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(54) **ORTHODONTIC TREATMENT ALIGNERS  
BASED ON CT DATA**

(52) **U.S. Cl.**  
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(57) **ABSTRACT**

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A system and method for orthodontic alignment includes a radiographic template. The radiographic template has a plurality of metallic markers. A negative impression of a patient's dental arch is made. At least one orthodontic treatment aligner is produced. The aligner is manufactured based in part on a computed axial tomography (CT) scan of a patient wearing the radiographic template and a separate scan of the radiographic template, wherein the data is processed by superimposition of the orthodontic aligner on the CT images of the patient including a jaw in axial and panoramic views. In this manner, the tooth above the gum line, represented by the negative impression as well as the tooth below the gum line, represented by the CT data is used to design the orthodontic aligner.

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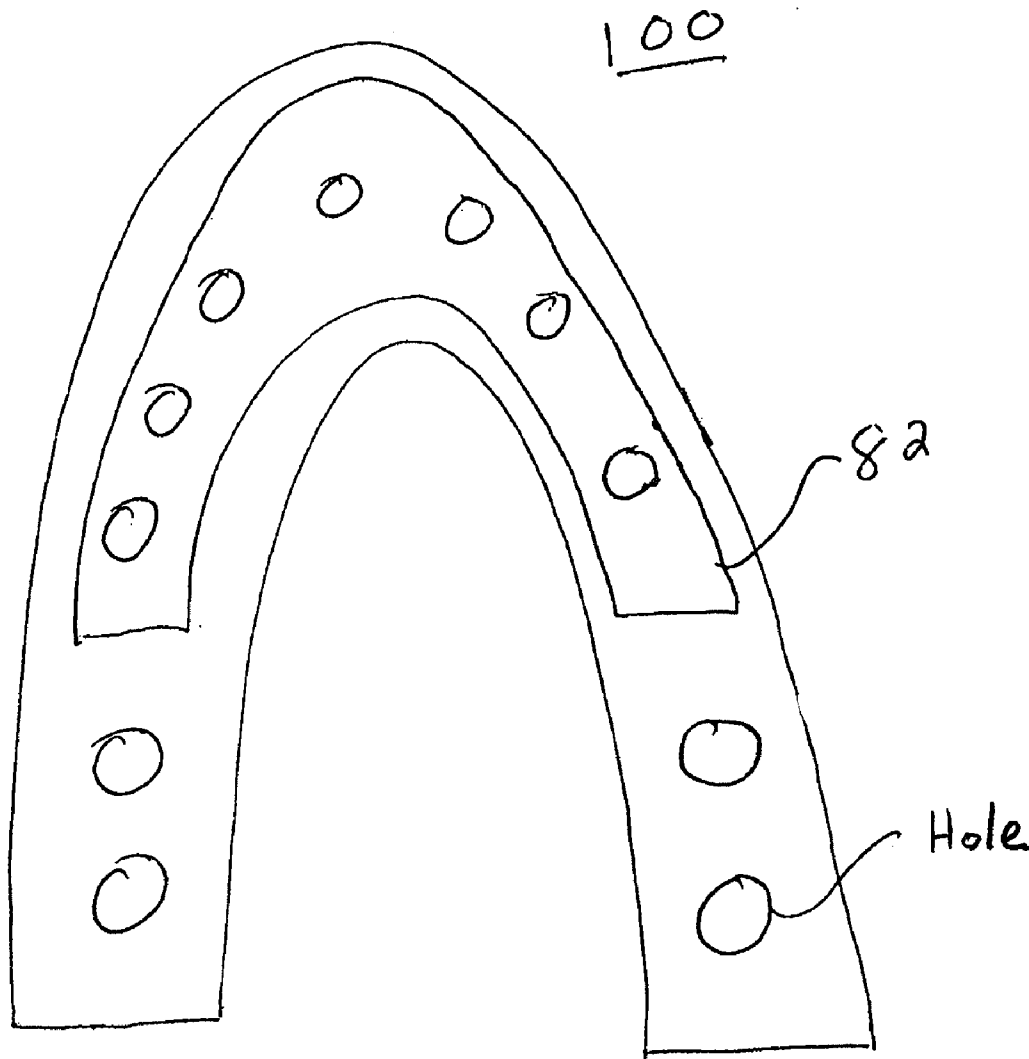


FIG. 1

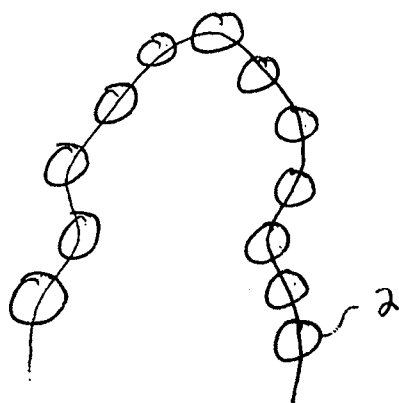
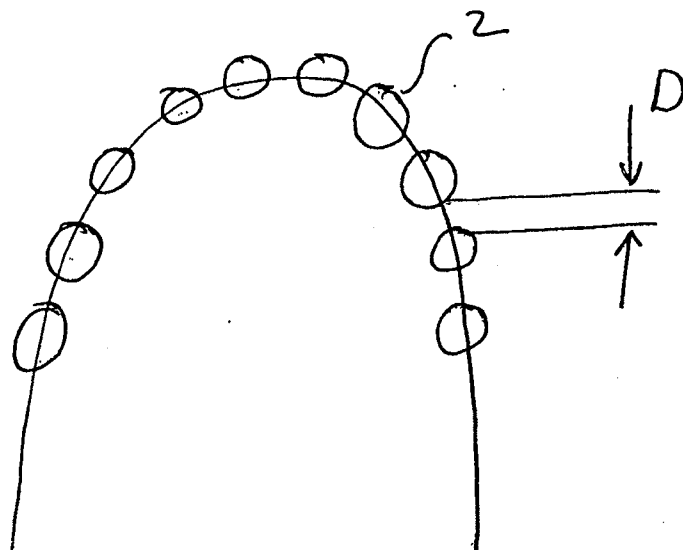


FIG. 2



PRIOR ART

FIG. 3

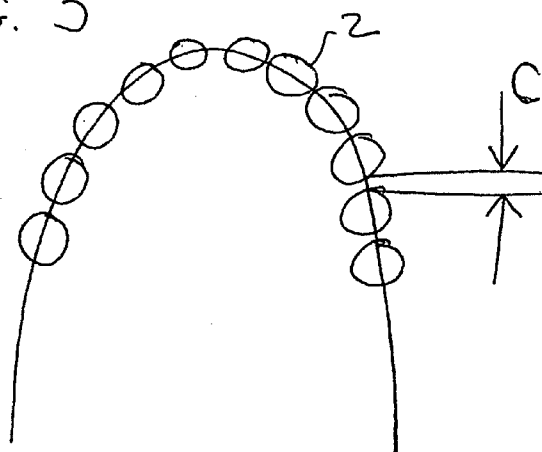


FIG. 4a

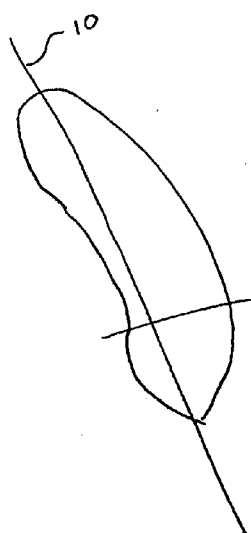


FIG. 4b

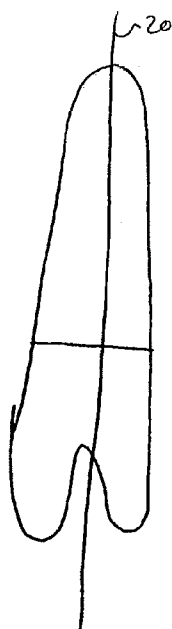


FIG. 4c

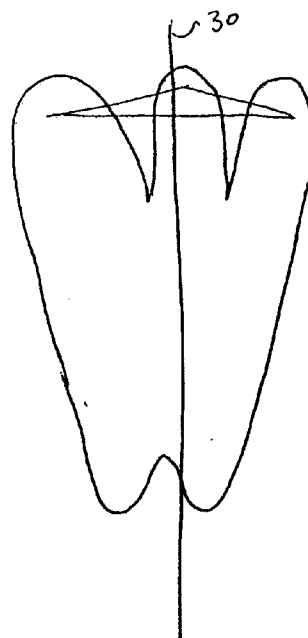


FIG. 5

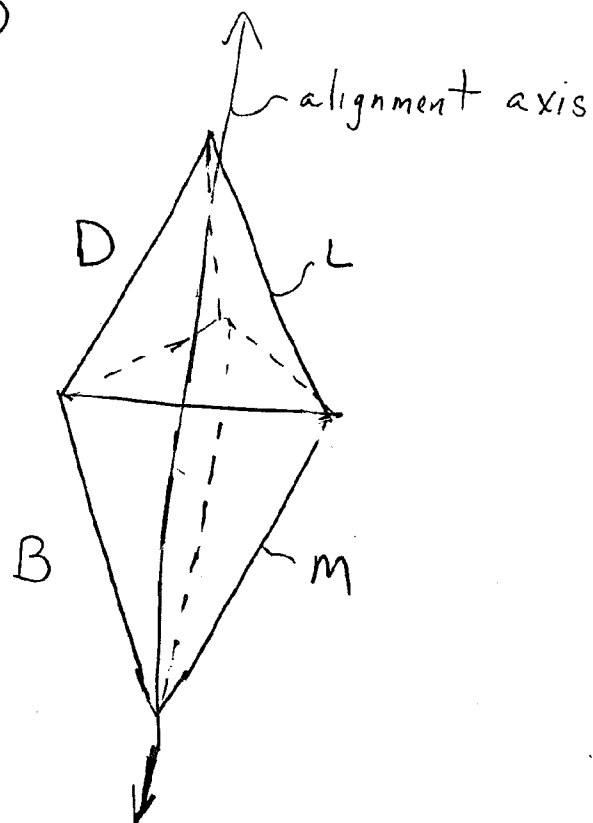


FIG. 6

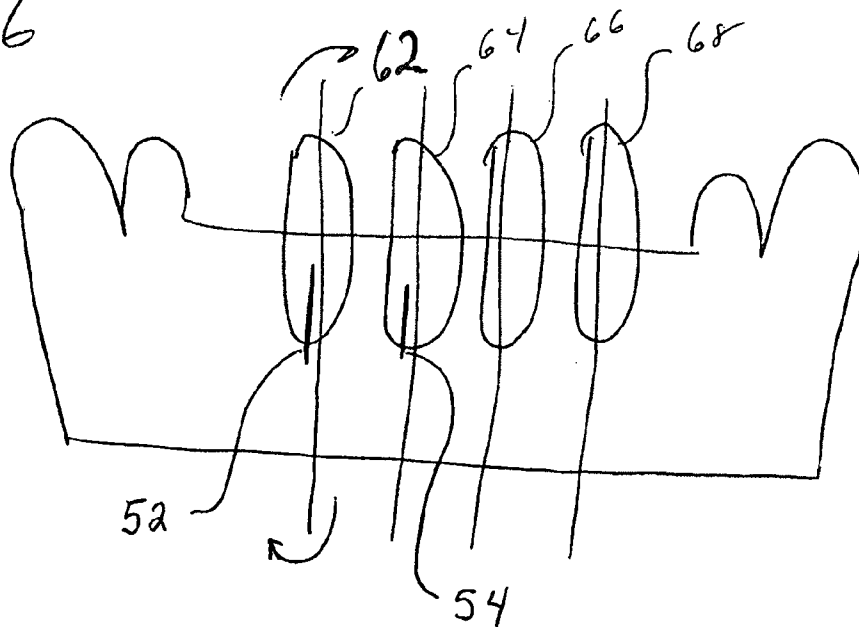


FIG. 7

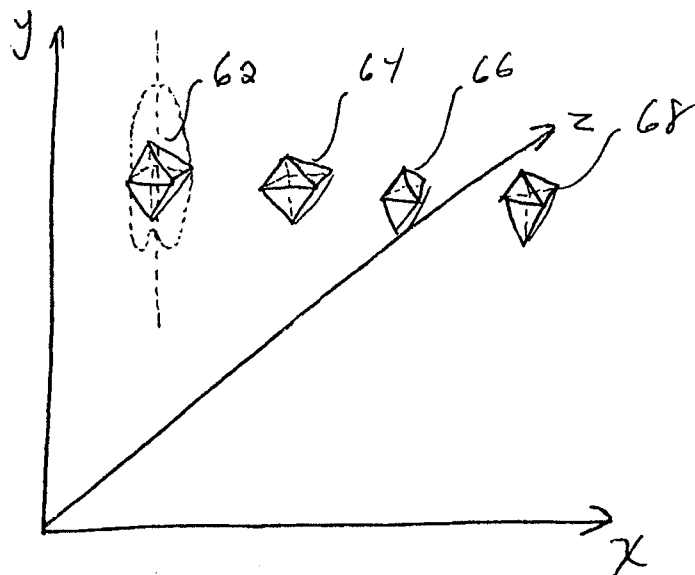


FIG. 8

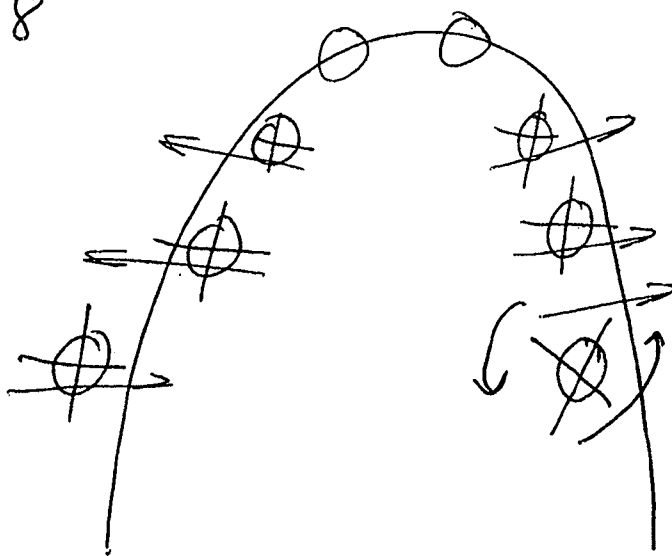
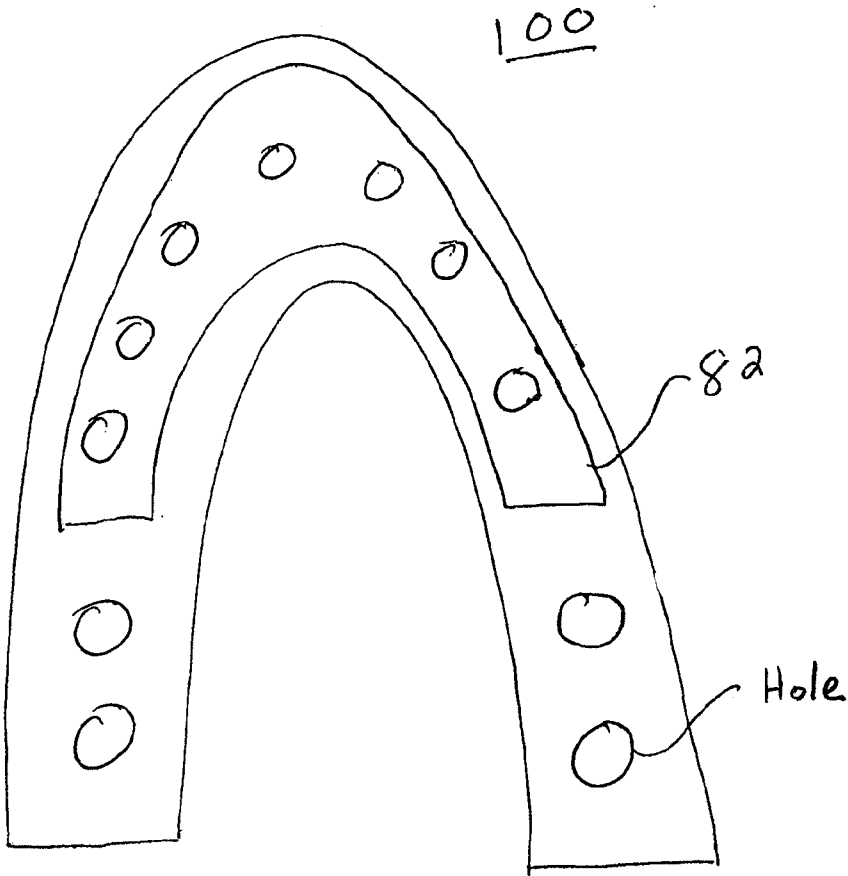


FIG. 9



**ORTHODONTIC TREATMENT ALIGNERS  
BASED ON CT DATA**

**CROSS REFERENCE TO RELATED  
APPLICATIONS**

**[0001]** This application is a divisional of U.S. patent application Ser. No. 12/290,745 which was filed with the U.S. Patent and Trademark Office on Nov. 3, 2008 and which claims the benefit of U.S. Provisional Application No. 61/001,341, filed Nov. 1, 2007.

**BACKGROUND OF THE INVENTION**

**[0002]** 1. Field of the Invention

**[0003]** This invention relates generally to the field of orthodontic appliances. More specifically, the present invention relates to a process for designing and manufacturing orthodontic aligners for use in orthodontic treatment in which individual teeth are urged along predetermined paths so as to cause realignment thereof.

**[0004]** 2. Description of the Related Art

**[0005]** Dentistry is currently involved in a process of rapid change in what has until recently been considered conventional practice. Such changes are taking place in many fields and are often the result of the integration of new computer-based digital technologies, which tend to become the core of powerful new methodologies. In the dental specialty of orthodontics, for example, the process of laser scanning and three-dimensional imaging of a patient's teeth and then the manipulation of the virtual tooth positions within a computer-aided-design (CAD) environment utilize these new technologies. Orthodontists and some dentists routinely use three-dimensional imaging and CAD manipulation of tooth positions and tooth relationships as part of an approach to straightening teeth.

**[0006]** To use the digital services, an impression of a patient's teeth, gums, and soft tissue is taken. From the impression, a positive stone model is poured and allowed to cure. Instead of retaining a patient's models for in-office case diagnosis and treatment planning as in the past, the attending orthodontist will instead ship the patient's models to a regional commercial orthodontic service center. A number of services are available to a doctor using such service centers, and these services will be provided according to a prescription and other instructions sent along with the patient's models to the service center.

**[0007]** U.S. Pat. No. 5,139,419 (Andreiko) discloses a methodology beginning with scanning of a patient's models as described above to produce a digital code that can be assimilated by computer software. For this step, models can be scanned by any of several current methods to create digital code representing a virtual model of the teeth above the gum line, gums, and soft tissues that can be visually displayed on a computer screen. Andreiko describe methods for the virtual separation of individual teeth from adjacent teeth and soft tissues, and methods for bodily repositioning of individual teeth and groups of teeth.

**[0008]** FIG. 1 is an occlusal view of a dental malocclusion. As shown, teeth 2 are not properly aligned. The dental malocclusions shown in FIG. 1 are typically corrected with a series of orthodontic aligners. The orthodontic aligners are typically manufactured based on dental casts that are optically scanned as discussed above. One or more orthodontic aligners are user during the treatment to realign the teeth.

**[0009]** FIG. 2 depicts a set of teeth that have undergone treatment using the optically scanned dental casts. The aligned teeth have a spacing D. This space between the teeth is based in part on using data regarding the teeth above the gum line, without considering the roots of the teeth.

**SUMMARY OF THE INVENTION**

**[0010]** A system for orthodontic alignment includes a radiographic template. The radiographic template has a plurality of metallic markers. A negative impression of a patient's dental arch is made. At least one orthodontic treatment aligner is produced. The aligner is manufactured based in part on a computed axial tomography (CT) scan of a patient wearing the radiographic template and a separate scan of the radiographic template, wherein the data is processed by superimposition of the orthodontic aligner on the CT images of the patient including a jaw in axial and panoramic views. In this manner, the tooth above the gum line, represented by the negative impression as well as the tooth below the gum line, represented by the CT data is used to design the orthodontic aligner.

**[0011]** A method of manufacturing a template for orthodontic movement of at least one tooth includes several steps. A malleable material and a plurality of radio-opaque markers are placed in contact with a tooth surface. A negative impression of the tooth surface is formed by conforming the malleable material to at least a portion of the tooth surface. Radio-opaque markers are located at defined positions in the material in contact with the tooth surface. Two radiographs, CT scans are taken, a first radiograph of the tooth surface and the malleable material and a second radiograph of the negative impression apart from the tooth surface. The first and second radiographs are compared to determine the entire shape of the tooth surface, including the root. A desired location for the at least one tooth is then determined. A desired position for the at least one tooth at the desired location is then determined. A desired movement of for the at least one tooth at the desired location is then determined. An aligner for orthodontic movement for the at least one tooth is then formed. The orthodontic aligner conforms to the negative impression and includes an altered form of the negative impression along the desired position for the at least one tooth so that the aligner contacts the tooth surface to effect orthodontic movement of the at least one tooth at the desired location.

**[0012]** Other objects and features of the present invention will become apparent from the following detailed description considered in conjunction with the accompanying drawings. It is to be understood, however, that the drawings are designed solely for purposes of illustration and not as a definition of the limits of the invention, for which reference should be made to the appended claims. It should be further understood that the drawings are not necessarily drawn to scale and that, unless otherwise indicated, they are merely intended to conceptually illustrate the structures and procedures described herein.

**[0013]** Other objects and features of the present invention will become apparent from the following detailed description considered in conjunction with the accompanying drawings. It is to be understood, however, that the drawings are designed solely for purposes of illustration and not as a definition of the limits of the invention, for which reference should be made to the appended claims. It should be further understood that the drawings are not necessarily drawn to scale and that, unless

otherwise indicated, they are merely intended to conceptually illustrate the structures and procedures described herein.

#### BRIEF DESCRIPTION OF THE DRAWINGS

- [0014]** The invention will be explained in more detail with reference to the drawing, which illustrates only exemplary embodiments. In the drawing:
- [0015]** FIG. 1 is an occlusal view of a dental malocclusion;
- [0016]** FIG. 2 is an occlusal view after orthodontic treatment;
- [0017]** FIG. 3 is an occlusal view after orthodontic treatment in accordance with an embodiment of the invention;
- [0018]** FIG. 4a is depiction of an incisor;
- [0019]** FIG. 4b is a depiction of a premolar;
- [0020]** FIG. 4c is a depiction of a molar;
- [0021]** FIG. 5 is 3D representation of a tooth;
- [0022]** FIG. 6 is a panoramic view of a patients dentition;
- [0023]** FIG. 7 is a 3D representation of a patients dentition;
- [0024]** FIG. 8 an orthodontic alignment plan; and
- [0025]** FIG. 9 is an aligner in accordance with one embodiment of the invention.

#### DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

**[0026]** A patient seeking to correct a dental malocclusion visits an orthodontist. FIG. 1 depicts the dental occlusion. To treat the dental malocclusion, the orthodontist makes an orthodontic appliance that is a negative impression of the dental arch. The orthodontic appliance is made with a malleable material. The orthodontic appliance is preferably formed of acrylic, silicone, or other suitable radio-transparent material. The material preferably completely conforms to the entirety of each tooth crown of the negative impression. The orthodontic aligner can be placed and removed. In a preferred embodiment, at least 6 fiducial markers are placed on the appliance at the buccal or lingual surfaces of the teeth at a known distance from the crowns, because the crowns typically contain metallic restorations. The fiducial markers are wires or other radio-opaque markers placed to outline the buccal, incisal, and lingual contours. Preferably, one or more teeth are marked. In a preferred embodiment, the radio opaque markers are of titanium to avoid scatter interference.

**[0027]** The patient wears the appliance during a CT scan. After the scan, the appliance is scanned separately, i.e. without it being worn by the patient, but preferably in the same orientation as when the patient was wearing it. The CT scans are used to generate a three-dimensional image each tooth from a large series of two-dimensional X-ray images preferably taken around a single axis of rotation. The data from both scans is then uploaded and processed by medical image processing algorithms. Preferably, the data is in a Digital Imaging and Communications in Medicine (dicom) format. In this manner, complete data for each tooth, both above and below the gum line is obtained. It should be further noted that due to the CT scans, no mold of the teeth above the gum line is required. Registration of the fiducial markers is performed and the two data sets are superimposed. The two data sets are merged using a computer program such as the one disclosed in the referenced published U.S. Patent Application No. 2005/0084144 using the radiographic markers as the points of alignment. The data is then processed with superimposition of the orthodontic aligner on the CT images of the jaw in axial and panoramic views. A series of orthodontic aligners are

produced based on the CT data. It should be noted that no mold has to be produced due to the data in the CT images. After treatment with the series of orthodontic aligners, the patient's teeth are aligned as shown in FIG. 3. As shown, the teeth have a spacing C, which is smaller than the spacing D in the prior art.

**[0028]** As shown in FIG. 4a, software tools are used to place an alignment line 10 bisecting the apex of the tooth through the incisal edge of incisors. Similarly, FIG. 4b shows an alignment line 20 drawn at the central fossa of a premolar and FIG. 4c shows an alignment line 30 drawn at the central fossa of a molar. For multiple rooted teeth, such as a molar, an average of the root apices is created and the bisecting line is oriented through the central fossa of the tooth. In a preferred embodiment, a computer program is used in which there is a representation of these alignment lines in a panoramic view, depicting the tooth coronal-apical trajectories.

**[0029]** Each individual tooth can be manipulated into a desired position, which correlates to a 3D image of the dentition. As shown in FIG. 5, each tooth is represented by a 3D image, which is a pair of tetrahedrons connected at the bases with apices as opposing pyramids. An alignment axis passes through each apex and each side corresponding to one of the buccal, lingual, mesial, and distal aspects of each tooth. Preferably, all of the teeth in undergo automatic conversion to these dual tetrahedrons. In one embodiment, for multi-root teeth, a tetrahedron is added which represents each root.

**[0030]** A panoramic view is created as shown in FIG. 6. Once the panoramic view is created manipulation of the alignment plane is performed which correlates in real time to the 3D image of the dentition. The panoramic view includes the teeth 62, 64, 66, and 68 as well as additional fiducial markers 52 and 54. A corresponding 3D image is shown in FIG. 7. The 3D image depicts the spatial relationships between the teeth being adjusted. A corresponding sagittal view, shown in FIG. 8, depicts the required manipulation for each tooth. The alignment of each tooth is performed which correlates in real time to a 3D image of the dentition.

**[0031]** The axial views are manipulated in a similar manner with correlation to a 3D image of the dentition. The 3D treatment positioning of the teeth in the final desired outcome of the treatment is displayed as shown in FIG. 7. The orthodontic aligner used to reposition the teeth is registered using the fiducial markers or optically scanned data of the dentition. The paired tetrahedrons, with the ability to further superimpose the shape of the individual teeth and roots based on the CT scan data and a positive impression of the virtual negative impression of the radiographic, are used to design the orthodontic aligner. It should be noted that the original radiographic aligner and the fiducial markers provide a reference baseline from which the teeth are moved either individually or as a group. Additionally, because the CT scan included the roots and jaw, an improved orthodontic aligner is produced.

**[0032]** Using the fiducial markers, the original radiographic aligner is aligned in the 3D space grid. The practitioner approves of the final treatment plan, decides on an appropriate tooth position for each tooth, and allows software to convert the data of the radiographic orthodontic aligner template into a treatment orthodontic aligner. The alignment software typically has appropriate 3D representations of the tooth positions and the movement of each tooth corresponds to a 3D grid. Each tooth is individually mapped in the 3D space and is mapped in relation to the other teeth. The individual teeth can then be further manipulated into the desired position. In other



words, a triangulation occurs between the rotation, intrusion, tipping, extrusion, or bodily movement of the teeth and the alignment line.

[0033] The serial planned tooth movements in orthodontics require: tipping, bodily movement, rotation, intrusion, and extrusion. This change is then virtually translated in the orthodontic aligner. The final orthodontic treatment aligner with the new tooth positions is approved and a video of the planned movement is reviewed. The virtual orthodontic aligners are sent via e-mail or burned on a CD ROM to the manufacturer for a rapid manufacturing process that results in production of the orthodontic treatment aligner as a series.

[0034] As individual or multiple teeth are moved, the software changes the position of each tooth and, by using the alignment lines, ensures that the movement of the tooth avoids contact between tooth roots which is provided by the CT data. Therefore, a triangulation occurs between the rotation, intrusion, tipping, extrusion or bodily movement of the tooth and the alignment line. This change is then virtually translated in the orthodontic aligner, which is a digital conversion of the radiographic aligner, with the new tooth positions from the digitally converted aligner sent to a 3D printer for production. Each video clip of each stage of the orthodontics is accomplished with a different aligner produced by the 3D printer.

[0035] In one embodiment, as shown in FIG. 9, a modular aligner 100 is created. In one embodiment, only the portion of the aligner 82 that is concerned with the tooth movement is produced. These inserts 82 are easier to manufacture than an entire alignment device. As the realignment of the teeth is effected, the inserts 82 are changed until the overall treatment plan is completed. The original or subsequent orthodontic aligners as inserts reduce the production time, amount of material used, and cost. In another embodiment, the aligner 82 and the frame are a single structure.

[0036] Additionally, other features can be incorporated into the aligner 82. In one embodiment, the aligner 82 creates a space for a dental implant. The aligner 82 would then include an element such as a sleeved stop for a drill bit, as disclosed in U.S. Pat. No. 7,210,881 and U.S. application Ser. No. 11/157,882, the both of which are incorporated herein by reference in their entirety.

[0037] Thus, while there have shown and described and pointed out fundamental novel features of the invention as applied to a preferred embodiment thereof, it will be understood that various omissions and substitutions and changes in the form and details of the devices illustrated, and in their

operation, may be made by those skilled in the art without departing from the spirit of the invention. For example, it is expressly intended that all combinations of those elements and/or method steps which perform substantially the same function in substantially the same way to achieve the same results are within the scope of the invention. Moreover, it should be recognized that structures and/or elements and/or method steps shown and/or described in connection with any disclosed form or embodiment of the invention may be incorporated in any other disclosed or described or suggested form or embodiment as a general matter of design choice. It is the intention, therefore, to be limited only as indicated by the scope of the claims appended hereto.

1. A system for orthodontic alignment comprising:

a radiographic template, the radiographic template being a negative impression of a dental arch and having a plurality of metallic markers; and

at least one orthodontic treatment aligner, the at least one orthodontic treatment aligner based in part on the negative impression of the dental arch, a CT scan of a patient wearing the radiographic template, and a separate CT scan of the radiographic template, wherein the plurality of metallic markers are used to align the CT from the separate CT scan and the CT image from the patient CT scan including data regarding the teeth below the gum line.

2. The system for orthodontic alignment according to claim 1, wherein the metallic markers are placed on the surfaces of the radiographic template corresponding to the buccal or lingual surfaces of teeth of the patient.

3. The system for orthodontic alignment according to claim 2, wherein the plurality of metallic markers are titanium.

4. The system for orthodontic alignment according to claim 2, wherein the at least one orthodontic treatment aligner comprises a set of orthodontic treatment aligners adapted to reposition the patient's teeth in incremental steps.

5. The system for orthodontic alignment according to claim 2, wherein each tooth is represented by a pair of tetrahedrons connected at their bases as opposing pyramids and an alignment line passing through each apex and each side corresponding to the buccal, lingual, mesial, and distal aspects of each tooth.

6. The system for orthodontic alignment according to claim 2, further comprising an orthodontic treatment aligner holder, wherein the holder is adapted to removeably retain each of a plurality of orthodontic treatment aligners.

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