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White

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[54] **ANTRAL CATHETER FOR REDUCTION OF FRACTURES**

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[51] **Int. Cl.** **A61f 5/04**
[58] **Field of Search** 128/83, 342, 344, 348, 128/349

[56] **References Cited**

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[57] **ABSTRACT**

An inflatable catheter for insertion into the maxillary sinus cavity via the nasal opening, which when inflated with sterile water or air will exert pressure on the bone surrounding the sinus and will move intruding bone portions such as may be present upon fracture of the maxilla or other bones to reduce such fracture. The catheter head is formed of a pyramidal shape as to conform to the generally triangular configuration of the maxillary sinus.

3 Claims, 4 Drawing Figures

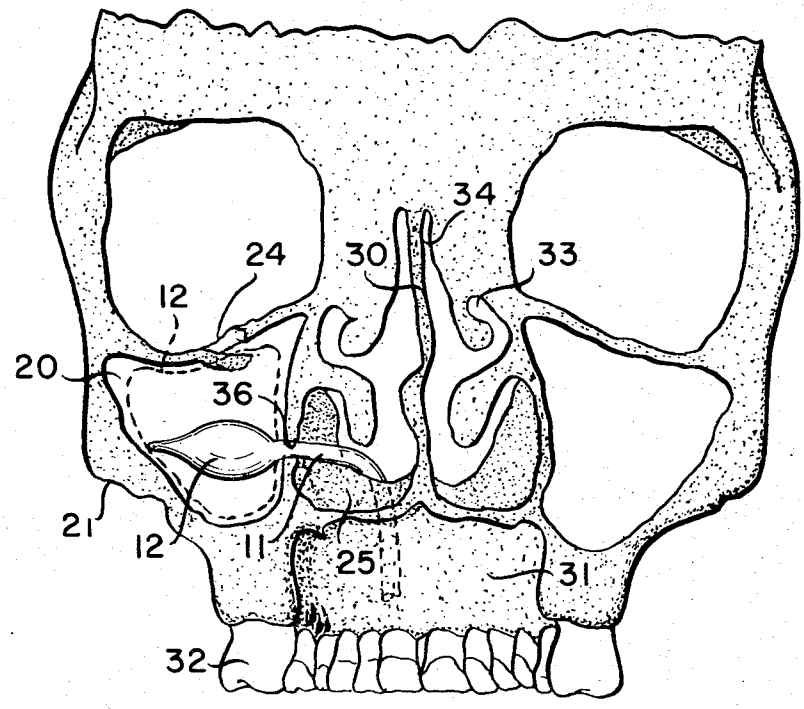


Fig. 1

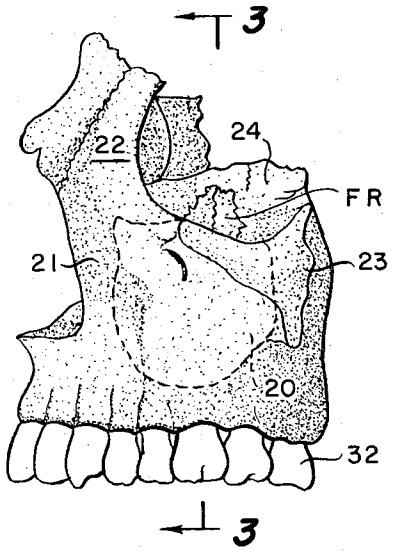


Fig. 2

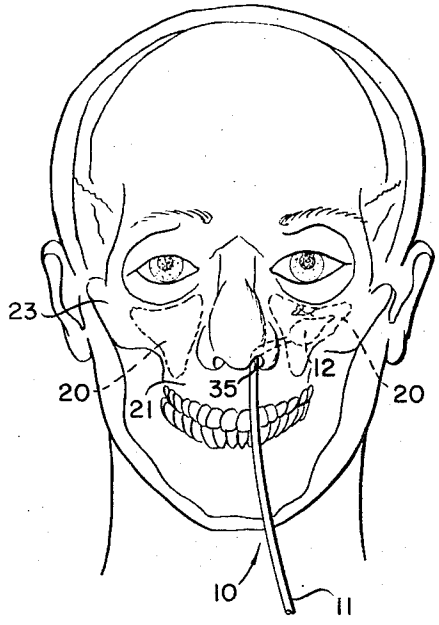
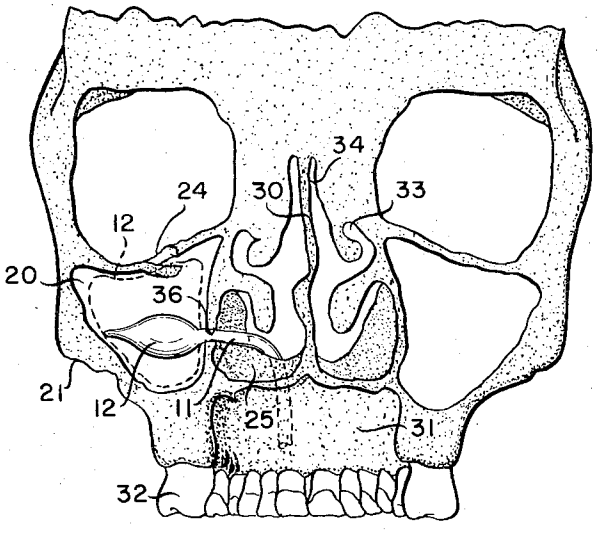


Fig. 3



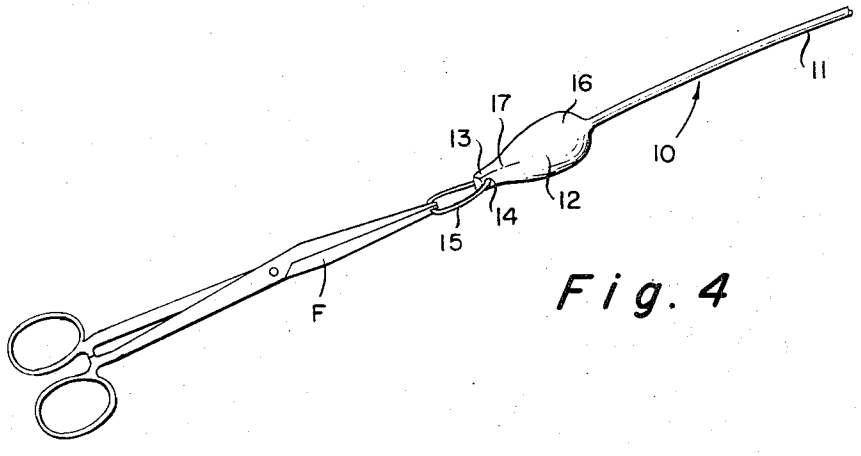


Fig. 4

ANTRAL CATHETER FOR REDUCTION OF FRACTURES

BACKGROUND OF THE INVENTION

This invention relates generally to devices for reduction of fractures of certain facial bones. More specifically, this invention relates to an inflatable catheter construction which may be passed into the maxillary antrum or sinus through the nasal cavity and subsequently inflated with a fluid to provide an outwardly directed force or pressure which will reduce a fracture in the surrounding bone structure.

Fractures of the facial bones, and especially of the floor of the orbit, the zygomatic process, and the lateral and anterior walls of the maxilla, have always presented difficult problems for the surgeon. Reduction and stabilization of fractures in these areas have generally required open reduction with considerable external manipulation. In the alternative procedures have been employed utilizing entrance through the intranasal route and even by the dental route which necessitates the sacrifice and extraction of a molar tooth and subsequent drilling through the alveolar process in order to gain access to the maxillary sinus. All of these present procedures require relatively long operations with their associated trauma and complications and a relatively lengthy convalescent period to insure healing.

Inflatable catheters have been known to the medical professions for many years as exemplified by the patent to Raiche, U.S. Pat. No. 2,687,131, issued Aug. 24, 1954. In such devices, an inflatable cuff or balloon is employed principally as a retention means to prohibit inadvertent withdrawal of the catheter from the body. Inflatable catheters have also been used as pressure exerting devices in numerous procedures where such pressure therapy has been deemed to be useful. The patent to Robison, U.S. Pat. No. 2,525,183, issued Oct. 10, 1950, teaches such a device for application within a sinus to apply interior pressure thereto allegedly to facilitate molecular diffusion and lymph flow in the treatment of sinusitis.

SUMMARY OF THE INVENTION

I have discovered that even internal pressure on the walls of the interior of the maxillary sinus will serve to relocate and reduce most fractures in the bony areas surrounding a sinus cavity. In order to provide an efficient means for obtaining such pressure, I have designed a catheter having a balloon tip of such configuration that upon inflation it will totally fill the void of the sinus which has been found to be somewhat triangular in shape. A generally conical or pyramidal shape has been found to be satisfactory. The tip of this new catheter is formed with means for connection to a suture or the like to assist in its placement within the sinus cavity by use of a hemostat or forceps.

It is a principal object of the present invention to provide an inflatable catheter which applies pressure against displaced bone fragments when inserted within a sinus cavity to reduce a fracture.

It is a further object of this invention to provide an inflatable fracture reducing catheter which may be filled with radio opaque fluid to enable placement utilizing X-ray observation.

A further object of the invention is to provide an inflatable catheter having a head portion of such a shape as to conform to the generally triangular configuration of the maxillary sinus.

Yet a further object of my invention is to provide an inflatable catheter having attachment means adjacent its head for securing a suture or the like to assist in its placement by means of a forceps or a hemostat.

Another object of this invention is the provision of a novel inflatable catheter which is of generally simple construction, is inexpensive, and is safe and efficient in use.

The above and other objects and features of the invention will become more apparent from a consideration of the following disclosure.

BRIEF DESCRIPTION OF THE DRAWING

In the drawings:

FIG. 1 is a side elevation of the left human maxilla and zygomatic bone;

FIG. 2 is an elevation of the human head showing the maxillary sinuses in phantom and the catheter of the present invention in place;

FIG. 3 is a coronal section of the nasal cavities passing inferiorly between the first and second molars looking from the rear forward; and

FIG. 4 is a perspective view of the catheter with associated suture and installation forceps.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The inflatable catheter of the present invention is shown generally at **10** which is preferably formed of flexible rubber such as latex and includes an elongated cylindrical tubular body portion **11** having a central lumen provided therein. An inflatable, specially shaped balloon **12**, preferably conical or pyramidal, is provided at the distal end of the catheter which is in communication with the tube lumen and whereby a suitable fluid may be introduced into the balloon to distend the same.

While the catheter could be formed of plastic, rubber is preferable since it has the characteristic of complete recovery and will return to its original shape when the fluid pressure is withdrawn.

Extending from the distal end of balloon **12** is a solid tab **13** provided with an aperture **14** through which a conventional suture **15** may be drawn and tied to aid in the handling and placement of the catheter. Any suitable gripping instrument such as forceps F or a hemostat may be employed to grip the suture **15** as shown in FIG. **4.**

The balloon is formed in a special shape so as to fill the human maxilla sinus cavity **20** which has a generally triangular or pyramidal configuration. The proximal portion **16** of the balloon **12** is quite wide and tapers toward the distal portion **17.** The transverse section through the balloon at any point along its length is preferably circular, and hence the balloon is generally conical. Since the balloon portion **12** is formed of a thinner wall section than the tube **11,** it is evident that the balloon will expand when a fluid under pressure is introduced through the lumen of the tubular body portion **11.**

In order to better understand the application of the catheter, attention is directed specifically to FIGS. **1–3.**

The maxillary sinus **20** is the largest of the accessory nose sinuses also called the Antrum of Highmore and

is a large pyramidal cavity within the maxilla **21.** Its walls are relatively thin and correspond to the nasal, orbital, anterior, and infra-temporal surfaces of the body of the bone. Its nasal wall presents a large irregular aperture, communicating with the nasal cavity. As seen in FIG. **1,** the frontal process is shown at **22** and the zygomatic bone or process at **23.** Above the maxillary sinus is the floor of the orbit **24.**

In the articulated skull, the aperture noted above is partly closed by the following bones: the uncinate process of the ethmoid, the ethmoidal process of the inferior nasal concha, the vertical part of the palatine, and a small part of the lacrimal. The sinus communicates with the middle meatus **25** generally by two small apertures left between the above-mentioned bones. In the intact body, usually only one small opening is present adjacent the upper part of the cavity; the other is closed by mucous membrane. On the posterior wall of the sinus are the alveolar canals. The floor of the maxillary sinus is formed by the alveolar process of the maxilla, and in the average, the floor is on a level with the floor of the nose. The size of this cavity will be found to vary in different individuals and even on two sides of the same skull. It has been noted, however, that the average maxillary sinus cavity measures approximately 25mm in width from the nasal side to the zygomatic bone; 35mm in height; and 30mm in depth. Its volume is about 14.75cc. Hence, when the balloon of the present invention is inflated, it should extend to at least these average dimensions.

Orientation of the maxillary sinuses may also be seen from FIG. **3.** The nasal cavity is divided by the septum **30** into two symmetrical chambers. The hard palate is designated at **31** and molar teeth **32.** The middle concha **33** and superior meatus **34,** which are nasal passageways, are also depicted. A typical fracture of the floor of the orbit is shown in FIG. **1** at FR. In this case a fracture fragment has intruded into the maxillary sinus and the same must be displaced outwardly to achieve reduction and retained in reduction during healing of the bone.

In use, a suture **15** is first passed through the opening **14** in the catheter balloon **12** and the entire distal end of the catheter with suture is prepared to be passed into the appropriate nasal canal **35.** Preliminary to passage of the catheter, a small hole is punched or drilled through the antrum wall as at **36** by an appropriate trochar or antral burr.

The suture **15** may be grasped by forceps F or otherwise maneuvered through the nasal passage, and under the inferior nasal concha and the hole **36** so that the entire balloon portion **12** of the catheter will rest within the maxillary sinus as in FIG. **3.** It will be apparent that the suture obviates grasping of the ballooon itself with the instrument and damaging or rupturing of the same. Further passage through the small hole **36** is facilitated. The balloon may then be partially inflated with an appropriate fluid such as a saline solution or sterile water to assist in accurate placement. If desired, the inflation fluid may be an appropriate contrast media introduced under moderate pressure. Radiographic study will then permit surveilance of the sinus and proper placement of the catheter. In the preferred procedure, an infra-orbital incision may be made directly under the lower eyelid to permit visual observation of catheter placement and effect. After it is assured that the catheter is in its proper position, additional fluid is introduced through the lumen of the body portion **11** until the balloon has been inflated sufficiently to displace the bone fragments to their proper anatomical position. The body portion **11** may then be clamped off and the catheter left in place for the time required to achieve healing of the bone fracture.

To remove the catheter, the fluid is withdrawn from the balloon. The catheter may then be easily withdrawn from the nasal cavity.

The catheter of this invention may find utility in other procedures involving the maxillary sinus. The literature has discussed the application of pressure to the antral lining for relief of the chronically inflamed Schneiderian membrane. Note the treatment for sinusitis suggested in the patent to Robison, U.S. Pat. No. 2,525,183, issued Oct. 10, 1950. My new catheter construction may be used in the manner suggested in this patent to exert the desired controllable pressure on the walls of the sinus cavity.

I claim:

1. An inflatable one-piece antral catheter for use in the reduction of fractures adjacent the maxillary sinus, including a tubular body portion having a longitudinally extending lumen therein, an integral inflatable elastic balloon on the distal end of said body portion and in communication therewith, said balloon being conical in shape in its flaccid condition, the base of said conical balloon being adjacent the distal end of the body portion, and an integral noninflatable semi-rigid tip means forming the apex of said cone to facilitate handling and insertion of the balloon portion into said sinus cavity, said balloon portion being adapted upon expansion by fluid pressure to exert even presure against the walls of the generally pyramidal shaped sinus cavity.

2. An inflatable catheter as defined in claim **1,** wherein suture-receiving means is formed in the tip means.

3. An inflatable catheter as defined in claim **1,** wherein the wall thickness of said balloon is less than the wall thickness of said body portion.

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