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(54) **Title:** METHOD FOR MANUFACTURING ORTHODONTIC APPLIANCES

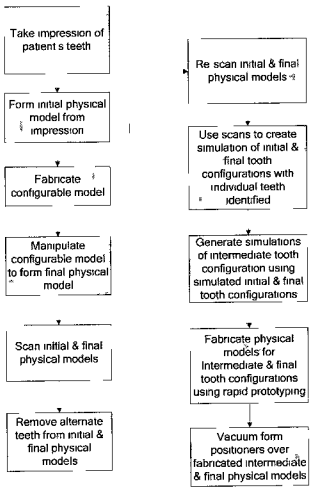

FIGURE 4

(57) **Abstract:** A method of fabricating one or more intermediate physical models of a patient's teeth that can be used in the manufacture of a series of tooth positioners for incrementally repositioning one or more teeth of a patient from an initial configuration to a final configuration via one or more intermediate configurations. The method comprises, providing a computer simulation of the patient's teeth in an initial configuration and in a final configuration, the computer simulation having been obtained by digitising physical models of the teeth in the initial and final configurations, producing one or more computer simulations of intermediate configurations of the teeth based on the computer simulations of the teeth in their initial and final configurations, and, directly fabricating one or more intermediate physical models of the patient's teeth using the computer simulations of the intermediate configurations of the teeth to form one or more intermediate models of the patient's teeth.

WO 2009/068892 A1

METHOD FOR MANUFACTURING ORTHODONTIC APPLIANCES

Field of Invention

The present invention relates generally to the field of orthodontics and more specifically to methods for the manufacture of orthodontic appliances that can be used to reposition teeth.

Background

Repositioning teeth to correct malocclusions (i.e. faulty contact between upper and lower teeth) is desirable for functional as well as aesthetic reasons. Uneven distribution of masticatory forces, for example, can result in excessive wear and loosening of teeth and crowding of teeth can mean cleaning is more difficult leading to increased plaque and greater susceptibility to caries.

Conventionally, malocclusions are corrected through the use of orthodontic appliances, commonly known as "braces", that include a series of metal or ceramic attachments that are cemented to the teeth and connected by tensioned wires that apply forces to the attachments, and hence to the teeth, to give the desired movement. These conventional appliances are, however, not without problems. The procedures for attaching the appliances to the teeth are not straightforward and can cause discomfort, as can the installed appliance. These appliances are generally unsightly and cause problems themselves in maintaining dental hygiene, with the attachments acting as traps for food as it is chewed.

Tooth positioners are an alternative to conventional metal braces that have gained in popularity in recent years.

The concept was first proposed in the 1940s by Dr. Harold Kesling as an appliance for the final positioning of teeth following use of more conventional orthodontic appliances (see: kesling, *"The Philosophy of the Tooth Positioning Appliance", Am. J. Orthod. Oral. Surg.* (1945) 31(6):297-304). Kesling proposed a positioner made of a resilient deformable rubber that had opposed 'U'-shape channels moulded to fit over the occlusal and incisal surfaces of the upper and lower arches respectively, applying forces to the teeth to influence their position as well as to maintain a desired relationship between the upper and lower arches. Kesling's positioners are also described in his US patent no. 2,531,222 and another early example of a tooth positioner is seen in GB 1550777 (Suyehiro).

It is only much more recently, however, that positioners have been proposed as a realistic alternative to conventional metal braces. Recent examples of tooth positioners include those

provided by Ortho-Pro-Teknica Ltd under the brand name ClearStep™ and by Align Technology, Inc. under the brand name Invisalign™.

These positioners are moulded polymeric trays or shells of generally U-shape form that fit over the teeth of the upper and / or lower arch. They are colourless and transparent so are aesthetically much improved compared with the conventional braces. A realignment of the teeth is achieved by using a series of positioners, each positioner typically to be worn for a period of several weeks, to incrementally reposition the teeth. The positioners can be removed by the patient themselves to allow their teeth to be cleaned avoiding the dental hygiene problems associated with the fixings of metal braces.

The applicant's own earlier International patent application published under publication number WO2007/077429 describes a method and apparatus for manufacturing positioners. The approach described in this earlier application uses a configurable physical model of the patient's teeth that can be manipulated in incremental steps, the configuration of the model being duplicated at each step to create a cast from which a positioner can be formed. A series of casts taken from the physical model is used to fabricate a corresponding series of positioners.

Align Technology describe in their US Patent No. 5,975,893 another process by which a series of moulded polymeric tooth positioners can be produced. In this process, a digital model of the patient's initial (malformed) tooth arrangement is obtained by laser scanning a plaster cast of the patient's teeth obtained in a conventional manner. The digital model is manipulated to produce a final tooth arrangement (i.e. with the teeth correctly positioned with respect to one another) and, through a number of complex computations, the system creates a series of intermediate tooth arrangements representing the incremental steps in the tooth repositioning process. Rapid prototyping methods are then used to create a corresponding series of 'positive' tooth moulds, one for each intermediate tooth arrangement and one for the final tooth arrangement, on which the positioners themselves can be formed. This approach requires a trade off between the level of detail in the digital models and the computational overheads when creating the digital models of the final and intermediate teeth arrangements. Any discrepancies in the model compared with the patient's teeth will likely be compounded as the model is digitally manipulated.

Summary of Invention

At a general level, the present invention proposes fabricating a series of tooth positioners based on a combination of computer simulated and physically modelled tooth configurations. More specifically, the proposal is to create physical models of two end points of a series of incremental tooth positions and to create a computer simulation of one or more intermediate tooth positions between the two end points. A series of positioners can then be fabricated

corresponding to the series of positions defined by the physically modelled end points and one or more simulated intermediate positions.

In one aspect, the invention provides a method of fabricating one or more intermediate physical models of a patient's teeth that can be used in the manufacture of a series of tooth positioners for incrementally repositioning one or more teeth of a patient from an initial configuration to a final configuration via one or more intermediate configurations, the method comprising:

providing computer a simulation of the patient's teeth in an initial configuration and in a final configuration, the computer simulation having been obtained by digitising physical models of the teeth in the initial and final configurations;

producing one or more computer simulations of intermediate configurations of the teeth based on the computer simulations of the teeth in their initial and final configurations; and

directly fabricating one or more intermediate physical models of the patient's teeth using the computer simulations of the intermediate configurations of the teeth to form one or more intermediate models of the patient's teeth.

The term "direct fabrication" used herein is intended to preclude the case where the computer simulations of intermediate configurations are used to control the manipulation of a configurable model of a patient's teeth, each intermediate model subsequently being fabricated from the appropriately manipulated configurable model (this being the subject of the applicant's earlier but not yet published International patent application PCT/GB2007/003920). The fabrication proposed by the present invention is thus "direct" in the sense that there is no intermediate, configurable model but the fabrication may still be a multi-step process (e.g. involving the production of a sequence of non-configurable negative and/or positive moulds).

Examples of suitable fabrication methods for producing the intermediate physical models include rapid prototyping (also referred to as "rapid manufacturing" and "solid freeform fabrication") techniques such as stereolithography and 3D printing.

The method may include the steps of:

providing a physical model of the patient's teeth in an initial configuration;

providing a physical model of the patient's teeth in a final configuration; and

digitising the two models in order to obtain the computer simulation of the teeth in their initial and final configurations.

The physical model of the patient's teeth in the initial configuration can be obtained from an impression taken from the patient using conventional techniques.

The physical model of the final configuration is preferably created by manipulating a configurable model of the patient's initial tooth configuration. The configurable model may, for

example, take the form of the "composite model" described in the applicant's earlier WO2007/077429.

Various well known techniques exist for digitising physical models, including for example techniques using one or more lasers to scan the models.

The positioners themselves can be formed by moulding over the intermediate physical models fabricated in accordance with the method set forth above. Methods for moulding positioners are well known and discussed, for instance, in the applicant's earlier WO2007/077429. They may, for example, be vacuum formed from a polymeric material (e.g. PET).

A positioner corresponding to the final position can be moulded over the previously produced physical model of the desired final position of the patient's teeth. Alternatively, a new final model can be fabricated in a similar fashion to the intermediate models, based on the computer simulation of the final position obtained by digitising the original final model. This latter approach may be desirable, for example, where the original final model is created at a geographically remote location to the fabrication of the positioners.

Similarly, if a positioner corresponding to the initial tooth configuration is required, it can be fabricated using the original initial model or a newly created model derived from the simulated initial position.

By using this combination of physical and digital modelling of the incremental repositioning of a patient's teeth, it is possible to obtain the benefits of speed and (to a degree) de-skilling of the creation of a series of positioners, whilst still retaining most of the benefits of using physical ('analogue') models, in particular a very accurate compliance with the patient's teeth.

This latter benefit of embodiments of the present invention is particularly apparent if the movements of the individual teeth between initial and final configurations are not too great, for example no more than about 1mm to 2mm. Generally, therefore, in preferred embodiments a series of positioners used to incrementally move the teeth from the initial configuration to the final configuration will include a maximum of 20 positioners, more preferably a maximum of 15 or 10 positioners, and often no more than 8 positioners.

Where a greater number of positioners are required to achieve the desired results, the treatment is preferably completed in stages, a first stage of the treatment being completed with a first set of positioners based on first initial and final physical models. Second and subsequent stages can be completed with new sets of positioners fabricated based on newly created initial and final physical models. In this way, large movements without reference back to the actual position of the patient's teeth at regular intervals are avoided.

It will be understood, therefore, that the terms "intermediate" and "final" used herein are relative terms relating to start and intended finish points for a series of positioners. They do not necessarily correspond to the teeth positions at the beginning and end of a complete treatment.

Preferably, the computer program determines appropriate intermediate configurations for the teeth based on treatment and planning procedures. For example, the computer program may be programmed such that one or more teeth are moved by approximately 0.2 mm, which may be the maximum limit of movement that will not cause damage to the teeth or surrounding gum. Other limitations may be provided for e.g. the maximum degree of tooth rotation or movement in and out of the gum.

Persons skilled in the software modelling arts will be well aware of various techniques that can be used to derive the intermediate configurations between the initial and final configurations. The techniques described in US5975893 for producing intermediate digital data sets can be employed, for example. Other techniques are well known, for example in the context of planning tooth movements and planning orthognathic surgical procedures for example.

One of the challenges that must be met in order to generate the simulations of the intermediate positions is to create a simulation in which the individual teeth that are to be moved are distinguished from one another in order that their movements can be simulated individually. It is known to do this automatically using image recognition techniques. It is also known to achieve separation of teeth in a digital model by having a user manually mark out the tooth boundaries on a representation of the model displayed on a screen. Hybrid approaches have also been proposed, in which manual adjustments are made to an automatically arrived at 'first pass' at separating the teeth in a digital model.

These known approaches have been shown to work with varying degrees of success. They suffer from the disadvantage of a trade off between digital processing resource and speed / accuracy of the end results.

A further proposal arising out of the present invention is a new approach to generating digital models of patients' arches including individually identified teeth or groups of teeth in the arch. In particular the proposal is to treat the physical model to mark the boundaries of the teeth of interest (preferably both the boundaries with adjacent teeth and with the gingiva) and then to digitise the treated physical model. The digitised treated model can then be used, in some embodiments along with one or more digitised models of the complete arch and/or parts of the arch (e.g. individual teeth) to generate a simulation of the arch with the teeth or groups of teeth of interest (typically those to be moved) individually identified.

Conveniently this approach can be used in conjunction with the methods discussed above to generate the simulations of the initial and / or final tooth configurations. However, this approach has independent merit and can be applied to other applications.

The "treatment" of the physical model may comprise marking the surface of the model (e.g. applying a visible marker or scoring the surface) in a manner that can be distinguished by the digitising (e.g. scanning) process.

An alternative, and currently preferred, "treatment" is to physically separate one or more teeth from the physical model and to digitise the model absent these teeth. This generates a digital model with very clear boundaries defined between the missing teeth and the remaining teeth and gingiva adjacent the teeth that have been removed. For instance, alternate teeth may be removed from the model in the region of the arch in which teeth are to be moved during the treatment.

To obtain the information needed to create the simulation of the complete arch it is necessary to supplement the digital model of the arch with the teeth removed with a digital model of the removed teeth themselves. This can be achieved by digitising a physical model of the complete arch (i.e. with no teeth removed), by digitising the removed teeth individually, or by creating a second physical model of the arch leaving the teeth removed from the first model intact and removing the teeth that remained in the first model, and digitising this second model. The digital models can then be combined to create the simulation of the complete arch with individual teeth of interest identified.

Brief Description of Drawings

An embodiment of the present invention will now be described by way of example only, with reference to the accompanying drawings, in which:

Fig. 1 shows a physical, configurable model for use with an embodiment of the present invention;

Fig. 2 shows a physical model with alternate teeth removed in preparation for scanning to create a digital model in which individual teeth are distinguished, in accordance with an embodiment of the present invention;

Figs. 3 shows a physical model fabricated in accordance with an embodiment of the present invention, over which a positioner can be vacuum formed; and

Fig. 4 is a process flow diagram illustrating the overall process of manufacturing a series of positioners in accordance with an embodiment of the present invention.

Description of an Embodiment

This embodiment is concerned with a method of fabricating a series of positioners for incrementally moving teeth from an initial configuration to a final configuration ('final' in the sense that it is the intended final position to which the series of positioners is to move the teeth - subsequent series of positioners may be used for further movements beyond this 'final' position).

The configurations for the positioners in the series are determined, in accordance with the invention, using a combination of physically moulded models and computer simulated models of the patient's teeth.

The description below is primarily addressed at models (and therefore positioners) for one of the patient's arches. In a typical treatment, however, the teeth of both arches will be repositioned simultaneously, with a pair of positioners (one for the upper and one for the lower arch) being worn at any one time. Both positioners can be fabricated in accordance with the procedures discussed below.

With reference to fig. 4, the starting point is to obtain an impression of the patient's teeth as they are, termed an "initial configuration" herein. Conventional orthodontic techniques can be used to do this. The impression is then used to form an initial physical model (e.g. cast) of the patient's teeth corresponding to the initial configuration. This physical model can be digitised (e.g. scanned) to create a digital version of the initial model.

The initial physical model is used, in the manner described in WO2007/077429, to create a configurable version of the initial model.

Figure 1 shows a physical, configurable model 1 for use with an embodiment of the present invention. In this example the model is for a patient's lower complete set of teeth (mandibular arch). A similar model can be produced for the upper set of teeth (maxial arch) or for selected portions of one or other of the arches only.

As explained in WO2007/077429, the model comprises a base 10 that can be a gypsum derivative or a polymeric material for instance. In this example the rear three teeth 12 on each side of the arch are retained as an integral part of the base 10 as the planned treatment does not include any movement of these teeth. Depending on the planned movement, more or fewer (or even no) teeth 12 may be formed integrally with the base 10.

At the forward part of the base 10 there is a recessed portion 14 into which a mounting material, in this example wax 16, is moulded to model the gum and underlying bone of the mandible in which the teeth that are to be moved are supported.

The teeth that are to be moved during the planned treatment are represented in the model by discrete model teeth 18, each of which has a crown portion 20 and a root portion 22. The root portion 22 is imbedded in and retained by the wax mounting material 16.

In use, tooth movements within the model are achieved by warming the wax 16 (e.g. by immersing the configurable model in a bath of hot water) to soften it. Once the wax 16 is sufficiently softened to allow some movement of the root portions of the teeth within it, whilst still retaining the model tooth 18, one or more of the model teeth 18 can be manipulated to modify their position in accordance with the planned treatment. The wax 16 provides resistance to movement of the root 22. The presence of the root 22 as part of the tooth model serves to constrain the possible movements to more realistically represent what is possible in the patient.

In contrast to the process described in WO2007/077429, the configurable model is not used to determine any intermediate tooth configurations (between the initial configuration and a final configuration). Instead, the configurable model is manipulated from the initial configuration directly to the final configuration. This model, once manipulated to the final configuration, can then be digitised (e.g. scanned) directly to generate a digital version of the final configuration. Alternatively, a fixed physical version of the final configuration can be fabricated by duplicating the final configuration of the configurable model, also in the manner described in WO2007/077429.

In some embodiments, the digital versions of the initial and final configurations, once captured, can be manipulated to define individual teeth within the arch. In this embodiment, the identification of the teeth is aided by treatment of the initial and final physical models to remove alternate teeth, as seen for example in fig. 2. Once the teeth have been removed, the models are re-scanned and the boundaries of the gaps (i.e. absent teeth) in the digital models generated from this re-scan are superimposed onto the models of the initial and final tooth configurations obtained from the first scans in order to generate simulations (i.e. digital models) of the initial and final tooth configurations with the teeth of interest individually identified and separable from adjacent teeth in order that they can be independently moved within the digital model.

A series of intermediate digital models, representing intermediate tooth configurations, are then generated by interpolation between the digital models of the initial and final configurations. These intermediate models can then be used, employing conventional rapid prototyping techniques (including, for example, sterolithography) to fabricate a corresponding series of

intermediate physical models, an example of which is shown in fig. 3. A final physical model can also be fabricated in the same way or it may be obtained by duplicating the final position of the physical configurable model.

The positioners, which are preferably formed from a transparent polymeric material, can then be vacuum formed over the fabricated models to provide the desired sequential series for repositioning the patient's teeth from the initial configuration to the final configuration via the intermediate configurations.

Generally, there will be eight positioners in the series. The series of positioners can then be provided to the patient in a single batch to be used in sequence to incrementally move the patient's teeth. If necessary, further batches of positioners can be fabricated and provided to the patient, each batch being created starting from a fresh impression of the patient's teeth in their new 'initial' configuration (following treatment with the preceding batch of positioners).

Claims:

1. A method of fabricating one or more intermediate physical models of a patient's teeth that can be used in the manufacture of a series of tooth positioners for incrementally repositioning one or more teeth of a patient from an initial configuration to a final configuration via one or more intermediate configurations, the method comprising:

providing a computer simulation of the patient's teeth in an initial configuration and in a final configuration, the computer simulation having been obtained by digitising physical models of the teeth in the initial and final configurations;

producing one or more computer simulations of intermediate configurations of the teeth based on the computer simulations of the teeth in their initial and final configurations; and,

directly fabricating one or more intermediate physical models of the patient's teeth using the computer simulations of the intermediate configurations of the teeth to form one or more intermediate models of the patient's teeth.

2. The method of claim 1, including the steps of:

providing a physical model of the patient's teeth in an initial configuration;

providing a physical model of the patient's teeth in a final configuration; and

digitising the two models in order to obtain the computer simulation of the teeth in their initial and final configurations.

3. The method of claims 1 or 2, where the physical model of the patient's teeth in the initial configuration is obtained from an impression taken from the patient using conventional techniques.

4. The method of claim 1, wherein the technique for digitising physical models involves using one or more lasers to scan the models.

5. The method of claims 1 or 2, wherein the final configuration is created by manipulating a configurable model of the patient's initial tooth configuration.

6. The method of claim 1, wherein the series of positioners used to incrementally move the teeth from the initial configuration to the final configuration includes a maximum of 20 positioners.

7. The method of claim 1, wherein the computer program determines appropriate intermediate configurations for the teeth based on treatment and planning procedures.

8. The method of claim 1, wherein the method further comprises generating digital models of patients' arches including individually identified teeth or groups of teeth in the arch.

9. The method of claim 8, wherein the simulation of the arch is supplemented with a digital model of the removed teeth themselves.

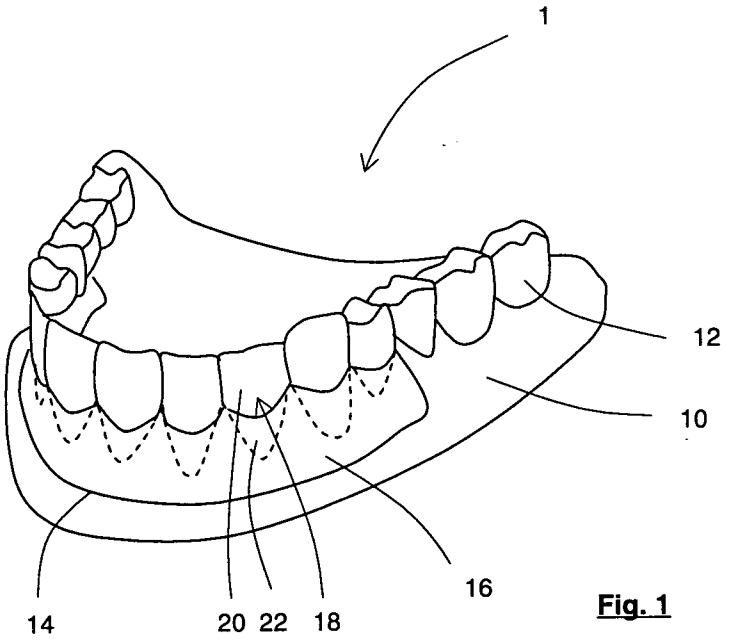

Fig. 1

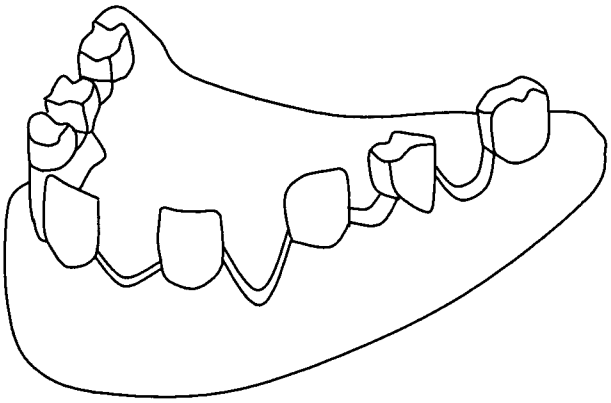

Fig. 2

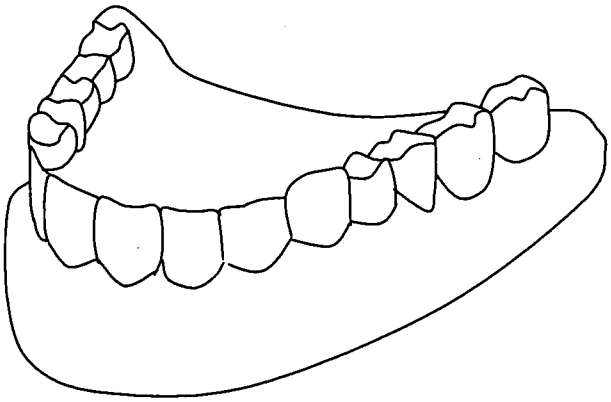

Fig. 3

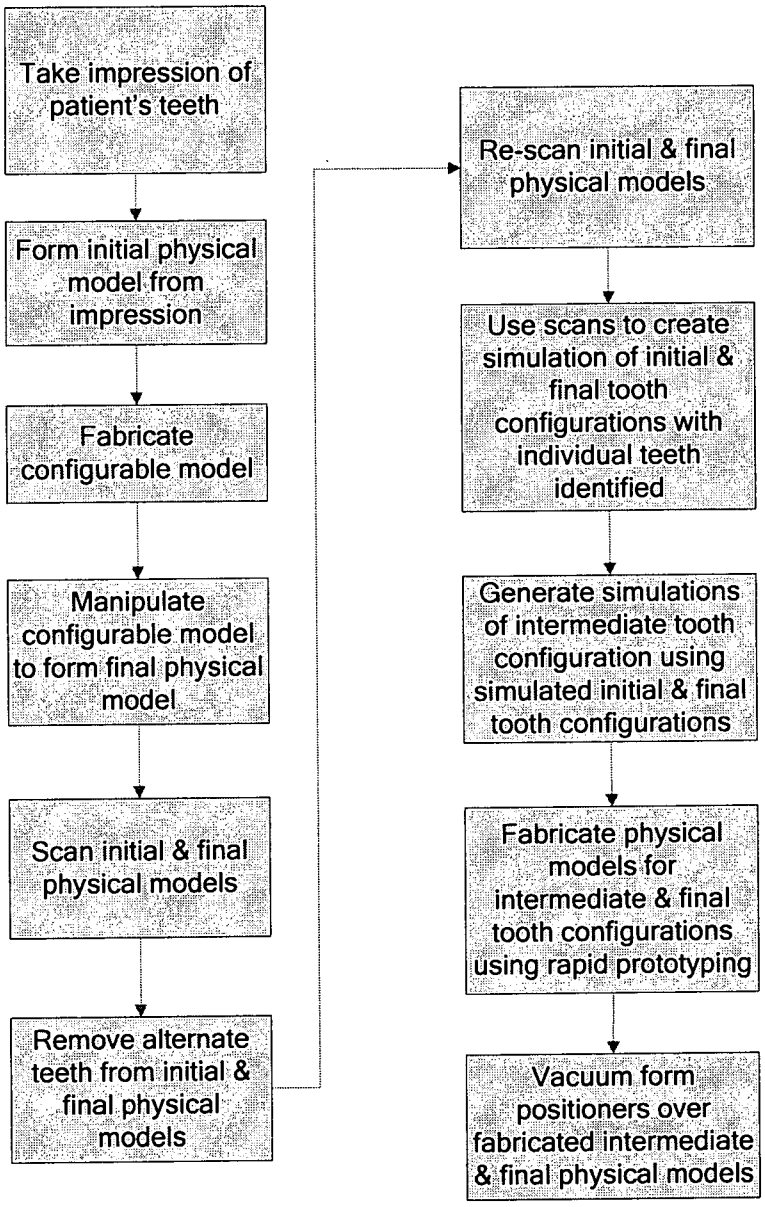
Take impression of patient's teeth
Form initial physical model from impression
Fabricate configurable model
Manipulate configurable model to form final physical model
Scan initial & final physical models
Remove alternate teeth from initial & final physical models
Re-scan initial & final physical models
Use scans to create simulation of initial & final tooth configurations with individual teeth identified
Generate simulations of intermediate tooth configuration using simulated initial & final tooth configurations
Fabricate physical models for intermediate & final tooth configurations using rapid prototyping
Vacuum form positioners over fabricated intermediate & final physical models

FIGURE 4

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2008/003980

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61C9/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61C

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No
X	US 2007/243502 A1 (WEN HUAFENG [US]) 18 October 2007 (2007-10-18) claims 1,2,4,8-12,14-16 paragraph [0072] -----	1-9
A	WO 00/33759 A (ALIGN TECHNOLOGY INC [US]) 15 June 2000 (2000-06-15) page 16, line 30 - page 18, line 15 -----	1-9

D Further documents are listed in the continuation of Box C

[X] See patent family annex

* Special categories of cited documents

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"E" earlier document but published on or after the international filing date

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"P" document published prior to the international filing date but later than the priority date claimed

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"X" document of particular relevance, the claimed invention cannot be considered novel or cannot *be* considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the International search	Date of mailing of the international search report
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2007243502 A1	18-10-2007	WO 2007120920 A2	25-10-2007
WO 0033759 A	15-06-2000	AU 2164100 A	26-06-2000