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(54) Title: METHOD AND SYSTEM PROVIDING IMPROVED DATA MATCHING FOR VIRTUAL PLANNING

(57) Abstract:

METHOD AND SYSTEM PROVIDING IMPROVED DATA MATCHING FOR VIRTUAL PLANNING**Field of the Invention**

This invention pertains in general to the field of craniofacial treatments. More particularly,
5 the invention relates to a method and system of matching of a first set of data and a second set of data related to a region of interest in a craniofacial space.

Background of the Invention

In WO 2008/083857 A1 of the same applicant as the present application, which hereby is
10 incorporated in its entirety by reference for all purposes, a method and system for planning a dental restorative procedure of a patient and for producing a dental restoration or product related thereto and to be used in the dental restorative procedure are disclosed. Input data from different sources, e.g. 3D data from a CT scan of a patient with a dental impression tray including a previously prepared dental impression of the patient in the patient's mouth, is matched with data from a high
15 resolution 3D scan of the same dental impression. The resulting data may be matched using fiducial markers arranged at a dental impression tray.

However, the method and system disclosed in WO 2008/083857 A1 may be further improved with regard to the procedure of matching a first set of data and a second set of data related to a region of interest in a craniofacial space. There is in particular a need of facilitating this matching
20 when the first set of data and the second set of data are provided from two different input sources having different spatial resolution, compared to what is described in WO 2008/083857 A1. When matching data elements from input sources having different spatial resolution, misalignment of products that are produced based on matched data from the first set of data and the second set of data may occur, e.g. due to interpolation errors when identifying the fiducial markers for matching.

25 Therefore, an improved or refined matching method and system providing or facilitating improved or refined matching would be advantageous. There is in particular a need for providing matched data for use in virtual planning and provision of production data from the virtual planning for producing dental restorations or products related thereto, for allowing reliable dental restorative procedures.

In US 6,947,038 systems and methods for generating an appliance with tie points are
30 disclosed. A marker attachable to a tooth is described having a plastic carrier and mounted on top of it a radiopaque tie point. Top points of the radiopaque tie point are visible at the surface of the plastic carrier. The top point is identifiable from an x-ray map and a 3D image map. The system and methods disclosed US 6,947,038 are subject to the same issues as WO 2008/083857, due to the fact that 3D objects reconstructed from the different maps will have different resolutions, which lead
35 to matching misalignments.

Hence, an improved method and system of facilitating matching of a first set of data and a second set of data related to a region of interest in a craniofacial space would be advantageous and

in particular allowing for improved precision, increased flexibility, cost-effectiveness, and/or patient safety would be advantageous.

Summary of the Invention

Accordingly, embodiments of the present invention preferably seek to mitigate, alleviate or
5 eliminate one or more deficiencies, disadvantages or issues in the art, such as the above-identified, singly or in any combination by providing methods, a system, and a computer program product according to the appended patent claims.

According to a first aspect of the invention, a method of facilitating matching of a first and a
second set of data related to a region of interest in a craniofacial space is provided. The method
10 comprises (a) identifying at least a portion of a surface object in the first set of data; (b) identifying a first coordinate based on the surface object; (c) identifying at least a portion of a volume object in the second set of data; (d) identifying a second coordinate based on the volume object; wherein the first and second coordinate have a pre-defined relationship to each other. By using the identified first coordinate and the second coordinate, matching of the first set of data and the second set of data to
15 a matched set of data may be based on the pre-defined relationship of the first coordinate and the second coordinate.

According to a second aspect of the invention, a system is provided, which system is adapted to facilitate matching of a first and a second set of data related to a region of interest in a craniofacial space. The system comprises at least one unit configured to (a) identify at least a portion
20 of a surface object in the first set of data, (b) identify a first coordinate based on the surface object, (c) identify at least a portion of a volume object in the second set of data, (d) identify a second coordinate based on the volume object; wherein the first and second coordinate have a pre-defined relationship to each other. The identified first coordinate and the second coordinate may be provided further in a system for matching of the first set of data and the second set of data to a matched data
25 set, wherein a unit for matching is arranged to base the matching on the pre-defined relationship of the first coordinate and the second coordinate.

According to a third aspect of the invention, a computer program product, executable on a programmable device containing instructions, which when executed, performs the method of the first aspect of the invention. The computer program product may be stored storeable on a computer-
30 readable medium, and is configured to facilitate matching of a first and a second set of data related to a region of interest in a craniofacial space. The computer program product comprises (a) a first code segment for identifying at least a portion of a surface object in the first set of data; (b) a second code segment for identifying a first coordinate based on the surface object; (c) a third code segment for identifying at least a portion of a volume object in the second set of data; (d) a fourth code
35 segment for identifying a second coordinate based on the volume object; wherein the first and second coordinate have a pre-defined relationship to each other. By adding further code segments, the computer program product may be provided for matching of the first set of data and the second

set of data to a matched set of data based on the pre-defined relationship of the first coordinate and the second coordinate.

By means of the aforementioned method or system, at least two points (coordinates) are determinable in the first set of data and the second set of data, respectively. The points have a pre-defined relationship relative to each other. The points may be common points. For instance the points are a common center point of both the surface object and the volume object. A common center point is always exactly identical in a vector basis, independent of a scaling factor of the two data sets in relation to each other. Thus matched data that is provided based on such a pre-defined relationship of coordinates is provided with very high precision. In addition, when a plurality of such common points, which have a pre-defined relation to each other, is determined in this manner, reliability of matching may become further improved – due to the fact that even when e.g. one or more objects are missing in one of the first and second data sets, e.g. due to image artefacts, it may be reconstructed based on the remaining objects that are identifiable in the data sets. For a more reliable matching at least three such points in space or one axis having a pre-determined direction may be provided in each set of data to be matched with each other.

This was previously not possible as only surfaces were identified and matched to each other. Due to the fact that data for the surfaces has different resolution in the first and second data set, matching was hitherto done with certain tolerances.

Hence, in a fourth aspect of the invention, a method of matching a first and a second set of data related to a region of interest in a craniofacial space is provided. The method comprises in an embodiment the method according to the first aspect of the invention, and transforming a coordinate system of the first set of data to a coordinate system of the second set of data based on the pre-defined relationship between the first coordinate and the second coordinate, for generating a matched data set of the region of interest in the craniofacial space.

In a fifth aspect of the invention, a method of virtually planning a dental restoration is provided. The method comprises the method of matching according to the fourth aspect of the invention, and performing the virtual planning based on the matched data set. The method further comprises providing a production data set as a result of the virtual planning based on the matched data set.

According to a sixth aspect of the invention, a method of producing a product for use in a medical procedure for providing a dental restoration is provided. The method comprises producing the product, at least partly based on the production data set based on the method of the fifth aspect of the invention.

According to a seventh aspect of the invention, a scanning appliance is provided that has at least one surface with a shape adapted to conform to a portion of a craniofacial space. The scanning appliance comprises at least one surface object, which is at least partly identifiable from a first set of data, and wherein a first coordinate is identifiable based on the surface object; at least one

volume object, which is at least partly identifiable from a second set of data, and wherein a second coordinate is identifiable based on the volume object; wherein said surface object is arranged in relation to said at least one volume object such that said first coordinate and said second coordinate have a pre-defined relationship to each other.

5 The scanning appliance may for instance be a dental impression tray or a radiographic guide.

 According to an eighth aspect of the invention, a method of manufacturing a scanning appliance, such as a dental impression tray or a radiographic guide, is provided. The method may comprise freeform manufacturing the scanning appliance including at least one surface object and at
10 least one volume object.

 Further embodiments of the invention are defined in the dependent claims, wherein features for the second and subsequent aspects of the invention are as for the first aspect *mutatis mutandis*.

 Some embodiments of the invention provide for a more precise matching of a first set of
15 data and a second data set, providing a more precisely matched data set.

 Some embodiments of the invention provide for more precise manufacturing data based on the matched data set, and thus products manufactured based on this manufacturing have higher precision.

 Some embodiments of the invention provide an improved conformity of matched data to
20 the anatomical craniofacial situation.

 Some embodiments of the invention provide for introduction of fewer errors in a dental planning and production system.

 Some embodiments of the invention provide for less sources of error in a chain of production of a dental planning and production system.

25 Some embodiments of the invention provide for final products that conform to the real anatomical craniofacial situation with high precision. Some embodiments thus provide for production of products to be used in dental restorative procedures with improved fit.

 The term "surface object" in the context of the present specification is an object that has at least partly an outer, external surface, which surface is detectable by non-material penetrating
30 scanning device or technique, such as a surface scanner, including for instance an optical scanner, including a light based scanner such as a laser scanner, holographic scanner and/or a camera, or a contact scanner such as a touch probe scanner. A surface object has at least partly a shape or plane that is visible from the surface of a structure to which it is attached or integrated with. A surface object may be a surface of a defined shape from which a coordinate is identifiable. In addition, the
35 surface object may have a volume adjoining the outer, external surface. The surface object may be a real surface object on a product or a virtual surface object in a data set generated from the real

surface object. Some examples of such surface objects are given in the detailed description of embodiments.

The term "volume object" in the context of the present specification is an object that has a volume of defined shape. At least a part of the shape of the volume of the volume object is detectable by a material penetrating data generating device or technique, such as a CT scanner, a cone beam CT scanner, an MRI scanner, or an ultrasound based scanner. The volume object may be a real volume object on a product or a virtual volume object in a data set generated from the real surface object. A volume object may for instance be at least partly embedded within a structure, such as a scanning structure. Some examples of such volume objects are given in the detailed description of embodiments.

According to The American Heritage® Dictionary of the English Language, Fourth Edition, © 2006 by Houghton Mifflin Company, the term "coordinates" is defined as any of a set of two or more numbers used to determine the position of a point, line, curve, or plane in a space of a given dimension with respect to a system of lines or other fixed references. Only one number is needed if the point is on a line, two if the point is in a plane, and three if it is in space. This meaning of the term "coordinate" or "coordinates" is used in the context of the present specification. A coordinate may be determined by identifying a surface object and calculating the coordinate based on the identified surface object. Alternatively, or in addition a coordinate may be determined by surface matching the identified surface object with a CAD object for which the coordinate is known.

It should be emphasized that the term "comprises/comprising" when used in this specification is taken to specify the presence of stated features, integers, steps or components but does not preclude the presence or addition of one or more other features, integers, steps, components or groups thereof.

Brief Description of the Drawings

These and other aspects, features and advantages of which embodiments of the invention are capable of will be apparent and elucidated from the following description of embodiments of the present invention, reference being made to the accompanying drawings, in which

Fig. 1 is a flowchart of a method;

Figs. 2 to 3 are schematic illustrations of a dental impression tray having a plurality of surface objects and volume objects;

Figs. 4A-4C are schematic illustrations of various surface objects and volume objects;

Fig. 4D is a schematic illustration of a plurality of coordinates of a plurality of surface objects and volume objects in a geometric interrelation;

Fig. 5 is a schematic illustration of a radiographic guide having a plurality of surface objects and volume objects;

Fig. 6 is a schematic illustration of a surgical drill guide produced from production data based on matched data;

Fig. 7 is a schematic illustration of a system; and

Fig. 8 is a schematic illustration of a computer program.

5

Description of embodiments

Specific embodiments of the invention will now be described with reference to the accompanying drawings. This invention may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the invention to those skilled in the art. The terminology used in the detailed description of the embodiments illustrated in the accompanying drawings is not intended to be limiting of the invention. In the drawings, like numbers refer to like elements.

The following description focuses on an embodiment of the present invention applicable to a drill guided dental restorative procedure. However, it will be appreciated that the invention is not limited to this application but may be applied to many other dental restorative procedures, including for example bone shaping by means of surgical templates, positioning of anchoring elements, orthodontic procedures, etc.

As described in the background section, a first set of data and a second set of data, from different sources, are merged for virtually planning craniofacial treatment procedures, such as dental restorative procedures, orthodontic procedures, dental surgical procedures, etc. in a computer based environment. The merged set of data is a basis for providing production data as a result of the virtual planning, e.g. for production of dental restorations or products related thereto.

A reason for using data from two different sets of data is to provide data for different aspects for the virtual planning, which are only available separately from using different data generating devices.

During virtual planning of a surgical procedure, all aspects are needed for a reliable planning. For instance visualization of an anatomical situation at a surgical site in a craniofacial space, needs to include both visible and hidden structures. For instance, planning of positions of dental implants requires data concerning the jaw bone tissue in order to find a suitable implantation position. The data may provide information about the topography, bone density, etc. of jaw bone tissue.

Information for such virtual planning is provided based on the merged data from a first set of data provided for surface structures, and a second set of data provided for anatomical structures hidden under the surface, e.g. of the oral cavity.

In more detail, the different aspects may relate e.g. to hidden structures of patient anatomy, such as bone tissue; high precision determination of positions of existing structures, like

soft tissue, remaining teeth, or already implanted dental implants; etc. For production of dental restorations or related products, such as dental implants, bridge frameworks, anchor pins, surgical templates, etc., high precision data is needed for production thereof.

For instance, the first set of data is generated of a scanning appliance by means of a surface scanning device. The scanning appliance is for instance an impression tray including a dental impression made of at least a portion of the patient's oral cavity. The first set of data comprises thus information about the topography of the anatomical surface in the craniofacial space. Thus, the first set of data may comprise information concerning the actual situation in the oral cavity, including e.g. the outer topography of soft tissue, existing teeth, and connection interfaces of existing dental implants, etc.

In case the scanning appliance comprises at least one surface object, the first set of data will provide for identification of a first coordinate based on the surface object. The position and orientation of at least one outer surface of the surface object allows for identification of a position and orientation of the surface. The entire surface object may thus be determined from that at least one outer surface. Based on the identified surface object, a first coordinate may be identified. In case of a plurality of surface objects, each having an individual at least one outer surface allowing for identification of a position and orientation of the surface, several of the plurality of surface objects may be identified. A coordinate is identifiable for each of the identified surface objects.

The second set of data of the patient's craniofacial space is generated from e.g. a CT scan of a patient. When generating this second data set, the aforementioned scanning appliance, such as the previously prepared dental impression tray and dental impression of the patient, is arranged in the patient's mouth. The second set of data provides data for identifying anatomical objects that are concealed in the oral cavity, such as bone tissue. Furthermore, the position of the scanning appliance relative the bone tissue is determinable from the second data set.

At least one volume object is identifiable in the second data set. The volume object is e.g. attached to the scanning appliance or integrated with the latter. Alternatively, the volume object may be affixed to an anatomically existing structure. This structure may e.g. be a tooth, which in turn is identifiable in the first set of data by surface scanning, e.g. an impression of the oral cavity or directly in the oral cavity. From the second data set, at least a portion of the volume object is identified in the second set of data. Based on the volume object, a second coordinate is identified.

Hence, in the first set of data, data only of the scanning appliance is comprised. In the second set of data, data from bone tissue is provided, but not data for the scanning appliance itself. For instance, CT scanning parameters are adjusted to bone tissue imaging, such that soft tissue is not reliably generating data in CT imaging. As scanning appliances often have similar radiopacity as soft tissue, no useful data for the scanning appliance itself is provided. During virtual planning, it is desired to have the position of the scanning appliance in relation to the bone tissue.

A surface object determined from the first set of data has a resolution that is different than the resolution of a surface object the second set of data. For instance, a fiducial marker having a surface determined from surface scanning has a different resolution than a surface of the same fiducial marker determined from a set of data from CT scanning. Furthermore, the first set of data
5 comprises information that would not be available from a CT scan of the scanning appliance, as the latter often is radiolucent for CT scanning. These issues are effectively avoided by embodiments of the invention.

In embodiments, the first coordinate and the second coordinate have a pre-defined relationship to each other, which allows for improved matching of the first set of data and the second
10 set of data.

When matching the two sets of data based on this pre-defined relationship of the first coordinate and the second coordinate, virtual planning may be performed with high precision. Production data based on the virtual planning has consequently also high precision. This is due to the fact that the matched data is provided with ultimate precision and provides for correct planning
15 with regard to both bone tissue and the existing intra oral anatomy. As mentioned above, previously, matched data was not matched with such a degree of precision, and several issues arose, including potential erroneous fit of dental restorations produces based on the matched data, etc. These issues are now resolved.

Hence, a method and system useful for planning a dental restorative procedure of a patient
20 and for producing at least one dental restoration or product related thereto to be used in the dental restorative procedure are disclosed and embodiments described in more detail hereinafter.

In an embodiment of the invention according to Fig. 1, a method 1 of facilitating matching of a first set of data and a second set of data related to a region of interest in a craniofacial space is illustrated. The method 1 may be used in one or more of planning craniofacial treatment procedures,
25 as discussed above. The method 1 comprises:

- (a) identifying 100 at least a portion of a surface object in the first set of data;
- (b) identifying 110 a first coordinate based on the surface object;
- (c) identifying 120 at least a portion of a volume object in the second set of data; and
- (d) identifying 130 a second coordinate based on the volume object; wherein the first and

30 second coordinate have a pre-defined relationship to each other.

The first set of data may be generated using a first, non-material penetrating, 3D data generating device.

Identifying 100 at least a portion of the surface object in the first set of data may be performed by various techniques, such as surface recognition, and/or object recognition. The
35 identification may be made manually or semi-automatically. The first set of data may be combined with supplementary CAD data, which is not necessary when a shape, or a sufficient portion of the object to determine the coordinate, is identifiable from the first set of data itself.

Identifying 110 a first coordinate based on the surface object may be made manually, semi-automatically or automatically, and is described in more detailed below.

The second set of data may be generated using a second, material penetrating, data generating device, e.g. by CT scanning, or with a cone beam CT scanner.

5 Identifying 120 at least a portion of a volume object in the second set of data may e.g. be based on threshold identification via, e.g., Hounsfield grey values and/or shape identification. The volume object has e.g. a known volume, and/or shape, etc. which is identifiable.

Identifying 130 a second coordinate based on the volume object may be made manually, semi-automatically or automatically, and is described more detailed below.

10 The first and second coordinate have a pre-defined relationship to each other, which provides for advantageous matching of the first set of data and the second set of data to merged data, which is described more detailed below.

In embodiments, the first, non-material penetrating, data generating device is a 3D surface scanner. The 3D surface scanner may be a stand alone scanner, a desktop scanner or the like. The 15 3D surface scanner is for instance an optical scanner, including a light based scanner such as a laser scanner, holographic scanner and/or a camera. The optical scanner may be an intraoral 3D surface scanner. Alternatively, or in addition, the 3D surface scanner is a contact scanner such as a touch probe scanner. The generating the first set of data comprises surface scanning at least a portion of a surface of the surface object by means of the first data generating device.

20 In embodiments, the second, material penetrating, data generating device is a CT scanner, a Cone Beam CT scanner, an MRI scanner, or an ultrasound based scanner. Generating the second set of data comprises thus CT scanning, MRI scanning or ultrasound scanning the volume object by means of the second 3D data generating device.

The first and second 3D data generating devices are different. The first 3D data generating 25 device is arranged to provide surface data, e.g. of the intraoral space, from which surface objects are identifiable. The first data set is either provided directly from the intraoral space, or from an impression made thereof. The second data generating device is arranged to provide data from entities at least partly covered under a surface, such as bone tissue and/or entities at least partly embedded in other entities, such as internally in the structure of an impression tray 200.

30 A region of interest in the craniofacial space is chosen. The region of interest is for instance a site at which a surgical procedure is to be performed, e.g. a portion of the oral cavity where one or more dental implants are to be implanted. Virtual planning will be done in the region of interest.

The combined data of the first set of data and the second set of data comprises all 35 information that is needed for a virtual planning of a dental restorative procedure in the region of interest in the craniofacial space. When the combined data is used for critical applications, such as virtual planning of dental restorations, it is critical that the two data sets are merged with extremely

high precision. To this end, merging the first and second 3D data set is facilitated as described herein. An advantageous starting point for the merging of data is provided by the method.

In order to facilitate identification of the surface object and/or the volume object, they may be displayed as an image for user identification via a suitable user interface. The identification
5 comprises manual identification of the surface object and/or the volume object. A graphical user interface is provided for facilitating matching of a first set of data and a second set of data related to the region of interest in the craniofacial space.

Alternatively, or in addition, the selection is performed automatically or semi-automatically. A user identifies in the case of semi-automatically identification a position in the region of interest,
10 preferably adjacent to, close to, or at the surface object and/or the volume object. They are then each further identified by suitable algorithms. The first coordinate and/or the second coordinate is determined. This may provide to save time of the matching procedure. Identification of the surface object and/or the volume object is thus made quicker. Consequently, matching will be performed quicker too. Less computational power is needed than previously.

In an embodiment, a plurality of these surface objects and volume objects are shown at an impression tray 2, for instance as shown in Figs. 2 to 3. The surface objects, and/or the volume
15 objects may be affixed to the impression tray 2. Alternatively, or in addition, at least one of the surface objects, and/or the volume objects may be an integral part of the impression tray 2.

Figs. 4A-4C are schematic illustrations of various embodiments of surface objects and
20 volume objects, as well as related first coordinates and second coordinates, wherein a cross sectional view is shown in the upper part of the Figs. 4A-4C, and a top view from above is shown in the lower portion of the Figs. 4A-4C.

The surface object is at least partly externally arranged on or at a unit. The unit may be a scanning appliance. Alternatively, or in addition, the unit may be a tooth, a bone anchor, an implant,
25 a screw in implant, a position locator, etc. The unit is fixed in relation to the craniofacial anatomy, i.e. bone tissue structures, of a subject when generating the second set of data. When generating the first set of data, it is sufficient, that the surface object is affixed to the unit.

The volume object is in an embodiment a volume enclosed by the surface object. The enclosed volume may be filled with air. Alternatively, or in addition, the volume may be filled with a
30 material that is radiopaque for detection by the material penetrating data generating device. Suitable materials comprise Gutta Percha, aluminum, aluminum oxide, glass, ceramic material, etc. These materials (and air) have a known pre-defined Hounsfield (HU) value different from bone.

As shown in the embodiments of Figs. 4A, 4B and 4C, the surface objects and volume
35 objects are arranged concentrically and the first coordinate and the second coordinate is a common center thereof (in one cut-plane of the object shown in these Figs. 4A, 4B and 4C). In 3D space, the surface objects and volume objects are arranged co-axially and the first coordinate and the second coordinate is a common axis thereof, here the longitudinal axis 405, 415, 425.

In more detail, in an embodiment a first aggregate 4a comprises a surface object having two halves 401, 402 which enclose an inner volume 403. The two halves are for instance assembled together as two halves 230, 240 of a dental impression tray 200, as shown in Figs. 2 and 3.

Alternatively, or in addition, the surface object and the volume object may be arranged
5 separately. The surface object and the volume object may be individual objects.

Alternatively, or in addition, the surface object and/or the volume object may have other forms or shapes than cylindrically. The shape of the surface object and/or the volume object may be rectangular, square, oval, or an asymmetrical, or irregular form that is identifiable from the first set of data.

10 The surface object has at least one external surface that is detectable and allows for data generation by means of the first, non-material penetrating, data generating device. In this manner one or more surfaces, such as the top surface of the upper half 401 (shown in a top view in the lower part of Fig. 4A), the lower surface, or the lateral surface are identifiable by suitable algorithms known in the art, such as object identification CAD object identification, including surface
15 identification, grey value identification, identification of specific shapes, pattern recognition, identification on an arbitrary scale related to radiopacity, etc. In this manner, the entire surface object is detectable from the external surface. The detection may also comprise identifying one or more surfaces, and from supplementary CAD data, such as a CAD model of the dental tray 200 comprising the surface objects, the entire surface object may be identified with improved precision.
20 CAD data is vector based and has thus optimum resolution compared to 3D data generating devices having a sampling, pixel or voxel resolution. An object, such as the surface object or volume object, is identified in a 3D data set by suitable algorithms, such as discussed above. The identified object is aligned with the corresponding object in a CAD data set. From this outset, the first coordinate is identified in a first relation to the surface object based on the CAD data. In this manner, the first
25 coordinate is identified with optimum precision in a vector based system.

Hence, from aggregate 4a, a first set of data is generated using a first, non-material penetrating, data generating device. The first data generating device is for instance a surface scanner, such as an optical scanner or a touch probe scanner. The surface object in the first set of data is identified as the two halves 401, 402. From the surface object, a first coordinate is identified
30 based on the surface object. Here, the longitudinal axis 405 is identified as the first coordinate.

The inner volume 403 of the first aggregate 4a is filled with a radiopaque material.

The radiopaque material of embodiments of the volume object is for instance air or any other material that provides a detectable specific radiopacity in generated data. The radiopaque material of the volume object is for instance Gutta Percha, aluminum, aluminum oxide, glass, or
35 ceramic material. Thus, the volume object is arranged to provide a difference in detectable radiopacity, from the second set of data, between the radiopaque material of the volume object and the structure that surrounds the volume object. In this manner, the volume object is identifiable.

The volume object is advantageously provided when assembling the two halves 230, 240 of the impression tray, together with the affixed two halves 401, 402 of the first aggregate.

In the aggregate 4a, the volume object 403 is the inner volume thereof. A second set of data, comprising data elements for identifying the volume object 403 in form of the inner volume, is generated. This is performed by means of a second, material penetrating, 3D data generating device, such as CT, cone beam CT, ultrasound, or MRI. The volume object 403 in form of the inner volume is thus identifiable in the second set of data. As the volume object 403 in form of the inner volume is arranged inside the two halves 401, 402, the volume object is arranged in a defined spatial relation to the surface object comprising the assembled first and second halves 401, 402. Having 3D data available for the inner volume, the aforementioned coinciding first coordinate and second coordinate, namely the longitudinal axis 405, are then identified based on the surface object and the volume object 403. This identification may be made by image processing algorithms, such as described above.

Data generated by material penetrating devices, for instance CT based 3D data, has a low resolution in comparison to non-material penetrating, 3D data generating devices. By using embodiment of the invention, the first coordinate and the second coordinate, here coinciding as the longitudinal axis 405, are identified with much higher precision than the volume object itself would be identified in form of the inner volume from the data generated by material penetrating devices. This is due to the fact that pixel or voxel based object identification is a compromise due to interpolation errors when generating surfaces for 3D objects. This compromise leads to the fact that the position in space of the inner volume then determined based on the data generated by material penetrating devices is less precise than the coordinate which is determined based on the surface object obtained from the first set of data.

In addition, when small surface objects, such as beads or similar fiducial markers are used for detection in first and second data sets, the relative spatial error when detecting the spatial position thereof in 3D data generated by material penetrating devices is even larger, leading to misalignment errors when matching data based on such small surface objects.

The first and second coordinates have a pre-defined relationship to each other. As the first coordinate and the second coordinate are identified with high precision, and the relationship between the latter is pre-defined (e.g. same longitudinal axis) the data now available (the first and second coordinate and the pre-defined inter-relationship) may be used for providing a matched 3D data set of the first set of data and a second set of data, e.g. by means of suitable coordinate transformations between the first set of data and the second set of data.

In the embodiment illustrated in Fig. 4b, an aggregate 4b comprises a surface object in form of a body 411 and a cap 412 enclosing a volume object in form of an inner volume 413. The inner volume 413 and the body 412 share a common longitudinal axis 415. The inner volume 413 is formed as a recess in body 412. The cap 413 is a releasably attachable closing cap, such that the

recess is enclosed in the aggregate 4b when the cap is in position, as shown in the upper portion of Fig. 4B. The volume object in form of inner volume 413 is accessible for the second, material penetrating, 3D data generating device, even when the cap is in the illustrated position. In addition, the recess is accessible for the first, non-material penetrating, data generating device when the cap is removed, such as for a touch probe scanner. This is illustrated in the lower portion of Fig. 4B.

Another embodiment having a recess, but no closing cap is illustrated in Fig. 4C. An aggregate 4c of surface object in form of a body 421 surrounds a volume object in form of an inner volume 423 around a common longitudinal axis 425. The inner volume 423 may be filled with specific radiopaque materials, such as the materials described above, and as illustrated in Fig. 4C. The radiopaque material may be provided with an adhesive, or as a solidifying material for permanent attachment to the inner volume of the body 421.

In embodiments the surface object and the volume object share a substantially identical mating interface, i.e. a surface object and a volume object have a common surface where the two objects adjoin. For instance, in the embodiments shown in Figs. 4A-4C, the surface objects and volume objects share a substantially identical mating interface, namely the inner surfaces of the body 401, 411, 421 of the surface objects, respectively. For instance in the aggregate 4c, the surface object in form of the body 421 has a mating interface to the volume object in form of the inner volume 423 inside the body 421 in form of the cylindrical inner surface. Here, the surface object and the volume object share an identical mating interface, namely the cylindrical inner surface of the body 421.

However, in other embodiments, the surface objects and volume objects may be completely different and separate entities spatially arranged away from each other. However, in all embodiments, the surface objects and volume objects have the pre-defined relationship between first coordinates and second coordinates in common. For instance, in one of the surface objects having an external surface, such as one of the surface objects 210 to 215 may be determined in relation to a first coordinate, such as a center, axis, plane, or outside surface related to or part of the dental impression tray 200, or of an anatomically fixed unit.

As mentioned afore, a plurality of surface objects and/or volume objects might improve accuracy in some applications, where e.g. scattering due to existing teeth or fillings thereof renders image data of a volume object or a surface object unusable for identifying the latter, or identifying a coordinate based on the latter.

A typical CT related issue is that CT scanning sometimes is not capable of accurately representing the oral anatomy. For instance, existing metal based dental restorations in the patient may cause severe scattering during CT scanning.

In the latter case, the surface data of the surface object is reliably provideable, as well as the data for the volume object, positioned outside of an area of potential distorted data due to e.g. scattering.

Alternatively, or in addition, the surface object and/or the volume object may have in embodiments non-circular axial cross sections (not shown). For instance the surface object may have an elliptical, square, rectangular, triangular, etc. outer shape in axial cross section. The volume object may also have other cross sectional shapes than circular, such as square, rectangular, or triangular cross sectional shapes in axial cross section. Alternatively, or in addition, the surface object and/or the volume object may have asymmetrical shapes. These shapes may be advantageously used for identifying the shape and thus the surface object or volume object which is known to have the specific shape. Thus identifying an orientation in space of the object is facilitated, which facilitates identification of coordinates based on the surface object or volume object.

In order to even further improve precision or reliability of facilitating matching of data, the method may comprise linking a plurality of the surface objects and volume objects sharing one or more common structures. Fig. 4D is a schematic illustration of a plurality of an exemplary kit of surface objects and volume objects having a geometric relation to each other and to a plurality of structures.

The method of facilitating matching of a first set of data and a second set of data may in embodiments thus comprise identifying a linked relationship between a plurality of the surface objects and the volume objects. The method may comprise identifying a plurality of said surface objects and said volume objects; and identifying a plurality of first coordinates and second coordinates; wherein pairs of said plurality of first coordinates and second coordinates have the linked relationship.

Sub-sets of surface objects and volume objects may share one or more common first coordinates and second coordinates. In this case, the identified first coordinate(s) and related second coordinates may be checked against each other in relation to each sub-set in order to improve precision of a subsequent matching action. Identification or check of the linked relationship may be made manually, semi-automatically or automatically in a computer based virtual environment. Linked objects provide for a fine tuning of the method for providing the matched data, including further improved reliability. This provides for an advantageous matching of first and second sets of data.

For instance, as illustrated in Fig. 4D, a plurality of aggregates 4a, 4b, 4c is arranged in a spatially defined relation to each other. In the example, four aggregates 4a_i, 4a_{ii}, 4b, and 4c are arranged at different angular positions on a virtual circle line 440 having a center 450. Each of the four aggregates has a, in the present case common, first and second coordinates 405_i, 405_{ii}, 425, 415 respectively identifiable as described above. In addition, these coordinates are provided in a defined relationship to each other, as illustrated by virtual straight connection lines 460. In the present embodiments a set of three lines form a virtual triangle in a defined plane, which can be identified as the linked relationship. The linked relationship may be used to identify coordinates of one or more objects that cannot be identified in a data set based on the remaining coordinates in the

linked relationship. Another common identifiable linkage of coordinates is for instance the circle line 440, the common center 450 thereof, or a plane defined by a triangle delimited by three of lines 460.

In case one or more objects are not identifiable, e.g. because they are knocked-out by image artefacts during data generation, e.g. to existing teeth fillings or prosthesis, their position may be reconstructed based on a pre-defined relationship to other objects.

For instance, if a first volume object is not identifiable from the second set of data, and two other volume objects are identifiable from the second data set, the position of the eliminated first volume object may be reconstructed based on a pre-defined relationship to the remaining two other volume objects after the latter are identified.

Likewise, surface objects may not be identifiable in the first set of data, e.g. because impression material has flown off before curing and covers a surface of a surface object after curing. Having at least two further identifiable surface objects and a pre-defined relationship between the pluralities of objects, the position in space of the non-identifiable object is reconstructable from the latter.

The present pre-defined relationship between several objects may be established in various ways, e.g. based on CAD data of a scanning appliance. Alternatively, or in addition, the pre-defined relationship may be established based on identified objects in the respectively other data set of the first or second data sets. For instance, in case three volume objects are identifiable in the second set of data, and these volume objects have known spatial relationships to surface objects, the spatial position of at least one non-identifiable surface object may be reconstructed in the first set of data.

When the remaining object thus is identified, the coordinate related to the now identified object is identifiable. Hence, the data set can be reliably rotated for the matching of the two data sets.

The surface objects and volume objects are for instance affixed to or integral parts of a radiographic guide 5, as shown in Fig. 5. The radiographic guide 5 is used to simulate teeth 520, soft tissue surface 510 and edentulous space during a CT scan. The radiographic guide may be made of an acrylic non radio opaque material, and fabricated in a laboratory from a maxillary impression, a mandibular impression, and a bite registration index taken from the patient. Surface objects and volume objects, e.g. arranged in aggregates 500, 501, 502, 503, 504, 505, are comprised in the radiographic guide 5. By identifying the aggregates and related coordinates thereof, as described above, matching of two sets of data is facilitated. The first device may be a surface scanner and the second device a CT scanner. The first set of data is provided from the radiographic guide 5. The second set of data may be provided by CT scanning a subject wearing the radiographic guide 5.

The surface objects and volume objects may alternatively or in addition be affixed to an anatomically fixed structure, such as a tooth, or a splint. In such embodiments, CAD data of only the surface object and/or volume object may be provided.

In an embodiment, a method of matching a first set of data and a second set of data related to a region of interest in a craniofacial space is provided. The matching method comprises using the above described method, and transforming a coordinate system of the first set of data to a coordinate system of the second set of data based on the pre-defined relationship. In this manner, a
5 matched data set is obtained with high precision.

In a method of virtually planning a craniofacial treatment procedure, virtual planning of the procedure is performed based on the matched data set, and a production data set is provided as a result of the virtual planning. The virtual planning comprises for instance planning a dental restoration with regard to a number of parameters, including the real anatomical situation, as
10 provided in the matched set of data, desired biological, functional, biomechanical and esthetic aspects, outcome of the restoration, available sizes of product for the restoration, etc. When the virtual planning is finished, production data is provided in a suitable format, such as in STL format.

Further, the production data may be used in a method of producing a product for use in a craniofacial treatment procedure, such as a medical procedure for providing a dental restoration. The
15 method comprises producing the product based on the production data set. An embodiment of such a product is shown in Fig. 6. A surgical drill guide 6 comprises a plurality of drill guides 601-606. The drill guide is a result of the virtual planning of a dental restoration, including positions of dental implants. The surgical drill guide is used to provide bores in the oral cavity with high precision for implanting dental implants. Other examples for products produced from the production data are
20 bridge frameworks, abutments, anchor pins, orthodontic appliances etc.

Fig. 7 is a schematic illustration of an embodiment of a system 7 that is adapted to facilitate matching of a first and a second set of data related to a region of interest in a craniofacial space. The system may be a sub-system in a system for planning a craniofacial treatment procedure, such as dental restoration, maxillofacial bone surgery, or production of products to be used in the craniofacial
25 treatment procedure, such as dental restoration or maxillofacial bone surgery. The system 7 comprises units 700-730, including a unit 700 to identify at least a portion of a surface object in the first set of data; a unit 710 to identify a first coordinate based on the surface object; a unit 720 to identify at least a portion of a volume object in the second set of data; and a unit 730 to identify a second coordinate based on the volume object. The first and second coordinate have a pre-defined
30 relationship to each other as described above. The system 7 may comprise further units to perform the above described method. The units of the system 7 are operatively connected to each other. The system may provide data further processing in a matching unit for providing the matched data set from matching the first set of data and second set of data. The system may comprise separate devices for generating the first and second set of data. Moreover, the system may comprise a unit for
35 performing the virtual planning of the craniofacial treatment procedure. In addition, the system may comprise production units for production of products based on production data provided by the unit for virtual planning.

Fig. 8 is a schematic illustration of a computer program product 81, executable on a programmable device 81, containing code segments 800-830. The code segments 800-830, which when executed, perform in an embodiment the method 1 as described above. The computer program product 81 is storeable on a computer-readable medium 80, and configured to facilitate matching of a first set of data and a second set of data related to a region of interest in a craniofacial space. The computer program product 81 is adapted for use in one or more of planning a craniofacial treatment procedure, such as a dental restoration or maxillofacial bone surgery, or production of products to be used in the craniofacial treatment procedure, such as the dental restoration or maxillofacial bone surgery. The code segments or instructions comprise a first code segment 800 for identifying at least a portion of a surface object in the first set of data; a second code segment 810 for identifying a first coordinate based on the surface object; a third code segment 820 for identifying at least a portion of a volume object in the second set of data; and a fourth code segment 830 for identifying a second coordinate based on the volume object. The first and second coordinate have a pre-defined relationship to each other as described above. The fourth code segment 830 may provide data for further processing in a matching unit or program product for providing the matched data set from matching the first set of data and second set of data. The program product may comprise further code segments for performing the virtual planning.

Further, a scanning structure or scanning appliance is provided. The scanning structure is related to data generation by scanning. As already mention above, a scanning structure is inserted in the mouth of a patient during generation of the second set of data. The scanning structure has the purpose to provide a relation between bone tissue topography and reference structures, as well as surface topography in the craniofacial space. The scanning structure has a shape that conforms to a surface topography of the craniofacial space. The scanning structure is e.g. an impression tray with an impression of the oral cavity, or a radiographic guide.

In more detail, a scanning structure is provided that has at least one surface with a shape adapted to conform to a portion of a craniofacial space. The scanning structure comprises at least one surface object, which is at least partly identifiable from a first set of data, and wherein a first coordinate is identifiable based on the surface object; and at least one volume object, which is at least partly identifiable from a second set of data, and wherein a second coordinate is identifiable based on the volume object; wherein the first and second coordinate have a pre-defined relationship to each other, as explained above. In an embodiment, the surface object is arranged in relation to the at least one volume object such that the first coordinate and the second coordinate have a pre-defined relationship to each other.

In an embodiment, the scanning structure is a dental impression tray for use in obtaining an impression of at least a part of a dental structure. The dental impression tray comprises a tray portion adapted to be loaded with impression material, the tray portion being contoured to fit over at

least a part of the upper and/or lower dental structure of a patient such that an impression can be obtained from the upper and/or the lower dental structure.

In an impression tray is provided with a surface object is provided having an external surface identifiable from data obtained by a first, non-material penetrating, data generating device. A structure has a first relation to the surface object. The tray further comprises a volume object, identifiable from data obtained by a material penetrating, 3D data generating device.

Furthermore, a method of manufacturing a scanning structure, such as a dental impression tray or a radiographic guide, is provided. In an embodiment, the method comprises freeform manufacturing said dental impression tray including at least one surface object and one volume object. The method of manufacturing a dental impression tray may comprise manufacturing said dental impression tray as two halves, wherein each of said halves comprises a portion of said surface object, and assembling the two halves to each other thus integrating the surface object with the dental impression tray. The assembling may comprise encasing the volume object in a volume between the two halves. The method may comprise filling a volume of the scanning structure with a radiopaque medium thus forming the volume object.

The method of manufacturing a scanning structure may comprise attaching to or integrating with the scanning structure at least one of the surface objects and at least one of the volume objects; whereby the at least one surface object is at least partly identifiable from a first set of data, and wherein a first coordinate is identifiable based on the surface object; and whereby the at least one volume object is at least partly identifiable from a second set of data, and wherein a second coordinate is identifiable based on the volume object; wherein the at least one surface object and the at least one volume object are attached to or integrated with the scanning structure such that the first and second coordinate have a pre-defined relationship to each other.

The method may be a method of manufacturing the dental impression tray, and comprises freeform manufacturing the dental impression tray including at least one surface object and one volume object. The dental impression tray is for instance produced as two mating halves, wherein each of the halves comprises a portion of the surface object. The two halves are assembled to each other, thus integrating the surface object with the dental impression tray. The volume object may be encased in a volume between the two halves upon the assembling, as e.g. illustrated in Fig. 4 and Fig. 4A. The volume may be filled with a radiopaque medium. The method may comprise attaching at least one of the surface objects to the dental impression tray.

The present invention has been described above with reference to specific embodiments. However, other embodiments than the above described are equally possible within the scope of the invention. Different method steps than those described above, performing the method by hardware or software, may be provided within the scope of the invention. The different features and steps of the invention may be combined in other combinations than those described. The scope of the invention is only limited by the appended patent claims.

CLAIMS

1. A method of facilitating matching of a first set of data and a second set of data related to a region of interest in a craniofacial space, said method comprising
- 5 (a) identifying at least a portion of a surface object in said first set of data;
(b) identifying a first coordinate based on said surface object;
(c) identifying at least a portion of a volume object in said second set of data; and
(d) identifying a second coordinate based on said volume object;
wherein said first and second coordinate have a pre-defined relationship to each other.
- 10 2. The method of claim 1, wherein said first coordinate is a center point of said surface object, and said second coordinate is a longitudinal central axis of said volume object; or wherein said first coordinate is a central axis through a center point of said surface object, and said second coordinate is a longitudinal central axis of said volume object, and wherein said surface object and said volume object are arranged co-axially, such that said first coordinate and said second
- 15 coordinate are a common center axis; or wherein said surface object and said volume object are arranged concentrically and said first coordinate and said second coordinate have a common center point.
3. The method of any of claims 1 or 2, wherein said pre-defined relationship comprises that said first coordinate and second coordinate coincide.
- 20 4. The method of any of claims 1 to 3, wherein said volume object is a volume of air at least partly enclosed by said surface object.
5. The method of any of the claims 1 to 4, wherein said surface object and said volume object have a substantially identical mating interface; or wherein said surface object and said volume object have a substantially identical mating interface and wherein said volume object is a recess in
- 25 said surface object; or wherein said surface object and said volume object have a substantially identical mating interface and wherein said volume object is a recess in said surface object, and wherein said recess is provided with a releasably attachable closing cap, such that said recess is enclosed when said cap is in position at said recess.
6. The method of any of claims 1 to 5, wherein both said surface object and said volume object are affixed to or integral parts of a scanning structure; and/or wherein said surface object and said volume object are affixed to an anatomically fixed structure, such as a tooth, or a splint.
- 30 7. The method of any of claims 1 to 6, wherein said first set of data of said surface object is generated by scanning said surface object using a first, non-material penetrating, 3D data generating device; and wherein said second set of data of said volume object is generated by using a material penetrating, 3D data generating device; and/or wherein identifying a first coordinate based on said
- 35 surface object comprises identifying said first coordinate based on a CAD data of said surface object.

8. A method of matching a first and a second set of data related to a region of interest in a craniofacial space, said method comprising said method according to any of claims 1-7, and transforming a coordinate system of said first set of data to a coordinate system of said second set of data based on said pre-defined relationship between said first coordinate and said second coordinate, for generating a matched data set of said region of interest in said craniofacial space.

9. A method of virtually planning a craniofacial treatment procedure, said method of virtually planning comprising said method of matching according to claim 8, and performing said virtual planning based on said matched data set; and providing a production data set as a result of said virtual planning based on said matched data set for production of at least one product to be used in said craniofacial treatment procedure.

10. A method of producing a product for use in a craniofacial treatment procedure, said method comprising producing said product, at least partly based on said production data set of claim 9.

11. A computer program product, executable on a programmable device containing instructions, which when executed, performs the method as in any of the claims 1 to 7, wherein said computer program is storeable on a computer-readable medium, and configured to facilitate matching of a first set of data and a second set of data related to a region of interest in a craniofacial space, said computer program product comprising

(a) a first code segment for identifying at least a portion of a surface object in said first set of data;

(b) a second code segment for identifying a first coordinate based on said surface object;

(c) a third code segment for identifying at least a portion of a volume object in said second set of data;

(d) a fourth code segment for identifying a second coordinate based on said volume object; wherein said first and second coordinate have a pre-defined relationship to each other.

12. A scanning structure having at least one surface with a shape adapted to conform to a portion of a craniofacial space, said scanning structure comprising

at least one surface object, which is at least partly identifiable from a first set of data, and

wherein a first coordinate is identifiable based on said surface object; and

at least one volume object, which is at least partly identifiable from a second set of data,

and wherein a second coordinate is identifiable based on said volume object;

wherein said surface object is arranged in relation to said at least one volume object such that said first coordinate and said second coordinate have a pre-defined relationship to each other.

13. The scanning structure of claim 12, wherein said scanning structure is a dental impression tray for use in obtaining an impression of at least a part of a dental structure, the dental impression tray comprising a tray portion adapted to be loaded with impression material, the tray

portion being contoured to fit over at least a part of the upper and/or lower dental structure of a patient such that an impression can be obtained from the upper and/or the lower dental structure; or wherein said scanning structure is a radiographic guide.

5 **14.** A method of manufacturing a scanning structure, such as a dental impression tray or a radiographic guide, according to any of claims 12 or 13, said method comprising manufacturing said scanning structure as two halves, wherein each of said halves comprises a portion of said surface object, and assembling said two halves to each other thus integrating said surface object with said scanning structure; or said method comprising manufacturing said scanning structure as two halves, wherein each of said halves comprises a portion of said surface object, and assembling said two
10 halves to each other thus integrating said surface object with said scanning structure, wherein said assembling comprises encasing said volume object in a volume between said two halves; and/or said method comprising freeform manufacturing said scanning structure including at least one surface object and at least one volume object; and/or said method comprising filling a volume of said scanning structure with a radiopaque medium, thus forming said volume object.

15 **15.** The method of manufacturing a scanning structure according to claim 14, said method comprising attaching to or integrating with said scanning structure at least one of said surface objects and at least one of said volume objects; whereby said at least one surface object is at least partly identifiable from a first set of data, and wherein a first coordinate is identifiable based on said surface object; and whereby said at least one volume object is at least partly identifiable from a
20 second set of data, and wherein a second coordinate is identifiable based on said volume object;

 wherein said at least one surface object and said at least one volume object are attached to or integrated with said scanning structure such that said first and second coordinate have a pre-defined relationship to each other.

25

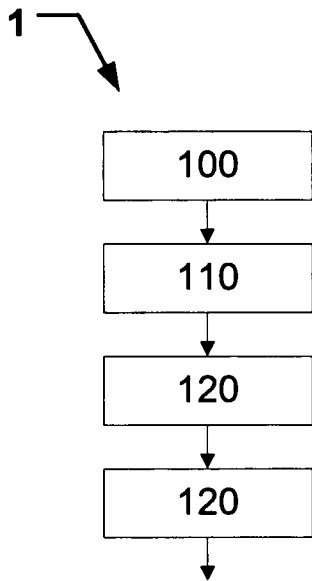


Fig. 1

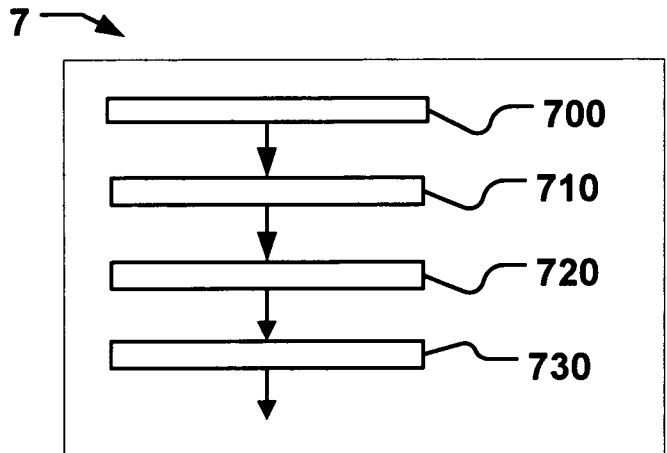


Fig. 7

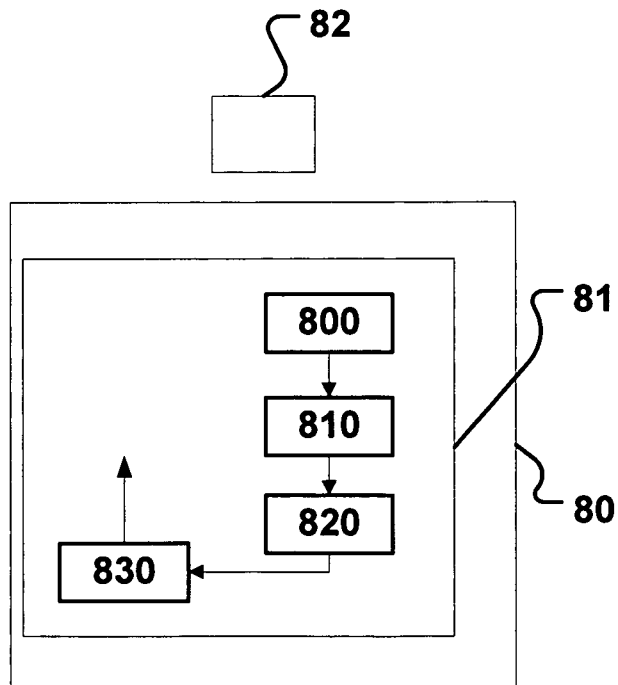


Fig. 8

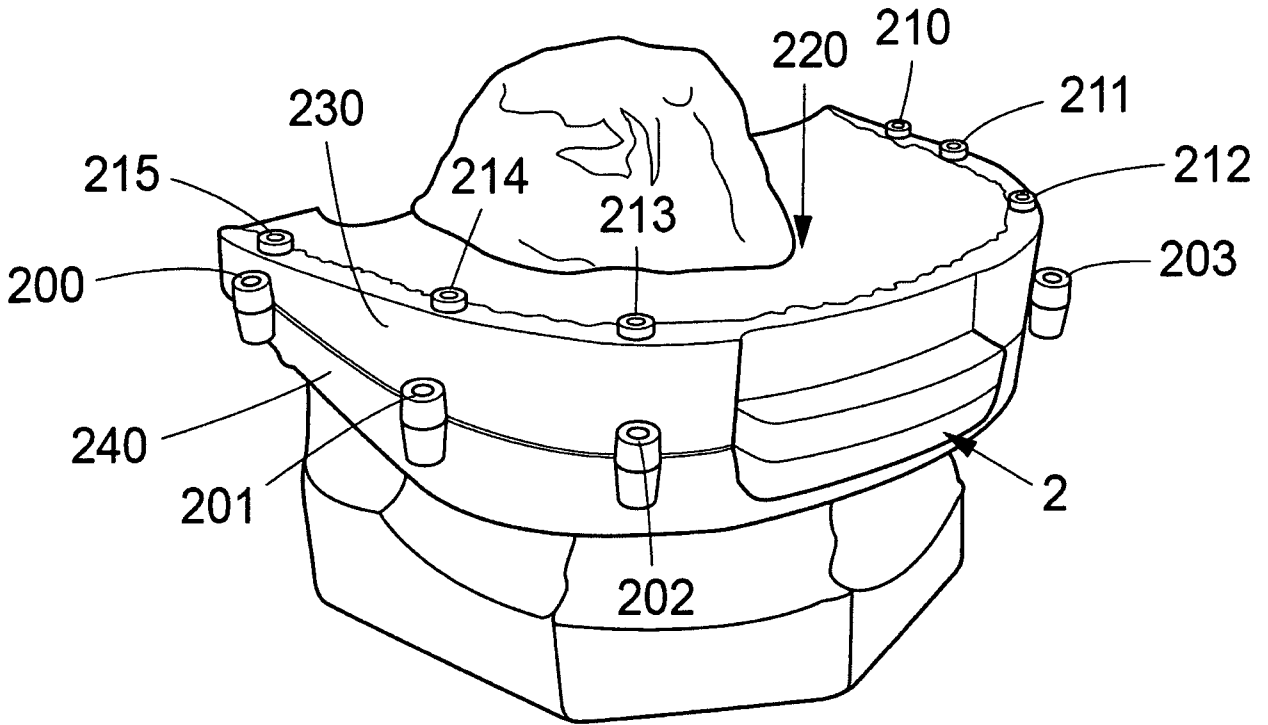


Fig. 2

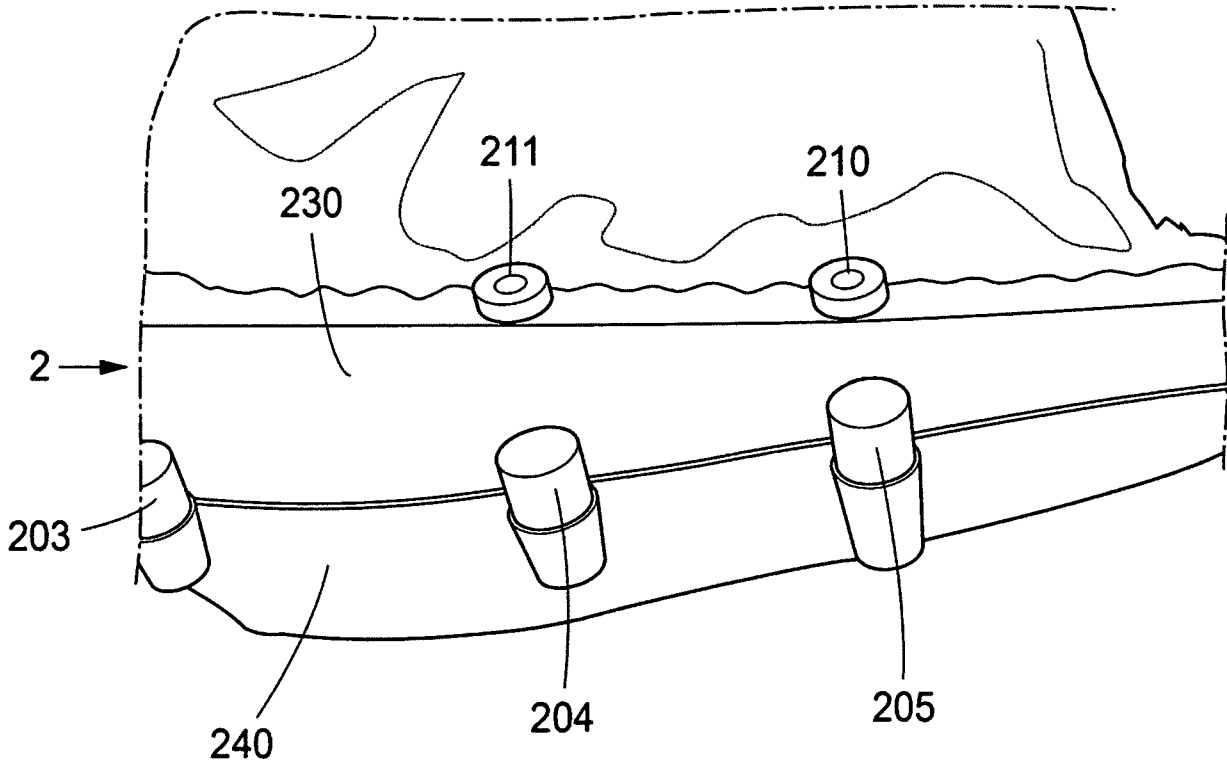


Fig. 3

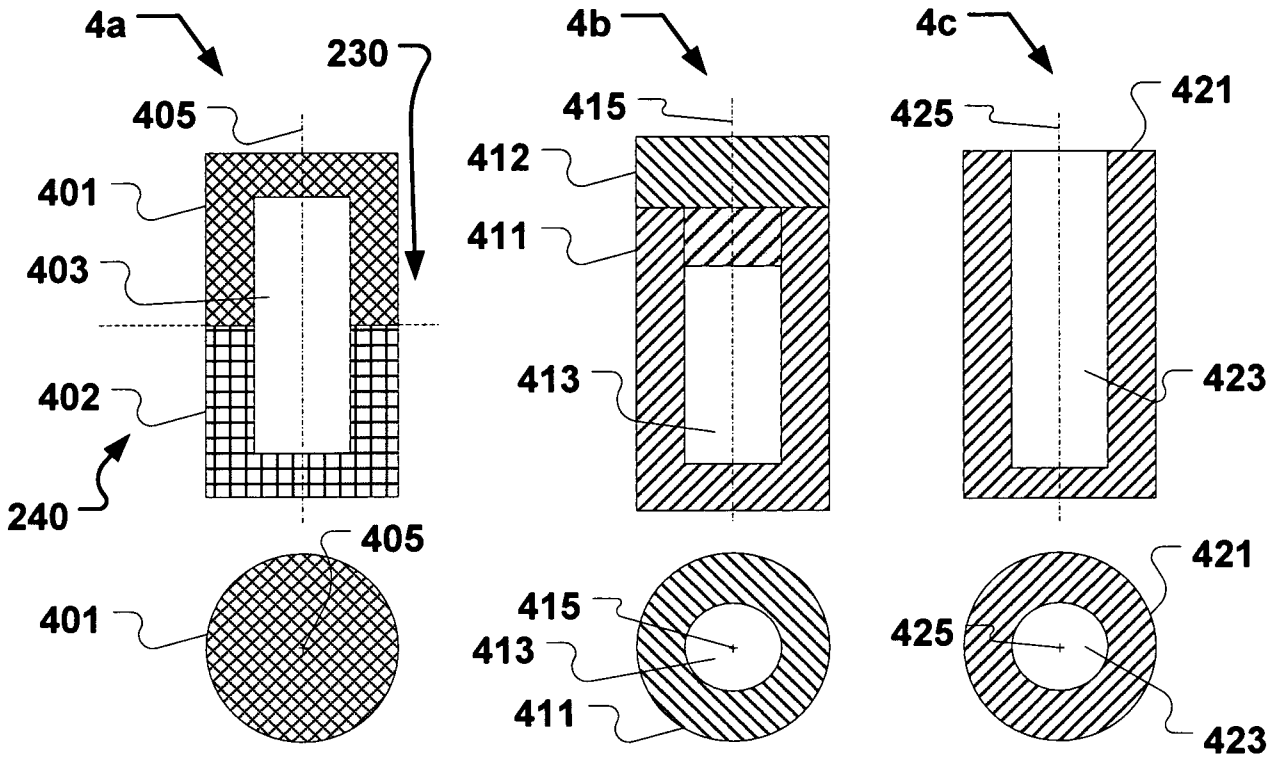


Fig. 4A

Fig. 4B

Fig. 4C

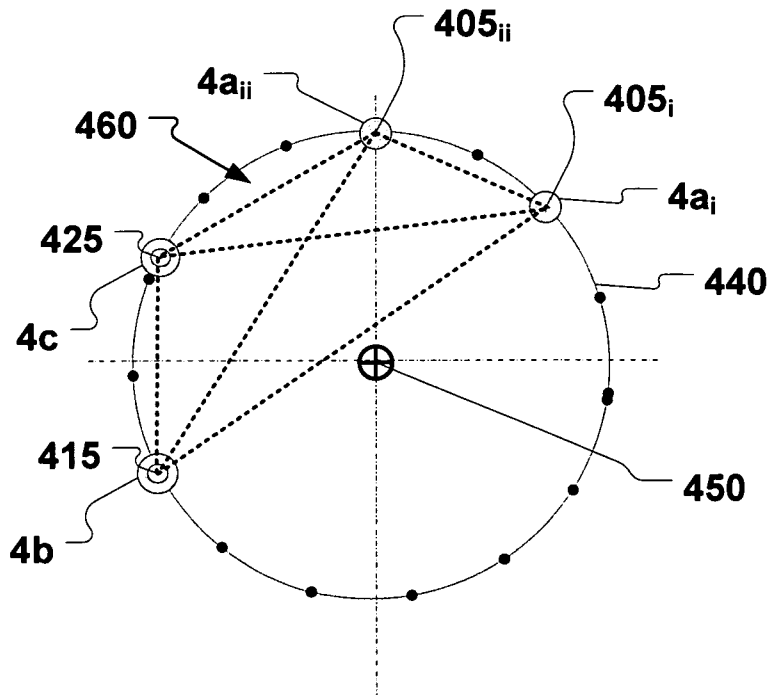


Fig. 4D

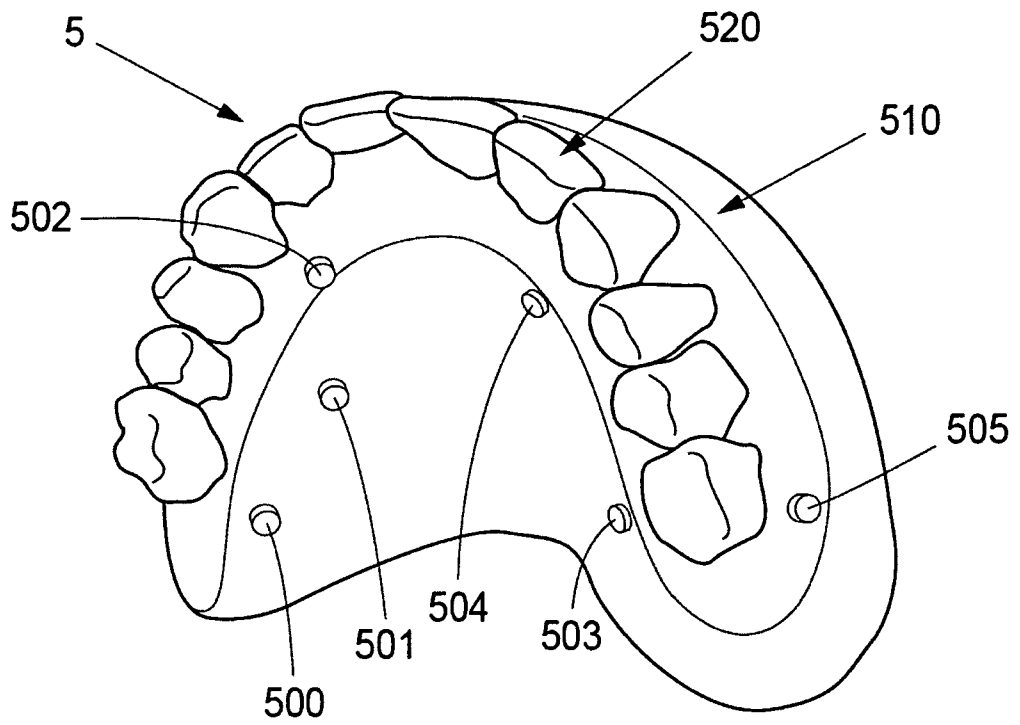


Fig. 5

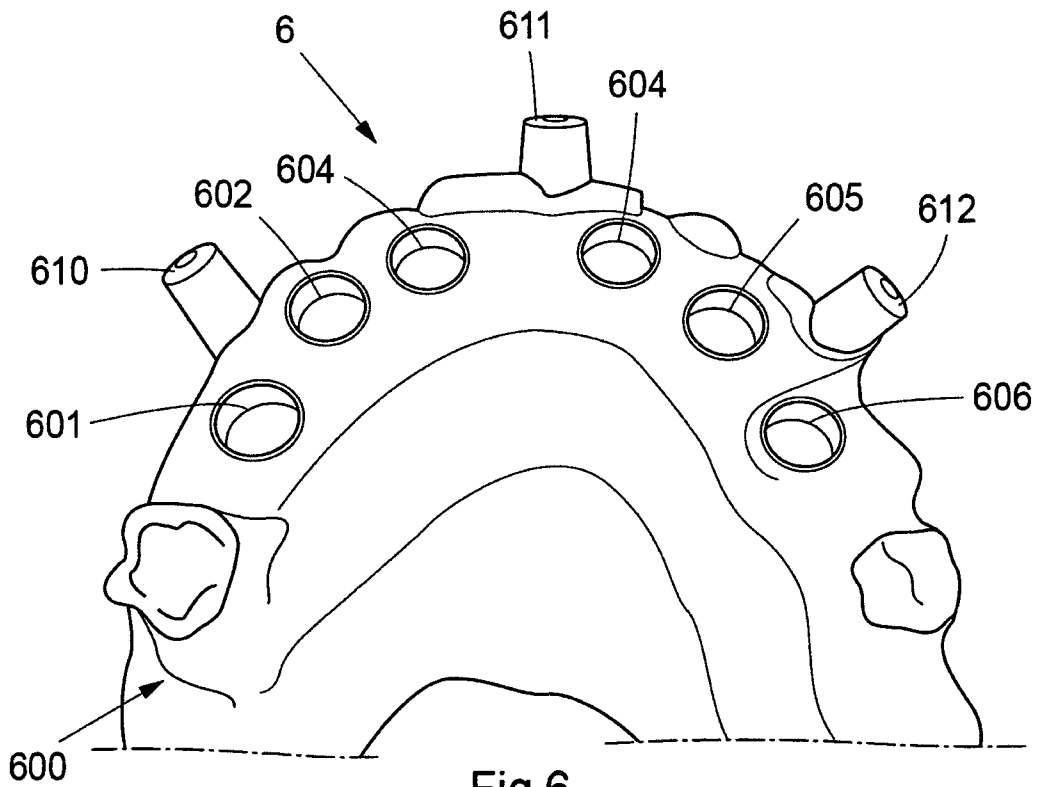


Fig.6

PATENT COOPERATION TREATY

PCT

DECLARATION OF NON-ESTABLISHMENT OF INTERNATIONAL SEARCH REPORT


(PCT Article 17(2)(a), Rules 13ter.1(c) and Rule 39)

Applicant's or agent's file reference P1446PC00	IMPORTANT DECLARATION	Date of mailing(<i>day/month/year</i>) 6 September 2010 (06-09-2010)
International application No. PCT/EP2010/002998	International filing date(<i>day/month/year</i>) 17 May 2010 (17-05-2010)	(Earliest) Priority date(<i>day/month/year</i>) 18 May 2009 (18-05-2009)
International Patent Classification (IPC) or both national classification and IPC G06F19/00		
Applicant NOBEL BIO CARE SERVICES AG		

This International Searching Authority hereby declares, according to Article 17(2)(a), that **no international search report will be established** on the international application for the reasons indicated below

1. The subject matter of the international application relates to:
 - a. scientific theories
 - b. mathematical theories
 - c. plant varieties
 - d. animal varieties
 - e. essentially biological processes for the production of plants and animals, other than microbiological processes and the products of such processes
 - f. schemes, rules or methods of doing business
 - g. schemes, rules or methods of performing purely mental acts
 - h. schemes, rules or methods of playing games
 - i. methods for treatment of the human body by surgery or therapy
 - j. methods for treatment of the animal body by surgery or therapy
 - k. diagnostic methods practised on the human or animal body
 - l. mere presentations of information
 - m. computer programs for which this International Searching Authority is not equipped to search prior art
2. The failure of the following parts of the international application to comply with prescribed requirements prevents a meaningful search from being carried out:

the description
 the claims
 the drawings
3. A meaningful search could not be carried out without the sequence listing; the applicant did not, within the prescribed time limit:
 - furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
 - furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
 - pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13ter.1(a) or (b).
4. Further comments:

Name and mailing address of the International Searching Authority  European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040 Fax: (+31-70) 340-3016	Authorized officer SOMMERMEYER, Katrin Tel: +49 (0)89 2399-7677
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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 203

1 The present set of claims is so broad and unclear that the claims as a whole are not in compliance with the provisions of clarity of Article 6 PCT, as it is particularly burdensome for a skilled person to establish the subject-matter for which protection is sought, the reasons therefor are the following.

1.1 The present application contains 15 claims, of which 7 are independent. There is no clear distinction between the independent claims because of overlapping scope. The claims are drafted in such a way that the claims as a whole are not in compliance with the provisions of clarity and conciseness of Article 6 PCT, as it is particularly burdensome for a skilled person to establish the subject-matter for which protection is sought. Moreover, also when making reference to the present description no passages could be found that might suggest or guide to a possible interpretation or understanding of the extent of the scope of the subject matter intended to be claimed. This reasoning is also valid considering that the claims are drafted in such broad and unclear manner that for the skilled person it would be difficult, if not at all impossible, to determine the extent of the scope of the subject matter claimed. Therefore, the non-compliance with the substantive provisions is to such an extent, that a meaningful search of the whole claimed subject-matter could not be carried out (Article 17 (2) PCT and PCT Guidelines 9.30).

1.2 Moreover, because also throughout the originally filed description the same vague and broad wordings have been used, no reasonable basis in the application that clearly indicates the subject-matter which might be expected to form the subject of the claims later in the procedure could have been determined, no search at all was deemed possible.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.2), should the problems which led to the Article 17(2) declaration be overcome.