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Development of patient-specific orbital floor implants made of shape memory alloys

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Abstract

The shape memory alloy NiTi has successfully proved in many areas of medical technology. This paper describes the innovative idea and development of orbital floor implants made of NiTi. Pseudoelastic NiTi has the peculiarity to withstand large mechanical deformations of up to 8% without being plastically deformed, i.e. it returns to its original shape with relief of the strain. This material property can be used to produce flexible, yet stable implants. The NiTi implants can be implanted into the body in compressed form through relatively small approaches. Arriving at the fracture position, they develop self-reliantly in the previously memorized shape. The perioperative trauma is reduced. The treatment of orbital floor fractures is often done surgically by use of implants made of rigid materials such as titanium, which are inserted in the eye socket through an open approach on the lower eyelid. Implants made of a pseudoelastic shape memory alloys can help to reduce the required incision length of the approach. It is even possible to insert the implant in a minimally invasive procedure via endoscopic access routes and to completely avoid open approach. In this paper first design variants of pseudoelastic orbital floor implants are presented and considerations on the manufacturing process are made.

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Keywords: NiTi, orbital floor fracture; orbital reconstruction; patient-specific implants; shape memory alloys

1. Introduction

Fractures of the orbit are mostly caused by blunt trauma to the eye, for example, in traffic, work and sports accidents. A special case of orbital fractures represent the isolated orbital floor fractures (blow-out fractures), where only the bottom wall of the orbit is broken. The orbital floor is a relatively thin bony structure. It delimits the orbit of the underlying maxillary sinus [1] (Fig. 1). A fracture of the orbital floor can lead to irruption into the antrum. Soft tissue sinks in the fracture gap and muscles or nerves can be trapped between the bone splinters. The consequences of orbital floor fractures can be, for example, diplopia, movement and nervous disorders and visual limitations [2, 3]. Surgical treatment of orbital fractures has to take place promptly, often with the aid of implants. The implants are used to reconstruct the bony structure of the eye socket. They are supposed to support the defect bone, keep the eyeball in place and allow the attachment of new tissue cells. The implants are usually inserted into the patient by large open accesses, where a lot of soft tissue must be cut (Fig. 2). This is due to the material properties of the commonly used implant material titanium [4]. The used titanium meshes are stiff and inflexible. When placing an access to the defective orbit, a skin incision of at least 3 cm length is created. The incision runs either subciliary [5] or transconjunctivally [6, 7]. To protect the eyeball and the soft tissue in the orbit, the tissue

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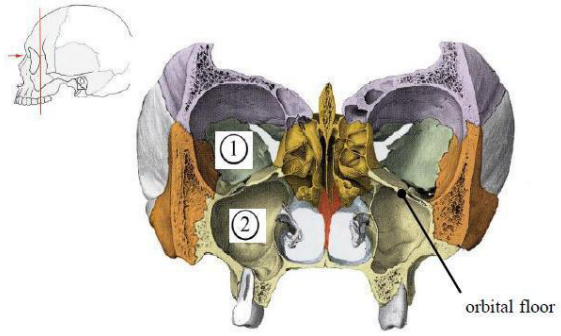

Fig. 1. Schematic sectional view of a skull. The orbital floor is located between the orbit (1) and the maxillary sinus (2). [1]

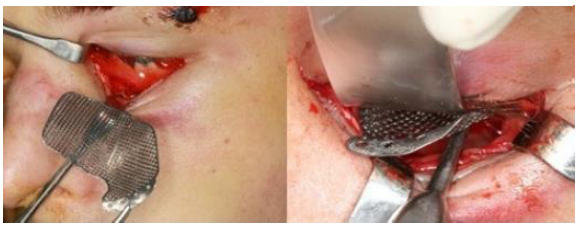

Fig. 2. Insertion of a titanium implant to the orbital floor. The approach is made by an incision at the lower eyelid.

is displaced upward, before the implant is inserted after preparation of the bony supporting surface. The fixation of the implant is often done via a screw on the bony orbital rim. The more soft tissue must be cut during the operation, the greater is the risk of violating critical structures such as nerves, tear ducts or vessels. Furthermore the lower eyelid is at risk due to the incision. The damage can cause eyelid dysfunctions and unfavorable scarring.

Orbital floor implants made of NiTi can help to reduce the risks and complications of orbital reconstructions by reducing the perioperative trauma. Components made of pseudoelastic NiTi can be relatively highly deformed and take back their original form with relief of strain. The implants should be guided in a compact shape through more gently approaches to the fracture location, where they unfold in the final form on their own. A more gently access using the conventional incision on the lower eyelid can be made possible by a reduced incision length. An alternative to this method of operation is the treatment of orbital floor fractures from the side of the maxillary sinus. The access to the maxillary sinus can be minimally invasively realized through the nasal passages (transnasal) or through the oral vestibule (transantral). Transnasal and transantral approaches are already being used to examine the antrum.

In summary, the following objects can be achieved by using implants made of shape memory alloy:

- shorter convalescence and hospitalization times
- reduction of perioperative trauma
- diminution of the risk of injury to the eyeball and other risk structures
- avoid necessary follow-up operations
- no visible scars due to alternative access routes and reduced risk of eyelid malpositions due to smaller open access

2. Requirements for the implants

Basically a material inserted in the human body must be biocompatible because of its direct contact to biological tissue. The implants may be neither toxic nor carcinogenic and do not trigger allergic reactions. Care is also taken that implants show a good corrosion resistance and that they can be sterilized trouble-free. Specific requirements for orbital floor implants exist in shape and positional stability. The bony orbit is a complex anatomical structure. A good fit is necessary in order to enable a firm and stable seat of the implants. Since there are sensitive, easily vulnerable structures in the eye socket, the implants may also not have any sharp corners or edges. Moreover, they must also possess sufficient large perforation holes so that existing wound fluid can drain out of the eye socket. It is assumed that the implant completely covers the fracture and is fixed in a stable position. Since the shape memory implants are inserted in compressed form through smaller accesses, a high flexibility and a high potential of compressibility are required. Simultaneously, a sufficient stability is provided, so that the implant can carry the contents of the orbit without a loss of shape. Since the implant rests – depending on the access method – either on the orbital floor or on the roof of the maxillary sinus, various attachment options must be thought through. Two possibilities would be the fixation via bone screws and the automatic tensioning of the geometry on the surrounding bone. Special requirements also exist with regard to the unfolding mechanisms. When placing through the eyelid incision, the implant is in direct contact with the soft tissues in the eye socket. The unfolding must occur deliberated and slowly to prevent damage to the tissue. The unfolding in the antrum, however, is less problematic. The cavity offers enough space to ensure a free unfolding of the implant.

3. Material

Shape memory alloys (SMA) are functional materials with special properties. Shape memory describes the peculiarity of a material to be able to remember a previously memorized shape. The basis for this extraordinary property is a crystallographic reversible phase transformation in the material. Shape memory alloys may show different effects. For the orbital floor implants the property of pseudoelasticity is used. Pseudoelasticity is based on the mechanical memory of the material. Even after large strains and deformations of up to 8 %, the material is able to assume its original shape when the strain is withdrawn. The maximum reversible deformation is thus many times higher than that of ordinary metals ($\leq$ 1%).

Shape memory alloys are used in a wide variety of research areas. Pseudoelastic shape memory alloys are often used in medical applications. The most famous product - NiTi stents –