(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
13 December 2012 (13.12.2012)

WIPO | PCT

(10) International Publication Number
WO 2012/169990 A2

(51) International Patent Classification:
A61B 6/03 (2006.01) ***A61B 8/00*** (2006.01)
A61B 5/055 (2006.01) ***G06T 7/60*** (2006.01)

(21) International Application Number:
PCT/US2011/000786

(22) International Filing Date:
5 May 2011 (05.05.2011)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/331,252 4 May 2010 (04.05.2010) US

(71) Applicant *(for all designated States except US)*: **PATHFINDER THERAPEUTICS, INC.** [US/US]; 2969 Armory Drive, Suite 100A, Nashville, TN 37204 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **CLEMENTS, Logan** [US/US]; 2969 Armory Drive, Suite 100A, Nashville, TN (US). **STEFANSIC, James** [US/US]; 2969 Armory Drive, Suite 100A, Nashville, TN (US). **DUMPARI, Prashanth** [US/US]; 2969 Armory Drive, Suite 100A, Nashville, TN (US). **LI, Senhu** [US/US]; 2969 Armory Drive, Suite 100A, Nashville, TN (US).

(74) Agent: **MILCH, Erik, B.**; Cooley LLP, 777 6th Street, NW, Washington, DC 20001 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

— *with information concerning request for restoration of the right of priority in respect of one or more priority claims (Rules 26bis.3 and 48.2(b)(vii))*

(54) Title: SYSTEM AND METHOD FOR ABDOMINAL SURFACE MATCHING USING PSEUDO-FEATURES

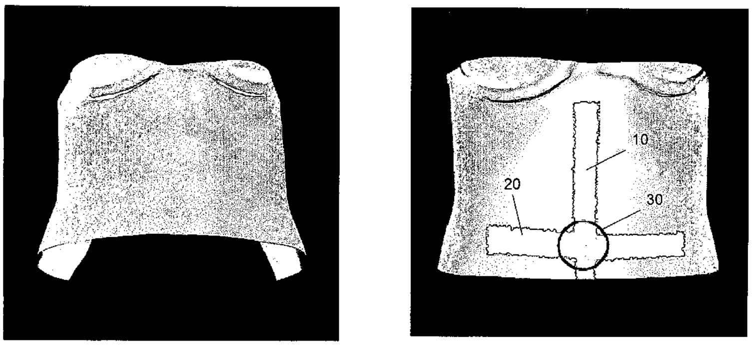

FIGURE 3

(57) Abstract: A system and method for using pre-procedural images for registration for image- guided therapy (IGT), also referred to as image-guided intervention (IGI), in percutaneous surgical application. Pseudo-features and patient abdomen and organ surfaces are used for registration and to establish the relationship needed for guidance. Three-dimensional visualizations of the vasculature, tumor(s), and organs may be generated for enhanced guidance information. The invention facilitates extensive pre-procedural planning, thereby significantly reducing procedural times. It also minimizes the patient exposure to radiation.

WO 2012/169990 A2

SYSTEM AND METHOD FOR ABDOMINAL SURFACE MATCHING USING PSEUDO-FEATURES

This application claims benefit of and priority to U.S. Provisional Application No. 61/331,252, filed May 4, 2010, by Logan W. Clements, et al., and is entitled to that filing date for priority. The specification, figures and complete disclosure of U.S. Provisional Application No. 61/331,252are incorporated herein by specific reference for all purposes.

This invention was made with the partial support of the United States government under NIH SBIR Grant Contract No. CA119502. The Government may have certain rights in this invention.

FIELD OF INVENTION

This invention relates generally to a system and related methods for abdominal surface matching for image-guidance during percutaneous surgical procedures.

BACKGROUND OF THE INVENTION

Image-guided therapy (IGT), which is also often referred to as image-guided intervention (IGI), has gained widespread attention and clinical acceptance for use in localizing tumors in abdominal organs. Procedures that utilize IGT include, but are not limited to, tumor biopsy and ablation.

IGT essentially describes the interactive use of medical images during a percutaneous procedure, and is often referred to as a "global positioning system" (GPS) for interventional radiology. For example, in an automobile GPS, the current position of a vehicle is accurately localized or "registered" onto an electronic roadmap located on the dashboard. As the automobile moves, its position is updated on this roadmap. The driver can use the GPS as a guide to see where their vehicle is, where it has been and where it is headed, and can follow a planned route to a selected destination. IGT allows the physician to accomplish the same thing with their tracked medical instruments on the 3-D "roadmap" of highly detailed tomographic medical images of the patient that are ideally acquired and studied well before the interventional procedure. The key step in an IGT procedure is the accurate registration between real "patient" space and medical image space.

In an ideal IGT procedure, a 3D map or plan is created from the preoperative diagnostic images, possibly days before the actual procedure and in consultation with a variety of physicians in different disciplines. On the day of the percutaneous procedure, the position of the patient and the medical instruments are accurately localized or "registered" onto these preoperative images in the interventional suite. As the physician moves the instrument, the precise location of its tip is updated on the 3-D images. The physician can then quickly follow a planned path to a selected destination (for example, a tumor or other lesion of interest). The exact location of the instrument is confirmed with a form of real-time imaging, including, but not limited to, intraoperative computerized tomography (CT), 2-D fluoroscopy, or ultrasonic (US) imaging.

U.S. Patent No. 7,853,307, "*Methods, Apparatuses, And Systems Useful In Conducting Image Guided Interventions*," which is incorporated herein in its entirety by specific reference for all purposes, discloses a method to register the pre-operative images to patient space using non-tissue reference markers/skin fiducial markers. This invention uses radio opaque fiducial markers (also known as skin fiducial markers) attached to the patient's abdomen, and a full CT scan of the patient's abdomen immediately before the procedure (also known as intra-procedural images), and performs a point-based registration to achieve correspondence between the fiducial markers' location on the abdomen and its corresponding position in the intra-procedural CT images. Similarly, U.S. Patent No. 6,785,571, "*Device and Method for Registering A Position Sensor In An Anatomical Body*," which is incorporated herein in its entirety by specific reference for all purposes, discloses a method to register pre-operative images to patient space using a tracked instruments inserted into the patient's body.

Both these prior arts suffers from the disadvantage that the highly detailed diagnostic images cannot be easily used during the interventional procedure. This means that the physicians do not have access to detailed visualizations of lesions and vasculature, and also do not have the time to create an ideal procedure plan. The existing technology also requires that the patients be scanned at least twice (once for pre-procedural diagnostic images and a second time for the intra-procedural images), which increases their exposure to X-ray radiations. Therefore, it would be ideal to use the high quality diagnostic CT or MR medical images directly for percutaneous guidance by performing a registration using those images. Point-based registration techniques discussed in the prior art are not accurate and inaccurate registrations compromise the accuracy of guidance during interventional procedures.

U.S. Patent App. No. 60/859,439, "*Apparatus And Methods For Compensating For Organ Deformation, Registration Of Internal Structures To Images, And Applications Of The Same*," which is incorporated herein in its entirety by specific reference for all purposes, details a method to perform registrations using pre-operative diagnostic images. The registration method disclosed in the patent uses surfaces generated from pre-operative diagnostic images and surfaces obtained during surgical or interventional procedures and "salient anatomical features" (anatomical regions that can be easily identified on both the surfaces) and performs a rigid surface-based registration to align the surfaces obtained during surgical or interventional procedures to the pre-operative surfaces. However, the method relies on the assumption that "salient anatomical features" can be easily identified on both sets of surfaces. Further, "salient anatomical features" cannot be obtained during percutaneous procedures. Therefore, there is a need to perform registration using something other than skin markers and salient anatomical features.

Surface registration using salient anatomical features in image-guided surgery is described more fully in Clements, et al, "Robust surface registration using salient anatomical features in image-guided liver surgery," Medical Imaging 2006: Visualization, Image-guided Procedures, and Display: Proc. of the SPIE (2006), and Clements, et al, "Robust surface registration using salient anatomical features for image-guided liver surgery: Algorithm and validation," Medical Physics, Vol. 35, No. 6, pp. 2528-2540 (2008); copies of the above are appended to U.S. Provisional Application No. 61/331,252, all of which are incorporated herein in their entireties by specific reference for all purposes.

SUMMARY OF INVENTION

In various embodiments, the present invention comprises a system and method for using the contrasted pre-procedural images for interventional guidance. Since the prior art uses intra-procedural images, physicians do not have sufficient time to generate 3D visualizations, nor do they have the time to generate detailed procedural plans. In contrast, the present invention uses 3D visualizations of the vasculature, tumor(s), and organs for enhanced guidance information. The present invention further facilitates extensive pre-procedural planning, thereby significantly reducing procedural times. Since this invention uses pre-procedural images instead of intra-procedural images, it also minimizes the patient exposure to radiation. It is also efficient from the perspective of workflow for incorporation into fluoroscopy suites.

In one embodiment of the present invention, pseudo-features and surfaces are used for registration and to establish the relationship needed for guidance. Pseudo-features include defined features identified on the external surface of the patient, and can be obtained using non-contact imaging devices (such as laser range scanning) or contact-based imaging devices (such as handheld ultrasound probes or optically tracked pen probes). Corresponding pseudo-features are marked on the external pre-operative surface obtained from the patient's pre-operative diagnostic images. A registration algorithm combines the pseudo-features with the external surfaces.

In another embodiment, the present invention also uses organ surfaces in addition to the pseudo-features for registration. In one exemplary embodiment, organ surfaces, such as the surface of the liver, obtained from pre-operative diagnostic images, and the intra-operative surface description of the liver, obtained using intra-operative imaging devices such as intra-operative ultrasound or intra-operative CT, are used. These organ surfaces are used to either refine the registration obtained using external surfaces and pseudo-features, or are used as the primary surfaces for registration.

Other exemplary embodiments of the registration include, but are not limited to, an image-based registration using pre-operative diagnostic images and intra-procedural images when obtained.

DESCRIPTION OF THE DRAWINGS

Figure 1 shows examples of hardware used for purposes of abdominal surface acquisition.

Figure 2 shows an example of a navigation software program interface for mapping the location of tracked percutaneous ablation instrumentation onto pre-procedural tomographic image data.

Figure 3 shows the process of delineation of pseudo-features from the pre-procedural image data.

Figure 4 shows the process of surface registration after delineation of pseudo-feature regions.

Figure 5 shows an example of a visualization of the abdominal surface and organ models used in validation trials.

Figure 6 shows an example of a visualization of a sample abdominal registration result and texture mapping of the closest point distance measurements between the two surfaces.

Figure 7 shows another example of a visualization of a sample abdominal registration result and texture mapping of the closest point distance measurements between the two surfaces.

Figure 8 shows another example of a visualization of a sample abdominal registration result and texture mapping of the closest point distance measurements between the two surfaces.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

In one exemplary embodiment, the invention is intended to provide a framework for registering intra-procedural surface images of the abdomen with surfaces extracted from pre-procedural image data (e.g., magnetic resonance imaging (MRI) or computed tomography (CT) volumes) for the purposes of providing image-guidance during percutaneous surgical procedures. Registration is a method of determining the mathematical relationship between two coordinate spaces and is a critical component in image-guided surgery (IGS) devices. The goal of IGS is to allow the clinician to interactively use high resolution, high contrast pre-procedural tomographic image data within the intervention via overlay display of tracked surgical instrumentation.

Intra-procedural surface images of the abdomen can be acquired using laser range scanning (LRS) technology, manually with an optically tracked stylus, or via any other imaging modality that can be used for abdominal surface extraction (e.g., ultrasound, CT, or MRI images acquired during the procedure). The registration process is then used within an image-guidance system to provide the mathematical mapping required to interactively use the pre-procedural image data for guidance within the intervention.

The primary hardware components used in exemplary embodiments of the present invention include those which pertain specifically to the methods of surface and pseudo-feature acquisition during the percutaneous procedure. Examples of such hardware, including an optically tracked probe **2** (left) and a laser range scanner **4** (right), are shown in Figure 1. Optically tracked probes designed for use with off-the-shelf tracking equipment (such as that provided by Northern Digital, Inc., Waterloo, Ontario) can be used for manual surface acquisition and pseudo-feature delineation. Laser range scanning (LRS) technology can be use to generate high resolution surface scan data in a non-contact fashion. While both technologies are equally useful as exemplary embodiments, other methods of abdominal surface acquisition can be used, including, but not limited to, intraoperative US, CT, or MR.

In addition to hardware that is capable of performing surface data acquisition during percutaneous procedures, an image guidance device using the methods and system of an embodiment of the present invention may provide guidance information via a software interface. Figure 2 shows an example of a navigation software interface using an embodiment of the present invention to map the location of tracked percutaneous ablation instrumentation onto the pre-procedural tomographic data. In one specific example, an exemplary embodiment of the invention is used to compute the mathematical transformation that allows for the display of the location of tracked instrumentation on the pre-procedural tomographic image data (shown as the crosshair **6** in Figure 2). The crosshair **6** location indicates the tracked tip position, while the line **8** (blue, in one embodiment) indicates the trajectory of the instrument. More sophisticated visualizations can be provided wherein the trajectory of the device can be displayed, and the trajectory and device locations can be displayed relative to targets planned prior to surgery. It should be noted that this ability is a differentiating factor between exemplary embodiments of the invention and the prior art. In particular, pre-procedural image data is used for guidance, which allows for pre-procedural planning and 3-D model generation. Guidance visualization such as that shown in the bottom right quadrant of Figure 2 is not currently possible with the prior art.

In one exemplary embodiment, the method of registration of the present invention comprises the following steps.

1. Extraction of abdominal surface and delineation of pseudo-features from the pre-procedural image data.

First, the abdominal surface is extracted from the pre-operative image data. In one embodiment, the abdominal surface extraction method is a semi-automated process that is initialized via input of a seed point within the parenchyma of an abdominal organ. From this seed point, the difference between tissue and air regions can be determined and the abdomen can be extracted. The abdomen surface is then tessellated from the segmented abdomen image in a manner similar to the methods described for liver surface generation in the prior art. In another embodiment, the abdominal surface is generated automatically.

Given the tessellated abdominal surface, a set of pseudo-features are then manually marked on the abdominal surface for use in the registration process. As opposed to the "salient anatomical features" described in the prior art, pseudo-features are regions that can be identified on the abdomen of the patient during the procedure that do not directly correspond with specific anatomical landmarks on the abdomen itself and are not associated with internal organ anatomical regions. "Pseudo-feature" regions are used to initially align the surface data during the registration process. An example of potential pseudo-feature regions, as shown in Figure 3, involve a strip of feature points

10, 20 marked in the superoinferior direction along the patient's midline and across the patient's abdomen normal to the vertical line intersecting at the navel. This allows the generation of four separate features corresponding with the superior, inferior, left, and right directions.

Additionally, a fifth feature **30** is generated representing the intersection of the four feature regions. Delineating the region of intersection is performed by first finding the overlapping points. After finding the overlapping points within the four regions, the method computes the mean position in the set of overlapping points and then collects all points within a specified radius of the mean overlapping point. Registration accuracy using these five feature regions is appropriate for use in IGS systems. In one exemplary embodiment, registration trials were performed using abdominal surfaces extracted from venous and arterial phase CT sets, with errors determined via manual selection of three vessel bifurcation targets in the image sets. Mean surface residual error was 0.77 mm (2.7 mm maximum), while subsurface target error was 3.3 mm (3.6 mm maximum).

2. Acquisition of intra-procedural surface and features.

The intra-procedural protocol involves first acquiring a surface image of the patient's abdomen using an LRS device, optically tracked stylus, or any other imaging modality from which the abdominal surface can be extracted. Once the abdomen surface image has been acquired, as shown in Figure 4, the feature acquisition protocol highlighted is performed. An optically tracked stylus, or similar device, is used by the physician to digitize a contour in the superoinferior direction along the patient midline. Second, a contour is digitized normal to the midline contour from patient left to patient right intersecting the first contour at the navel. As shown in Figure 3, five separate features are then generated and used in the registration process. Given the *a priori* information about order of contour acquisitions, the five features can be automatically generated from the two swabbed contours.

3. Calculation of Registration Transform.

Upon the generation of the models and delineation of pseudo-feature regions described above, the surface registration is performed. Surface registration methods can be those described in the prior art.

There are numerous advantages to the present invention over the prior art. The prior art proposes the use of anatomical features for the registration of surface data acquired of internal organ surfaces. However, in the method of the present invention, the feature regions used are "pseudo-features" and do not fall within the definition of "salient anatomical features," which refer to formally defined anatomical landmarks. Additionally, the invention generates registrations for use in IGS technology for percutaneous procedures, while the prior art generates registrations on a specific organ of interest on which surgery will be performed. In other words, the abdominal surface registration generated by the invention can be used for percutaneous interventions on any abdominal organ (e.g., kidney, liver, etc.), while the prior art registration could be performed on the liver, for example, and the guidance information would not be accurate over the kidneys of the patient.

While percutaneous applications are known in the prior art, the present invention is significantly different. The prior art percutaneous systems use point-based methods to perform the registration; in contrast, the present invention is a method for surface-based registration. The point-based registration is performed using skin affixed fiducial markers. Generally speaking, the registration protocol for the alternate embodiments involves the placement of skin affixed markers that can be tracked in the interventional suite. A full CT tomographic image set is then obtained in which the locations of the skin affixed markers can be identified and used for registration.

The distinction between using skin affixed fiducial markers for registration and the surface based method of the invention has a number of direct implications. First, since it is not feasible to use skin affixed markers during the acquisition of the contrasted, pre-procedural diagnostic tomographic image sets, the use of the currently available systems requires a fiducial marker configuration to be affixed to the patient's abdomen immediately prior to the performance of the procedure. Once the fiducial marker setup has been attached to the patient, a full CT scan of the patient's abdomen is performed. While this full CT scan is routinely performed in CT-guided percutaneous procedures, it is not uncommon for this data set to be acquired without contrast agent, which can impair visualization of the lesion as well as vasculature. The present invention allows the initial registration for guidance to be performed without the use of the CT scan that is acquired immediately prior to the procedure since the fiducial markers are not required. This facilitates an even greater minimization of radiation dose than provided by the current systems.

Further, by using the contrasted, pre-procedural image data for interventional guidance, the present invention can utilize extensive 3-D visualizations of the vasculature, tumor(s), and organs for enhanced guidance information. Since the current technology cannot use the pre-procedural CT data for guidance (due to the fiducial marker constraints), sufficient time does not exist to generate the 3-D visualizations for use during the procedure.

Additionally, by circumventing the need to acquire a set of CT images immediately prior to performing image-guidance, the present invention is much more efficient from the perspective of workflow for incorporation into fluoroscopy suites. Fluoroscopy allows the acquisition of 2-D projection images that are real-time and is frequently used for catheter placement procedures that would benefit greatly from 3-D image guidance. As discussed above, the requirement of skin-affixed fiducials in the alternate embodiments necessarily requires a CT scan to be acquired immediately before the use of the guidance system. This required scan imposes a less efficient workflow than would be necessary for a device using the invention.

Finally, more extensive procedural planning can be incorporated with use of the present invention, given the ability to use the pre-procedural image data. Planning the needle entry point on the abdomen and required needle trajectories is of significant benefit in reducing procedure times and patient exposure to radiation.

In order to demonstrate the application and validity of the methods of the present invention, a set of simulation registration trials were performed. Abdominal surface and organ models were generated from a sample set of CT images, shown in Figure 5. The visualization of Figure 5 includes models of the liver, hepatic and portal veins, pancreas, kidneys, and spleen, as well as the locations of the anatomical fiducials used to compute the target errors in the simulation experiments. The anatomical targets points used in the experiments are as follows: (1) right hepatic vein insertion, (2) portal vein bifurcation,

(3) gallbladder fossa, (4) right renal vein insertion, (5) left renal vein insertion, (6) splenic vein insertion, and (7) superior mesenteric artery near the pancreas.

Once the abdominal surface and organ surface models were generated, the pseudo-features were delineated on the abdominal surface. Simulated LRS-based and probe-based abdominal surface acquisitions were generated using a portion of the full abdominal surface generated from the CT image set and a set of perturbation trials were performed to ascertain the registration accuracies of the device using the two potential embodiments.

The simulated LRS-based surface acquisitions included surfaces comprised of 12,000 and 5,000 total surface and pseudo-feature points. As manually acquired surfaces will be sparser compared with LRS data, the simulated probe-based surfaces were comprised of 5,000 and 3,000 points. The overall extent of the full CT abdominal surface used in generating the simulated surfaces was a reasonable estimate of the extent of the abdomen that can be acquired during a percutaneous intervention.

In order to simulate localization error in the surface acquisition process, each of the surface points were perturbed by a random displacement vector. Registration trials (N = 200) were performed over three different maximum vector magnitudes. The maximum vector magnitudes were selected to be 1 mm and 5 mm for the simulated LRS-based acquisitions while vector magnitudes of 10 mm and 20 mm were selected for the simulated probe-based surface acquisitions. Higher magnitudes were selected for the simulated probe-based surfaces due to the fact that there is a higher propensity for manual errors in surface acquisition using this technique (e.g., lifting of the probe off the abdomen surface slightly during acquisition). It should be noted that vector magnitudes of 5 mm and 20 mm represent the very high end of the conceivable range of errors associated with surface acquisitions using the two exemplary embodiments. The random vectors and magnitudes were generated using a uniformly distributed random number generator.

In addition to the displacement vector perturbations, the initial alignment of the surfaces was also perturbed for each registration trial. The random transformations were computed by generating a set of six random parameters (i.e., three translation and three rotation). A uniformly distributed random number generator was used to supply the rotation parameters $(\theta_x,\theta_y,\theta_z)$ and translation parameters (t_x,t_y,t_z) for the perturbation transformation matrices. The rotation parameters were generated on the interval [-180°, 180°] ($\mu = -0.7 \pm 106.1$) and the translation parameters were generated on the interval [-200 mm, 200 mm] ($\mu = -3.4 \pm 119.3$). The registrations were then computed using the surface registration algorithm described by the prior art (i.e., in the Clements, et al, references identified previously).

The results for the simulated LRS-based abdominal registrations are summarized in Table 1 below. The results of the perturbation registrations are reported both in terms of the surface root mean square (RMS) residual (i.e., the RMS of the closest point distances between the source and target surfaces) and the sub-surface landmark target registration error (i.e., RMS distance between the internal anatomical target positions after registration). The distribution of the seven sub-surface anatomical targets used in the registration trials are shown in Figure 3. The targets selected include various vessel targets in a variety of internal abdominal organs that could be targeted for percutaneous intervention.

TABLE 1

Target	12,000 Point Sampling		5000 Point Sampling	
	1mm Perturbation	5mm Perturbation	1mm Perturbation	5mm Perturbation
(1) Right Hepatic Vein Insertion	0.82±0.82 (1.9)	0.09±0.24 (3.4)	0.88±0.85 (1.9)	0.15±0.05 (0.31)
(2) Portal Vein Bifurcation	0.68±0.67 (1.4)	0.07±0.16 (2.2)	0.70±0.66 (1.5)	0.10±0.04 (0.27)
(3) Gallbladder Fossa	0.71±0.70 (1.5)	0.07±0.14 (2.0)	0.71±0.68 (1.5)	0.10±0.04 (0.28)
(4) Right Renal Vein Insertion	0.54±0.55 (1.3)	0.06±0.09 (1.3)	0.51±0.49 (1.4)	0.10±0.05 (0.33)
(5) Left Renal Vein Insertion	0.34±0.36 (0.93)	0.07±0.14 (2.0)	0.40±0.40 (1.1)	0.10±0.05 (0.27)
(6) Splenic Vein Insertion	0.50±0.57 (1.4)	0.08±0.23 (3.2)	0.62±0.64 (1.5)	0.11±0.06 (0.31)
(7) Superior Mesenteric Artery	0.39±0.39 (0.86)	0.06±0.13 (1.8)	0.41±0.39 (0.89)	0.09±0.05 (0.22)
MEAN	**0.57±0.56 (1.2)**	**0.07±0.16 (2.3)**	**0.60±0.57 (1.3)**	**0.10±0.04 (0.26)**

Table 1 summarizes the registration results in terms of sub-surface target errors target errors [stated in mm units – mean ± standard deviation (maximum)] using the simulated LRS-based surface acquisitions. The surfaces used were comprised of a total of approximately 12,000 and 5,000 surface and pseudo-feature points and 200 perturbation registrations were performed for each combination of surface sampling and noise displacement magnitude. For reference, the closest point distances over the trials using the 12,000 point surface were 0.72 ± 0.16mm (0.93 mm maximum) and 1.84 ± 0.02mm (2.04 mm maximum) for the 1mm and 5mm maximum displacement magnitudes. The closest point distance errors using the 5,000 point surface were 0.73 ± 0.17mm (0.96mm maximum) and 1.84 ± 0.02mm (1.88mm maximum) for the 1mm and 5mm maximum displacement magnitudes.

An example registration result from one of the registration trials is shown in Figure 6. Figure 6 is a visualization of a sample abdominal registration result (left) and texture mapping of the closest point distance measurements between the two surfaces (right) computed for the simulated LRS-based abdominal surface acquisition including approximately 12,000 total surface and pseudo-feature points and a maximum noise magnitude of 5mm. For reference, the mean closest point distance between the surfaces was found to be 1.16mm (3.57mm maximum).

It should be noted that over all of the registration trials (N = 800) and for all anatomical targets, the mean target registration error (TRE) was less than 1mm. Further, there seems to be little correlation between the degree of surface error perturbation and the overall target accuracy of the exemplary embodiment. The overall surface errors do, however, increase with the maximum magnitude of the random perturbation vector representing noise in the surface acquisition. However, this test demonstrates that an LRS-based embodiment of the present invention provides sufficient guidance accuracy for use in percutaneous interventions.

The results for the simulated probe-based surface registrations are summarized in Table 2 below.

TABLE 2

Targets	**5,000 Point Sampling**		**3,000 Point Sampling**	
	10mm Perturbation	**20mm Perturbation**	**10mm Perturbation**	**20mm Perturbation**
(1) Right Hepatic Vein Insertion	0.36±0.33 (1.7)	0.93±0.53 (3.1)	0.53±0.41 (1.9)	1.2±0.57 (3.1)
(2) Portal Vein Bifurcation	0.33±0.34 (1.8)	0.96±0.57 (3.4)	0.49±0.42 (2.2)	1.1±0.62 (3.3)
(3) Gallbladder Fossa	0.34±0.36 (1.9)	1.0±0.62 (3.6)	0.51±0.45 (2.4)	1.2±0.70 (3.6)
(4) Right Renal Vein Insertion	0.29±0.29 (1.6)	0.83±0.47 (3.0)	0.44±0.36 (1.7)	0.99±0.55 (2.9)

(5) Left Renal Vein Insertion	0.30±0.31 (1.8)	0.80±0.50 (3.2)	0.42±0.38 (1.9)	0.97±0.51 (2.9)
(6) Splenic Vein Insertion	0.33±0.32 (1.9)	0.86±0.50 (3.2)	0.46±0.39 (1.8)	1.1±0.54 (2.8)
(7) Superior Mesenteric Artery	0.29±0.33 (1.8)	0.84±0.52 (3.3)	0.43±0.39 (2.0)	0.95±0.54 (2.9)
MEAN	**0.32±0.31 (1.7)**	**0.90±0.48 (3.2)**	**0.47±0.38 (2.0)**	**1.1±0.50 (2.8)**

Table 2 summarizes the registration results in terms of sub-surface target errors [stated in mm units – mean ± standard deviation (maximum)] for the simulated probe-based surface acquisitions. The surfaces used were comprised of a total of approximately 5,000 and 3,000 surface and pseudo-feature points and 200 perturbation registrations were performed for each combination of surface sampling and noise displacement magnitude. For reference, the closest point distances over the trials using the 5,000 point surface were 3.42 ± 0.04mm (3.5mm maximum) and 6.68 ± 0.07mm (6.8mm maximum) for the 10mm and 20mm maximum displacement magnitudes, respectively. The closest point distances for the trials performed with the 3,000 point surface were over the 3.42 ± 0.04mm (3.5mm maximum) and 6.67 ± 0.09mm (6.9mm maximum) for the 10 mm and 20 mm maximum displacement magnitudes, respectively.

A sample registration result from one of the perturbation trials is provided for visualization in **Figure 5**. Shown is the abdominal registration result (left) and texture mapping of the closest point distance measurements between the two surfaces (right) computed for the simulated probe-based abdominal surface acquisition including approximately 3,000 total surface and pseudo-feature points and a maximum noise magnitude of 20 mm. For reference, the mean closest point distance between the surfaces was found to be 2.91 mm (14.95 mm maximum).

It should be noted that while extremely large maximum perturbation vector magnitudes were used to simulate noise in the manual abdominal surface collection process, the average target errors were found to be less than 1mm for all trials except for the abdominal surface sampled at 3,000 points and subject to a maximum noise vector magnitude of 2cm. Even given the use of extreme noise perturbation magnitudes, the maximum errors over all trials (N = 800) and over all anatomical targets were found to be less than 4mm. The TRE errors shown in **Table 2** indicate that the exemplary embodiment of probe-based, manual abdominal surface and pseudo-feature acquisitions for registration in percutaneous image guidance provides information of sufficient accuracy to be clinically useful.

In addition to simply using the abdominal surface for the purposes of registration for percutaneous image guidance, in another exemplary embodiment additional surface data acquired of the internal organs is used to facilitate registration. Such surface data can be acquired through a variety of imaging modalities. In one embodiment, the organ surface imaging is derived from ultrasound imaging. Such additional surface data helps to improve the accuracy of the device with respect to the specific internal organ. Further, this particular embodiment is completely novel with respect to the prior art used in percutaneous procedures. All known prior art in the realm of percutaneous image guidance use a fiducial apparatus that is attached to the abdomen of the patient for the purposes of registration, and no surface or other information from imagery of the internal organs is used.

In a further experiment, simulated ultrasound surface data of the liver was generated to be used in addition to the simulated abdominal surface data used in the previous registration trials described above. The surface sampling used in the registration experiment included the 5,000 point abdominal and pseudo-feature surface along with a simulated liver surface derived from ultrasound of 1,000 points. Additionally, the 3,000 point abdominal and pseudo-feature surface was used in conjunction with a 500 point simulated liver surface.

As was performed in the previous experiment, noise in the surface acquisitions was simulated via the addition of a random displacement vector generated for each of simulated surface points. Trials were performed using a maximum displacement vector magnitude of 10 mm. Additionally, the initial alignment between the two surfaces was generated via perturbation with a random transformation matrix as described previously. The surface registration performed then proceeded as described in the prior art (as described in the Clements references identified above).

The results for the simulated abdominal surface and pseudo-feature data used in conjunction with internal organ surface data are summarized in Table 3 below.

TABLE 3

Target	**5,000 Point Abdomen & 1,000 Point Liver Sampling**	**3,000 Point Abdomen & 500 Point Liver Sampling**
	10mm Perturbation	**10mm Perturbation**
(1) Right Hepatic Vein Insertion	0.30±0.32 (1.6)	0.45±0.41 (1.9)
(2) Portal Vein Bifurcation	0.29±0.35 (1.7)	0.44±0.46 (2.1)
(3) Gallbladder Fossa	0.29±0.36 (1.7)	0.46±0.50 (2.3)
(4) Right Renal Vein Insertion	0.28±0.31 (1.6)	0.41±0.39 (1.9)
(5) Left Renal Vein Insertion	0.30±0.31 (1.6)	0.43±0.40 (2.1)
(6) Splenic Vein Insertion	0.31±0.30 (1.6)	0.45±0.41 (2.1)
(7) Superior Mesenteric Artery	0.29±0.34 (1.7)	0.42±0.44 (2.0)
MEAN	**0.29±0.32 (1.6)**	**0.44±0.42 (2.0)**

Table 2 summarizes the registration results in terms of sub-surface target errors [stated in mm units – mean ± standard deviation (maximum)] using the simulated probe-based surface acquisitions in conjunction with simulated liver surface data derived from ultrasound imaging. The surfaces used were comprised of a total of approximately 5,000 abdominal surface and pseudo-feature points with 1,000 liver surface points and 3,000 abdominal surface and pseudo-feature points with 500 liver surface points. 200 perturbation registrations were performed for each combination of surface sampling and noise displacement magnitude. For reference, the closest point distance over the trials using the 5,000 point abdominal surface and 1,000 point liver surface was 3.42 ± 0.03 mm (3.5 mm maximum). The closest point distance for the trials performed with the 3,000 point abdominal surface and 500 point liver surface was 3.42 ± 0.04 mm (3.5 mm maximum).

A visualization of a sample registration performed as part of this experiment is shown in Figure 8. Shown is a sample abdominal registration result (left) and texture mapping of the closest point distance measurements between the two surfaces (right) computed for the simulated probe-based abdominal surface acquisition including the simulated ultrasound surface data of the liver. The simulated surface shown included approximately 5000 total abdominal surface and pseudo-feature points as well as approximately 1000 simulated liver surface points acquired via ultrasound imaging. A maximum noise vector magnitude of 10 mm was used in the visualized registration. For reference, the mean closest point distance between the surfaces was found to be 1.84 mm (6.70m m maximum).

The results indicate that including the internal organ surface data results in TRE measurements of less than 1mm on average and that the registration accuracies are similar to those reported in Table 2. Additionally, the maximum TRE measurement over all of the registration trials (N = 400) and over all anatomical targets was found to be 2.3mm. As with the exemplary embodiment using probe-based abdominal and pseudo-feature acquisitions, the data in Table 3 show that including internal organ surfaces also provides suitable registration accuracies for the purposes of percutaneous image guidance.

Additional embodiments include, but are not limited to, the following:

- The acquisition of abdominal surface and pseudo-feature data using different imaging and instrumentation.
    - Examples of embodiments include surface acquisition using optically or magnetically tracked stylus devices for manual use as well as non-contact imaging devices (e.g., laser range scanning) that can be used for automatic acquisition of abdominal surface and surface pseudo-features.
    - The abdominal surfaces with pseudo-features are then used for the purposes of calculating the mathematical registration transform required for use in image-guidance devices.
- Performance of surface matching for percutaneous image guidance using a combination of abdominal surface with pseudo-features and internal organ surface(s) extracted from other imaging modalities.
    - An examplary embodiment includes the use of liver surface data extracted from ultrasound (US) images as well as the abdominal surface data acquired

with a tracked stylus to perform the registration for percutaneous image guidance.

- Refining of abdominal surface matching with pseudo-features with organ surface acquisitions extracted from other imaging modalities.
  - An examplary embodiment is for the guidance system to compute the registration between the pre-procedural tomographic image data and the intra-operative abdominal surface with pseudo-features. This initial registration is then be used as an initial pose to compute a refined registration between an internal abdominal organ surface acquired in the operative suite and the organ surface extracted from pre-procedural image data.
- Providing percutaneous guidance information on procedural tomographic image sets via image-to-image registration of procedural image data to pre-procedural image data.
  - Since the percutaneous image guidance device performs registration between the pre-procedural tomographic images, it is possible to extend the percutaneous guidance information to the image data acquired throughout the procedure in “real time” by performing a registration between the “real time” procedural image data and the pre-procedural image data.

Thus, it should be understood that the embodiments and examples described herein have been chosen and described in order to best illustrate the principles of the invention and its practical applications to thereby enable one of ordinary skill in the art to best utilize the invention in various embodiments and with various modifications as are suited for particular uses contemplated. Even though specific embodiments of this invention have been described, they are not to be taken as exhaustive. There are several variations that will be apparent to those skilled in the art.

CLAIMS

What is claimed is:

1. A method for performing registration for percutaneous surgical procedures, comprising the steps of:

generating a computer model of a portion of the outer surface of a patient from pre-procedural image data;

marking a set of pseudo-features on the generated surface;

acquiring an intra-procedural image of the corresponding portion of the outer surface of the patient;

generating a set of intra-procedural pseudo-features by digitizing one or more contours on the corresponding portion of the outer surface of the patient;

and performing an alignment or registration of the model generated from the pre-procedural data with the intra-procedural patient surface data.

2. The method of claim 1, wherein the portion of the outer surface of a patient comprises the abdomen of the patient.

3. The method of claim 1, wherein the intra-procedural image of the patient surface is acquired through a laser range scanner, or an optically or magnetically tracked stylus or instrument.

4. The method of claim 1, wherein the pseudo-features comprise four quadrants formed by the intersection of a series of points in the superoinferior direction along the patient's midline and across the patient's abdomen normal to the vertical line intersecting at the navel.

5. The method of claim 4, further wherein the pseudo-features comprise a fifth feature representing the intersection of the four quadrants.

6. The method of claim 1, wherein the step of alignment or registration further comprises the use of pre-procedural surface data for one or more internal organs of the patient.

7. The method of claim 1, further comprising the step of displaying data for facilitating the percutaneous surgical procedure based on said alignment.

8. The method of claim 7, further wherein the display comprises a three-dimensional model of a portion of the patient.

9. The method of claim 8, wherein the three-dimensional model includes the surface of the patient abdomen, and one or more organs inside the abdomen.

10. A system for collecting and processing physical space data for use while performing an image-guided surgical (IGS) procedure, the system comprising:

a storage medium for storing a computer model of a portion of the outer surface of a patient based on pre-operative data;

at least one sensor device for generating inter-operative surface data associated with said outer surface of the patient; and

a processing element communicatively coupled to said storage medium and said sensor device, wherein said processing element is configured for obtaining a alignment of the computer model and inter-operative surface data.

11. The system of claim 10, further comprising a display device communicatively coupled to said processing element and configured for displaying data for facilitating said IGS procedure based on said alignment.

12. The method of claim 11, further wherein the display comprises a three-dimensional model of a portion of the patient.

13. The method of claim 12, wherein the three-dimensional model includes the surface of the patient abdomen, and one or more organs inside the abdomen.

14. The system of claim 10, wherein the IGS procedure is a percutaneous procedure.

15. The system of claim 10, wherein the storage medium further may store a computer model of a non-rigid structure of interest in the patient.

16. The system of claim 10, wherein the portion of the outer surface of a patient comprises the abdomen of the patient.

17. The system of claim 10, wherein the sensor device comprises a laser range scanner or an optically or magnetically tracked stylus or instrument.

18. The system of claim 10, wherein the alignment is obtained by the generation of corresponding pseudo-features for the computer model and the intra-operative surface data.

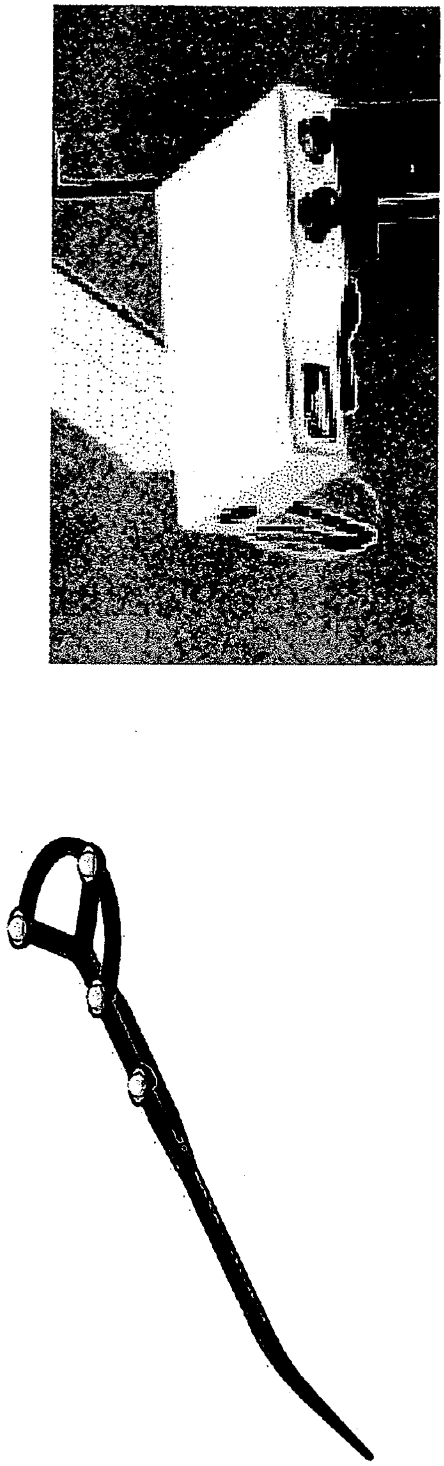

FIGURE 1

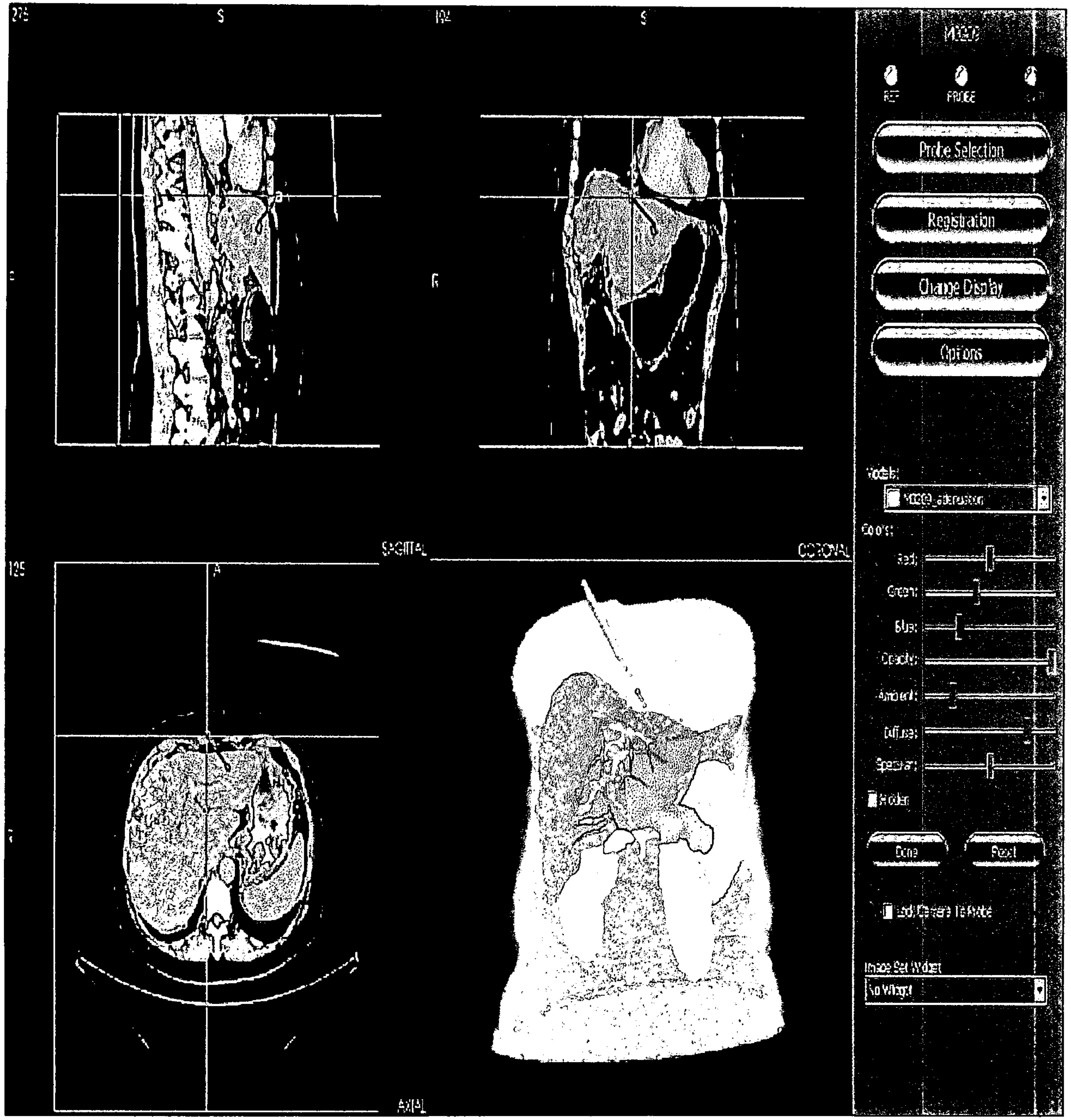
276
S
104
S
R
SAGITTAL
CORONAL
125
A
AXIAL
REF
PROBE
Probe Selection
Registration
Change Display
Options
Models:
Colors:
Red:
Green:
Blue:
Opacity:
Ambient:
Diffuse:
Specular:
Shaded
Done
Reset
Lock Camera To Probe
Image Set Widget
No Widget

FIGURE 2

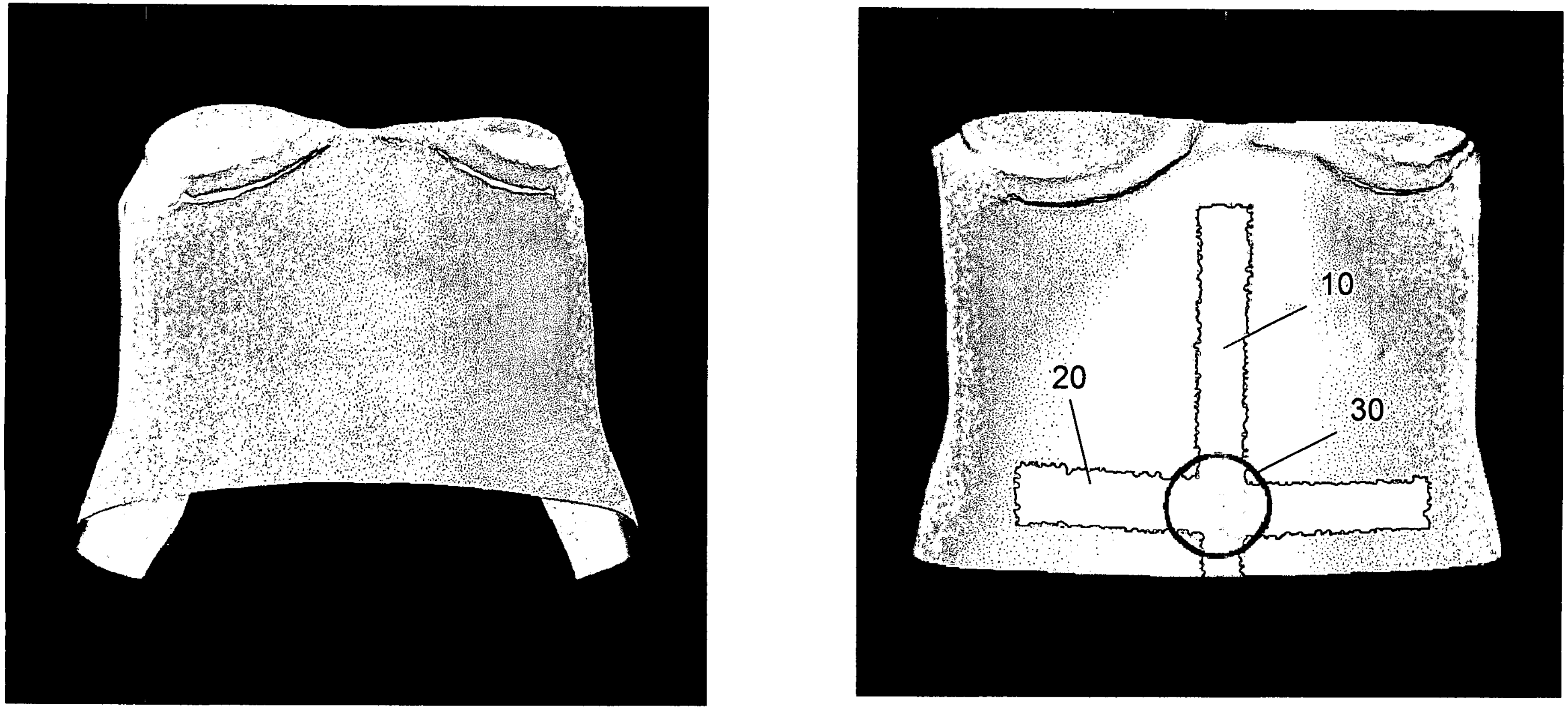

FIGURE 3

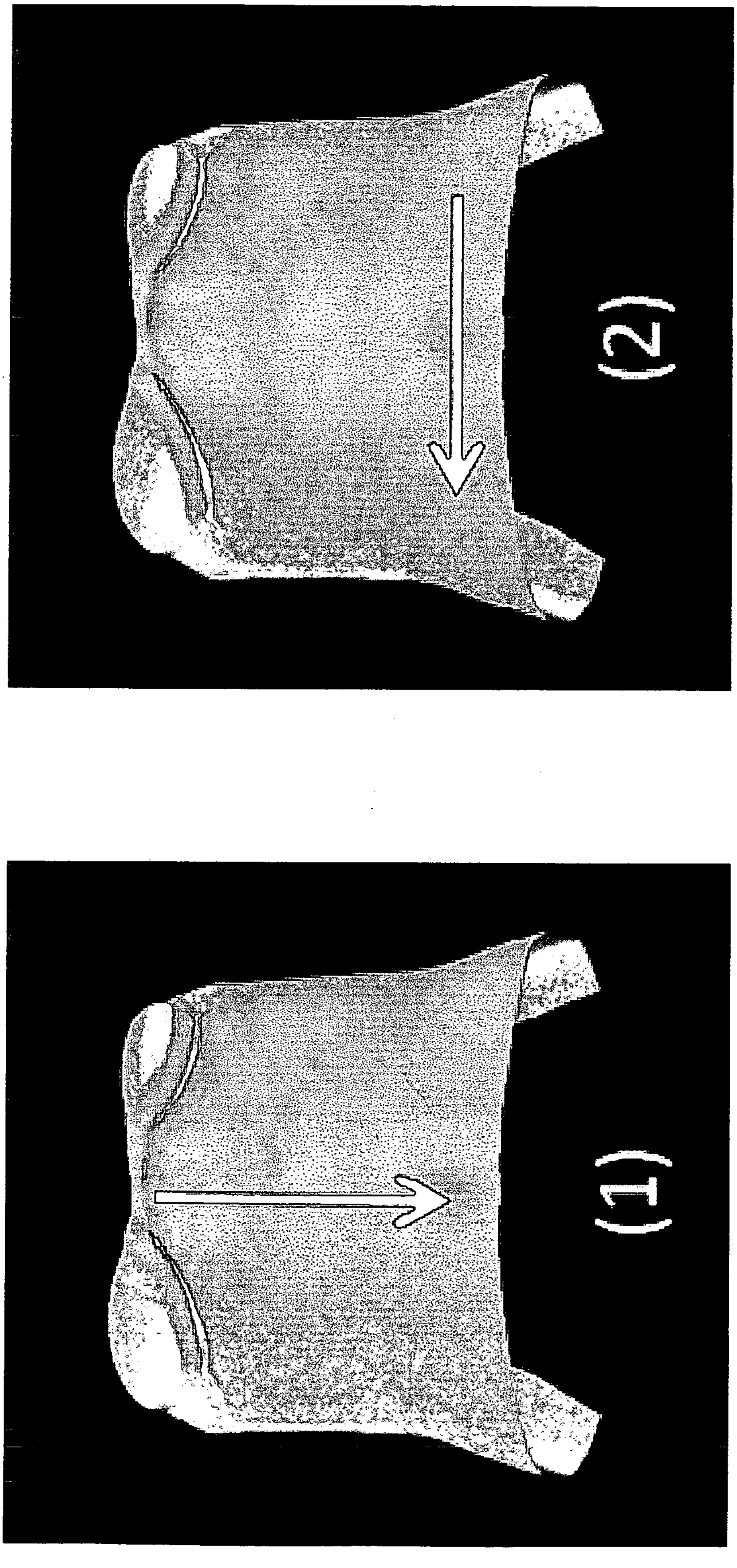

FIGURE 4

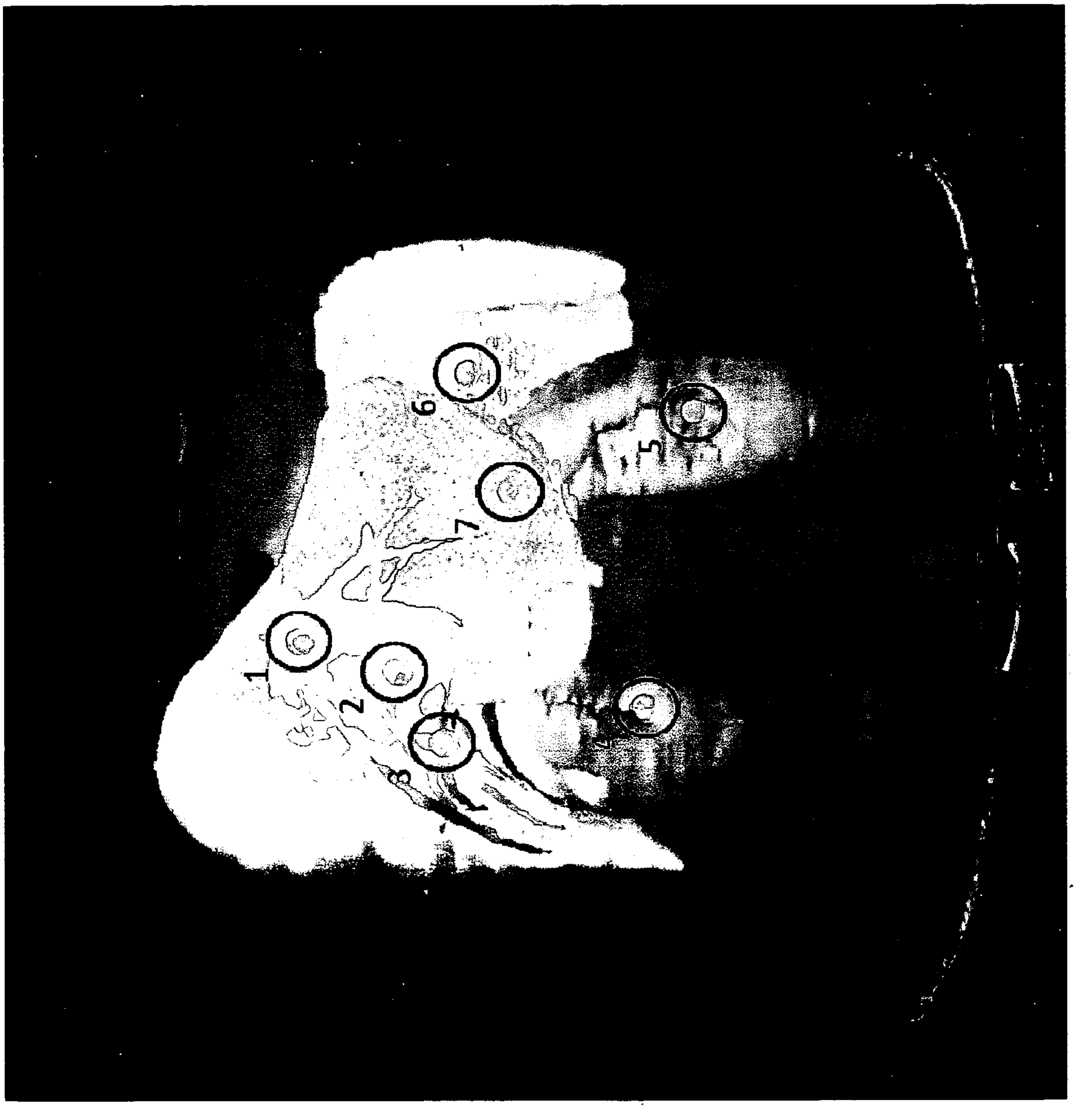

FIGURE 5

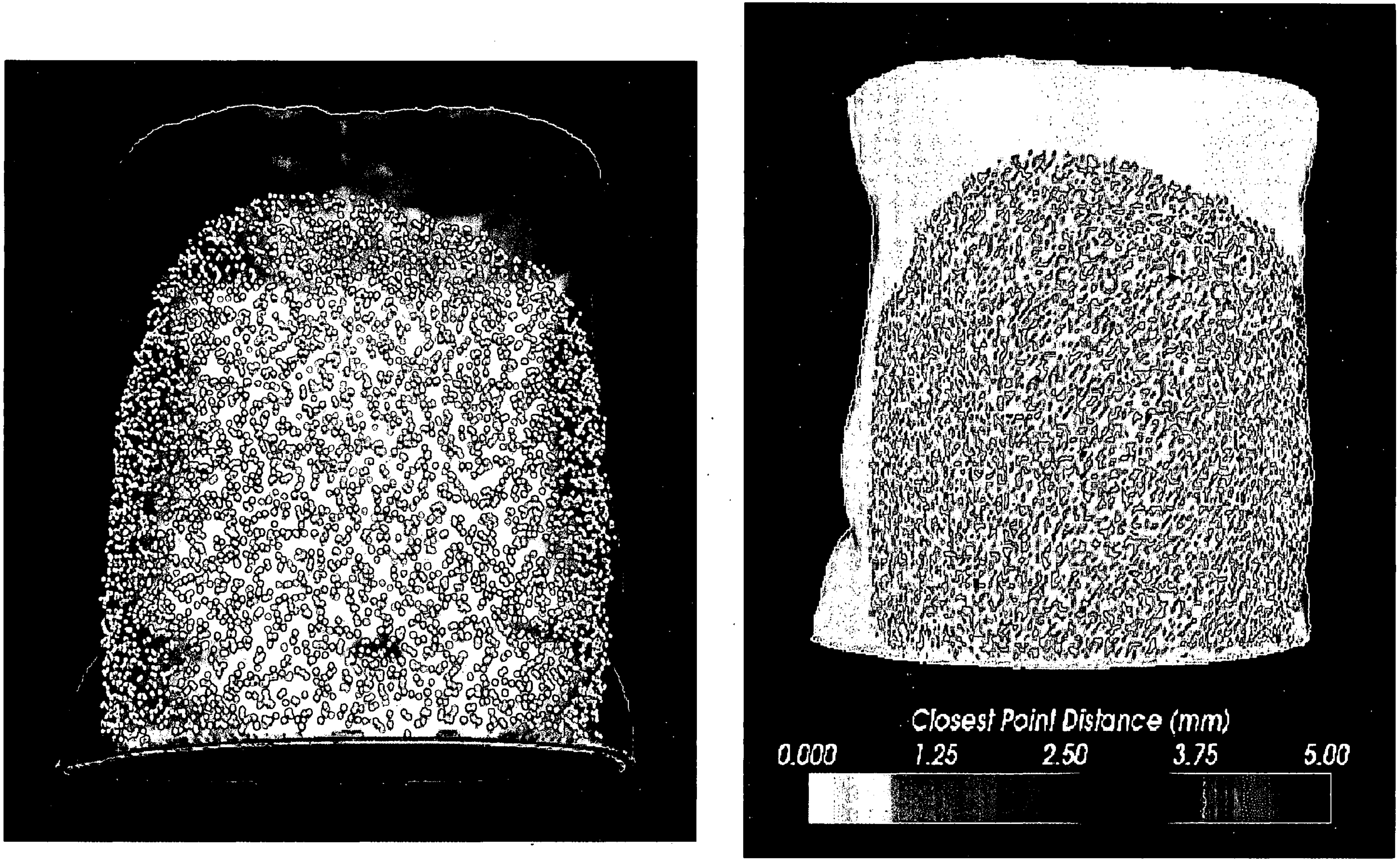

FIGURE 6

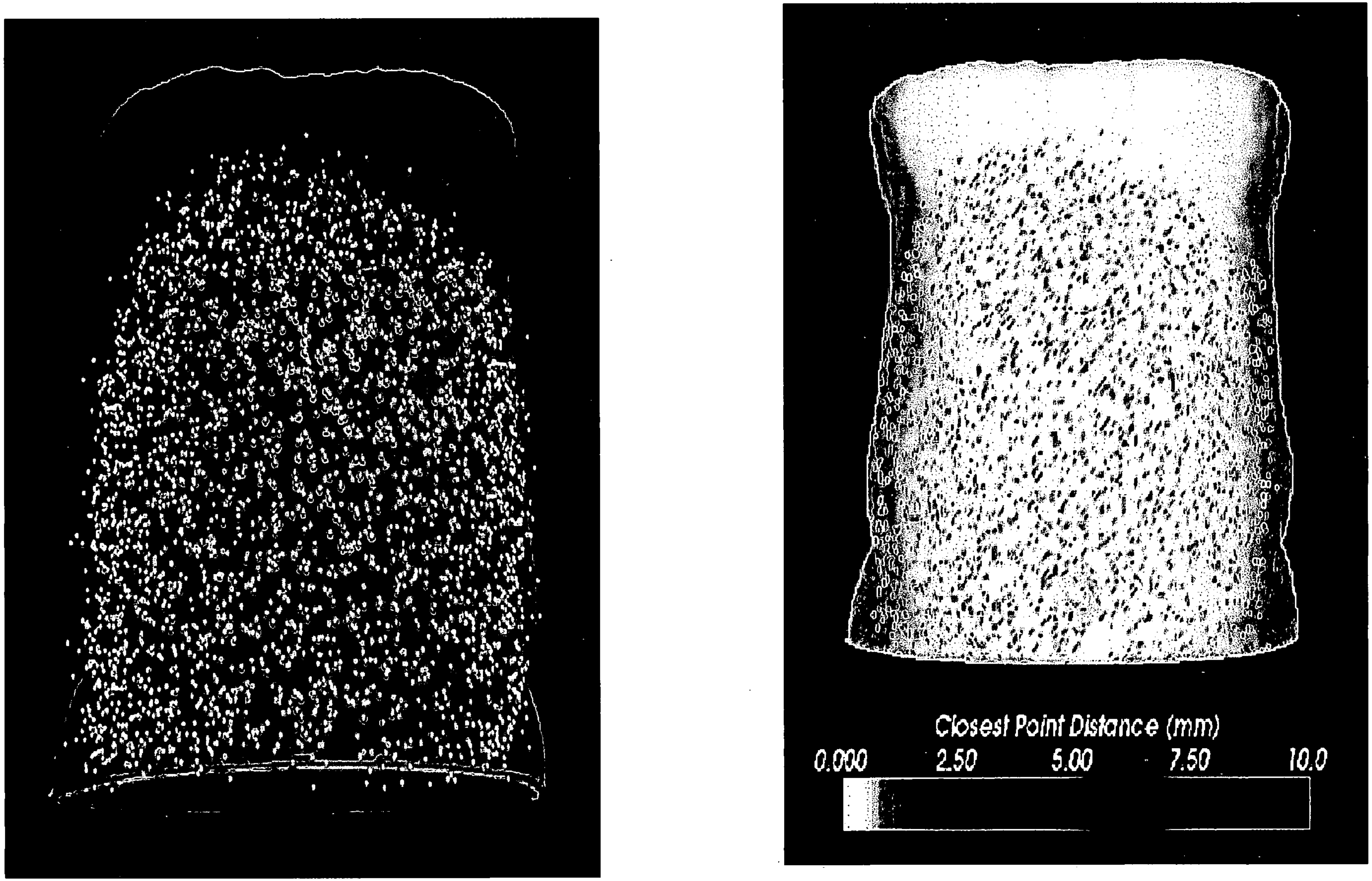

FIGURE 7

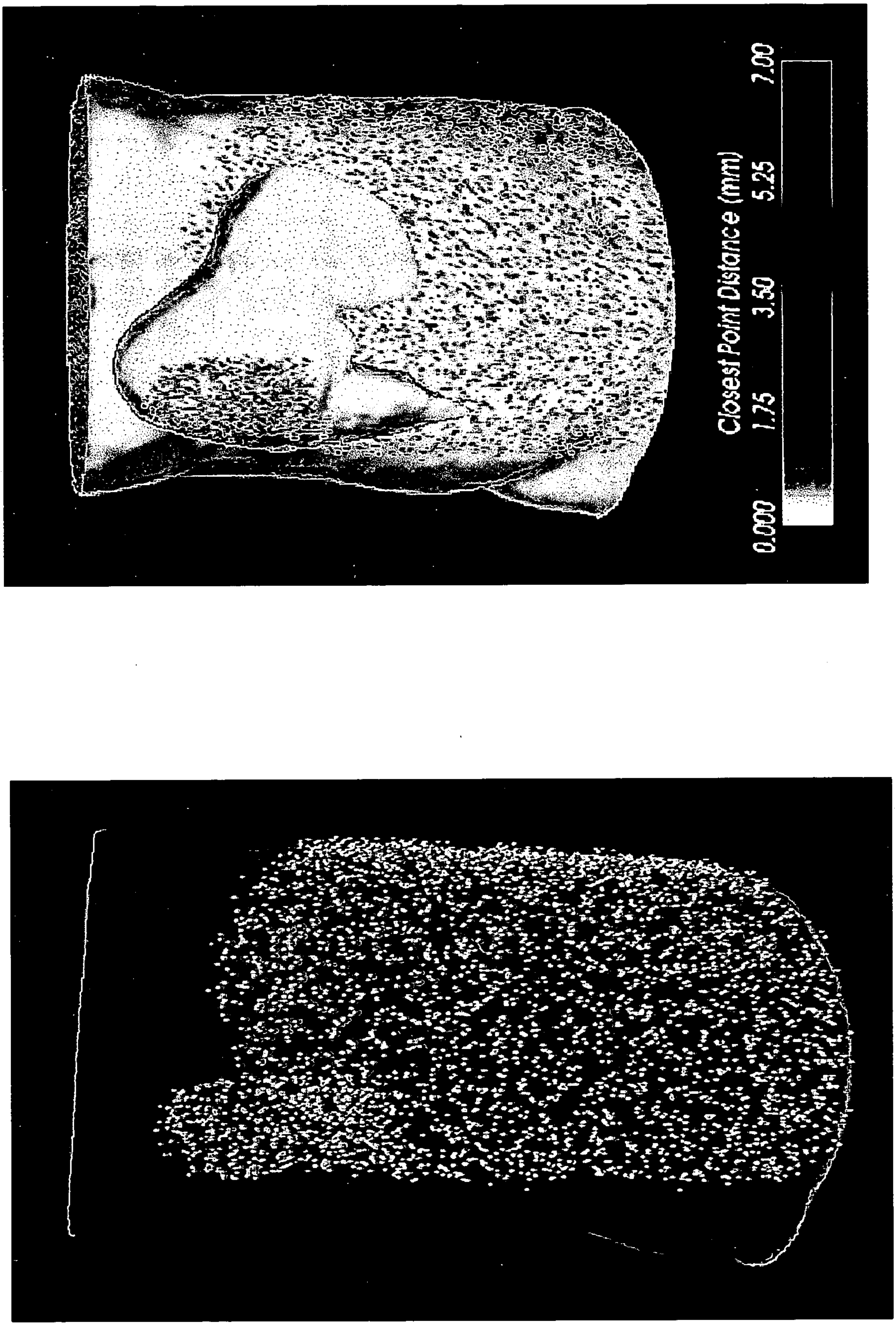

FIGURE 8