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(54) Title: A LIP POSTURE CORRECTOR

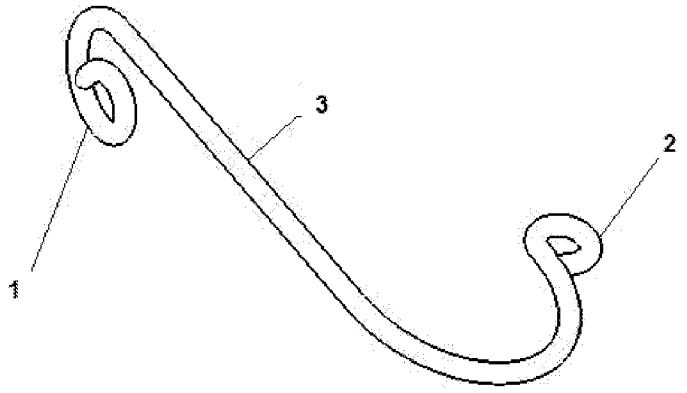

Figure 1

(57) **Abstract:** Disclosed is a lip posture corrector consist of an intra-oral component (1); an ear support component (2); a connector (3) being positioned between the intraoral component (1) and ear support component (2); wherein the device is made up of a combination of polymethylmethacrylate acrylic resin and copolymer of sodium acrylate and acrylamide in a weight ratio 1:2; wherein the sodium acrylate and acrylamide is 10:90 by weight.

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FIELD OF THE INVENTION

The present invention relates to a medical device. More particularly, the present invention relates to a device (could be medically said as a “corrector”) which can improve the lip posture of a patient suffering from facial paralysis.

BACKGROUND OF THE INVENTION

Facial paralysis is a debilitating condition that is often associated with dramatic functional, psychological, and cosmetic sequel. Varied functional deficits pose significant physiologic challenges. The inability to express oneself with spontaneous facial expression or intelligible speech can have extraordinary psychological ramifications, and facial asymmetry can scar a patient’s self-image, rendering him or her less secure in everyday interactions with the world.

Manifestations of facial nerve paralysis are the facial laxity, asymmetric smile, lower lip asymmetry at rest, droopy oral commissure (from the weakened major and minor zygomatic muscles), inspiratory nasal collapse, oral incompetence (difficulty with mastication and speech), lower-eyelidectropion or laxity, lagophthalmos, a sense of disfigurement etc. Therefore, the goals of reconstruction of the paralyzed face may be the facial symmetry at rest, oral competence and eye closure; & voluntary facial movements with spontaneous facial expression

The surgical team has an armamentarium of surgical strategies for facial reanimation. These procedures are categorized as either dynamic or static.

Dynamic procedures aim to reanimate the face by local muscle transfer or by nerve grafting and free muscle transfer; they should be considered in every patient with facial nerve paralysis. But they may not be suitable for a patient who is debilitated or terminally ill (Why). Surgical correction, though, can be done, but it has its own limitations like prolonged treatment time, effects and consequences of surgery itself,

patients existing physical and mental condition to withstand surgery and bear its effects.

Static techniques are employed to suspend the soft tissue structures of the face, but they do not provide facial reanimation. There are often adjunctive maneuvers performed in conjunction with dynamic techniques to enhance facial symmetry.

However, static procedures may also be performed alone for patients who are not candidates for dynamic reanimation procedures (because of physical debilitation, advanced age, increased time delay from injury to repair, or poor health) but who would still benefit from the restoration of facial symmetry.

A literature reveals [Cerio DR. Static reconstruction for facial nerve paralysis. Downloaded from https://emedicine.medscape.com/article/1289348-print] that at times (e.g., in elderly patients), dynamic facial reanimation is not possible or indicated, and static reconstruction is performed. The goals of static suspension procedures are to protect the cornea by restoring eyelid competence, to enhance mastication and speech production through commissure elevation, and to achieve cosmetic improvement by restoring facial symmetry at rest. Not every patient is a suitable candidate for a dynamic procedure for facial reanimation. Patients who are severely debilitated or elderly may not be able to endure the lengthy operations required by dynamic reconstructions, nor can they wait for the delayed results generated by dynamic modalities (which sometimes take as long as 2-3 years to develop), given that their life expectancies are limited by advanced age or terminal illness. For these patients, static suspension of the lower face with autologous or alloplastic materials can provide symmetry at rest and may improve oral incompetence and nasal collapse. These improvements in function enhance quality of life despite life expectancy.

This literature also addresses that the static techniques generally are unsatisfactory as a single modality for rehabilitation of the paralyzed lower face and thus should not be used as a primary modality of reconstruction. Static procedures are most appropriate for debilitated patients who are unable or unwilling to endure the extensive operations of dynamic reanimation or those who are not expected to have a life expectancy beyond the nerve and muscle recovery period following dynamic strategies. They can also enhance dynamic reanimation by augmenting facial symmetry.

A static surgical approach suggested by Rana et al., [Rana H., Shaikh MF., Shah A., Dodia H. Static suspension technique wih fascia lata for facial reanimation in facial palsy. IOSR-JDMS:16(4);90-96] in which it was found that the static facial suspensions are an effective method of correcting facial nerve deficits in cases where nerve repair is not planned or possible.

Another literature [Iseli TA., Harris G., Dean NR., Iseli CE., Rosenthal EL. Outcomes of static and dynamic facial nerve repair in head and neck cancer. Laryngoscope 120:478-483] reveals that although elderly patients with parotid malignancy have traditionally been considered poor candidates for nerve grafting, still it was found that nerve grafting is the good method of facial nerve reconstruction.

As all the aforesaid approaches are surgical, these approaches may not be suitable for the patients who cannot be subjected for surgery due to significant health high risk issues and who have lower lip deficit causing drooping of lip and drooling of saliva, effacement /obliteration of nasolabial fold on the affected side [Affected side means the side which has been affected by paralysis due to inappropriate nerve conduction resulting in loss of muscle function. Due to this, drooping of lip and its consequences as stated above occurs].

Currently, the existing device takes the support from teeth (in persons with teeth present i.e. dentulous) or they are attached to complete dentures (in persons without any teeth i.e. edentulous). These devices are more of support to cheek than lips. Hence they are termed as cheek bumpers or cheek plumbers. They actually have no effect on correction of lip posture. Their function is to correct cheek position and is more of an aesthetic/cosmetic appliance rather than a functional appliance. When these appliances take support from teeth (in dentulous condition), they make the patients very uncomfortable and when these are component of complete denture, (in edentulous condition) these device make complete denture very heavy and reduce the ease of their use.

Currently, various synthetic polymers are used intra-orally. One of the polymers is PMMA i.e. polymethylmethacrylate acrylic resin *[(Bhola et al., Biocompatible Denture Polymers – A Review, Trends Biomater. Artif. Organs, Vol 23(3), pp 129-136 (2010)]* which may be good in view of tensile strength but leaching of MMA resulting stomatitis is reported over this literature. Further PMMA is carciogenic over Bhola et al. Therefore, it is a need of hour to provide a solution such that PMMA can be used intra-orally safely.

Regarding drug treatment, the facial paralysis or idiopathic Bell's palsy are normally treated with oral glucocorticoids such as Deltasone (prednisone) within three days of symptom onset. Individuals with severe cases often receive the combination of Deltasone (prednisone) and Valtrex (valacyclovir). Botox (botulinum toxin) injections can be beneficial for patients who do not completely recover. However, these drugs are known with the side effects.

Prior art:

JP3129305 discloses lip dysplasia correction tool in which the tool is capable of preventing a lip perfection by improving the function of the oral cavity and correcting the dentition by normalizing the posture of the tongue and the posture of the jaw.

JP'305' is applicable for correcting tongue and jaw not lip. Also, it requires the teeth support.

US9936792 discloses a facial lift device to be placed behind the lips and above the gums disposed alongside the buccal and facial surface of a living human maxilla or a human mandible no further than the most posterior tooth of one side to the most posterior tooth of the opposite side of said maxilla or mandible. The facial device embodies an outward lifting force when placed within the human mouth under the lips and alongside the anterior vestibule centered on the frenulum, such that when said facial lift device is forced behind the maxilla or mandible lips, the facial lift will forcibly lift out the dermal layer reducing and removing lower facial wrinkles within the perioral region. US'792' does not suggest the improvement of lip posture. Again it needs the teeth support.

Therefore, there is a need of hour is to provide a non-surgical approach (also could medically be said as an "external device or a lip posture corrector") that could improve/correct the lip posture of a patient suffering from facial paralysis or of those who cannot be subjected for the surgery. There is a further need to provide a solution for correcting lip posture without drugs.

OBJECT OF THE INVENTION

It is an objective of the invention is to provide a device or a corrector that could improve the lip posture of a patient who is suffering from facial paralysis.

It is another objective of the invention is to provide a lip posture corrector for those who cannot be subjected for the surgery for instance surgical sling procedure.

It is yet another objective of the invention is to provide a device for improving the lip posture without teeth support.

It is yet another objective of the invention is to provide a lip posture corrector using a novel polymeric combination.

It is yet another objective of the invention is to provide a lip posture corrector without any toxic effect on human body.

It is yet another objective of the invention is to provide a device which can be used to improve the lip posture of the patients who have undergo MRI or CT scan.

It is another objective of the invention is to provide a lip posture corrector which itself is capable of correcting the lip posture in other words, no oral or other dose is simultaneously required in order to correct the lip posture.

It is further objective of the invention is to provide a lip posture corrector which is cost effective, easy to use and having minimum discomfort.

SUMMARY OF THE INVENTION

Accordingly there is provided a lip posture corrector consists of:

an intra-oral component (1);

an ear support component (2);

a connector (3) being positioned between the intraoral component (1) and ear support component (2);

wherein the device is made up of a combination of polymethylmethacrylate acrylic resin and copolymer of sodium acrylate and acrylamide in a weight ratio 1:2;

wherein the sodium acrylate and acrylamide is 10:90 by weight.

In accordance with these and other objects which will become apparent hereinafter, the instant invention will now be described with componenticular reference to the accompanying drawing.

BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS

Figure 1 illustrates the lip posture corrector in accordance with the present invention;

Figure 2 is the image (front view) of a patient suffering from facial palsy and drooping of the affected side of the lip in accordance with present invention;

Figure 3 is the image (side view) of a patient suffering from facial palsy and drooping of the affected side of the lip in accordance with present invention;

Figure 4 is the image (front view) of a patient illustrating the clinical application of the device in accordance with the present invention;

Figure 5 is the image (side view) of a patient illustrating the clinical application of the device in accordance with the present invention.

Other objects, features and advantages of the inventions will be apparent from the following detailed description in conjunction with the accompanying drawings of the inventions.

DETAILED DESCRIPTION OF THE INVENTION

The phrase “device”, “static suspension device”, “lip posture corrector” herein is the same and could be used interchangeably.

The phrase “static suspension” herein refers to equilibrium or balancing of the lip posture.

The present invention provides a static suspension device for improving a lip posture of a patient suffering from facial paralysis.

As shown in Figure 1, the device of the present invention consists of three components:

an intra-oral component (1)

an ear support component (2)

a connector (3) between the intraoral component (1) and ear support component (2)

In preferred embodiment of the invention, the shape of the intra-oral component and ear support component is the circular or the like.

In preferred embodiment of the invention, the diameter of the intra-oral component is 18-22mm, while the diameter of the ear support component is 41-49mm. In preferred embodiment, the length of the connector is 90-130mm.

The whole device according to the present invention is made up of a polymeric blend which should be met with the following properties i) sufficient strength such that the device would not be deformed during the use; ii) should not exhibit the toxic effect to the user; iii) should be light weight such that the user would not feel the discomfort. In preferred embodiment, the polymeric blend is a combination of polymethylmethacrylate acrylic resin (PMMA) and copolymer of sodium acrylate: acrylamide 10:90 (PAA 1115). Both the polymers are well known in pharmaceutical/medical field for various applications including thickening agent, viscosity enhancer, sustained release polymer. Use of PMMA in denture application is also known *[(Bhola et al., Biocompatible Denture Polymers – A Review, Trends Biomater. Artif. Organs, Vol 23(3), pp 129-136 (2010)].* Bhola et al., addresses PMMA as a good polymer as the strength is concerned, but it leaches the free-radicals (MMA and formaldehyde) which causes stomatitis and this prior art also addresses the MMA/PMMA as carciogenic.

The present inventor surprisingly found that a weight ratio of PMMA and PAA 1115 1:2 provides the desired effect i.e. lip-lifting without the toxic effect of PMMA to the user.

In present invention, the method for preparing the device is known flasking procedure, except the polymer ratio.

As the device of the present invention is made up without metal, it can be used in MRI, CT scan and other detection parameter.

The present invention is now illustrated with non-limiting examples:

Example 1:

PAA 1115 (sodium acrylate: acrylamide 10:90) was purchased from Suyog Chemical, Nagpur, Maharashtra, India and PMMA was procured from SMCO International, Mumbai India.

The working of the device to establish the advantageous effect of the present invention is demonstrated in Figure 2 and 5. The studies were performed at **Krishna Institute of Medical Sciences and Krishna Hospital, Karad** and 10 elder patients suffering from drooping of lip (facial paralysis) and not be subjected to the surgery were chosen from each group as follows:

Group 1: The static suspension device using PMMA and PAA 1115 1:1; &

Group 2: The static suspension device using PMMA and PAA 1115 1:2

Both front (Figure 2 & 4) and side view (Figure 3 & 5) of the patient (Patient 5, Age 68) was taken before and after using the device. The patients (Group 1 & 2) were worn (Figure 4 & 5) the device in which the Intra-oral component (1) was retained through the buccal mucosa and another component (2) was retained through the ear support in a manner like a spectacle (Through connector 3). The patients were given the prescribed oral doses as required for other purposes for instance the patient who was suffering from diabetes and facial paralysis, the prescribed dose of metformin HCl was given but no oral/parenteral dose of the glucocorticoid (as referred in the background) was given to him/her.

The improvement (100%) was evaluated by correcting the lip posture to its original position of above patients and there was symmetry of the lip bilaterally (both left side and right side of the face). For example, if the lip had dropped to 1cm below its

normal level (here normal level means position of the lip on the other unaffected side), and if the device brings the lip position back to its normal position by lifting it to 1cm.

Table 1

Group 1 (The static suspension device using PMMA and PAA 1115 1:1)	Lip drooping/Lip lifting		Side effects
	Lip drooping	Lip lifting	
Patient 1 (Age 60)	0.8cm	0.8cm	Stomatitis
Patient 2 (Age 62)	0.5cm	0.5cm	Stomatitis
Patient 3 (Age 64)	0.9cm	0.7cm	Stomatitis
Patient 4 (Age 66)	0.8cm	0.6cm	Stomatitis
Patient 5 (Age 68)	1.0cm	1.0cm	Stomatitis and allergic reaction
Patient 6 (Age 70)	0.8cm	0.7cm	Stomatitis
Patient 7 (Age 72)	0.8cm	0.7cm	Stomatitis
Patient 8 (Age 74)	0.8cm	0.6cm	Stomatitis
Patient 9 (Age 76)	0.8cm	0.5cm	Stomatitis
Patient 10 (Age 80)	0.9cm	0.9cm	Stomatitis, allergic reaction

Wherein the patient was worn the device up to 6 months from the date of first using the device.

Table 2

Group 2 (The static suspension device using PMMA and PAA 1115 1:2)	Lip drooping/Lip lifting		Side effects
	Lip drooping	Lip lifting	
Patient 1 (Age 60)	0.8cm	0.8cm	No sign of stomatitis and allergic reaction
Patient 2 (Age 62)	0.5cm	0.5cm	
Patient 3 (Age 64)	0.9cm	0.9cm	
Patient 4 (Age 66)	0.8cm	0.7cm	
Patient 5 (Age 68)	1.0cm	1.0cm	
Patient 6 (Age 70)	0.8cm	0.8cm	
Patient 7 (Age 72)	0.8cm	0.8cm	
Patient 8 (Age 74)	0.8cm	0.8cm	
Patient 9 (Age 76)	0.8cm	0.8cm	
Patient 10 (Age 80)	0.9cm	0.9cm	

Wherein the patient was worn the device up to 6 months from the date of first using the device.

Figure 4 & 5 shows the clinical improvement of the lip posture.

The present inventors found that the static suspension device using PMMA and PAA 1115 1:2 shows the desired effects i.e. 100% lip-lifting effect without toxicity (Patient 5, Table 2). Further, the present inventors found that the static suspension

device itself is a sufficient in order to correct the lip posture i.e. without glucocorticoid.

Although the foregoing description of the present invention has been shown and described with reference to particular embodiments and applications thereof, it has been presented for purposes of illustration and description and is not intended to be exhaustive or to limit the invention to the particular embodiments and applications disclosed. It will be apparent to those having ordinary skill in the art that a number of changes, modifications, variations, or alterations to the invention as described herein may be made, none of which depart from the spirit or scope of the present invention. The particular embodiments and applications were chosen and described to provide the best illustration of the principles of the invention and its practical application to thereby enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the componenticular use contemplated. All such changes, modifications, variations, and alterations should therefore be seen as being within the scope of the present invention as determined by the appended claims when interpreted in accordance with the breadth to which they are fairly, legally, and equitably entitled.

CLAIMS:

1. A lip posture corrector consists of:

   an intra-oral component (1);

   an ear support component (2);

   a connector (3) being positioned between the intraoral component (1) and ear support component (2);

   wherein the device is made up of a combination of polymethylmethacrylate acrylic resin and copolymer of sodium acrylate and acrylamide in a weight ratio 1:2;

   wherein the sodium acrylate and acrylamide is 10:90 by weight.

2. The lip posture corrector as claimed in claim 1, wherein the shape of the intra-oral component is circular or the like.

3. The lip posture corrector as claimed in claim 1, wherein the shape of the ear support component is circular or the like.

4. The lip posture corrector as claimed in claim 1, wherein the length of the connector is 90-130mm.

5. The lip posture corrector as claimed in claim 1, wherein the diameter of the intra-oral component is 18-22mm.

6. The lip posture corrector as claimed in claim 1, wherein the diameter of the ear support component is 41-49mm.

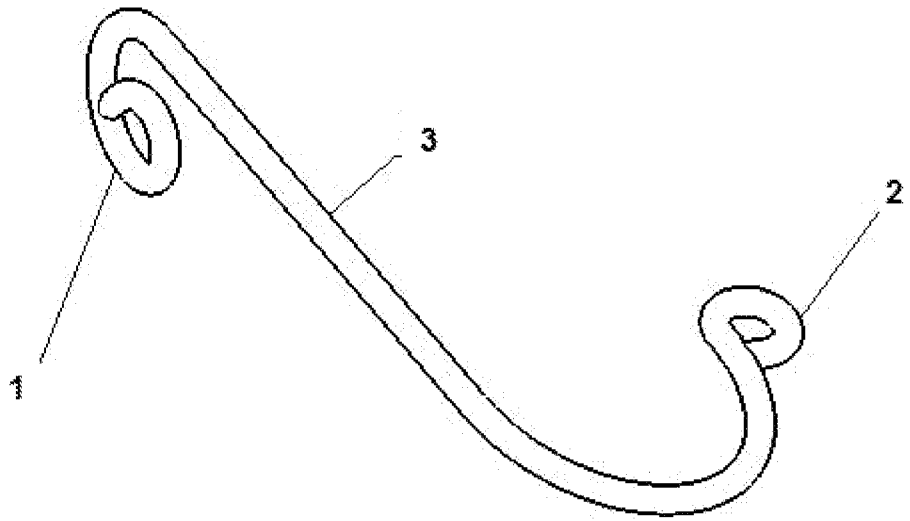

Figure 1

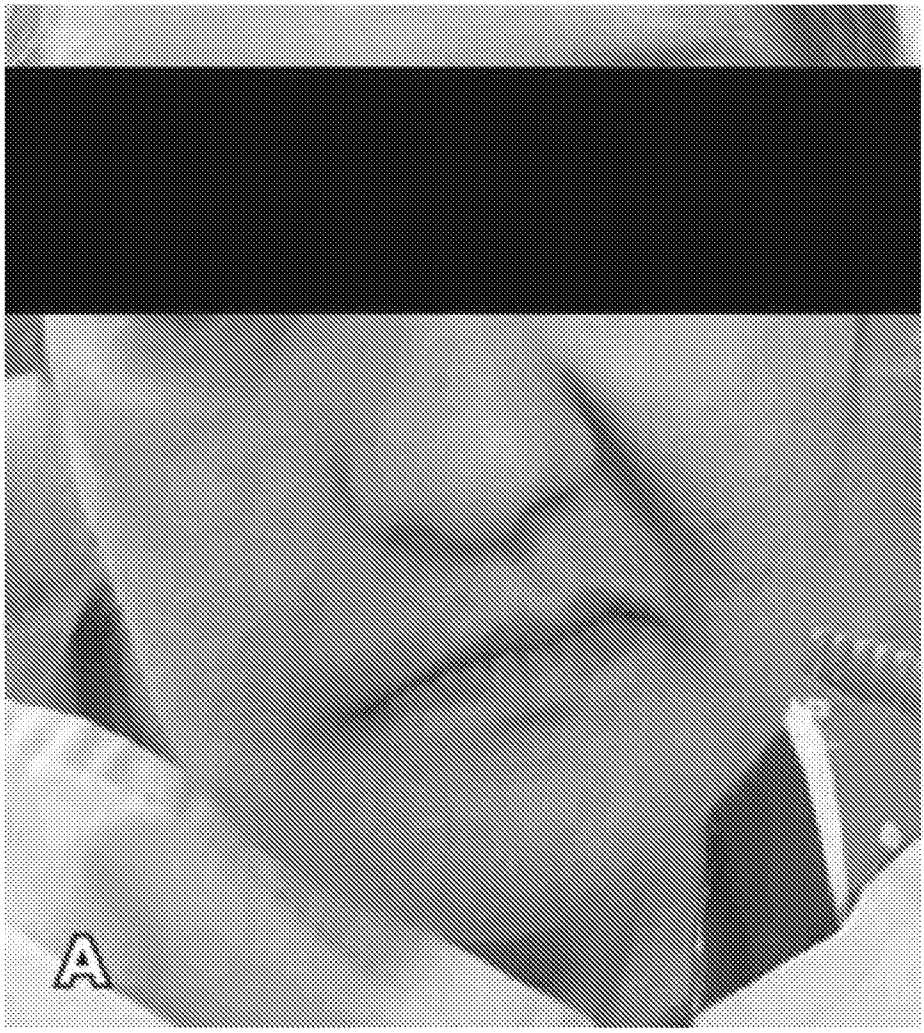

Figure 2

Figure 3

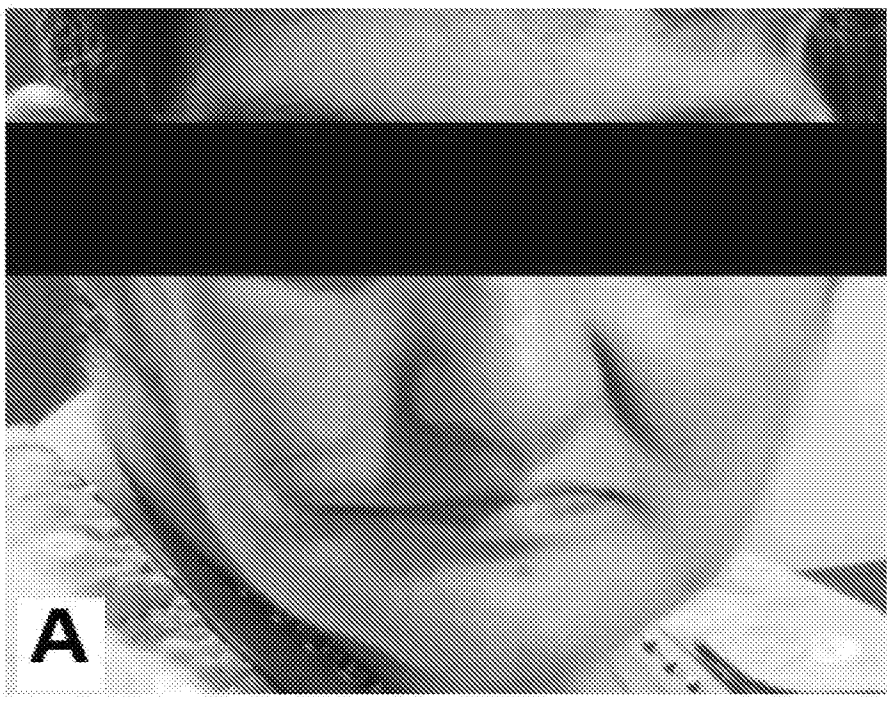

Figure 4

Figure 5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IN2019/050596

A. CLASSIFICATION OF SUBJECT MATTER
A61C7/00,A63B23/03 Version=2019.01

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)

A63B; 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 practicable, search terms used)

DATABASES: TotalPatent One, IPO Internal Database
KEYWORDS: intra-oral component; ear support component;

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	KR100932956B1 (BAIK, OK SEON), 22 December 2009 (22-12-2009). whole document	1-6
A	KR100817325B1 (KOREA MEDICAL SCIENCE INSTITUTE), 27 March 2008 (27-03-2008). whole document	1-6

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"D" document cited by the applicant in the international application
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"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
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17-09-2019	17-09-2019
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