Title: MANDIBULAR PROSTHESIS AND A TEMPOROMANDIBULAR ANCHOR FOR JAW RECONSTRUCTION

Abstract: There is provided a mandibular prosthesis comprising: temporomandibular anchor configured for fixation to a temporal bone in use; and a mandible portion having at least one ascending ramus portion, wherein the ramus portion and the temporomandibular anchor portion are secured together by a rotational attachment such that the mandible portion is able to rotate at least anteroposteriorly with respect to the temporomandibular anchor; and travel mediolaterally with respect to the temporomandibular anchor to facilitate chewing and opening and closing of the prosthetic mandible relative to the upper jaw. There is also provided a temporomandibular anchor configured for fixation to a temporal bone in use wherein, the temporomandibular anchor is configured for forming a rotational attachment with a mandible portion such that the that the mandible portion is able to rotate at least anteroposteriorly with respect to the temporomandibular anchor; and travel mediolaterally with respect to the temporomandibular anchor to facilitate chewing and opening and closing of the prosthetic mandible relative to the upper jaw.
Mandibular prosthesis and a temporomandibular anchor for jaw reconstruction

Field of the Invention
[1] The present invention relates to medical prosthesis for jaw reconstruction and in particular, but not necessarily entirely, to mandibular prosthesis and a temporomandibular anchor for jaw reconstruction.

Background of the Invention
[2] Mandibular reconstructive surgery following ablative tumour resections of the mandible has resulted in limited success as far as dental rehabilitation is concerned.

[3] Mandibular resections are often reconstructed with straight tubular vascularized fibula bone flaps that fail to follow the natural contour of the mandible and lack the bone mass required to support dental implants. Hence, most patients who are reconstructed in this way are left without teeth to chew.

[4] Earlier experiences using vascularized ilium (hip bone) to reconstruct the mandible were fraught with difficulty due to the restricted vascular pedicle and the significant abdominal dissection required to harvest the bone which left the patient with significant morbidity from the donor site (lifelong limping & pain). Current mandibular reconstruction plates are only used as adjunctive fixation for bone grafts as they are not designed take the full load of mandibular function when placed across the missing span of jaw.

[5] There is a pressing need to develop an alloplastic jaw (mandibular) replacement that provides a reliable and accurate substitute for resected mandibular segments.

[6] Furthermore, reconstructive mandibular surgery following ablative tumour resections of the mandible comprises the mandibular condyle being resected together with the ascending ramus and part of the body of the mandible. However, the reconstructive plate and/or the bone graft are passively enlocated in the mandibular fossa and secured with non-resorbing sutures which are flimsy and readily break, resulting in an unstable plate and bone graft that quickly fail and need to be removed.

[7] Furthermore, existing mandibular prosthetic devices passively engage either the natural glenoid fossa of the skull base or a prosthetic fossa component that is essentially a cup into which the prosthetic condyle articulates against. In both situations the condylar head is not supported so that it is essentially unstable during functional movements of the jaw and will have a tendency to fall away and disengage from the fossa.
[8] It is to be understood that, if any prior art information is referred to herein, such reference does not constitute an admission that the information forms part of the common general knowledge in the art, in Australia or any other country.

Summary of the Disclosure

[9] The present invention seeks to provide a mandibular prosthesis and a temporomandibular anchor for jaw reconstruction, which will overcome or substantially ameliorate at least some of the deficiencies of the prior art, or to at least provide an alternative.

[10] As will be described in further detail below, the mandibular prosthesis follows the natural contour of the mandible, withstands full functional jaw loads and provide direct attachments for artificial teeth via an internal screw interface and allows for accurate and easy placement. The mandibular prosthesis also eliminates the need for distant tissue donor sites which not only reduces the overall morbidity of the reconstructive process but also significantly reduces the operating time.

[11] Furthermore, the mandibular prosthesis has the unique temporomandibular anchor where the condylar head is functionally secured by the temporomandibular anchor to the fossa allowing for the opening and closing movements of the prosthetic jaw while preventing the condyle from falling out of the fossa. The temporomandibular anchor holds and supports the round condylar head of the mandibular prosthesis so it does not drift from its predetermined ideal position during jaw function.

[12] The mandibular prosthesis may further comprise a dental abutment interface that allows direct connection of artificial teeth to the mandibular frame via an external hexagonal abutment screw mechanism. Existing mandibular prosthetic devices have no provision for dental attachments and rely on additional bone grafts to support conventional osseointegrated dental implants.

[13] The dental abutments, which are integrated into the mandibular prosthesis, allow for direct support of overlying dental prosthesis via an internal screw mechanism that is similar to that found in conventional dental implants so that Dentists who are building teeth over the mandibular prosthesis are familiar with the connections that makes dental rehabilitation very easy.

[14] As such, in accordance with one aspect, there is provided a mandibular prosthesis comprising: temporomandibular anchor configured for fixation to a temporal bone in use; and a mandible portion having at least one ascending ramus portion, wherein the ramus portion and the temporomandibular anchor portion are secured together by a rotational attachment such that the mandible portion is able to: rotate at least anteroposteriorly with respect to the temporomandibular anchor; and travel mediolaterally with respect to the temporomandibular anchor to facilitate chewing and opening and closing of the prosthetic mandible relative to the upper jaw.
[15] The temporomandibular anchor may be configured for securement at the root of the zygomatic arch of the temporal bone.

[16] The temporomandibular anchor may be to conform substantially with the zygomatic arch of the temporal bone.

[17] The temporomandibular anchor may comprise a superiorly projecting lateral flange exposing bone screw fixation holes therein for fixation of the superiorly emanating lateral flange to the temporomandibular articular eminence.

[18] The superiorly projecting lateral flange may comprise at two rows of screw fixation holes.

[19] The temporomandibular anchor may comprise a mediolateral channel being open-ended at the lateral face of the temporomandibular anchor and closed at an opposite lateral end thereof.

[20] The rotational attachment may comprise the ascending ramus portion terminating in a ball-head and wherein the ball-head may be configured for insertion into the open-end of the channel at the lateral face to form the rotational attachment.

[21] The channel may be inferiorly open ended to as to define an inferior mediolaterally orientated lengthwise opening through which a neck of the ball-head extends.

[22] The channel may comprise a substantially circular cross-section.

[23] The channel may comprise a substantially oval cross-section.

[24] Inferior edges of the inferior channel are bevelled to increase the anteroposterior travel of the neck of the ball-head.

[25] The anchor may have an anteroposterior width of approximately 20.7 mm.

[26] The anchor may have an mediolateral width of approximately 19.6 mm.

[27] The anchor may have a height of approximately 13.1 mm.

[28] The anchor may have a superiorly projecting lateral flange having a height of approximately 18 mm.

[29] The anchor may have a superiorly projecting lateral flange having an angle of more than 90° between the face of the lateral flange and an inferior face of the anchor.

[30] The channel may have a diameter of approximately 9.5 mm.

[31] The ball-head may have a diameter of approximately 8.5 mm.

[32] The ball-head may comprise a neck having a diameter of approximately 3 mm.

[33] The inferior channel may comprise an anteroposterior width of approximately 7 mm.

[34] The inferior channel may comprise a mediolateral width of more than approximately 7 mm.

[35] The inferior opening may be restricted towards the lateral face of the temporomandibular anchor.
The inferior opening defines narrowing nibs towards the lateral face of the temporomandibular anchor.

The narrowing nibs may have sufficient width to allow a neck of the ball-head to be pressed therethrough.

The ramus portion may be angled outwardly from the base thereof.

The at least one ascending ramus portion may be two ascending ramus portions and wherein the mandible portion curves between the two ascending ramus portions.

The mandible portion may comprise dental means engagements.

The dental means engagements comprise a plurality of teeth prosthesis socket defining abutments located at a superior edge of the mandible portion.

The abutments comprise an upright body to which the dental prosthesis are fastened and wherein the upright body may have a height configured to allow the abutments to traverse through the gums so as to present an upper surface corresponding substantially in elevation with the gum surface.

The mandible portion may comprise six abutments

The six abutments comprise three abutments either lateral side of the mandible portion.

The abutments are spaced by approximately 12 mm.

The abutments comprise a height of approximately 4.7 mm.

The abutments comprise a cylindrical body having threading therein.

The threading may have a spacing of approximately .4 mm.

The threading may have a major diameter of approximately 2 mm and a minor diameter of approximately 1.57 mm.

The mandible portion may comprise perforations.

In accordance with another aspect, there is provided a temporomandibular anchor configured for fixation to a temporal bone in use wherein, the temporomandibular anchor is configured for forming a rotational attachment with a mandible portion such that the that the mandible portion is able to: rotate at least anteroposteriorly with respect to the temporomandibular anchor; and travel mediolaterally with respect to the temporomandibular anchor to facilitate chewing and opening and closing of the prosthetic mandible relative to the upper jaw.

The temporomandibular anchor may be utilised in conjunction with the mandible portion described herein or alternatively utilised in isolation for other application.

The temporomandibular anchor may be configured for securement at the root of the zygomatic arch of the temporal bone.
The temporomandibular anchor may be shaped to conform substantially with the zygomatic arch of the temporal bone.

The temporomandibular anchor may comprise a superiorly projecting lateral flange exposing bone screw fixation holes therein for fixation of the superiorly emanating lateral flange to the temporomandibular articular eminence.

The superiorly projecting lateral flange may comprise at two rows of screw fixation holes.

The temporomandibular anchor may comprise a mediolateral channel being open-ended at the lateral face of the temporomandibular anchor and closed at an opposite lateral end thereof.

The rotational attachment may comprise the mediolateral channel configured for receiving a ball-head of a mandible portion therein and wherein the ball-head may be inserted into the open-end of the channel at the lateral face of the anchor.

The channel may be inferiorly open ended to as to define an inferior mediolaterally orientated lengthwise opening through which a neck of the ball-head extends.

The channel may comprise a substantially circular cross-section.

The channel may comprise a substantially oval cross-section.

Inferior edges of the inferior channel are bevelled to increase the anteroposterior travel of the neck of the ball-head.

The anchor may have an anteroposterior width of approximately 20.7 mm.

The anchor may have a mediolateral width of approximately 19.6 mm.

The anchor may have a height of approximately 13.1 mm.

The anchor may have a superiorly projecting lateral flange having a height of approximately 18 mm.

The anchor may have a superiorly projecting lateral flange having an angle of more than 90° between the face of the lateral flange and an inferior face of the anchor.

The channel may have a diameter of approximately 9.5 mm.

The channel may be configured for receiving a ball-head therein having a diameter of approximately 8.5 mm.

The inferior channel may be configured for receiving a neck of a ball-head therein having a diameter of approximately 3 mm.

The inferior channel may comprise a anteroposterior width of approximately 7 mm.

The inferior channel may comprise a mediolateral width of more than approximately 7 mm.

The inferior opening may be restricted towards the lateral face of the temporomandibular anchor.
The inferior opening defines narrowing nibs towards the lateral face of the temporomandibular anchor.

It should be noted that advantages, benefits and the like referred to herein should be understood as not necessarily being applicable to each and/or every of the claims claimed herein.

Other aspects of the invention are also disclosed.

Brief Description of the Drawings
Notwithstanding any other forms which may fall within the scope of the present invention, preferred embodiments of the disclosure will now be described, by way of example only, with reference to the accompanying drawings in which:

Figure 1 shows a placed mandibular prosthesis in accordance with a first embodiment of the present disclosure;

Figure 2 shows a cross-sectional and top view of the prosthesis of Figure 1 in accordance with an embodiment of the present disclosure;

Figure 3 shows the prosthesis 1 comprising dental means engaging sockets and blanks for the sockets for use during surgery in accordance with an embodiment of the present disclosure;

Figure 4 shows the prosthesis configured for hemimandible replacement in accordance with an embodiment of the present disclosure;

Figure 5 shows a further embodiment of the prosthesis of Figure 1 in accordance with an embodiment of the present disclosure; and

Figure 6 shows the further embodiment of the prosthesis of Figure 5 rotatably attached to an anchor at the terminus of the ascending ramus portion in accordance with an embodiment of the present disclosure.

Figures 7-9 show a mandibular prosthesis in accordance with a further, preferred embodiment of the present disclosure;

Figure 10 shows the temporomandibular anchor shown in situ, in accordance with a first embodiment of the present disclosure;

Figure 11 shows a lateral view of the temporomandibular anchor of Figure 1 in accordance with embodiments of the present disclosure;

Figure 12 shows a perspective view of the temporomandibular anchor of Figure 1 in accordance with embodiments of the present disclosure;

Figure 13 shows a side view of the temporomandibular anchor of Figure 1 in accordance with embodiments of the present disclosure; and
Figure 14 shows a side elevation view of the lateral face of the anchor in accordance with a further, preferred embodiment wherein the device comprises a ball-and-socket rotational configuration;

Figure 15 shows a cross-sectional elevation view of the anchor of Figure 14 in accordance with the further, preferred embodiment of the present description;

Figure 16 shows a bottom perspective view of the anchor of the device in accordance with the further, preferred embodiment of the present description;

Figure 17 shows the ball and rod member for the anchor of Figure 14 in accordance with the further, preferred embodiment of the present description; and

Figures 18 - 20 show various exemplary dimensions of the anchor of the in accordance with the further, preferred embodiment of the present description.

Figures 21 - 26 is a variation of the further, preferred embodiment of the anchor of the present description;

Figures 27 - 28 show a dental prosthesis abutment for the mandible portion in accordance with an embodiment of the present disclosure; and

Figures 29 - 30 show exemplary dimensions of the dental prosthesis abutment in accordance with an embodiment of the present disclosure.

Description of Embodiments

For the purposes of promoting an understanding of the principles in accordance with the disclosure, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the disclosure is thereby intended. Any alterations and further modifications of the inventive features illustrated herein, and any additional applications of the principles of the disclosure as illustrated herein, which would normally occur to one skilled in the relevant art and having possession of this disclosure, are to be considered within the scope of the disclosure.

Before the structures, systems and associated methods relating to the mandibular prosthesis and a temporomandibular anchor for jaw reconstruction are disclosed and described, it is to be understood that this disclosure is not limited to the particular configurations, process steps, and materials disclosed herein as such may vary somewhat. It is also to be understood that the terminology employed herein is used for the purpose of describing particular embodiments only and is not intended to be limiting since the scope of the disclosure will be limited only by the claims and equivalents thereof.
In describing and claiming the subject matter of the disclosure, the following terminology will be used in accordance with the definitions set out below.

It must be noted that, as used in this specification and the appended claims, the singular forms "a," "an," and "the" include plural referents unless the context clearly dictates otherwise.

As used herein, the terms "comprising," "including," "containing," "characterised by," and grammatical equivalents thereof are inclusive or open-ended terms that do not exclude additional, unrecited elements or method steps.

It should be noted in the following description that like or the same reference numerals in different embodiments denote the same or similar features.

Mandibular Prosthesis in accordance with a first embodiment

Figures 1 - 9 showing mandibular prosthesis 1 for replacing at least a portion of a mandible.

Specifically, figures 1 - 6 show the prosthesis 1 in accordance with a first embodiment and figures 7 - 9 show the prosthesis 1 in accordance with a further, preferred embodiment.

In the main embodiments described herein, the prosthesis 1 will be described with reference to replacing the entire mandible. However, as can be seen from figure 4 as will be described in further detail below, in embodiments, the prosthesis 1 may be configured to replacing a portion of a mandible also ("hemimandibles").

Preferably, the mandibular prosthesis 1 is made of medical grade titanium (Ti-6Al-4V).

As can be seen from Figure 1, the mandibular prosthesis 1 is substantially anatomically contoured to follow the natural curvature of the mandible. Figure 2B shows a top cross-sectional view of the prosthesis 1.

As can be seen from Figure 1, in first embodiment, the prosthesis 1 comprises two 7-8mm thick round bars 4, 5 separated by a flat plate 6 being 10-12mm high and 2mm thick and perforated at regular intervals with 3-4mm round holes. Figure 2A shows a cross-sectional view of the prosthesis showing the bars 4, 5 and plate 6 in further detail.

The inferior bar 5 may follow the anatomical contour of the lower border of the replaced mandible portion from angle to angle. The superior bar 4 may follows the alveolar ridge of the replaced mandible portion.

Referring again to figure 1, posteriorly, the inferior and superior bars converge superiorly, recreating the ascending ramus of mandible to end in a round condylar process/rotational attachment that hinges on a temporomandibular anchor 2.

In embodiments, the superior bar 4 comprises dental means engagements 7 for engaging artificial teeth. Specifically, the superior bar 4 may comprise strategically placed screw holes that
ultimately connect artificial teeth directly to the prosthesis. Figure 2B shows exemplary positioning of the screw holes 8 for attaching the artificial teeth or other dental arrangement.

[112] Turning now to figure 3, cover screws/banks 9 may be used to protect the screw holes 8 during the initial surgery. These cover screws 9 may be swapped out some 2-4 weeks post-surgery, upon which a framework 7 is constructed to support artificial teeth by a dental practitioner.

[113] It should be noted that the interconnecting plate 6 between the superior 4 and inferior 5 bars not only provide strength and stability to the prosthesis 1, but, in embodiments, is perforated to allow attachment of the various muscles and ligaments of the peri-mandibular soft tissues directly to the prosthesis 1 via non-dissolving sutures and/or anchor pins.

[114] The inferior bar 5 may be rounded to provide contour and support for the surrounding soft tissues as well as additional mechanical strength to counter the functional stresses and strains of normal jaw movements. Muscles and ligaments of the floor of mouth can also be directly anchored to the inferior bar.

[115] Posteriorly, the rotational attachment 3 is designed for attachment to the anchor 2. The anchor 2 may be secured to the temporal bone at the root of the zygomatic arch.

[116] As is shown in figure 1, the rotational attachment 3 may comprise a large hole within the neck of the condylar component through which a pin is inserted and secured to the medial and lateral flanges of the anchor 2. This anchorage of the condylar process/rotational attachment to the anchor 2 provides secure fixation of the prosthesis to the cranial base while allowing hinge type rotation of the prosthetic 1 to facilitate chewing and opening and closing of the prosthetic mandible relative to the upper jaw.

[117] As alluded to above, and, referring to figure 4, while the main embodiment described herein describes the prosthesis 1 being configured to replace the entire mandible, in embodiments, the prosthesis 1 may be configured to replace smaller segments of the mandible such as hemimandibles or less.

[118] In this embodiment where smaller segments of mandible are required, the prosthesis 1 may incorporate extended screw fixation plates 10 to attach the prosthesis directly to the remaining segments of the resected mandible.

[119] The prosthesis 1 may be custom made to order using CAD-CAM and 3-D printing technology so that segments of jaw can be rapidly produced according to the surgical resection margins planned by the surgeons.
Mandibular Prosthesis in accordance with a preferred embodiment

120 Turning now to figure 7 - 9, there is shown a further, preferred embodiment of the mandibular prosthesis 1.

121 The mandibular prosthesis comprises temporomandibular anchor 2 configured for fixation to the temporal bone and a mandible portion 11 having at least one ascending ramus portion 13.

122 As can be seen, the ramus portion 13 and the temporomandibular anchor 2 are secured together by a rotational attachment 14 such that the mandible portion 11 is able to rotate at least anteroposteriorly with respect to the temporomandibular anchor 2 to facilitate chewing and opening and closing of the mandible portion 11 relative to the upper jaw in use.

123 As can be seen in this embodiment, the prosthesis 1 is distinguished in several respects from that which was described above with reference to the first embodiment of figures 1 - 6. Specifically, as can be seen, the prosthesis 1 comprises a differing temporomandibular anchor configuration 2 having a ball-and-socket type configuration opposed to a rod-and-ring configuration. These two types of temporomandibular anchors 2 will be described in further detail below.

124 Furthermore, the mandible portion 11 does not comprise the superior and inferior bars 4, 5 and interposed plate 6 as was described above, rather having a unitary body which, in an embodiment, may also be custom made to order using CAD-CAM and 3-D printing technology.

125 The mandible portion 11 may be perforated to allow attachment of the various muscles and ligaments of the peri-mandibular soft tissues directly to the prosthesis 1 via non-dissolving sutures and/or anchor pins. The perforation may further facilitate osseo integration.

126 Specifically, figure 7 shows the mandible portion 11 rotatably coupled to the temporomandibular anchor 2.

127 Figure 8 shows the mandible portion 11 in isolation showing the ball shaped condylar head for insertion into the temporomandibular anchor 2.

128 Figure 9 shows a top perspective view of the mandible portion 11 illustrating the curvature of the mandible portion 11 and the poise of the ascending ramus portion 13. In the embodiment shown, the prosthesis 1 is configured for replacing the entire mandible. However, as alluded to above, the mandible portion 11 may be hemimandibular so as to be suited for replacing a portion of the mandible.

129 As can also be seen from the preferred embodiment, the mandible portion 11 comprises dental abutments 12 suited for the insertion of prosthetic teeth as will be described in further detail below with reference to figures 27 - 30.
Temporomandibular anchor in accordance with a first embodiment

Turning now to figures 10 - 13, there will be described the temporomandibular anchor 2 with reference to a first embodiment. As will be appreciated, the first embodiment comprises a rod-and-ring rotational type engagement.

A further, preferred embodiment of the temporomandibular anchor 2 will be described with reference to figures 14 - 26 below wherein the anchor 2 rather comprises a ball-and-socket type rotational engagement.

Turning now to figure 10, there is shown a temporomandibular anchor 2 shown in situ in a reconstructed jaw. As can be seen, a portion of the right mandible 5 has been resected and subsequently reconstructed using the temporomandibular anchor 2 wherein the temporomandibular anchor 2 is adapted for fastening to the cranium 15 (and specifically the zygomatic arch 14 of the temporal bone of the cranium 15).

The anchor 2 may pivotally couple the mandibular portion 11 described herein. However, it should be noted that, in embodiments, the anchor 2 may be utilised for pivotally coupling a bone graft 4 (such as a fibula bone graft), a reconstruction plate or directly to the remaining mandible.

As alluded to above, the temporomandibular anchor 2 is designed to provide a relatively reliable and strong anchorage point to the cranial base 2 for a large bone graft 4 or reconstruction plate following extensive mandibular tumour resections when compared to existing arrangements.

Furthermore, the temporomandibular anchor 2 also allows the reconstructed jaw to open and close and move side to side to facilitate speech and chewing.

Specifically, referring now to figure 2, the temporomandibular anchor 2 is made up of two main parts comprising the anchor base 16 that attaches to the temporal bone 2, and the anchor plate 17 to which the bone graft or mandibular reconstruction plates attach.

The anchor plate 17 is adapted to pivot with respect to the anchor base 16 so as to allow the reconstructed jaw to open and close. In one embodiment, and referring now specifically to figure 12, the temporomandibular anchor 2 comprises a rod and ring pivot arrangement. Specifically, in this embodiment, the plate 17 is suspended from the base 16 via a ring attachment 18 that swings freely around a fixed horizontal rod 19.

In this embodiment, the anchor base 16 defines a 3mm thick titanium rod 19 that is fixed to the oppositely located and substantially triangular shaped plates 10 both medially and laterally.

In embodiments, the anchor base 16 is made of 1.5mm thick medical grade titanium (Ti-6Al-4V) and is secured to the base of skull with screws on the lateral aspect.

Freely hanging off the rod 19 is a 4mm wide polyethylene ring 18 with preferably a 5mm internal diameter that is attached to a substantially elongate portion 21 (preferably comprising
titanium and preferably comprising 3 fastening holes 22) that swings in the antero-posterior direction with minor twisting motion in the medial-lateral direction, which allows for grinding action of molar teeth to better chew the food.

As can be appreciated, in addition to the rod and ring arrangement allowing the plate 17 to pivot with respect to the base 16, the length of the rod 19 being greater than the width of the ring 18 allows the ring 18 to travel along at least a portion of the length of the rod 19 so as to allow the jaw to move mediolaterally in the manner described above.

Furthermore, the internal diameter of the ring 18 may be greater than that of the diameter of the rod 19 so as to allow the plate 17 to twist slightly with respect to the anchor base 16. In embodiments, the internal diameter of the ring 18 may be substantially 5 mm whereas the diameter of the rod 8 may be substantially 3 mm.

In use, the base 16 is positioned over the temporomandibular articular eminence (which may be surgically flattened 2-3mm to accommodate the flat base). The superior lateral flange 23 rises over the root of the zygomatic arch and preferably has 5 screw holes which secure the anchor base 16 to the bone with 2mm wide bone screws.

As can be seen from the embodiment, the superior lateral flange 23 may be shaped so as to least substantially conform to the external surface of the root of the zygomatic arch.

Furthermore, as can be seen, the holes 24 of the superior lateral flange 23 are arranged along spaced apart rows so as to minimise in-line fracturing of the cranial bone.

Inferiorly, the 3 hole plate 17 swings freely around the fixed titanium rod 19, the rod 19 being securely bonded to the anchor base 16.

As can be appreciated from the above 1, the temporomandibular anchor 2 is suited for mandibular reconstruction where large sections of the mandible, including the condyle, have been surgical removed.

Temporomandibular anchor in accordance with a preferred embodiment

Turning now to figures 14 - 26, there is shown a further, preferred embodiment of the temporomandibular anchor 2. As is immediately apparent, the temporomandibular anchor 2 of the preferred embodiment is distinguished in that the temporomandibular anchor 2 comprises a ball and socket type rotational engagement as opposed to the rod and ring pivot described above.

Specifically, turning to figure 14, there is shown the device 2 defining a laterally open-ended, mediolaterally traversing channel 25 configured for receiving a ball 26 therein.

In an embodiment, the ball 26 may constitute part of the mandible portion 11.
The ball 26 is fastened to a rod 27 which extends inferiorly therefrom. Primarily for illustrative convenience when focusing on the anchor 2, reference will be made to the rod 27. However, as alluded to above, a ball-head 26 may be fastened to the ramus portion 13 of the mandible portion 11. In embodiments, the rod 27 may be configured for being releasably fastenable wherein, for example, the rod 27 is threaded so as to be able to be screwed into the mandible portion 11 or other objects as required.

As can be seen, the channel 25 is open lengthwise along the inferior face of the anchor base 16 so as to allow the rod 27 to extend out and downwardly therefrom as will be described in further detail below.

As such, the ball 26 is able to rotate anteroposteriorly within the channel 25 so as to allow the reconstructed jaw to open and close with respect to the upper jaw.

Furthermore, the ball 26 is able to travel mediolaterally within the channel 25 so as to facilitate normal use of the jaw, including chewing. Furthermore, the ball 26 is able to rotate along the elongate axis of the rod 27 providing a twisting motion which may further facilitate chewing.

As can be seen, the anchor base 16 may similarly comprise fastening apertures 24 at a superior end to facilitate fastening to the temporal bone 2 by way of screw anchors including in a manner similar to that which was provided above.

Specifically, and turning now to figure 16, in use, the base 16 is positioned over the temporomandibular articular eminence (which may be surgically flattened/shaped 2-3mm to accommodate the base of the anchor). The superior lateral flange 23 rises over the root of the zygomatic arch and preferably has 5 screw holes 24 which secure the anchor base 16 to the bone with 2mm wide bone screws.

As can be seen from the embodiment, the superior lateral flange 23 may be shaped so as to least substantially conform to the external surface of the root of the zygomatic arch. Alternatively, the zygomatic arch may be shaped to conform to the external profile of the base 16.

Furthermore, as can be seen, the holes 24 of the superior lateral flange 23 are arranged along spaced apart rows so as to minimise in-line fracturing of the cranial bone.

Figure 15 shows an elevational cross-sectional view of the temporomandibular anchor 2 showing the arrangement of the temporomandibular anchor 2 of the second embodiment in further detail.

As described above, the channel 25 may be open at the lateral side of the anchor base 16 so as to facilitate the mediolateral insertion of the ball 26 into the channel 25.

In this regard, turning now to figure 16, there is shown a bottom perspective view of the temporomandibular anchor 2 showing the configuration of the channel 25 in further detail.
[162] As can be seen, and as alluded to above, the channel 25 extends transversely mediolaterally across the temporomandibular anchor 2 so as to be open-ended at the outer lateral face of the temporomandibular anchor 2 yet not extending sufficiently far such that the medial end of the channel 25 remains closed.

[163] Furthermore, as can be seen, the channel 25 is elongate defining an inferior mediolaterally orientated lengthwise opening 28 through which the rod 27 extends.

[164] As can be appreciated, such configuration allows the rod 27 to simultaneously rotate anteroposteriorly and also travel mediolaterally with respect to the base 16 allowing the opening and closing of the mandible with respect to the upper jaw and facilitating lateral movement required for chewing, speaking and the like.

[165] Furthermore, the inferior opening 28 may be restricted towards the lateral face of the temporomandibular anchor 2 by narrowing nubs 29. The narrowing nubs 29 extend sufficiently far into the inferior opening so as to interfere with the rod 27 or the neck of the mandible portion 11 so as to allow the neck of the mandible portion 11 to be pushed therethrough yet while preventing or substantially reducing the likelihood of the neck of the mandible portion 11 becoming inadvertently disengage from the channel 25 in use.

[166] Figures 19 - 22 show various exemplary dimensions of the temporomandibular anchor 2 in accordance with the further preferred embodiment.

[167] Figures 23 - 26 row a variation of the anchor 2 wherein, as is apparent from the illustrations, the variation 2 is characterised in that the channel 25 is substantially oval.

[168] Specifically, the A-A cross-section of figure 23 is provided substantially in figure 24. As can be seen, the oval channel 25 defines a more rounded channel roof as compared to the substantially circular channel 25 embodiment which allows the pivot point of the coupling to be located lower at the mouth of the inferior channel as opposed to being concentric with the ball.

[169] Furthermore, as can be seen, the lower edges 31 of the inferior channel 18 may be bevelled so as to allow for greater anteroposterior reach of the rod.

Dental prosthesis abutment 12

[170] Turning now to figures 27 - 30, there is shown the dental prosthesis abutment 12 in further detail.

[171] As described above, and as is shown in figure 9, the abutments 12 may be fastened directly to the mandible portion 11 so as to allow for the removable insertion of dental prosthesis therein.
In the particular embodiment shown in figure 9, six abutments 12 may be provided comprising three abutments on either lateral side of the mandible portion 11. Furthermore, in the embodiment shown in figure 9, the abutments 12 may be spaced apart by approximately 12 mm.

Figure 27 shows a top perspective view of the abutment wherein, as can be seen, the abutment 12 comprises a substantially cylindrical body. In embodiment, the cylindrical body may be formed as part of the mandible portion 11 or subsequently retrofitted thereto. For example, the mandible portion 12 may comprise threaded apertures which may be sealed with blanks until required wherein the blank may be removed and the cylindrical body of the abutment 12 inserted therein.

In embodiments, the abutment 12 comprises an upper hexagonal nut used for gripping for anti-rotation when screwing in a new tooth.

The cylindrical body 12 may be configured to have sufficient height so as to be able to extend from the mandible portion 11 through the gums so as to present an appropriately height located base for the securement of teeth prosthesis thereto.

Figure 29 shows a top plan view of the abutment 12 showing exemplary dimensions. Furthermore, Figure 30 shows a side elevation view of the abutment 12 further showing exemplary dimensions.

As can be seen from the cross-sectional elevation view of Figure 30, the interior of the cylindrical body may comprise threading into which teeth prosthesis may be screwed for fixation.

As alluded to above, in a preferred embodiment, the abutments 12 are configured for allowing use of conventional teeth prosthesis and, as such, in the abutment shown, the interior threading of the abutment 12 may have a .4 mm spacing and a minor interior diameter of 1.57 mm and a major interior diameter of 2 mm.

As can be appreciated from the above, the prosthesis 1 is a versatile, easy to install, dependable and accurate solution for mandibular reconstructive surgery. The prosthesis 1 not only supports artificial teeth, but allows stable functional movements of the jaw via the anchor 2, and direct attachment of muscles, ligaments and other soft tissues to the framework of the implant.

It is envisaged that the prosthesis 1 may supplant all existing forms of mandibular reconstructive surgery and hence reduce the morbidity and operating time, with better patient outcomes. The full functional rehabilitation capabilities of the prosthesis 1 is the distinct advantage the prosthesis 1 has over existing reconstructive options.
Interpretation

Embodiments:

[181] Reference throughout this specification to "one embodiment" or "an embodiment" means that a particular feature, structure or characteristic described in connection with the embodiment is included in at least one embodiment of the present invention. Thus, appearances of the phrases "in one embodiment" or "in an embodiment" in various places throughout this specification are not necessarily all referring to the same embodiment, but may. Furthermore, the particular features, structures or characteristics may be combined in any suitable manner, as would be apparent to one of ordinary skill in the art from this disclosure, in one or more embodiments.

[182] Similarly it should be appreciated that in the above description of example embodiments of the invention, various features of the invention are sometimes grouped together in a single embodiment, figure, or description thereof for the purpose of streamlining the disclosure and aiding in the understanding of one or more of the various inventive aspects. This method of disclosure, however, is not to be interpreted as reflecting an intention that the claimed invention requires more features than are expressly recited in each claim. Rather, as the following claims reflect, inventive aspects lie in less than all features of a single foregoing disclosed embodiment. Thus, the claims following the Detailed Description of Specific Embodiments are hereby expressly incorporated into this Detailed Description of Specific Embodiments, with each claim standing on its own as a separate embodiment of this invention.

[183] Furthermore, while some embodiments described herein include some but not other features included in other embodiments, combinations of features of different embodiments are meant to be within the scope of the invention, and form different embodiments, as would be understood by those in the art. For example, in the following claims, any of the claimed embodiments can be used in any combination.

Different Instances of Objects

[184] As used herein, unless otherwise specified the use of the ordinal adjectives "first", "second", "third", etc., to describe a common object, merely indicate that different instances of like objects are being referred to, and are not intended to imply that the objects so described must be in a given sequence, either temporally, spatially, in ranking, or in any other manner.

Specific Details

[185] In the description provided herein, numerous specific details are set forth. However, it is understood that embodiments of the invention may be practiced without these specific details. In other instances, well-known methods, structures and techniques have not been shown in detail in order not to obscure an understanding of this description.
Terminology
[186] In describing the preferred embodiment of the invention illustrated in the drawings, specific terminology will be resorted to for the sake of clarity. However, the invention is not intended to be limited to the specific terms so selected, and it is to be understood that each specific term includes all technical equivalents which operate in a similar manner to accomplish a similar technical purpose. Terms such as "forward", "rearward", "radially", "peripherally", "upwardly", "downwardly", and the like are used as words of convenience to provide reference points and are not to be construed as limiting terms.

Comprising and Including
[187] In the claims which follow and in the preceding description of the invention, except where the context requires otherwise due to express language or necessary implication, the word "comprise" or variations such as "comprises" or "comprising" are used in an inclusive sense, i.e. to specify the presence of the stated features but not to preclude the presence or addition of further features in various embodiments of the invention.

[188] Any one of the terms: including or which includes or that includes as used herein is also an open term that also means including at least the elements/features that follow the term, but not excluding others. Thus, including is synonymous with and means comprising.

Scope of Invention
[189] Thus, while there has been described what are believed to be the preferred embodiments of the invention, those skilled in the art will recognize that other and further modifications may be made thereto without departing from the spirit of the invention, and it is intended to claim all such changes and modifications as fall within the scope of the invention. For example, any formulas given above are merely representative of procedures that may be used. Functionality may be added or deleted from the block diagrams and operations may be interchanged among functional blocks. Steps may be added or deleted to methods described within the scope of the present invention.

[190] Although the invention has been described with reference to specific examples, it will be appreciated by those skilled in the art that the invention may be embodied in many other forms.

Industrial Applicability
[191] It is apparent from the above, that the arrangements described are applicable to the medical implant industries.
Claims

1. A mandibular prosthesis comprising:
   temporomandibular anchor configured for fixation to a temporal bone in use; and
   a mandible portion having at least one ascending ramus portion, wherein the ramus portion
   and the temporomandibular anchor portion are secured together by a rotational attachment such
   that the mandible portion is able to:
      rotate at least anteroposteriorly with respect to the temporomandibular anchor; and
      travel mediolaterally with respect to the temporomandibular anchor to facilitate chewing
   and opening and closing of the prosthetic mandible relative to the upper jaw.

2. A mandibular prosthesis as claimed in claim 1, wherein the temporomandibular anchor is
   configured for securement at the root of the zygomatic arch of the temporal bone.

3. A mandibular prosthesis as claimed in claim 2, wherein the temporomandibular anchor is
   shaped to conform substantially with the zygomatic arch of the temporal bone.

4. A mandibular prosthesis as claimed in claim 3, wherein the temporomandibular anchor
   comprises a superiorly projecting lateral flange exposing bone screw fixation holes therein for
   fixation of the superiorly emanating lateral flange to the temporomandibular articular eminence.

5. A mandibular prosthesis as claimed in claim 4, wherein the superiorly projecting lateral
   flange comprises at two rows of screw fixation holes.

6. A mandibular prosthesis as claimed in claim 1, wherein the temporomandibular anchor
   comprises a mediolateral channel being open-ended at the lateral face of the temporomandibular
   anchor and closed at an opposite lateral end thereof.

7. A mandibular prosthesis as claimed in claim 6, wherein the rotational attachment comprises
   the ascending ramus portion terminating in a ball-head and wherein the ball-head is configured for
   insertion into the open-end of the channel at the lateral face to form the rotational attachment.

8. A mandibular prosthesis as claimed in claim 1, wherein the channel is inferiorly open ended
   to as to define an inferior mediolaterally orientated lengthwise opening through which a neck of the
   ball-head extends.

9. A mandibular prosthesis as claimed in claim 8, wherein the channel comprises a substantially
   circular cross-section.

10. A mandibular prosthesis as claimed in claim 8, wherein the channel comprises a substantially
    oval cross-section.

11. A mandibular prosthesis as claimed in claim 10, wherein inferior edges of the inferior
    channel are bevelled to increase the anteroposterior travel of the neck of the ball-head.
12. A mandibular prosthesis as claimed in claim 8, wherein the anchor has an anteroposterior width of approximately 20.7 mm.

13. A mandibular prosthesis as claimed in claim 8, wherein the anchor has a mediolateral width of approximately 19.6 mm.

14. A mandibular prosthesis as claimed in claim 8, wherein the anchor has a height of approximately 13.1 mm.

15. A mandibular prosthesis as claimed in claim 8, wherein the anchor has a superiorly projecting lateral flange having a height of approximately 18 mm.

16. A mandibular prosthesis as claimed in claim 8, wherein the anchor has a superiorly projecting lateral flange having an angle greater than 90° between the face of the lateral flange and an inferior face of the anchor.

17. A mandibular prosthesis as claimed in claim 8, wherein the channel has a diameter of approximately 9.5 mm.

18. A mandibular prosthesis as claimed in claim 17, wherein the ball-head has a diameter of approximately 8.5 mm.

19. A mandibular prosthesis as claimed in claim 18, wherein the ball-head comprises a neck having a diameter of approximately 3 mm.

20. A mandibular prosthesis as claimed in claim 19, wherein the inferior channel comprises an anteroposterior width of approximately 7 mm.

21. A mandibular prosthesis as claimed in claim 19, wherein the inferior channel comprises a mediolateral width of more than approximately 7 mm.

22. A mandibular prosthesis as claimed in claim 9, wherein the inferior opening is restricted towards the lateral face of the temporomandibular anchor.

23. A mandibular prosthesis as claimed in claim 22, wherein the inferior opening defines narrowing nibs towards the lateral face of the temporomandibular anchor.

24. A mandibular prosthesis as claimed in claim 23, wherein the narrowing nibs have sufficient width to allow a neck of the ball-head to be pressed therethrough.

25. A mandibular prosthesis as claimed in claim 1, wherein the ramus portion is angled outwardly from the base thereof.

26. A mandibular prosthesis as claimed in claim 1, wherein the at least one ascending ramus portion is two ascending ramus portions and wherein the mandible portion curves between the two ascending ramus portions.

27. A mandibular prosthesis as claimed in claim 1, wherein the mandible portion comprises dental means engagements.
28. A mandibular prosthesis as claimed in claim 27, wherein the dental means engagements comprise a plurality of teeth prosthesis socket defining abutments located at a superior edge of the mandible portion.

29. A mandibular prosthesis as claimed in claim 28, wherein the abutments comprise an upright body to which the dental prosthesis are fastened and wherein the upright body has a height configured to allow the abutments to traverse through the gums so as to present an upper surface corresponding substantially in elevation with the gum surface.

30. A mandibular prosthesis as claimed in claim 28, wherein the mandible portion comprises six abutments.

31. A mandibular prosthesis as claimed in claim 29, wherein the six abutments comprise three abutments either lateral side of the mandible portion.

32. A mandibular prosthesis as claimed in claim 28, wherein the abutments are spaced by approximately 12 mm.

33. A mandibular prosthesis as claimed in claim 29, wherein the abutments comprise a height of approximately 4.7 mm.

34. A mandibular prosthesis as claimed in claim 28, wherein the abutments comprise a cylindrical body having threading therein.

35. A mandibular prosthesis as claimed in claim 34, wherein the threading has a spacing of approximately 0.4 mm.

36. A mandibular prosthesis as claimed in claim 35, wherein the threading has a major diameter of approximately 2 mm and a minor diameter of approximately 1.57 mm.

37. A mandibular prosthesis as claimed in claim 1, wherein the mandible portion comprises perforations.
38. A temporomandibular anchor configured for fixation to a temporal bone in use wherein, the temporomandibular anchor is configured for forming a rotational attachment with a mandible portion such that the that the mandible portion is able to:

   rotate at least anteroposteriorly with respect to the temporomandibular anchor; and

   travel mediolaterally with respect to the temporomandibular anchor to facilitate chewing and opening and closing of the prosthetic mandible relative to the upper jaw.

39. A temporomandibular anchor as claimed in claim 38, wherein the temporomandibular anchor is configured for securement at the root of the zygomatic arch of the temporal bone.

40. A temporomandibular anchor as claimed in claim 39, wherein the temporomandibular anchor is shaped to conform substantially with the zygomatic arch of the temporal bone.

41. A temporomandibular anchor as claimed in claim 40, wherein the temporomandibular anchor comprises a superiorly projecting lateral flange exposing bone screw fixation holes therein for fixation of the superiorly emanating lateral flange to the temporomandibular articular eminence.

42. A temporomandibular anchor as claimed in claim 41, wherein the superiorly projecting lateral flange comprises at two rows of screw fixation holes.

43. A temporomandibular anchor as claimed in claim 38, wherein the temporomandibular anchor comprises a mediolateral channel being open-ended at the lateral face of the temporomandibular anchor and closed at an opposite lateral end thereof.

44. A temporomandibular anchor as claimed in claim 43, wherein the rotational attachment comprises the mediolateral channel configured for receiving a ball-head of a mandible portion therein and wherein the ball-head is inserted into the open-end of the channel at the lateral face of the anchor.

45. A temporomandibular anchor as claimed in claim 43, wherein the channel is inferiorly open ended to as to define an inferior mediolaterally orientated lengthwise opening through which a neck of the ball-head extends.

46. A temporomandibular anchor as claimed in claim 43, wherein the channel comprises a substantially circular cross-section.

47. A temporomandibular anchor as claimed in claim 43, wherein the channel comprises a substantially oval cross-section.

48. A temporomandibular anchor as claimed in claim 47, wherein inferior edges of the inferior channel are bevelled to increase the anteroposterior travel of the neck of the ball-head.

49. A temporomandibular anchor as claimed in claim 45, wherein the anchor has an anteroposterior width of approximately 20.7 mm.
50. A temporomandibular anchor as claimed in claim 45, wherein the anchor has a mediolateral width of approximately 19.6 mm.

51. A temporomandibular anchor as claimed in claim 45, wherein the anchor has a height of approximately 13.1 mm.

52. A temporomandibular anchor as claimed in claim 45, wherein the anchor has a superiorly projecting lateral flange having a height of approximately 18 mm.

53. A temporomandibular anchor as claimed in claim 45, wherein the anchor has a superiorly projecting lateral flange having an angle of greater than 90° between the face of the lateral flange and an inferior face of the anchor.

54. A temporomandibular anchor as claimed in claim 45, wherein the channel has a diameter of approximately 9.5 mm.

55. A temporomandibular anchor as claimed in claim 45, wherein the channel is configured for receiving a ball-head therein having a diameter of approximately 8.5 mm.

56. A temporomandibular anchor as claimed in claim 45, wherein the inferior channel is configured for receiving a neck of a ball-head therein having a diameter of approximately 3 mm.

57. A temporomandibular anchor as claimed in claim 45, wherein the inferior channel comprises a anteroposterior width of approximately 7 mm.

58. A temporomandibular anchor as claimed in claim 45, wherein the inferior channel comprises a mediolateral width of more than approximately 7 mm.

59. A temporomandibular anchor as claimed in claim 45, wherein the inferior opening is restricted towards the lateral face of the temporomandibular anchor.

60. A temporomandibular anchor as claimed in claim 59, wherein the inferior opening defines narrowing nibs towards the lateral face of the temporomandibular anchor.
INTERNATIONAL SEARCH REPORT

International application No. 
PCT/AU2016/050863

A. CLASSIFICATION OF SUBJECT MATTER

A61F 2/30 (2006.01)  A61F 2/28 (2006.01)  F16C 11/06 (2006.01)

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)

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 practicable, search terms used)


Applicants/Inventors searched using internal databases (provided by IPAustralia)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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**INTERNATIONAL SEARCH REPORT**

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<td>AU 2012100561 B4 (DIMITROULIS) 14 June 2012 see figures 1, 4A, 5A-5B and page 3 lines 4-7, page 4 lines 9-11, page 4 lines 28-29, page 5 lines 7-16, page 6 lines 16-22, page 7 lines 34-35, page 8 line 3,</td>
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<td>WO 2013/034180 A1 (XILLOC MEDICAL B.V) 14 March 2013 See figures 3-5, page 11 lines 6-19, page 9 lines 8-11 and claims 3, 5, 6 and 8</td>
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