US009901506B2

(12) **United States Patent**
Clayton

(10) **Patent No.: US 9,901,506 B2**
(45) **Date of Patent: *Feb. 27, 2018**

(54) **EAR INSERT FOR RELIEF OF TMJ DISCOMFORT AND METHOD FOR USE THEREOF**

(71) Applicant: **Renew Group Private Limited**, Singapore (SG)

(72) Inventor: **Lawrence G. Clayton**, Rockford, IL (US)

(73) Assignee: **Renew Group Private Limited**, Singapore (SG)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **15/088,244**

(22) Filed: **Apr. 1, 2016**

(65) **Prior Publication Data**

US 2016/0213547 A1 Jul. 28, 2016

Related U.S. Application Data

(60) Continuation of application No. 13/912,529, filed on Jun. 7, 2013, now Pat. No. 9,339,376, which is a (Continued)

(51) **Int. Cl.**
A61F 2/18 (2006.01)
A61H 39/04 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61H 1/008*** (2013.01); ***A61F 2/18*** (2013.01); ***A61F 11/08*** (2013.01); ***A61H 39/04*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61F 11/00; A61F 11/08; A61F 2011/085; A61F 2/18
(Continued)

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,230,738 A 2/1941 Baum
4,094,303 A 6/1978 Johnston
(Continued)

FOREIGN PATENT DOCUMENTS

GB 8960 A * 4/1913
JP 3095344 U 7/2003

OTHER PUBLICATIONS

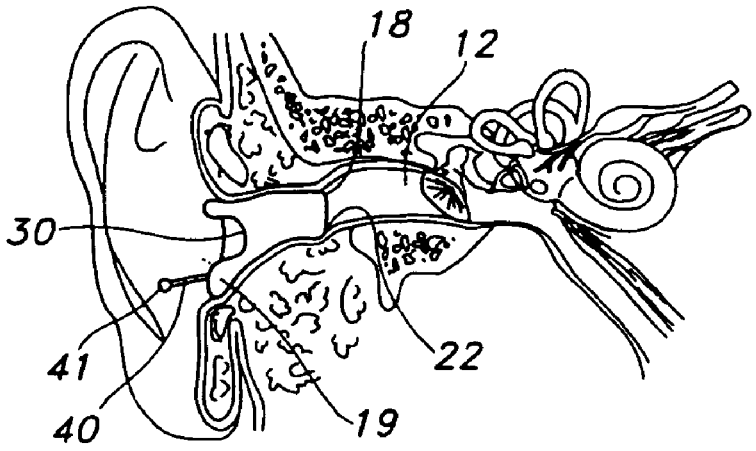
U.S. Patent & Trademark Office, International Search Report in International Patent Application No. PCT/US2008/077339 dated Nov. 29, 2008.
(Continued)

Primary Examiner — Marcia Watkins
(74) *Attorney, Agent, or Firm* — Oakland Law Group PLLC

(57) **ABSTRACT**

A prosthesis for insertion in an ear to reduce pain resulting from TMJ disorders. The ear insert has a predefined shape conforming to the shape of the ear canal when the jaw is in an open position. The ear insert supports the TMJ and associated secondary musculature to reduce strain in the TMJ area, including the muscles, ligaments, nerves, and the temporo-mandibular joint itself. The insert is hollow in the inside to permit hearing and is made of a rigid material which retains the shape of the ear canal. A scalloped indenture extends across a surface of the ear insert positioned behind the tragus.

19 Claims, 1 Drawing Sheet



Related U.S. Application Data

continuation of application No. 13/215,188, filed on Aug. 22, 2011, now Pat. No. 8,460,377, which is a division of application No. 12/075,046, filed on Mar. 7, 2008, now Pat. No. 8,002,829.

(51) **Int. Cl.**
A61F 11/08 (2006.01)
A61H 1/00 (2006.01)

(52) **U.S. Cl.**
CPC . *A61F 2011/085* (2013.01); *A61F 2210/0071* (2013.01); *A61H 2201/168* (2013.01); *A61H 2205/027* (2013.01)

(58) **Field of Classification Search**
USPC 623/10
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,776,322	A		10/1988	Hough et al.	
5,203,352	A		4/1993	Gardner, Jr.	
5,381,484	A		1/1995	Claes et al.	
5,395,168	A		3/1995	Leenen	
5,480,433	A		1/1996	Nadol, Jr.	
5,519,782	A		5/1996	Shinohara et al.	
5,553,152	A		9/1996	Newton	
5,573,015	A		11/1996	Williams	
5,645,584	A		7/1997	Suyama	
5,717,771	A		2/1998	Sauer et al.	
5,769,891	A	*	6/1998	Clayton	A61H 39/04 623/10
5,954,682	A		9/1999	Petrus	
6,055,319	A	*	4/2000	Shennib	H04R 25/00 379/52
6,122,388	A		9/2000	Feldman	
6,337,915	B1		1/2002	Lewis	
6,358,231	B1		3/2002	Schindler et al.	
6,398,758	B1		6/2002	Jacobsen et al.	
7,536,023	B2		5/2009	Leedom et al.	
8,002,829	B2	*	8/2011	Clayton	A61F 2/18 623/10
8,460,377	B2	*	6/2013	Clayton	A61F 2/18 623/10
9,339,376	B2	*	5/2016	Clayton	A61F 2/18
2003/0120333	A1		6/2003	Ouriel et al.	
2006/0052860	A1		3/2006	Gomez	
2006/0098833	A1		5/2006	Juneau et al.	
2006/0167540	A1		7/2006	Masters et al.	
2007/0162119	A1	*	7/2007	Johnson	A61F 2/18 623/10
2007/0179599	A1		8/2007	Brodbeck et al.	
2007/0183613	A1		8/2007	Juneau et al.	
2009/0228103	A1		9/2009	Clayton	
2014/0076336	A1		3/2014	Clayton	

OTHER PUBLICATIONS

U.S. Patent & Trademark Office, Written Opinion in International Patent Application No. PCT/US2008/077339 dated Nov. 26, 2008.
U.S. Patent & Trademark Office, International Search Report in International Patent Application No. PCT/US2010/048613 dated Nov. 1, 2010.
U.S. Patent & Trademark Office, Written Opinion in International Patent Application No. PCT/US2010/1348613 dated Nov. 1, 2010.
U.S. Patent & Trademark Office, International Preliminary Report on Patentability in International Patent Application No. PCT/US2008/077339 dated May 6, 2011.
Sander, Robert: Otitis Externa: A Practical Guide to Treatment and Prevention. American Family Physician. Mar. 1, 2001. vol. 63, No. 5. pp. 927-936.
Extended European Search Report with Opinion, European Patent Application 08873096.5, dated Feb. 6, 2015.

* cited by examiner

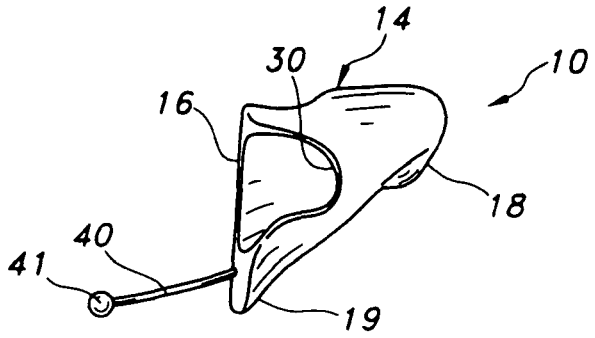


FIG. 1

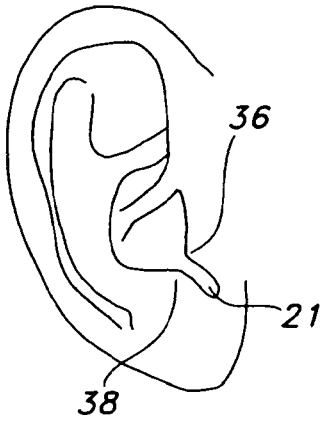


FIG. 2

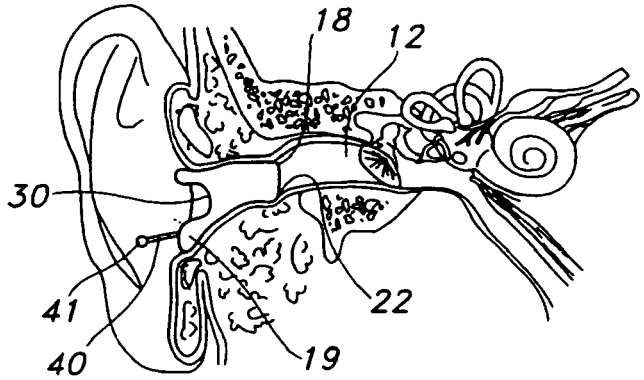


FIG. 3

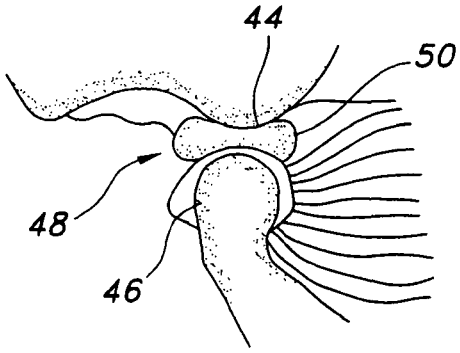


FIG. 4

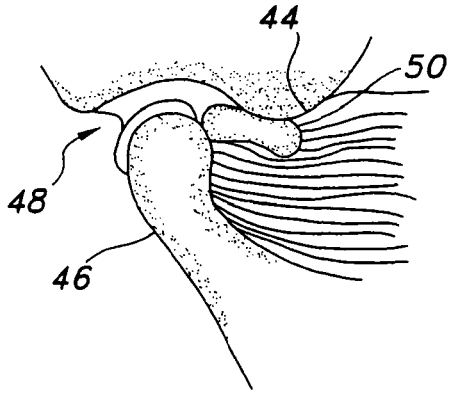


FIG. 5

EAR INSERT FOR RELIEF OF TMJ DISCOMFORT AND METHOD FOR USE THEREOF

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of application Ser. No. 13/312,529, filed Jun. 7, 2013, now U.S. Pat. No. 9,339,376, which is a continuation of application Ser. No. 13/215,188, filed Aug. 22, 2011, now U.S. Pat. No. 8,460,377 which is a division of application Ser. No. 12/075,046, filed Mar. 7, 2008, now U.S. Pat. No. 8,002,829, all of which are incorporated by reference herein.

TECHNICAL FIELD

The present disclosure relates generally to medical devices, and more particularly, to medical devices for alleviation of jaw discomfort.

BACKGROUND

Many people suffer from pain in the joint located between the skull and the jaw. The joint is formed between the temporal bone of the skull and the mandible or jaw bone, and is commonly known as the temporo-mandibular joint or "TMJ". The human body has two temporo-mandibular joints, one located on each side of the jaw in front of each ear. The TMJs move every time a person chews, talks, or swallows.

In greater detail, the TMJ is a paired joint articulating the mandibular condyle, articulator disc, and squamous portion of the temporal bone. The TMJ is capable of both glide and hinge movements. Specifically, the TMJ is formed by the mandibular condyle fitting into the mandibular fossa of the temporal bone. A separation of these two bones is accomplished by the articulator disc which is composed of dense fibrous connective tissue. Ligaments attach the articulator disc to the condyle, permitting rotational movement of the articulator disc during mouth opening and closure.

Displacement of the articulator disc introduces strain to the jaw muscles and causes muscle pain or fatigue around the jaw. In addition, articulator disc displacement often causes a painful clicking in the TMJ during certain jaw movements as the disc moves between normal and displaced positions. A number of other symptoms may occur as a result of a strained disc, including TMJ lock, shoulder, neck, and back pain, and headaches.

Unfortunately, conventional methods of treating temporo-mandibular joint disorders can be costly, physically cumbersome, involve invasive and irreversible treatment or be time consuming. Some conservative methods for treating TMJ discomfort include the use of an intra-oral splint, medication, and life style changes. One type of intra-oral splint is a stabilization apparatus which is used to help alter the posture of the mandible to a more open, relaxed, resting position. Another type of intra-oral splint is an anterior positioning apparatus. The anterior positioning apparatus attempts to decrease the compression load on the joint and alter the structural condyle disc relation. Both types of splints, however, cannot be used full time without risking displacement of teeth. Treatment by medication often involves the use of addictive drugs and/or anti-depressants and therefore can lead to misuse and abuse. In addition, medications often produce adverse side effects in the patient. Other conservative methods include chiropractic or physical therapy. Unfortunately, these methods require extensive time commitments and physical exertion by the patient.

More aggressive treatment of TMJ discomfort includes orthodontic treatment such as grinding down of teeth and various types of surgery. Orthodontic treatments, however, merely indirectly address TMJ pain by adjusting the dental articulation and overall bite of the patient. Furthermore, orthodontic approaches are invasive, irreversible, and expensive.

An alternative procedure and related apparatus for treatment of TMJ discomfort are disclosed in U.S. Pat. No. 5,769,891, the contents of which are incorporated by reference herein in their entirety. According to the disclosure in U.S. Pat. No. 5,769,891, a prosthesis is provided for insertion into the ear canal. The prosthesis has a rigid structural portion of a shape conforming to the ear canal when the jaw is in an open position. The prosthesis provides added support to the TMJ and associated secondary musculature to reduce strain in the TMJ area.

SUMMARY OF THE DISCLOSURE

According to one aspect, the present disclosure provides an ear canal insert for treating TMJ disorders which acts directly on the TMJ and associated ligament and muscle structures to reduce stress and loads placed on the articulator disc located between the temporal bone and the mandible, as well as supportive muscles and ligaments near the TMJ. The insert includes a base portion adapted to reside adjacent the opening of the ear canal with a portion of the base support extending into the inter-tragal notch to reside at a position between the tragus and anti-tragus portions of the outer ear following insertion. The base portion further includes a scalloped indenture extending away from a boundary edge of the base portion across an outwardly facing lateral surface of the insert.

According to another aspect, the present disclosure provides an ear canal insert for treating TMJ disorders which acts directly on the TMJ and associated ligament and muscle structures to reduce stress and loads placed on the articulator disc located between the temporal bone and the mandible, as well as supportive muscles and ligaments near the TMJ. The insert includes a base portion adapted to reside adjacent the opening of the ear canal following insertion. At least one anterior projecting post element projects outwardly away from a boundary edge of the base portion to a position outside of the ear canal to facilitate insertion and removal of the insert.

These and other aspects of the disclosure will become more apparent from the following detailed description when taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an isometric view of an exemplary prosthesis for insertion into an ear canal for treatment of TMJ discomfort;

FIG. **2** is a view illustrating an outer ear;

FIG. **3** is cut-away side view of the prosthesis of FIG. **1** inserted into an ear canal;

FIG. **4** is a side view of a TMJ in an unoccluded position showing a disc in the normal position; and

FIG. **5** is a side view of a TMJ in the closed position showing a disc in the displaced position.

While the concepts of the instant disclosure are susceptible to various modifications and alternative constructions, certain illustrative embodiments thereof have been shown in the drawings and will be described below in detail. It should

be understood, however, that there is no intention to limit the invention to the specific forms disclosed, but on the contrary, the intention is to cover all modifications, alternative constructions and equivalents falling within the spirit and scope of the disclosure as defined by the appended claims and all equivalents thereto.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

Exemplary constructions and practices will now be described through reference to the drawings, wherein like elements are designated by like reference numerals in the various views. For purposes of illustration, FIG. **1** illustrates a prosthesis **10** adapted for insertion into an ear canal **12** as shown generally in FIG. **3**. According to a contemplated practice, the prosthesis **10** includes a hollow structural body portion **14** molded from a substantially rigid material such as acrylic or the like. Accordingly, the structural body portion **14** is substantially incompressible and maintains its shape upon insertion.

In the illustrated construction, the structural body portion **14** is substantially hollow along its length to facilitate sound transmission. The structural body portion **14** has a three-dimensional exterior shape corresponding substantially to the shape of ear canal **12** when a user's mouth is in an open position. Thus, following insertion of the prosthesis **10**, the structural body portion **14** is in substantially conforming relation relative to contours at the inner surface of the ear canal **12** such that the prosthesis **10** is held in a substantially nested relation relative to the interior surface of the ear canal **12**. If desired, one or more additional compressible cushioning layers (not shown) may be provided around at least apportion of the rigid structural body portion **14**. However, such a cushioning layer is in no way essential. By way of example only, and not limitation, materials for forming such a cushioning layer may include PVC, silicone or the like.

As shown in the illustrated construction, the structural body portion **14** includes a proximal base portion **16** and a distal end portion **18**. The proximal base portion **16** is of greater diameter than the distal end portion **18**. As best illustrated in FIG. **3**, the proximal base portion **16** is adapted to be positioned in inserted relation substantially adjacent the opening of ear canal **12**. In the illustrated construction, the proximal base portion **16** includes an extended peninsular leg portion **19** adapted to project generally downwardly when the structural body portion **14** is in inserted position within the ear canal **12**. In this regard, the peninsular leg portion **19** projects into the inter-tragal notch **21** shown in FIG. **2** adjacent to the tragus **36** and the opposing anti-tragus **38** portions of the outer ear. The distal end portion **18** of the structural body portion **14** is adapted to extend approximately to the bend in the ear canal known as the isthmus **22**. The isthmus **22** is in close proximity to the temporo-mandibular joint and is located approximately 20-22 millimeters from the outside of an adult ear. However, this distance may vary in different individuals.

As best illustrated through joint reference to FIGS. **1** and **3**, according to the illustrated construction, a scalloped indenture **30** extends away from an edge of the proximal base portion **16**. In this regard, it is contemplated that the scalloped indenture **30** may be formed by any suitable technique as may be desired. By way of example only, and not limitation, one such technique involves post-formation sculpting using cutting tools or the like although other techniques may be used as desired. As shown, the scalloped indenture **30** extends generally towards the distal end portion **18** and is positioned across a surface of the structural body portion **14** adapted reside immediately behind the tragus **36** and opposing anti-tragus **38** of the outer ear. It is contemplated that the scalloped indenture **30** may have a length and width suitable to accept substantially the entire lobe of the tragus **36** thereby facilitating the ability of the tragus **36** to bend inwardly towards the opening of ear canal **12** substantially without obstruction. Surprisingly, it has been found that the structural body portion **14** incorporating such a scalloped indenture **30** maintains its structural integrity to provide jaw support as described further hereinafter despite the substantial reduction in supporting material.

According to the illustrated construction, it is contemplated that at least one anterior projecting post element **40** may extend away from a surface of the peninsular leg portion **19**. As shown, the post element **40** projects in a direction extending generally away from the distal end portion **18** so as to project towards the exterior of the ear. Following insertion, at least a portion of the post element **40** may reside outside of the ear canal **12** at a position within the vicinity of the inter-tragal notch **21**. In this position, a wearer may grasp the post element **40** to facilitate removal of the insert.

The post element **40** is preferably substantially pliable to enhance insertabilty and removability and to avoid discomfort to the wearer. At the same time, the post element **40** should be characterized by sufficient strength to avoid breakage. By way of example only, and not limitation, it has been found that a suitable post element **40** may be formed from thermoplastic monofilament nylon adhesively bonded onto a surface of the peninsular leg portion **19**. However, other suitable polymeric or non-polymeric materials may likewise be utilized if desired.

As shown, the post element **40** may include a bulbous head portion **41**. Such a bulbous head portion **41** may enhance the ability of a wearer to grasp the post element **40** during removal of the prosthesis **10** from the ear canal **12**. In the event that the post element **40** is formed from nylon or other thermoplastic material, a suitable bulbous head portion **41** may be formed by selectively melting the terminal end of the post element **40** to form a melted polymer bead which is thereafter permitted to resolidify. The surface of the resolidified bead may thereafter be smoothed by sanding or other suitable treatment to remove irregularities so as to enhance comfort during use.

Referring now to FIGS. **4** and **5**, the use of the prosthesis **10** influences the relationship between the temporal bone **44** and the mandible **46** in each temporo-mandibular joint **48**, thereby relieving pain inducing stress in the temporo-mandibular joint **48** and related muscles, ligaments, and nerves. In this regard, it will be appreciated that one source of temporo-mandibular joint discomfort is a dislocated articulator disc **50**. As shown in FIG. **4**, when the jaw or mandible **46** is in an open or unoccluded position corresponding to the mouth being open, the articulator disc **50** is usually in a normal, unstrained position between the temporal bone **44** and a condyle surface of the mandible **46**. As is often the case with a person experiencing temporo-mandibular joint discomfort, the articulator disc **50** slips to a displaced position when the mandible **46** is subsequently closed, as illustrated in FIG. **5**. The displacement of the articulator disc **50** is often indicated by a clicking or popping noise as the mandible **46** moves between open and closed positions. In the displaced position, the articulator disc **50** is no longer between the condyle surface and the temporal bone **44**, and the articulator disc **50** and attached ligaments become

strained. Strain on these members stresses the surrounding muscles, which may ultimately result in face, neck, and back pain.

To treat temporo-mandibular joint discomfort arising from a displaced articulator disc **50**, the prosthesis **10** is provided for reducing stresses and loads on the articulator disc **50**. The prosthesis **10** reshapes the ear canal and provides a rigid structure which helps align the temporo-mandibular joint **48** and associated muscle and ligament structures so that the temporo-mandibular joint **48** has a normal rotational movement . Strain or compression on the articulator disc **50** is therefore reduced, thereby alleviating pain in the temporo-mandibular joint and associated structures.

It is to be understood a dislocated disc is only one cause of temporo-mandibular joint discomfort and that there are many other sources of such pain. Nerves, ligaments, and muscle groups (such as the masticatory musculature) are located proximal to the temporo-mandibular joint, and improper loading, strain, or alignment of these members provide potential sources of temporo-mandibular joint pain. Rather than being limited to disc dislocation situations, as outlined above, the prosthesis **10** addresses misalignment and stress in the temporo-mandibular joint and related structures by supporting these structures for normal rotational movement.

It will be appreciated that the prosthesis **10** alleviates temporo-mandibular joint discomfort by supporting the temporo-mandibular joint **48** and associated muscles, nerves, and ligaments for proper rotation of the mandible between open and closed positions. The prosthesis **10** is formed to correspond to the shape of the ear canal **12** when the mandible **46** is open and disc **50** is in the normal position. When the mandible **46** is subsequently closed, the prosthesis **10** maintains the positioning of the mandible **46** the so that the disc **50** is not displaced. Accordingly, a natural body orifice is used to reposition the mandible **46** without requiring surgery or other painful and invasive techniques. As noted above, the example of a dislocated disc is merely illustrative of a temporo-mandibular joint condition addressed by the present device and is in no means meant to limit the scope of the present invention. Accordingly, it will be appreciated that the present device addresses stresses and misalignments in not only the disc but also any muscles, ligaments, and nerves associated with the temporo-mandibular joint.

It will be appreciated that the foregoing description provides examples of the disclosed apparatus and method of use. However, it is contemplated that other implementations of the disclosure may differ in detail from the foregoing examples. All references to examples herein are intended to reference the particular example being discussed at that point and are not intended to imply any limitation as to the scope of the disclosure or claims more generally. All language of distinction and disparagement with respect to certain features is intended to indicate a lack of preference for those features, but not to exclude such from the scope of the claims entirely unless otherwise indicated.

Recitation of ranges of values herein are merely intended to serve as a shorthand method of referring individually to each separate value falling within the range, unless otherwise indicated herein, and each separate value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context.

Accordingly, this disclosure contemplates the inclusion of all modifications and equivalents of the subject matter recited in the appended claims as permitted by applicable law. Moreover, any combination of the above-described elements in all possible variations thereof is contemplated unless otherwise indicated herein or otherwise clearly contradicted by context.

What is claimed is:

1. A prosthesis adapted to be inserted into an ear canal in an ear having a tragus for treating discomfort in a joint between a mandible and a corresponding temporal bone, wherein the ear canal includes an isthmus, the prosthesis comprising:

a substantially rigid and incompressible structural body adapted to conform to a contour of an interior surface of a portion of the ear canal which extends between an entrance to the ear canal and the isthmus when the joint is in an open position,

wherein said structural body is hollow along its length,

the structural body including a proximal base portion adapted for positioning adjacent the entrance of the ear canal, the structural body further including a distal end portion adapted to extend an effective distance into the ear canal to treat discomfort in the joint,

wherein a scalloped indenture is cut out from the structural body and extends away from a boundary edge of the proximal base portion across a surface of the structural body and is adapted for positioning behind the tragus of the ear.

2. The prosthesis as recited in claim **1**, wherein said structural body is formed from acrylic.

3. The prosthesis as recited in claim **1**, further including at least one post element projecting away from the proximal base portion, the post element adapted to extend to a position outside of the ear canal when the prosthesis is inserted within the ear canal.

4. The prosthesis as recited in claim **3**, wherein said post element is formed from a thermoplastic polymeric or non-polymeric material.

5. The prosthesis as recited in claim **4**, wherein said post element is formed from monofilament nylon.

6. The prosthesis of claim **1**, further comprising at least one compressible, cushioning layer around at least a portion of said structural body.

7. The prosthesis of claim **1**, wherein said proximal base portion has a greater diameter than said distal end portion.

8. The prosthesis of claim **1**, wherein said prosthesis is configured to be held in nested relation relative to the interior surface of the ear canal.

9. The prosthesis of claim **1**, wherein said scalloped indenture has a length and width suitable to accept and surround the tragus thereby facilitating a bending inwardly of the tragus towards the entrance of the ear canal without obstruction.

10. The prosthesis of claim **1**, wherein said proximal base portion includes a peninsular leg adapted to project downwardly.

11. A method of treating discomfort in a joint between a mandible and a corresponding temporal bone, the method comprising:

inserting the prosthesis of claim **1** into an ear canal in an ear having a tragus,

wherein the ear canal includes an isthmus.

12. The method as recited in claim **11**, wherein the structural body is free from any covering.

13. The method as recited in claim **11**, wherein said structural body is formed from acrylic.

14. The method as recited in claim 11, wherein said scalloped indenture is characterized by a length and width sufficient to accept and surround the tragus of the ear.

15. The method as recited in claim 11, wherein the prosthesis further includes at least one post element projecting away from the proximal base portion, the post element extending to a position outside of the ear canal when the prosthesis is inserted within the ear canal.

16. The method as recited in claim 15, wherein said post element is formed from a thermoplastic polymeric material.

17. The method as recited in claim 16, wherein said post element is formed from monofilament nylon.

18. The method as recited in claim 11, wherein the proximal base portion further includes an extended peninsular leg portion adapted to extend into an inter-tragal notch.

19. The method as recited in claim 18, wherein the prosthesis further includes at least one post element projecting away from the extended leg portion, the post element extending to a position outside of the ear canal when the prosthesis is inserted within the ear canal.

* * * * *