five sensors (or selected sectors) may be used in an algorithm or in a prediction model. For example, selected sectors may include static S6, static S8, dynamic peak S10, dynamic peak S14, and dynamic average S1.

[00128] As described above, using the static plantar pressure data and the dynamic plantar pressure data acquired over the course of a study that includes an initial part of the study and an expanded study, it was verified that the proposed method 600 could be used to identify early knee OA participants. Using the proposed method 600, a distinction could also be made between the normal participants and the early knee OA participants.

[00129] It can be seen that, compared against normal participants, early knee OA participants placed more pressure on a region extending from the lateral midfoot to forefoot during a walking gait. Further data collected in the expanded study included the sensor location and threshold plantar pressure values at specific gait events (e.g., maximum plantar pressure in each sector, the mean plantar pressure of each sector, the median plantar pressure of each sector. The centre of pressure (COP)

data was also tracked. A trend of a lateral shift of the COP was observed.

[00130] Based on the calculated results, it can be appreciated that the method 600 provides an effective tool for detecting early knee OA cases. The method 600 advantageously provides quantitative indicators based on objectively measurable values. Using the proposed system 300, useful pressure data can be collected without the presence of a healthcare professional. This could enable remote medicine to increase convenience, relieve the workload of hospitals and clinicians, etc. For example, a home can be provided with a pressure map to collect static pressure data much the same way many people have a weighing scale at home to measure BMI or weight. For example, the system may also be used to collect dynamic pressure data as the subject walks about as usual in daily life.

[00131] The system 300 could return more objective data collected from real life situations, not just for a one-time detection, but for multiple real-time detections. Data over a period of time may be collected and analyzed according to the proposed method 600 so that the subject as well as the healthcare professional can monitor the subject's knee health over time. Appropriate early intervention can be an option if knee OA can be identified early, even before the condition of the knee worsens to an advanced stage when subject is conscious of the pain and surgery becomes the only option.

[00132] According to various embodiments of the present disclosure, a system 300 is proposed to detect knee OA. The system 300 includes a processor configured to perform a method 600 according to instructions stored in a computer-readable memory. The method 600 includes: using a data set, the data set including measured pressure values associated with a plurality of selected sectors of a plantar pressure distribution, the data set excluding pressure values of advanced knee OA; and for each one of the plurality of selected sectors: calculating a change from a reference pressure value for a selected sector to the measured pressure value for the plurality of selected sector; and determining a result based on one or more sets of conditions. Each of the one or more sets of conditions includes any one or more of: the change in at least one of the plurality of selected sectors being a positive change; and the change in at least one other of the plurality of selected sectors being a negative change. The processor is configured to identify a presence

of early knee OA as the result if a first set of conditions are met, and to identify an absence of early knee OA as the result if the first set of conditions are not met.

[00133] The processor may be configured to identify the presence of early knee OA: (i) based on static measured pressure values, the change is determined to be positive in one or more first selected lateral sectors; (ii) based on the static measured pressure values, the change is determined to be negative in one or more first selected medial sectors; and (iii) based on dynamic measured pressure values, another of the change is determined to be negative in one or more second selected medial sectors.

[00134] The processor may be configured to calculate the change based on normalized pressure values, in which the normalized pressure values are based on the respective measured pressure values and/or the reference pressure values normalized to a body weight area.

[00135] The measured pressure values may include data from dynamic tests and/or static tests.

[00136] The processor may be configured to identify the presence of early knee OA responsive to: an absolute value of the change in each of the plurality of selected sectors being greater than or less than a respective threshold value.

[00137] The one or more first selected lateral sectors may include at least sector S8.

[00138] The second selected medial sectors comprise any one or more of the selected sectors from the group consisting of sector S10 and sector S14.

[00139] The reference pressure value may include a mean of peak pressure values from cases of normal knees.

[00140] The reference pressure value may include a mean of measured pressure values obtained from an earlier time.

[00141] The positive change may correspond to a measured pressure that is greater than the reference pressure.

[00142] The negative change may correspond to a measured pressure that is less than the reference pressure.

[00143] The processor may be configured to calculate each of the changes by subtracting the reference pressure value from the measured pressure value.

[00144] The method may further include: making a determination to classify a case under one of three categories of an early knee OA category, a high-risk category, and a normal category.

[00145] The processor may be configured to classify the case under the early knee OA category if respective normalized measured pressure values in sectors S1, S2, S8, S10, and S14 are equal to or greater than respective predetermined threshold values.

[00146] The system may further include a sensor array. The sensor array may be configured to be in signal communication with the processor to measure pressure values. The processor may be further configured to obtain the respective measured pressure values for at least the plurality of the selected sectors.

[00147] The system may further include a pressure mat. The pressure mat may be configured to be in signal communication with the processor to measure pressure values. The processor may be further configured to obtain the respective measured pressure values for at least the selected sectors based on the pressure values measured.

[00148] The system may further include a user interface. The user interface may be configured to be in signal communication with the processor to receive one or more input and/or to provide one or more output, in which the one or more input includes one or more demographic data, and in which the one or more output includes a result of detecting the presence of early knee OA or the absence of early knee OA.

[00149] The processor may be configured to plot a development of the knee OA over a period of time, in which the development includes a stage of early knee OA, the stage of early knee OA being distinguishable from a normal stage and/or an advanced knee OA stage.

[00150] All examples described herein, whether of apparatus, methods, materials, or products, are presented for the purpose of illustration and to aid understanding, and are not intended to be limiting or exhaustive. Modifications not involving inventive effort may be made by one of ordinary skill in the art without departing from the scope of the claimed invention.

CLAIMS

1. A system to detect knee osteoarthritis (OA), comprising:
a processor configured to perform a method according to instructions stored
in a computer-readable memory, the method including:
using a data set, the data set including measured pressure values associated
with a plurality of selected sectors of a plantar pressure distribution, the
data set excluding pressure values of advanced knee OA; and
for each one of the plurality of selected sectors:
calculating a change from a reference pressure value for a selected sector to
the measured pressure value for the plurality of selected sector; and
determining a result based on one or more sets of conditions, each of the one
or more sets of conditions including any one or more of:
the change in at least one of the plurality of selected sectors being a
positive change; and
the change in at least one other of the plurality of selected sectors
being a negative change,
wherein the processor is configured to identify a presence of early knee OA
as the result if a first set of conditions are met, and
wherein the processor is configured to identify an absence of early knee OA
as the result if the first set of conditions are not met.
2. The system as recited in claim 1, wherein the processor is configured to
identify the presence of early knee OA:
 - (i) based on static measured pressure values, the change is determined to be
positive in one or more first selected lateral sectors;
 - (ii) based on the static measured pressure values, the change is determined
to be negative in one or more first selected medial sectors; and
 - (iii) based on dynamic measured pressure values, another of the change is
determined to be negative in one or more second selected medial sectors.

3. The system as recited in claim 1 or claim 2, wherein the processor is configured to calculate the change based on normalized pressure values, wherein the normalized pressure values are based on the respective measured pressure values and/or the reference pressure values normalized to a body weight area.
4. The system as recited in any one of claims 1 to 3, wherein the measured pressure values comprise data from dynamic tests and/or static tests.
5. The system as recited in any one of claims 1 to 4, wherein the processor is configured to identify the presence of early knee OA responsive to: an absolute value of the change in each of the plurality of selected sectors being greater than or less than a respective threshold value.
6. The system as recited in any one of claims 2 to 5, wherein the one or more first selected lateral sectors comprises at least sector S8.
7. The system as recited in any one of claims 2 to 6, wherein the second selected medial sectors comprise any one or more of the selected sectors from the group consisting of sector S10 and sector S14.
8. The system as recited in any one of claims 1 to 7, wherein the reference pressure value comprises a mean of peak pressure values from cases of normal knees.
9. The system as recited in any one of claims 1 to 8, wherein the reference pressure value comprises a mean of measured pressure values obtained from an earlier time.
10. The system as recited in any one of claims 1 to 9, wherein the positive change corresponds to a measured pressure that is greater than the reference pressure.

11. The system as recited in any one of claims 1 to 10, wherein the negative change corresponds to a measured pressure that is less than the reference pressure.
12. The system as recited in any one of claims 1 to 11, wherein the processor is configured to calculate each of the changes by subtracting the reference pressure value from the measured pressure value.
13. The system as recited in any one of claims 1 to 12, the method further comprising: making a determination to classify a case under one of three categories of an early knee OA category, a high-risk category, and a normal category.
14. The system as recited in claim 13, wherein the processor is configured to classify the case under the early knee OA category if respective normalized measured pressure values in sectors S1, S2, S8, S10, and S14 are equal to or greater than respective predetermined threshold values.
15. The system as recited in any one of claims 1 to 14, further comprising a sensor array, the sensor array being configured to be in signal communication with the processor to measure pressure values, the processor being further configured to obtain the respective measured pressure values for at least the plurality of the selected sectors.
16. The system as recited in any one of claims 1 to 14, further comprising a pressure mat, the pressure mat being configured to be in signal communication with the processor to measure pressure values, the processor being further configured to obtain the respective measured pressure values for at least the selected sectors based on the pressure values measured.
17. The system as recited in any one of claims 1 to 16, further comprising a user interface, the user interface being configured to be in signal communication with the processor to receive one or more input and/or to provide one or more output,

wherein the one or more input includes one or more demographic data, and wherein the one or more output includes a result of detecting the presence of early knee OA or the absence of early knee OA.

18. The system as recited in any one of claims 1 to 17, wherein the processor is configured to plot a development of the knee OA over a period of time, the development comprising a stage of early knee OA, the stage of early knee OA being distinguishable from a normal stage and/or an advanced knee OA stage.