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(54) **METHOD OF TREATING MIGRAINE HEADACHE USING ULTRASOUND AND ELECTROCAUTERY OR RADIOFREQUENCY ABLATION**

(71) Applicant: **Bahman Guyuron**, Lyndhurst, OH (US)

(72) Inventor: **Bahman Guyuron**, Lyndhurst, OH (US)

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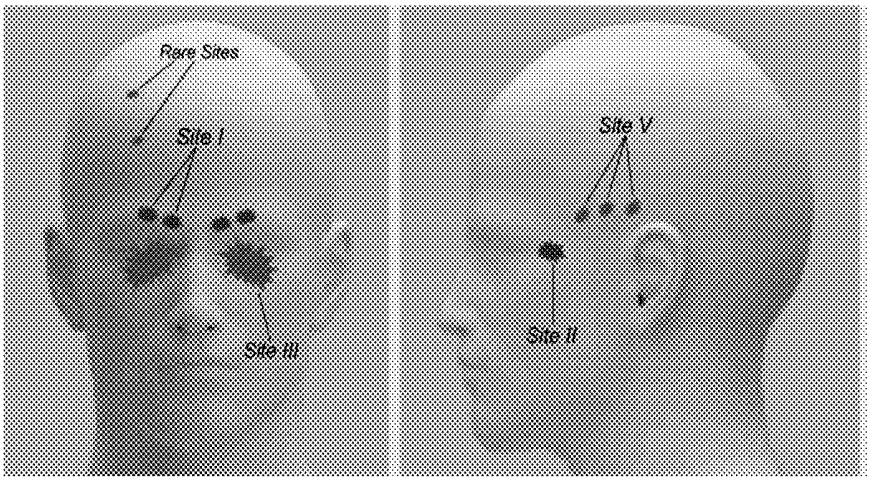
A61B 8/08	(2006.01)

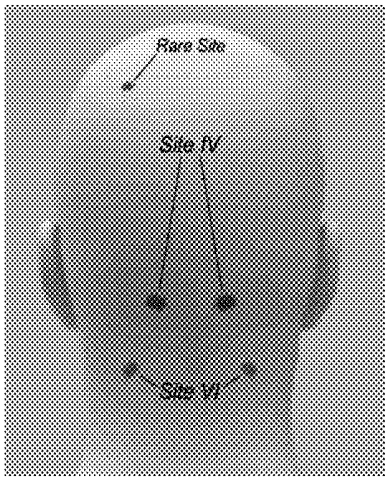
(52) **U.S. Cl.**

CPC ***A61B 18/14*** (2013.01); *A61N 7/02* (2013.01); ***A61B 8/488*** (2013.01); ***A61N 1/0456*** (2013.01)

(57) **ABSTRACT**

A method for treating headaches caused by a blood vessel irritating an associated nerve. The method is performed using a doppler ultrasound device and a treatment device (e.g., electrocautery or radiofrequency ablation). The method includes receiving an estimated location of an origin of the headaches. The estimated location is investigated for a blood vessel using the doppler ultrasound device. When the investigation of the estimated location identifies a blood vessel, the estimated location is cauterized or radiofrequency ablated using the treatment device, such that pressure is reduced on a nerve associated with the identified blood vessel and such that the treatment device does not directly stimulate the nerve.





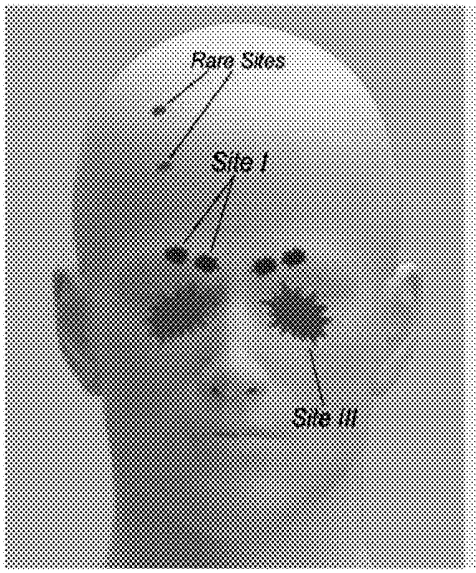


FIG. 1A

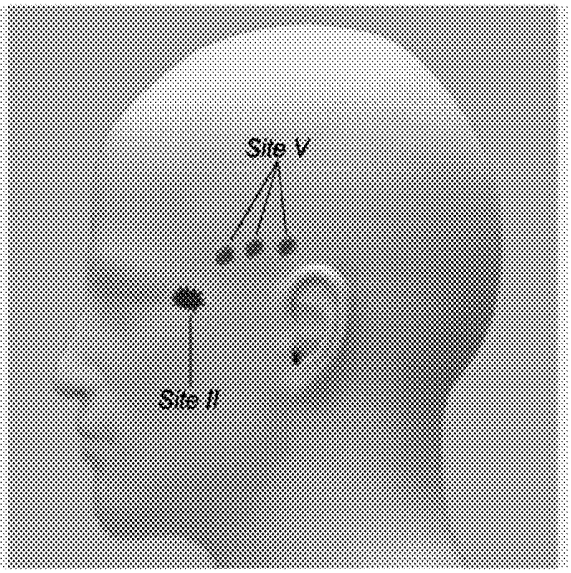


FIG. 1B

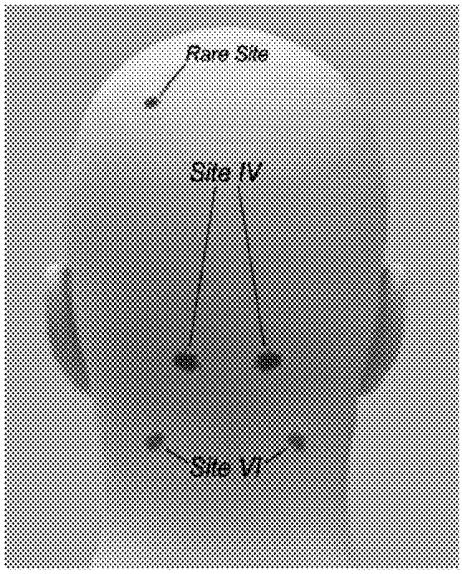


FIG. 1C

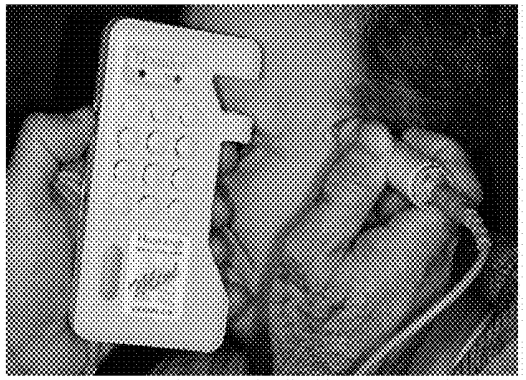


FIG. 2A

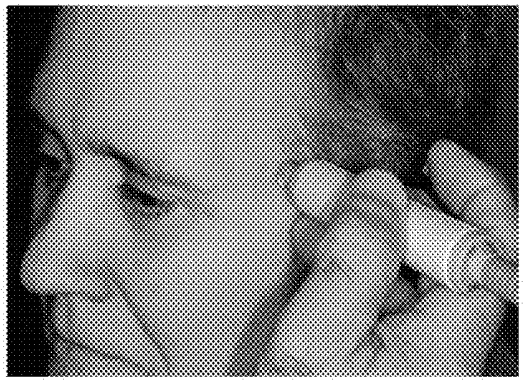


FIG. 2B

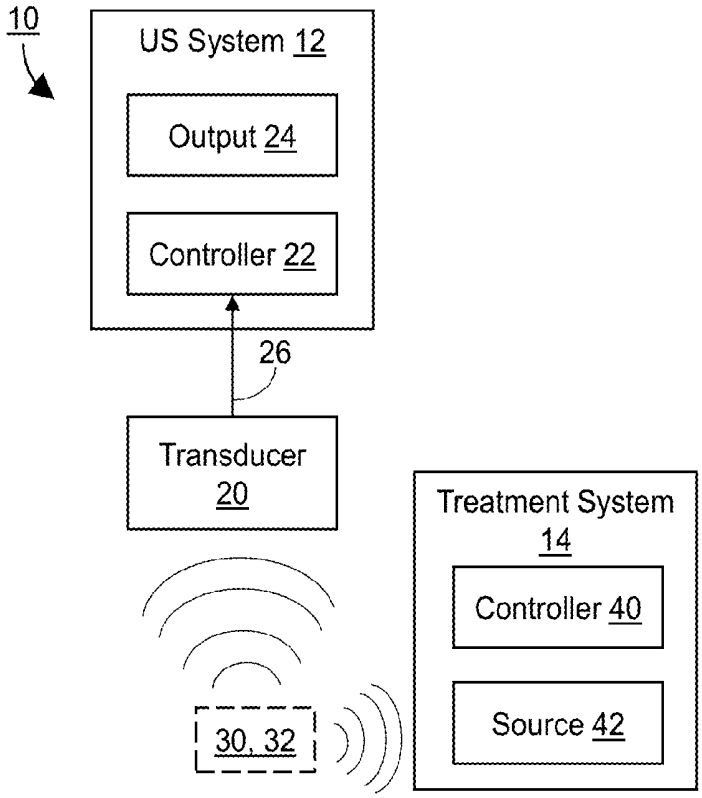

10
US System 12
Output 24
Controller 22
26
Transducer 20
Treatment System 14
Controller 40
Source 42
30, 32

FIG. 3A

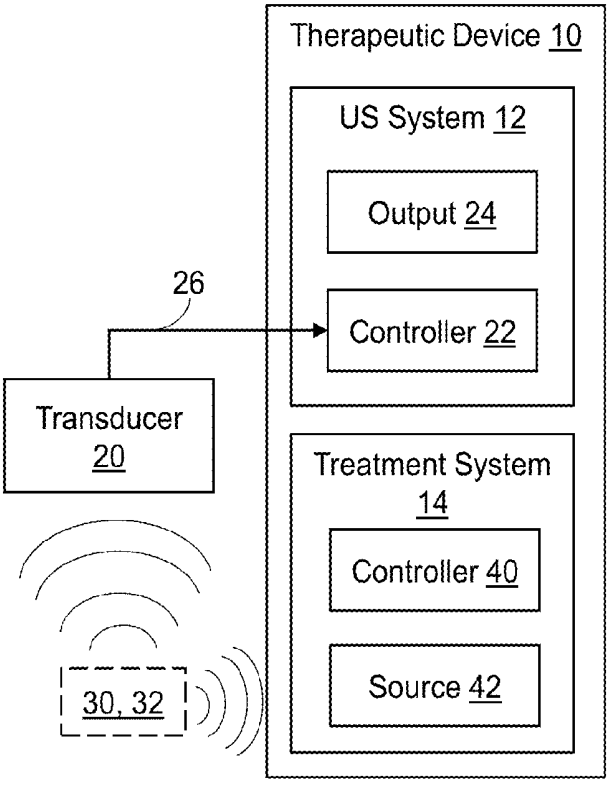

Therapeutic Device 10
US System 12
Output 24
26
Controller 22
Transducer 20
Treatment System 14
Controller 40
Source 42
30, 32

FIG. 3B

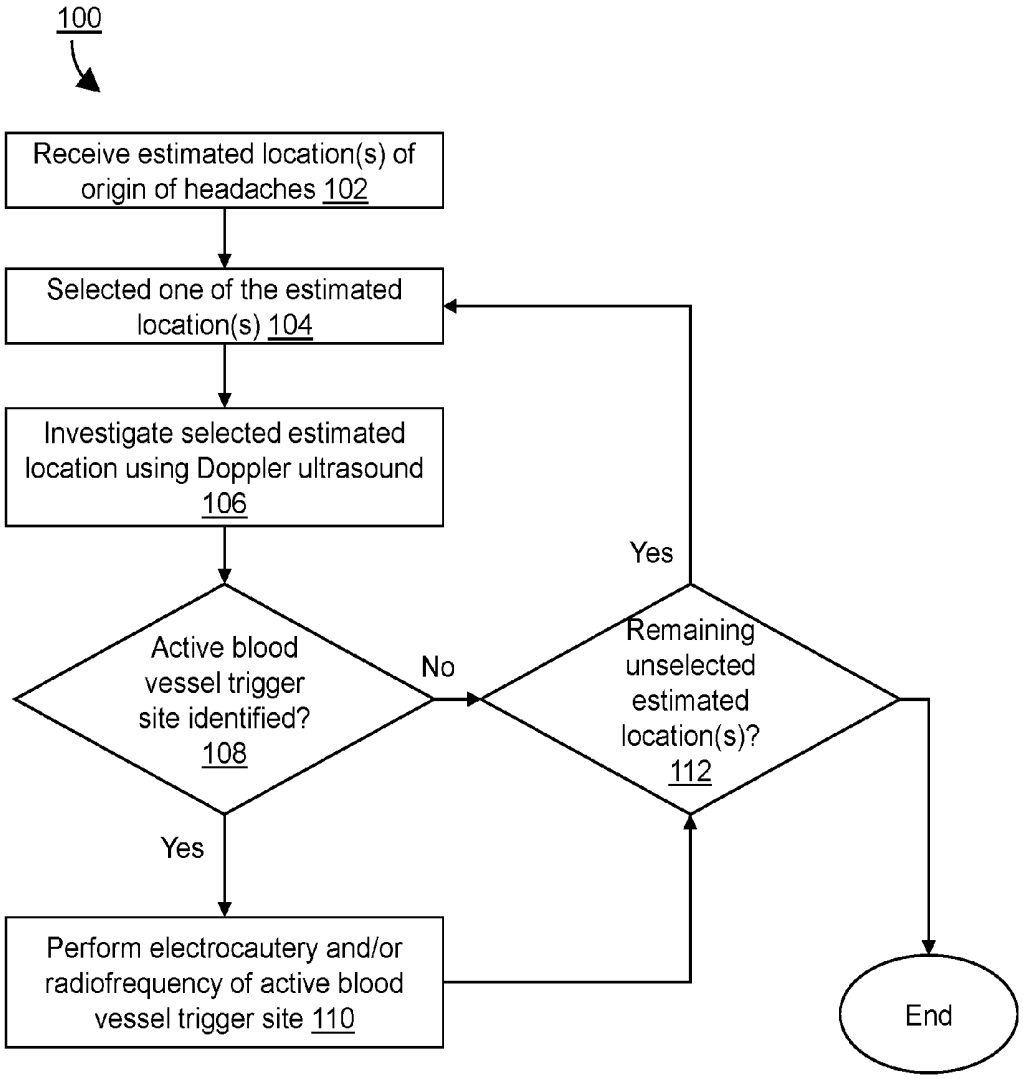

100
Receive estimated location(s) of origin of headaches 102
Selected one of the estimated location(s) 104
Investigate selected estimated location using Doppler ultrasound 106
Active blood vessel trigger site identified? 108
No
Yes
Perform electrocautery and/or radiofrequency of active blood vessel trigger site 110
Remaining unselected estimated location(s)? 112
Yes
End

FIG. 4

METHOD OF TREATING MIGRAINE HEADACHE USING ULTRASOUND AND ELECTROCAUTERY OR RADIOFREQUENCY ABLATION

RELATED APPLICATIONS

[0001] This application claims the benefit of Application No. 62/408,980 filed on Oct. 17, 2016 and Application No. 62/408,184 filed on Oct. 14, 2016. Which are both herein incorporated by reference in their entirety.

TECHNICAL FIELD

[0002] The present disclosure relates generally to treatment of migraine headaches and more particularly to treatment of migraine headache trigger sites using ultrasound and electrocautery or radiofrequency ablation.

BACKGROUND

[0003] Migraine headache is a common and often debilitating neurological condition. A number of surgical techniques have been developed targeting sensory nerves in the head and neck that are thought to play a role in the initiation of migraine headaches. Several clinical studies have verified the efficacy and safety of these surgical techniques, which can result in significant improvement or elimination of migraine headaches in nearly 90 percent of patients, with minimal operative complications. Those surgical interventions target four major and several minor trigger sites that are shown in FIG. **1**. The frontal trigger site (site I) involves the supraorbital and supratrochlear nerves, which are irritated by the glabellar muscles, the surrounding vessels, foramina, and fascial bands. In the temporal trigger site (site II), the zygomaticotemporal branch of the trigeminal nerve is compressed by the temporalis muscle and the tight deep temporal fascia, or irritated by the accompanying vessels. In the rhinogenic trigger site (site III), contact points between the septum, turbinates and concha bullosa, or sinus inflammation can irritate the terminal branches of the trigeminal nerve, triggering migraine headaches. In the fourth major site (site IV), the greater and/or the third occipital nerves are irritated by the semispinalis capitis muscle, fascial bands, and/or the occipital artery. The minor trigger sites consist of the auriculotemporal nerve (site V), which can be irritated by branches of the superficial temporal artery and fascial bands, the lesser occipital nerve (site VI), which can similarly be compressed by fascial bands and the occipital artery branches, and terminal branches of each of these main nerves.

[0004] Despite its high efficacy, a small number of patients who undergo migraine surgery do not have improvement in their migraine headaches. This unfavorable response in some patients has been ascribed to incomplete detection of all of the trigger sites and inadequate decompression of the primary trigger point. When a nerve has multiple compression or irritation points along its course, incomplete relief can be avoided by precise knowledge of the anatomy of the sensory nerves of the head and neck. The compression or irritation points of the frontal, temporal, occipital, and intranasal trigger points have been well described in several detailed anatomical studies.

SUMMARY

[0005] The most common reason for failure of migraine surgery is the presence of multiple trigger sites, which may be masked by a more dominant pain site, thus resulting in failure of detection of all of the trigger sites. With the discovery that not all compression points are muscular, and with the development of new diagnostic modalities, a broader algorithm is needed.

[0006] Identification of trigger sites is essential to treatment of migraine headaches. Each patient's constellation of symptoms can point toward one or multiple trigger points. In the described treatment method, the patient is asked to point to the most frequent site from which migraine headaches originate (e.g., with one fingertip), and then the site is explored with a Doppler ultrasound. If an arterial Doppler signal is identified at the site, it is considered an active blood vessel trigger site. Once a blood vessel trigger site has been identified through this reliable and objective tool, electrocautery and/or radiofrequency ablation is performed on the blood vessel. Ablation/cauterization of the blood vessel reduces pressure on an associated nerve that is responsible for triggering the migraine headache, which results in reduction or elimination of migraine headache symptoms without invasive surgery.

[0007] According to one aspect, there is provided a method for treating headaches caused by a blood vessel irritating an associated nerve. The method is performed using a doppler ultrasound device and an treatment device. The method includes investigating an estimated location of an origin of the headaches for a blood vessel using the doppler ultrasound device. When the investigation of the estimated location identifies a blood vessel, the treatment device is used to cauterize and/or radiofrequency ablate the identified blood vessel, such that pressure is reduced on a nerve associated with the identified blood vessel and such that the treatment device does not directly stimulate the nerve.

[0008] Alternatively or additionally, the estimated location of the origin of the headaches comprises a location on a surface of a head of a patient.

[0009] Alternatively or additionally, a blood vessel is identified when an arterial doppler signal is detected by the doppler ultrasound device.

[0010] Alternatively or additionally, cauterizing and/or radiofrequency ablating the estimated location comprises performing radiofrequency ablation of the estimated location.

[0011] Alternatively or additionally, the estimated location of the origin of the headaches comprises a plurality of estimated locations.

[0012] Alternatively or additionally, each of the plurality of estimated locations are investigated using the doppler ultrasound device and, for each of the plurality of estimated locations at which a blood vessel is identified by the investigation, cauterization and/or radiofrequency ablation is performed using the treatment device.

[0013] Alternatively or additionally, a new estimated location of the origin of the headaches is received following either investigation of the estimated location when a blood vessel is not identified or alternatively after cauterization and/or radiofrequency ablation when a blood vessel is identified. The new estimated location is investigated for a blood vessel using the doppler ultrasound device. When the investigation of the estimated location identifies a blood

vessel, the new estimated location is cauterized and/or radiofrequency ablated using the treatment device.

[0014] Alternatively or additionally, the method also includes, prior to cauterizing and/or radiofrequency ablating the estimated location, investigating the estimated location for an associated nerve. When the investigation of the estimated location identifies a blood vessel and an associated nerve, the estimated location is only cauterized and/or radiofrequency ablated using the treatment device when the identified blood vessel is sufficiently close to the associated nerve to be the cause of the headaches.

[0015] Alternatively or additionally, the identified blood vessel is sufficiently close to the associated nerve to be the cause of the headaches if the blood vessel is within 5 millimeters or 10 millimeters of the associated nerve.

[0016] Alternatively or additionally, the investigating of the estimated location for an associated nerve using ultrasound is performed using either the doppler ultrasound device or an ultrasound device that is separate from the doppler ultrasound device.

[0017] According to another aspect, there is provided a system for treating headaches caused by a blood vessel irritating an associated nerve. The system includes a doppler ultrasound device and an treatment device. The doppler ultrasound device is configured to investigate for a presence of a blood vessel using ultrasound at an estimated location of an origin of the headaches. The treatment device is physically separate from the doppler ultrasound device and is configured to cauterize and/or radiofrequency ablate the identified blood vessel when the investigation of the estimated location identifies a blood vessel, such that pressure is reduced on a nerve associated with the identified blood vessel.

[0018] Alternatively or additionally, the doppler ultrasound device is further configured to investigate using ultrasound the estimated location for a presence of a nerve causing the headaches.

[0019] According to a further aspect, there is provided a device for treating headaches caused by a blood vessel irritating an associated nerve. The device includes a doppler ultrasound transducer configured to investigate for a presence of a blood vessel using ultrasound at an estimated location of an origin of the headaches. The electrocautery source and/or radiofrequency source is physically connected to the doppler ultrasound transducer such that a focal point of the electrocautery source and/or radiofrequency source is focused on the estimated location when the doppler ultrasound transducer is positioned to investigate the estimated location. The electrocautery source and/or radiofrequency source is configured to cauterize and/or radiofrequency ablate the estimated location when the investigation of the estimated location identifies a blood vessel, such that pressure is reduced on a nerve associated with the identified blood vessel.

[0020] Alternatively or additionally, the device also includes a controller configured to cause the electrocautery source and/or radiofrequency source to perform cauterization and/or radiofrequency ablation of the estimated location simultaneously with the doppler ultrasound transducer imaging the estimated location.

[0021] Alternatively or additionally, the device further includes a controller configured to cause the electrocautery source and/or radiofrequency source to perform cauterization and/or radiofrequency ablation of the estimated location sequentially after investigation of the estimated location using the doppler ultrasound transducer.

[0022] Alternatively or additionally, the doppler ultrasound transducer is further configured to investigate using ultrasound the estimated location for a presence of a nerve causing the headaches.

[0023] A number of features are described herein with respect to embodiments of the invention; it will be appreciated that features described with respect to a given embodiment also may be employed in connection with other embodiments.

[0024] The following description and the annexed drawings set forth certain illustrative embodiments of the invention. These embodiments are indicative, however, of but a few of the various ways in which the principles of the invention may be employed. Other objects, advantages and novel features according to aspects of the invention will become apparent from the following detailed description when considered in conjunction with the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] The annexed drawings, which are not necessarily to scale, show various aspects of the invention in which similar reference numerals are used to indicate the same or similar parts in the various views.

[0026] FIG. **1** is a schematic view of the four major and several minor trigger sites.

[0027] FIG. **2** is an image of Doppler ultrasound being used at the temporal triggering site.

[0028] FIGS. **3**A and **3**B are diagrams of a treatment device.

[0029] FIG. **4** is a flow diagram of a method for treating headaches using the treatment device.

DETAILED DESCRIPTION

[0030] A treatment device **10** is shown in FIGS. **3**A and **3**B and a method of treating migraine headaches is described below. The method may be used to treat nummular headaches and any type of headache where a vessel is irritating an adjacent nerve. The treatment device **10** includes a Doppler ultrasound system **12** and a treatment system **14** (e.g., an electrocautery system and/or a radiofrequency ablation system). As is shown in FIG. **3**A, the ultrasound system **12** and the treatment system **14** may be separate devices that are used sequentially or simultaneously, e.g., after injection of small amount of local anesthetic that causes vasoconstriction. Alternatively, as is shown in FIG. **3**B, the ultrasound system **12** and the treatment system **14** may comprise a single integrated unit.

[0031] A user may use the Doppler ultrasound system **12** to identify trigger sites for migraine headaches. For example, a patient may be asked to point toward one or more trigger points from which migraine headaches have previously originated. The area identified by the patient may then be explored with Doppler ultrasound using the Doppler ultrasound system **12**.

[0032] Several of the nerves implicated in migraine headache pathogenesis may intersect with an artery, including the supraorbital and supratrochlear nerves and their branches, the auriculotemporal nerve and its branches, the zygomaticotemporal nerve and its branches, the greater occipital nerve, the lesser occipital nerve, and even the zygomaticofacial nerve. Patients who have such an intersection may

complain of pulsatile, throbbing headache. Doppler ultrasound is used to identify trigger points where an artery is irritating the nerve (see FIG. **4**). Doppler ultrasound is able to pick up an arterial signal at the location of pain identified by the patient. Doppler ultrasound may also be used to identify the location of the nerve.

[0033] The Doppler ultrasound system **12** includes an ultrasound transducer **20**, a controller **22**, and an output **24**. The ultrasound transducer **20** emits and detects ultrasound signals. In particular, the ultrasound transducer **20** emits ultrasound focused at a particular location **30** and detects ultrasound returning from this particular location **30**. The ultrasound transducer **20** outputs a signal **26** representing the ultrasound waves detected by the transducer **20**. The controller **22** controls emission of ultrasound signals by the ultrasound transducer **20** and receives from the ultrasound transducer **20** the output signal **26**. The controller **22** receives the output signal **26** and outputs to the output device **24** an indication of blood flow in particular location **30**. The output device **24** may comprise a speaker, displayer screen, or any suitable device for providing information to a user. For example, the returning Doppler ultrasound signal may be output as sound from the output device **24**. For example, the sound output by the output device **24** may be used to differentiate between an arterial blood vessel and a venous blood vessel.

[0034] If an arterial Doppler signal is identified at the particular location **30** (e.g., the area identified by the patient), then the particular location **30** may be considered an active blood vessel trigger site. Upon detecting a blood vessel trigger site, the treatment system **14** is used to ablate the active blood vessel trigger site.

[0035] Ultrasound may also be used to detect the nerve and/or the blood vessel causing the migraine headache. That is, ultrasound may be used to detect the nerve being triggered by the blood vessel, as well as the triggering blood vessel. Detecting the nerve using ultrasound may be performed using an ultrasound device (e.g., an imaging ultrasound device) separate from the ultrasound device used to emit the doppler ultrasound signal (e.g., the doppler ultrasound device). Alternatively, detecting the nerve using ultrasound may be performed using the same ultrasound device used to emit the doppler ultrasound signal.

[0036] By imaging the nerve as well as the blood vessel, it can be assured that blood vessels unrelated to the nerve are not mistakenly ablated with radiofrequency energy. For example, if a blood vessel is located near a nerve (but the blood vessel is not located close enough to the nerve to cause a migraine headache), then this blood vessel may be left alone and the search for the blood vessel triggering the nerve may continue or for the nerve that is being stimulated or irritated by the muscle, fascia or any other element that is identified with the ultrasound and is treated with the radiofrequency ablation or electrocautery. For example, a blood vessel may be considered close enough to a nerve to cause a migraine headache if the blood vessel is less than 3 millimeters (mm), less than 5 mm, less than 10 mm, or less than 15 mm from the nerve.

[0037] Electrocautery and radiofrequency ablation are medical procedure in which a tissue is ablated using heat generated from alternating current. By applying (e.g., radio) energy to a blood vessel, the targeted blood vessel may be closed. Blood vessels identified as causing migraine headaches often interact with nerves, such that the blood vessel applies pressure on the nerve. This pressure may be the cause of migraine headaches. By using electrocautery and/or radiofrequency ablation to close a blood vessel, pressure is reduced on the nerve, mitigating or eliminating the symptoms of migraine headaches.

[0038] Electrocautery and radiofrequency ablation allows migraine headaches to be treated without directly stimulating the nerve that is causing the migraine headaches and often without the need for general anesthetic. Also, using electrocautery or radiofrequency ablation in this manner specifically treats the desired blood vessel without significant collateral damage (e.g., to adjacent tissues).

[0039] The treatment system **14** includes a controller **40** and a source **42**. The controller **40** directs the source **42** to emit radio energy at a particular location **32**. The particular location **32** of the treatment system **14** and the particular location **30** of the Doppler ultrasound system **12** may be made to overlap, such that when an active blood vessel trigger site is identified at the particular location **30** of the Doppler ultrasound system **12**, the treatment system **14** may be used to cauterize and/or radiofrequency ablate the active blood vessel trigger site. For example, the Doppler ultrasound system **12** and the treatment system **14** may be physically joined (as shown in FIG. **3**B) such that the particular location **30** of the Doppler ultrasound system **12** and the particular location **32** of the treatment system **14** overlap. Alternatively, a user may first use the Doppler ultrasound system **12** to identify an active blood vessel trigger site based on the known relationship between the ultrasound transducer **20** and the particular location **30** of the Doppler ultrasound system **12**. Next, a user may position the treatment system **14** such that the particular location **32** of the treatment system **14** overlaps with the active blood vessel trigger site. The user may position the treatment system **14** based on a known location of the particular location **32** relative to the treatment system **14**.

[0040] A method **100** for treating headaches is shown in FIG. **4**. In process block **102** an estimated location(s) of headache origination is received. In process block **104**, one of the estimated location(s) is selected. In process block **106**, the selected estimated location is investigated using Doppler ultrasound as described above. If the selected estimated location is identified as an active blood vessel trigger site in decision block **108**, electrocautery and/or radiofrequency ablation is performed on the active blood vessel trigger site in process block **110**. If the selected estimated location is not an active blood vessel trigger site or after performing electrocautery/radiofrequency ablation, in decision block **112** a check is made to determine if there are any remaining received estimated location(s) that have not yet been selected and investigated using ultrasound. If there are remaining unselected estimated location(s) then processing returns to process block **104**. As will be understood by one of ordinary skill in the art, as opposed to receiving a number of estimated locations, the method may also operate by receiving a single estimated location for the origin of headaches, investigating this location, and then receiving another estimated location.

[0041] Although the invention has been shown and described with respect to a certain embodiment or embodiments, equivalent alterations and modifications will occur to others skilled in the art upon the reading and understanding of this specification and the annexed drawings. In particular regard to the various functions performed by the above

described elements (components, assemblies, devices, compositions, etc.), the terms (including a reference to a "means") used to describe such elements are intended to correspond, unless otherwise indicated, to any element which performs the specified function of the described element (i.e., that is functionally equivalent), even though not structurally equivalent to the disclosed structure which performs the function in the herein illustrated exemplary embodiment or embodiments of the invention. In addition, while a particular feature of the invention may have been described above with respect to only one or more of several illustrated embodiments, such feature may be combined with one or more other features of the other embodiments, as may be desired and advantageous for any given or particular application.

1. A method for treating headaches caused by a blood vessel irritating an associated nerve, the method performed using a doppler ultrasound device and an treatment device, the method comprising:

using the doppler ultrasound device, investigating an estimated location of an origin of the headaches for a blood vessel;

when the investigation of the estimated location identifies a blood vessel, cauterizing or radiofrequency ablating the identified blood vessel using the treatment device, such that pressure is reduced on a nerve associated with the identified blood vessel and such that the treatment device does not directly stimulate the nerve.

2. The method of claim **1**, wherein the estimated location of the origin of the headaches comprises a location on a surface of a head of a patient.

3. The method of claim **1**, wherein a blood vessel is identified when an arterial doppler signal is detected by the doppler ultrasound device.

4. The method of claim **1**, wherein cauterizing or radiofrequency ablating the estimated location comprises performing radiofrequency ablation of the estimated location.

5. The method of claim **1**, wherein the estimated location of the origin of the headaches comprises a plurality of estimated locations.

6. The method of claim **5**, wherein:

each of the plurality of estimated locations are investigated using the doppler ultrasound device; and

for each of the plurality of estimated locations at which a blood vessel is identified by the investigation, cauterization or radiofrequency ablation is performed using the treatment device.

7. The method of claim **1**, wherein:

a new estimated location of the origin of the headaches is received following either investigation of the estimated location when a blood vessel is not identified or alternatively after cauterization or radiofrequency ablation when a blood vessel is identified;

the new estimated location is investigated for a blood vessel using the doppler ultrasound device; and

when the investigation of the estimated location identifies a blood vessel, cauterizing or radiofrequency ablating the new estimated location using the treatment device.

8. The method of claim **1**, further comprising:

prior to cauterizing or radiofrequency ablating the estimated location, investigating the estimated location for an associated nerve using ultrasound; and

when the investigation of the estimated location identifies a blood vessel and an associated nerve, only cauterizing or radiofrequency ablating the estimated location using the treatment device when the identified blood vessel is sufficiently close to the associated nerve to be the cause of the headaches.

9. The method of claim **8**, wherein the identified blood vessel is sufficiently close to the associated nerve to be the cause of the headaches if the blood vessel is within 5 millimeters or 10 millimeters of the associated nerve.

10. The method of claim **8**, wherein the investigating of the estimated location for an associated nerve using ultrasound is performed using either the doppler ultrasound device or an ultrasound device that is separate from the doppler ultrasound device.

11. A system for treating headaches caused by a blood vessel irritating an associated nerve, the system comprising:

a doppler ultrasound device configured to investigate for a presence of a blood vessel using ultrasound at an estimated location of an origin of the headaches; and

a treatment device that is physically separate from the doppler ultrasound device and is configured to cauterize or radiofrequency ablate the identified blood vessel when the investigation of the estimated location identifies a blood vessel, such that pressure is reduced on a nerve associated with the identified blood vessel.

12. The system of claim **11**, wherein the doppler ultrasound device is further configured to investigate using ultrasound the estimated location for a presence of a nerve causing the headaches.

13. A device for treating headaches caused by a blood vessel irritating an associated nerve, the device comprising:

a doppler ultrasound transducer configured to investigate for a presence of a blood vessel using ultrasound at an estimated location of an origin of the headaches; and

an electrocautery source and/or a radiofrequency source that is physically connected to the doppler ultrasound transducer such that a focal point of the electrocautery source and/or radiofrequency source is focused on the estimated location when the doppler ultrasound transducer is positioned to investigate the estimated location;

wherein the electrocautery source and/or radiofrequency source is configured to cauterize and/or radiofrequency ablate the estimated location when the investigation of the estimated location identifies a blood vessel, such that pressure is reduced on a nerve associated with the identified blood vessel.

14. The device of claim **13**, further comprising a controller configured to cause the electrocautery source and/or radiofrequency source to perform cauterization and/or radiofrequency ablation of the estimated location simultaneously with the doppler ultrasound transducer imaging the estimated location.

15. The device of claim **13**, further comprising a controller configured to cause the electrocautery source and/or radiofrequency source to perform cauterization or radiofrequency ablation of the estimated location sequentially after investigation of the estimated location using the doppler ultrasound transducer.

16. The device of claim **13**, wherein the doppler ultrasound transducer is further configured to investigate using ultrasound the estimated location for a presence of a nerve causing the headaches.

* * * * *

专利名称(译)	使用超声和电烙术或射频消融治疗偏头痛的方法		
公开(公告)号	US20180103992A1	公开(公告)日	2018-04-19
申请号	US15/784329	申请日	2017-10-16
[标]申请(专利权)人(译)	GUYURON巴曼		
申请(专利权)人(译)	GUYURON，巴曼		
当前申请(专利权)人(译)	GUYURON，巴曼		
[标]发明人	GUYURON BAHMAN		
发明人	GUYURON, BAHMAN		
IPC分类号	A61B18/14 A61N1/04 A61B8/08		
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优先权	62/408980 2016-10-17 US 62/408184 2016-10-14 US		
外部链接	Espacenet USPTO		

摘要(译)

一种治疗由刺激相关神经的血管引起的头痛的方法。使用多普勒超声装置和治疗装置（例如，电烙术或射频消融术）执行该方法。该方法包括接收头痛的起源的估计位置。使用多普勒超声装置研究血管的估计位置。当对估计位置的调查识别血管时，使用治疗装置对估计的位置进行烧灼或射频消融，使得与识别的血管相关联的神经上的压力降低并且使得治疗装置不直接刺激血管。神经。