(54) Title: SURGICAL DRILL SYSTEM AND SURGICAL DRILL BIT TO BE USED THEREIN

(57) Abstract: Surgical drill system comprising a mechanical drill bit and means for imaging the vicinity of the drill bit tip, said means comprising: at least one optical fiber having a distal end and a proximal end, said distal end being located adjacent said drill bit tip, an optical processing unit, said proximal end of said at least one optical fiber being operatively connected to said processing unit, said at least one optical fiber directing light transmitted therethrough to the vicinity of said drill bit tip and collecting light reflected back from the vicinity of the drill bit tip, whereby an image in the vicinity of the drill bit tip is produced, wherein at least one optical fiber is housed within the drill bit.
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.
Surgical drill system and surgical drill bit to be used therein

The invention relates to a surgical drill system and to a surgical drill bit to be used therein.

Surgical drills are used to make holes in bone necessary for placement of various types of implants. They are used in orthopaedics but the use has also expanded to dentistry. In the following the invention will be elucidated with reference to dental applications although the invention is not limited to this specific field.

In 2004 the dental reconstructive implant market is estimated at approximately $1.145 million, growing 14-16% annually. The potential for this treatment is still large, as 69% of adults from 35 to 44 years were missing one or more teeth in 2000. An increasingly old population may thus benefit from a prosthetic replacement technique.

Furthermore, the clinical interest of reconstructive treatment should not be ignored. An approximate number of 910.000 osseointegrated implants were placed in the year 2000 only in the USA. This large figure implies that surgical complications affect many patients, even if their relative incidence is not high. Life-threatening perioperative bleeding, nerve lesions, damage to adjacent teeth and inadvertent perforation of the sinus membrane are reported persisting pitfalls.

The surgical procedures start with appropriate anaesthesia of the operating area. Then soft tissue is displaced by carefully cutting and detaching the periosteum membrane from the bone. This process is called flap reflection.

Once the bone is exposed, the first stage is completed and the instrument-set is changed. A series of rotating drill bits are brought into the operating area. During their usage, sufficient saline irrigation should be present, in order to keep the drill cool throughout the procedure. It has to be mentioned that some drilling systems incorporate internal irrigation through channels in the drill. Frequently, small bone fragments have to be retired from the drill end and a vertical oscillating movement is recommended.
for the saline solution to reach the bottom.

Despite all ongoing efforts to enhance patient safety, nerve damage and bleeding due to vessel injuries during bone drilling are still worrying complications in dental implant placement. Other surgical problems that trouble the practitioner are, inadvertent perforation of the sinus membrane, leading to sinusitis and oroantral communication, and damage to adjacent teeth.

Injury to the local nerve induces transient or permanent paresthesia (sensory disturbance) in the area surrounding the chin, in part of the tongue and in the gingiva. Damage to main vessels in the mouth floor is considered a rare complication of implant placement. However, at least ten of these potentially life-threatening episodes can be found in nine published articles. In them, damage to a branch of the lingual or facial arteries, mostly with the surgical drill, leads to a profuse haemorrhage. Blood streaming into the neighbouring tissues produces rapid swelling and tongue elevation, compressing and obstructing the airways.

All reported cases had to be attended in a hospital and most of them needed recovery in the intensive care unit.

From an anatomical point of view, the sub-mental and sub-lingual arteries are the two critical vessels in this kind of surgery. Anatomical variability makes their position and size somewhat uncertain and anastomoses between both of them are known to be common, what complicates haemorrhage contention. Complications are especially probable if the vessels run close to the jaw, for example along an extended fossa lingualis. The soft tissue anatomy that is relevant to assess risk appropriately in a preoperative phase is normally not available in a panoramic radiography or in a CT scan.

US-A-6,068,642 concerns a flexible cable comprising helically wound superelastic fibers, said cable having a drilling tip at its distal end and being housed in an elongated holder for supporting the cable during a drilling operation. Within said housing and adjacent to the drilling cable an optical fibre bundle may be provided permitting the position of the drilling cable to be continuously visualized
as flushing of the drilled site occurs.

US-B-6,419,484 teaches a combination of a dental drill and means for imaging the vicinity of the drill tip, said means comprising at least one optical fiber having a distal end and a proximal end, said distal end being located adjacent said drill tip, and further an optical coherence domain reflectometry (OCDR) unit, whereby the proximal end of said at least one optical fiber is operatively connected to said OCDR unit, and said at least one optical fiber directing light transmitted therethrough to the vicinity of said drill tip and collecting light reflected back from the vicinity of the drill tip, whereby an image of the vicinity of the drill tip is produced.

The optical coherence domain reflectometry system connected via the fiber optics to the dental drill according to this citation enables imaging of an area in front of the drilling area or ablated surface. This allows the user to identify the boundary between decayed and normal enamel (or dentine) or the boundary adjacent sensitive tissue or the nearness of nerves etc. Accordingly the drill of US-B-6,419,484 is surrounded with one or more optical fibers that are external from the mechanical drill bit and are connected to the optical coherence domain reflectometry system to image several millimetres ahead of the ablation surface.

The instant invention is aimed at improving the reliability and accuracy of this known system.

The surgical drill system according to the invention is to this end characterized in that said at least one optical fiber is housed within the drill bit.

With this measure it is possible that the investigative light is brought into close proximity of the bone which is being drilled, allowing for a more reliable and early detection of dangerous areas where drilling has to be avoided.

One possible and relatively straightforward means of housing the at least one optical fiber is to place same in a channel along the axis of the drill bit.

In a further preferred embodiment the surgical drill system of the invention is characterized in that there is a
plurality of optical fibers housed in the drill bit that are arranged around the axis of the drill bit. The thus during operation of the drill bit rotating optical fibers allow for a better detection of dangerous areas at the circumference of the rotating drill bit, albeit at the expense of an analysis that is required of the light reflected back from the vicinity of the drill bit tip that keeps track of the rotating angle of the drill bit, during transmission of the light.

To facilitate the surgical drill system to operate appropriately it is preferable that the at least one optical fiber is operatively connected to said optical processing unit through a rotatable optical interface.


To restrict the accuracy requirements on the construction of the surgical drill system of the invention it is preferred that the said at least one optical fiber is at its distal end provided with a micro-lens.

Several types of micro lenses could be used for this purpose but it is preferred that the micro-lens is selected from the group comprising ball-lens, C-lens, grin-lens.

It is further preferred that at the distal end of the at least one optical fibre a film of thermochromic material is provided. This film of thermochromic material can be used for the purpose of temperature measurement at the spot where the drilling occurs, which is helpful in preventing undesired damage at this drilling spot.

The invention is also embodied in a surgical drill bit, which can be used in the surgical drill system as elucidated above. This surgical drill bit is according to the invention characterized by at least one optical fiber housed therein.
Further preferable embodiments of the surgical drill bit of the invention are specified in claims 9-13.

The invention will hereinafter further be elucidated with reference to a preferred embodiment of the surgical drill system and surgical drill bit of the invention and with reference to the drawing.

In the drawing:
- Fig. 1 schematically shows the surgical drill system of the invention, and the light distribution in a model of the mandibular canal;
- Fig. 2 represents the time response of reflected photons, according to the same model;
- Fig. 3 shows a surgical drill bit according to the invention;
- Fig. 4 shows in detail the distal end of the surgical drill bit;
- Fig. 5 shows an alternative embodiment of the distal end of the surgical drill bit of the invention.

Wherever in the figures the same reference numerals are applied, they refer to the same parts.

US-B-6,419,484 represents an optical coherence domain reflectometry guided dental drill system of the prior art which is further improved by the instant invention. The general working principles of the system of the invention are disclosed in US-B-6,419,484 which document is incorporated herein by reference.

Fig. 1 schematically shows the surgical drill system 1 of the invention comprising a drill bit 2 and means for imaging the vicinity of the drill bit tip.

The said means for imaging the vicinity of the drill bit tip comprise in the shown example one optical fibre 3 having a distal end 4 located adjacent the drill bit tip and a proximal end 5 which is connected to an optical processing unit 6.

Through the optical fibre 3 light is transmitted to the vicinity of the tip of the drill bit 2 and at said distal end 4 light is collected that is reflected back from said vicinity of the tip of the drill bit 2. Using said light that
is reflected back, the processing unit 6 images the vicinity of the drill bit tip.

As Fig. 1 and Fig. 3 show, the optical fibre 3 is at least partly housed within the drill bit 2 in a channel 7 of this drill bit 2.

Another possibility is to house a plurality of optical fibres in the drill bit 2 and arrange them around the axis of the drill bit 2. This is not shown in the drawings but completely clear for the person skilled in the art so that a further elucidation thereof can be dispensed with.

It is preferable that the optical fibre 3 is operatively connected to the processing unit 6 through a rotatable optical interface 10 such as the micro-optical rotary joint mentioned above.

In a manner known to the person skilled in the art the optical fiber is at its distal end 4 provided with a micro lens 14 such as one selected from the group comprising ball lens, C-lens and GRIN lens.

Fig. 4 shows a detail of the drill bit shown in Fig. 3. This detail concerns the construction at the distal end of the optical fibre 3. At this distal end provision may be made for an alignment sleeve 12 in which a ferrule 11 is provided through which the optical fibre 3 is guided. The optical fibre 3 neighbours at its distal end to a micro lens 14, which in the case shown is provided in the form of a GRIN lens 14. At the far side of the optical fibre 3 the GRIN lens 14 is neighboured by a hard window 15.

Fig. 5 shows an alternative embodiment of the distal end of the drill bit tip. The difference of the embodiment shown in Fig. 5 as compared to the embodiment of Fig. 4 is that at the said distal end of the optical fibre 3 a film 13 of thermochromic material is provided. This thermochromic film 13 can be used for deriving a temperature measurement based on the measurement of the reflection peak of the light that returns through the hard window 15.

Returning to Fig. 1, the distribution of light-absorption is shown schematically. It can be seen that the superimposed canal influences heavily the light distribution
in tissue 8, with significant light fluence in the area of interest 9. This light distribution is to be studied and to this end use can be made of different techniques.

A first technique is represented by the time resolved reflected signal that is shown in Fig. 2. The reflected signal exhibits two peaks, the second peak being due to heavy scattering in the cortical enclosure of the canal in the bone structure. It is also possible to apply spatial or frequency domain methods. It is preferred however to apply optical coherence tomography as is generally described by J.G. Fujimoto and M.E. Brezinski in Biomedical Photonics Handbook, chapter 13. CRC Press, Boca Raton, 2003. ISBN 0-8493-1116-0.
CLAIMS

1. Surgical drill system (1) comprising a mechanical drill bit (2) and means for imaging the vicinity of the drill bit tip, said means comprising:
   at least one optical fiber (3) having a distal end (4) and a proximal end (5),
   said distal end (4) being located adjacent said drill bit tip,
   an optical processing unit (6),
   said proximal end (5) of said at least one optical fiber (3) being operatively connected to said processing unit (6),
   said at least one optical fiber directing light transmitted therethrough to the vicinity of said drill bit tip and collecting light reflected back from the vicinity of the drill bit tip,
   whereby an image in the vicinity of the drill bit tip is produced, characterized in that said at least one optical fiber (3) is housed within the drill bit (2).

2. Surgical drill system according to claim 1, characterized in that said at least one optical fiber (3) is housed in a channel (7) along the axis of the drill bit (2).

3. Surgical drill system according to claim 1, characterized in that there is a plurality of optical fibers housed in the drill bit (2) that are arranged around the axis of the drill bit.

4. Surgical drill system according to anyone of the claims 1-3, characterized in that the at least one optical fiber (3) is operatively connected to said optical processing unit (6) through a rotatable optical interface (10).

5. Surgical drill system according to anyone of the preceding claims, characterized in that the said at least one optical fiber (3) is at its distal end (4) provided with a micro-lens (14).

6. Surgical drill system according to claim 5, characterized in that the micro-lens is selected from the
group comprising ball-lens, C-lens, grin-lens (14).

7. Surgical drill system according to claim 5 or 6, characterized in that at the distal end (4) of said at least one optical fiber (3) a film (13) of thermochromic material is provided.

8. Surgical drill bit (2) characterized by at least one optical fiber (3) housed therein.

9. Surgical drill bit (2) according to claim 8, having an axis, characterized in that the at least one optical fiber (3) is housed in a channel (7) along said axis.

10. Surgical drill bit according to claim 8, characterized in that there is a plurality of optical fibers housed therein that are arranged around the said axis.

11. Surgical drill bit according to anyone of the claims 8-10, characterized in that the said at least one optical fiber (3) is at its distal end provided with a micro-lens (9).

12. Surgical drill bit according to claim 10, characterized in that the micro-lens is selected from the group comprising ball-lens, C-lens, grin-lens (14).

13. Surgical drill bit according to claim 11 or 12, characterized in that at the distal end (4) of said at least one optical fiber (3) a film (13) of thermochromic material is provided.
A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B17/16 A61B18/22

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)

A61B

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

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

EPO-Internal, PAJ, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

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<td>A</td>
<td>WO 99/18460 A (ACCUCLASE INC; HARTMAN, RAYMOND, A) 15 April 1999 (1999-04-15) page 10, line 18 - page 15, line 5; figures 1,2A-3B</td>
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Further documents are listed in the continuation of Box C.

See patent family annex.

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Date of the actual completion of the international search

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