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# Technical concept of patient-specific, ultrahigh molecular weight polyethylene orbital wall implant

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ABSTRACT

*Introduction:* The authors have been using patient-specific implants since 2006 and are constantly looking for new reconstructive materials, in order to create precise implants for orbital reconstruction. Such materials should be biocompatible and stable in the human body, as well as easy to machine and form into complex 3D shapes. Biocompatible ultrahigh molecular weight polyethylene (UHMW-PE) has several unique properties including high impact strength and a low friction coefficient that result in self-lubricating and thus non-sticking surfaces after processing.
*Aim:* To present the concept of a patient-specific, UHMW-PE orbital wall implant.
*Materials and methods:* The material used to manufacture the orbital implant was UHMW-PE converted into a solid block of medical polymer from a powder material. A delayed treatment unilateral orbital fracture case was chosen for reconstruction with patient-specific orbital wall implant. On the basis of computerized tomography, a virtual model of both orbits was prepared. The injured orbit was significantly enlarged due to dislocation of its walls. The 3D model of the facial skeleton was symmetrically divided into two parts. This resulted in two models – left and right orbit, then the uninjured orbit was superimposed onto the contralateral side. As a result two surfaces were created; the outer surface (taken from the injured orbit) was used to design the outer surface of the implant, and the inner (taken from the uninjured orbit) for the inner surface. By combining both these surfaces it was possible to determine the unique shape and thickness of the UHMW-PE implant that would allow for accurate reconstruction of the orbit. Following this, the CAD model was transferred to CAM software and a numerical code for a 5-axis milling machine was generated. The manufactured implant was sterilized in gas plasma and used to reconstruct three orbital walls.
*Results:* The thickness of the manufactured implant ranged from 0.2 mm to 1.5 mm and was successfully inserted via transconjunctival approach. The lower, medial and lateral walls were reconstructed. The correct position of the right eyeball was re-established by moving it upward and medially, which resulted in enophthalmos and diplopia correction. The described method features several advantages: accurate reconstruction of the original shape of the orbit, precise modification of local implant thickness during design of the CAD model, structural globe support combined with a thin implant, the possibility of repairing large orbital floor defects, corrections using scissor/scalpel during surgery are relatively uncomplicated, low level of morbidity, smooth edges and gradual, controlled variations in implant thickness between different regions. Disadvantages: changes to the curvature of the implant cannot be made during surgery, implant may require fixing with screws to be stabilized during the early phase of healing, long time required to design and manufacture implants (pre-op) and also UHMW-PE implants are radiolucent and cannot be imaged using X-rays.
*Conclusion:* UHMW-PE appears to have numerous advantages as a material for precise reconstruction of the orbits. Such patient-specific implants are durable, can even be used to reconstruct very thin walls, do not exhibit the high degree of morbidity typical for autogenous bone grafts and result in restoration of vision function.



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Since 2006 individual implants have been used for the reconstruction of orbital fractures (Schön et al., 2006; Kozakiewicz et al., 2009). This method is very promising because of the excellent ophthalmologic results that can be achieved (Kozakiewicz et al., 2011, Loba et al., 2011; He et al., in press). High-density polyethylene (HDPE) implants have been used with good results to restore the anatomical architecture of the human skeleton (Frodel and Lee, 1998; Liu et al., 2004; Hwang et al., 2009; Xu et al., 2009; Rhim et al., 2010; Kashkouli et al., 2011; Kirby et al., 2011). Results are comparable to reconstruction with the use of autogenous bone (Wajih et al., 2011). The rate of complications associated with this material is only 6.4% (Lee et al., 2005). However, the thickness of the implant is usually much greater than 0.5 mm (Tabrizi et al., 2010), and precise modification of thickness is limited. Sandwich onlays are commonly performed in order to increase implant thickness, although accurate control of the orbit shape and volume is difficult with this method. This in turn, makes restoration of the native orbital anatomy challenging.

The aim of this study was to present a unique method of orbital wall fracture reconstruction developed by the authors, using a custom implant made of ultrahigh molecular weight polyethylene.

## 1. Material and methods

Bioethics Committee approval was obtained for this study (Medical University of Lodz RNN/266/11/KB). Medical grade powder UHMW-PE for surgical implants produced in accordance with ISO 5834-1 2007 type 1, ISO 5834-2 2006 type 1 and ASTM F 648-07 type 1 standards (Ticona Engineering Polymers, 2011, Florence, USA; www.ticona.com) was chosen as the substrate material (Table 1). This material is a linear polyolefin resin in powder form with a molecular weight of approximately 5.0 MM calculated using Margolies' equation. The extremely high molecular weight of this resin yields several unique properties including high impact strength, low friction coefficient that result in self-lubricating, and thus non-sticking surfaces after processing. MediTECH, Quadrant Deutschland GmbH (Vreden, Germany; www.meditechpolymers.com) produced the final solid material from raw powder. The patient-specific orbital implant was manufactured from powder series lot no. 0000464290, and was certified for medical use (Table 2). After that, the substrate resin was processed by compression moulding and ram extrusion. The moulded forms were annealed under nitrogen atmosphere at 1100 °C. Next, the final material was tested for foreign substances and found to meet the technical requirements according to ISO 5834 part 2 and ASTM F 648 for moulded forms made of UHMW-PE moulding material for surgical implants (Table 3).

A case of delayed treatment of orbital fracture was chosen for this novel method of reconstruction. The fracture had been caused by a blunt injury to the right orbit 10 months earlier. Since then the patient had suffered from diplopia and had to use forced neck position to minimalize the degree of diplopia. Loss of binocular single vision was 65% of the vision field. The patient underwent high resolution computerized tomography (64-slice scanner, 0.6 mm layers, Siemens) in order to image the pathology. CT imaging showed involvement of the orbital floor, medial and lateral walls together with the lateral and lower rims. The orbital destruction intensity (ODI) was established as level 7 of the 8-level scale (Kozakiewicz et al., 2011). The lateral segment of the lower orbital rim and the floor were dislocated inferiorly, whilst the lateral rim inferior to the fronto-zygomatic suture and the lateral wall were dislocated laterally. Furthermore, the bone defect present in the medial wall resulted in medial dislocation of that wall. As a result of these dislocations, the overall volume of the orbit had increased and produced 5-mm deep enophthalmos.

**Table 1**
General substrate (UHMW-PE) characteristics according to Ticona Engineering Polymers, 2011.

| Physical features | Test standard | Value | Unit |
|---|---|---|---|
| Density | ISO 1183 | 930 | kg/m$^3$ |
| Elongational stress $F$ (150/10) | ISO 11542-2 | 0.22 | MPa |
| Intrinsic viscosity | ISO 1628-3 | 2100 | ml/g |
| Viscosity number | ISO 307, 1157, 1628 | 2400 | cm$^3$/g |
| Mechanical features | | | |
| Tensile modulus (1 mm/min) | ISO 527-2/1A | 720 | MPa |
| Tensile stress at yield (50 mm/min) | ISO 527-2/1A | 17 | MPa |
| Tensile strain at yield (50 mm/min) | ISO 527-2/1A | 20 | % |
| Nominal strain at break (50 mm/min) | ISO 527-2/1A | >50 | % |
| Tensile creep modulus (1 h) | ISO 899-1 | 460 | MPa |
| Tensile creep modulus (1000 h) | ISO 899-1 | 230 | MPa |
| Charpy impact strength (140 V-notch both sides) | ISO 11542-2 | 210 | kJ/m$^2$ |
| Shore hardness D scale 15 s value | ISO 868 | 60 | – |
| Ball indentation hardness | ISO 2039-1 | 36 | N/mm$^2$ |
| Thermal features | | | |
| Vicat softening temperature B50 (500 °C/h 50 N) | ISO 306 | 80 | °C |
| Coefficient of linear thermal expansion (parallel) | ISO 11359-2 | 2 | $10^{-4}$/°C |
| Thermal conductivity at 230 °C | Ticona | 0.41 | W/(m K) |
| Specific heat at 230 °C | Ticona | 1.84 | kJ/(kg K) |
| Electrical features | | | |
| Relative permittivity – 100 Hz | IEC 60250 | 2.1 | – |
| Relative permittivity – 1 MHz | IEC 60250 | 3 | – |
| Dissipation factor – 100 Hz | IEC 60250 | 0.00039 | – |
| Dissipation factor – 1 MHz | IEC 60250 | 0.001 | – |
| Volume resistivity | IEC 60093 | >1012 | Ohm*m |
| Surface resistivity | IEC 60093 | >1012 | Ohm |
| Electric strength | IEC 60243-1 | 45 | kV/mm |
| Comparative tracking index (CTI) | IEC 60112 | 600 | – |

The described method assumes that the injury is unilateral, the orbits are symmetrical and that reference points in the orbits can be established. Such reference points are necessary in order to perform a virtual superimposition of both orbits. This has been previously described by the authors (Kozakiewicz et al., 2009), however due to the importance of this technique, it will be briefly presented below.

The first stage of this method is to acquire data regarding the orbital anatomy and to create a 3D model of the patient's facial skeleton. CT DICOM data are segmented using Amira 5.4 (Visage Imaging GmbH, Germany) and a 3D surface model is created, which is subsequently exported as an .stl file. This is then imported into the reverse engineering software Geomagic Studio 11 (Geomagic Corp., Morrisville, USA), and the 3D model of the facial skeleton is divided into two symmetrical parts that include the left and the right orbit. The quality of the surface is verified with Geomagic Studio and any defects are repaired using specialist tools available in this software. The next stage is to ascertain the degree of displacement of the injured walls compared to the contralateral uninjured orbit. This can be assessed by superimposing two models on each other that should have a high degree of symmetry and comparing any differences between them i.e. regions where bone fragments have been displaced will exhibit a low degree of symmetry. Then, the unaffected orbit is mirrored onto the contralateral side and superimposed onto the injured orbit. The undamaged upper rim and upper wall are used as reference surfaces in order to achieve an accurate superimposition. Then, the two orbits



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**Table 2**
Raw material (UHMW-PE) characteristics before compression moulding (according ISO 5834 part 1 type 1, and ASTM F 648 type 1). Particular powder series used to manufacture patient-specific orbital implants (powder lot no. 0000464290; MediTECH, Quadrant).

| Feature | Test standard | | Requirement | Test result | | Unit |
|---|---|---|---|---|---|---|
| | ISO 5834 | ASTM F 648 | | ISO | ASTM | |
| Elongation stress | ISO 11542-2 | ASTM D 4020 | Min. 0.2 | 0.21 | 0.21 | MPa |
| Viscosity number | ISO 1628-3 | ASTM D 4020 | 2000–3200 | 2270 | 2270 | $cm^3/g$ |
| Extraneous matter | ISO 5834-1 | ASTM F 648 | Max. 3 | 0.3 | 0.3 | – |
| Ash content | ISO 3451-1 | ISO 3451-1 | Max. 125 | 35 | 35 | ppm |
| Trace element content | ISO 5834-1 | ASTM F 648 | | | | |
| Ti | | | Max. 40 | 10 | 10 | ppm |
| Al | | | Max. 20 | 3 | 3 | ppm |
| Ca | | | Max. 5 | 2 | 2 | ppm |
| Cl | | | Max. 30 | 10 | 10 | ppm |

**Table 3**
Final moulded forms (UHMW-PE) characteristics (ISO 5834 part 2 type 1, and ASTM F 648 type 1). Final polymer block product no. 152000 (MediTECH, Quadrant) patient-specific implants, presented in this paper, were cut from below described block.

| Feature | Test standard | | Requirement | Test result | | Unit |
|---|---|---|---|---|---|---|
| | ISO 5834 | ASTM F 648 | | ISO | ASTM | |
| Density | ISO 1183 | ASTM D 792 | 927 + 944 | 935 | 935 | $kg/m^3$ |
| Ash content | ISO 3451-1 | ISO 3451-1 | Max. 150 | 89 | 89 | ppm |
| Tensile stress at yield | ISO 527 | ASTM D 638 | Min. 21 | 22.4 | 21.8 | MPa |
| Tensile stress at break | ISO 527 | ASTM D 638 | Min. 35/40 | 51 | 48.4 | MPa |
| Elongation at break | ISO 527 | ASTM D 638 | Min. 300/380 | 447 | 476 | % |

are compared and the degree of symmetry is assessed using Geomagic Qualify (Geomagic Corp., Morrisville, USA). Regions that are damaged and displaced exhibit a low degree of symmetry, whist areas without displacement show a high level of symmetry. Such an analysis makes it possible to accurately assess to what degree these walls have been displaced and how the volume of the injured orbit has increased. Consequently, it is possible to calculate the thickness of the planned implant.

Subsequently, the 3D model is transferred to a CAD program SolidWorks (Dassault Systèmes SolidWorks Corp., Waltham, USA) and prepared for CNC milling. The virtual implant is inspected by a maxillofacial surgeon and divided into two pieces (one section for reconstruction of the lower and medial walls, and one for the lateral wall) in order to simplify the reconstruction process and decrease intra-surgical complications. The extent of the final surface area is determined and is carefully evaluated, in order to avoid creating an implant that would be too small. Any sharp edges and angles are removed to decrease the possibility of damaging intraorbital structures. The final virtual implant is then approved by a maxillofacial surgeon.

Then, the file is imported into a CAM program Pathtrace Edgecam (Edgecam, Berkshire, UK). The type of tools and milling strategy are carefully selected with this programme, in order to achieve maximum accuracy of the resulting physical implant. At first a 4 mm diameter burr is applied, then 2 mm, later 1 mm, and finally 0.5 mm. The direction of the burr movement is from the central part to periphery of the implant surface. As a result, the implant remains connected to the borders of the polyethylene block and does not break off which ensures stable milling and accurate control of the implant shape. Finally, the numerical code (NC) for the milling machine is generated.

A block of UHMW-PE is clamped into a holder on a computer numerical controlled, 5-axis milling machine Speed Hawk 650 (OPS-Ingersoll Funkenerosion GmbH, Burbach, Germany; www.en.ops-ingersoll.de) with a working space X650 Y550 Z500 mm. The dimensions of the block are 125 × 70 × 20 mm. Later, the milled implants are cleaned and their borders are thermally rounded.

## 2. Results

Two copies of the implant were milled from a block of UHMW-PE using CNC with air cooling. The thickness of the manufactured implant ranged from 0.2 mm to 1.5 mm. The changes in thickness were gradual and precisely controlled, which was essential in order to restore the physiological morphology of the orbit. As the two implants were manufactured for the patient, the cost of medical UHMW-PE was 8 Euros per patient (4 Euros if only one implant was to be made for a patient). The features of UHMW-PE used for this implant: stiffness with relative flexibility, no sharp/serrated edges, can be cut during surgery with a scalpel. The manufacturing method allows creation of an individual implant, with gradually altered curvature, ensures a possibility of designing and producing implants for surgeons in different parts of the world and is relatively cheap. After milling the implant was not polished. Its surface was not porous but slightly rough. Following confirmation by a maxillofacial surgeon, the implant was packed and sterilized in gas plasma (low temperature conditions). The following day the custom implant was ready for use.

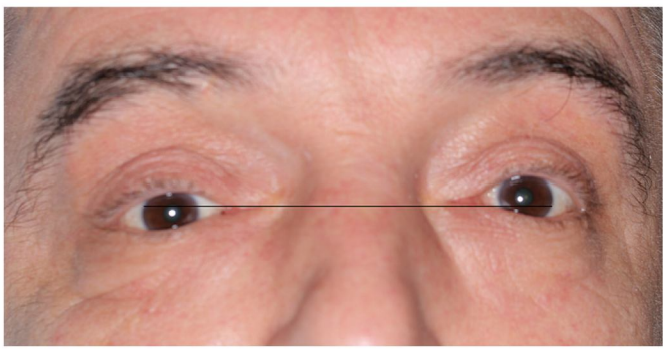

**Fig. 1.** Patient before treatment. A blunt injury of the right orbit 10 months ago. Eye globe is dislocated downward and laterally.



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Placement of the implants was made via a standard trans-conjunctival approach. The surgery was performed under general anaesthesia. The bone defect in the medial wall had healed, however some displaced fragments of the lateral wall were found. The orbital floor did not have any defects or foreign bodies. Herniated tissues were repositioned, and the two parts of the patient-specific implant were inserted into the orbit. The first part (lower section) was fixed to the lower rim using one 1.5 × 4 mm screw; the second part (lateral section) was fixed in the same manner to the lateral rim. Passive motility test was performed at the end of surgery. Post-surgery functional orthoptic examination was performed, as well as a CT scan to confirm the position of the globe and assess the retrobulbar space. Enophthalmos and diplopia were corrected. Binocular single vision was restored after 1 month and continued during 6-month follow-up (0% – binocular single vision loss).

The design, manufacture and clinical application of the described implant have been presented in the figures below (Figs. 1–6).

## 3. Discussion

The main field of application for ultrahigh molecular weight polyethylene (UHMW-PE) is orthopaedics, whilst Synpor® (www.synthes.com) is the only material based on UHMW-PE which is known to be used for maxillofacial reconstructions other than acetabular part of temporomandibular joint total replacements. UHMW-PE has rapidly gained wide acceptance as a means to remarkably reduce the wear and the associated peri-implant osteolysis. In vivo studies simulating the use of UHMW-PE for durations of up to 20 years have shown negligible wear (Jasty et al.,

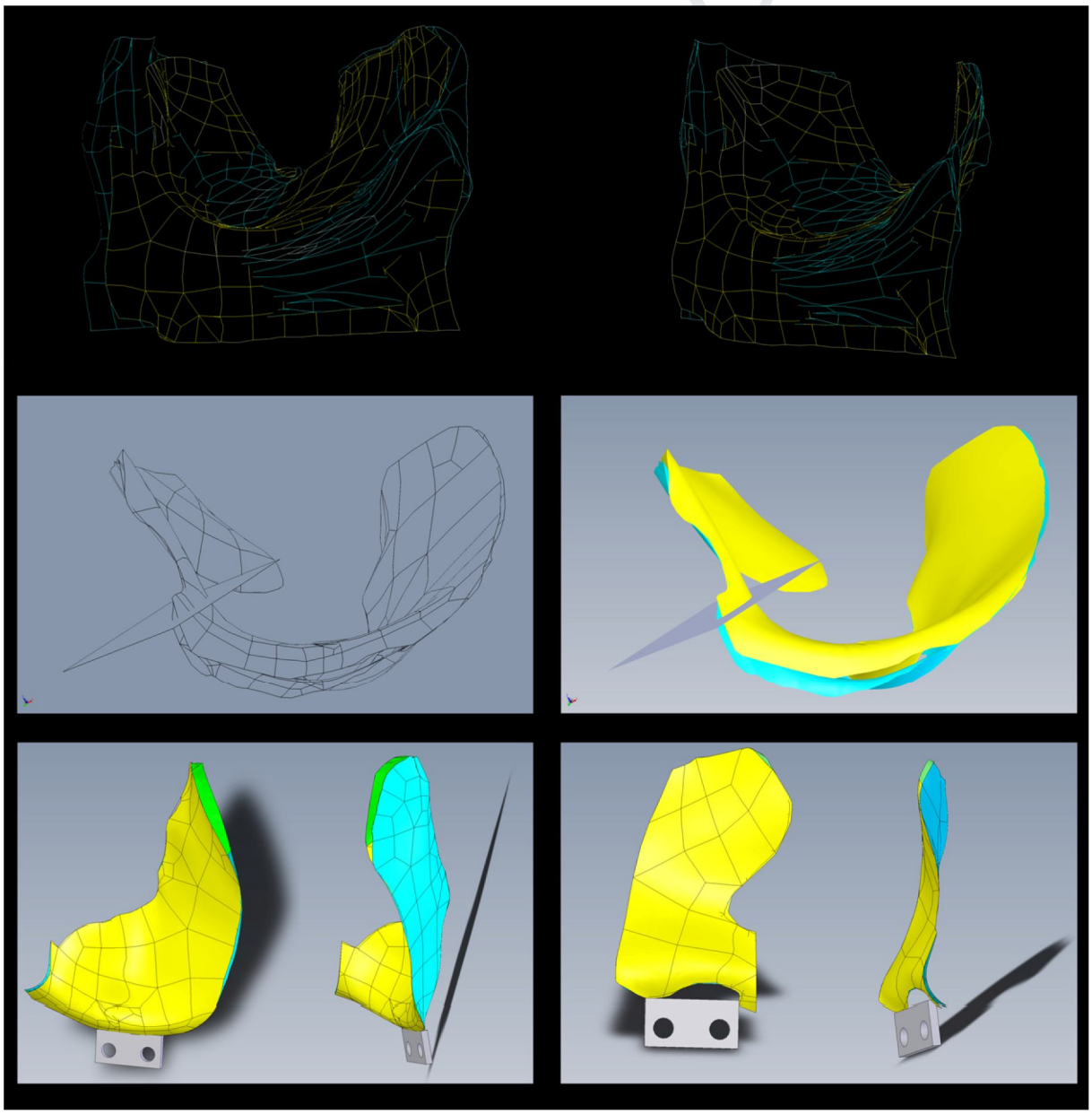

**Fig. 2.** Computer aided design (CAD). Left–right superimposition of virtual orbits, yellow mesh represents intact surfaces, blue mesh represents dislocated surfaces due to injury (upper couple of images). Planning the implant dimensions. Thickness of the implant is established by measuring the distance between the intact and the injured surfaces of the orbits walls. The plain of separation is used to manufacture two implants – one for floor and medial wall, and one for lateral wall reconstruction (middle couple of images). Figures of individual orbital implants. On the left: floor and medial wall implant. On the right: lateral wall implant (lower couple of images).

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**Fig. 3.** Presentation of a design of the vertical dimension of the orbital floor and medial wall implant. Mirrored, injured orbit superimposed on intact orbit visualized as one fused block. Antero-posterior cross-section through orbital floors and medial walls [white transparent plain in upper image] presents the implant thickness in section plain [lower image]. Two-dimensional graph shows positions of both floors [solid line — intact, dotted line — injured, segments reaching the dots describe the implant thickness].

2005). The stiffness of the polymer resin appears to be adequate for orbital reconstruction. UHMW-PE exhibits a combination of excellent properties: outstanding abrasion resistance, superior impact resistance, non-sticking and self-lubricating features and excellent mechanical properties. It is a polymer of extremely high viscosity that is produced in the form of powder and has an average particle size diameter typically ranging from 100 to 200 μm. Due to its viscosity, it generally cannot be processed by the common methods used for ordinary thermoplastics. Thus, compression moulding and ram extrusion processes are used to generate the high pressure needed to fuse UHMW-PE particles together and then the material is typically formed into stock shapes or solid blocks, as necessary for milling (Ticona Engineering Polymers, 2011).

Alloplastic materials have been shown to reduce the number of bacteria required to produce infection by a factor of 104–106 (Sclafani et al., 1997). Nonporous surfaces of the custom UHMW-PE implant make it more resistant to intra-operational infection. The material displayed some of the features of the well-known polytetrafluoroethylene (Sclafani et al., 1997). On the other hand, a surface that is not totally smooth makes an implant more resistant to late infections due to superficial fibrovascularization. This living tissue allows increased response from immune mediators at this expanded surface of alloplast (Zimmerli et al., 1982).

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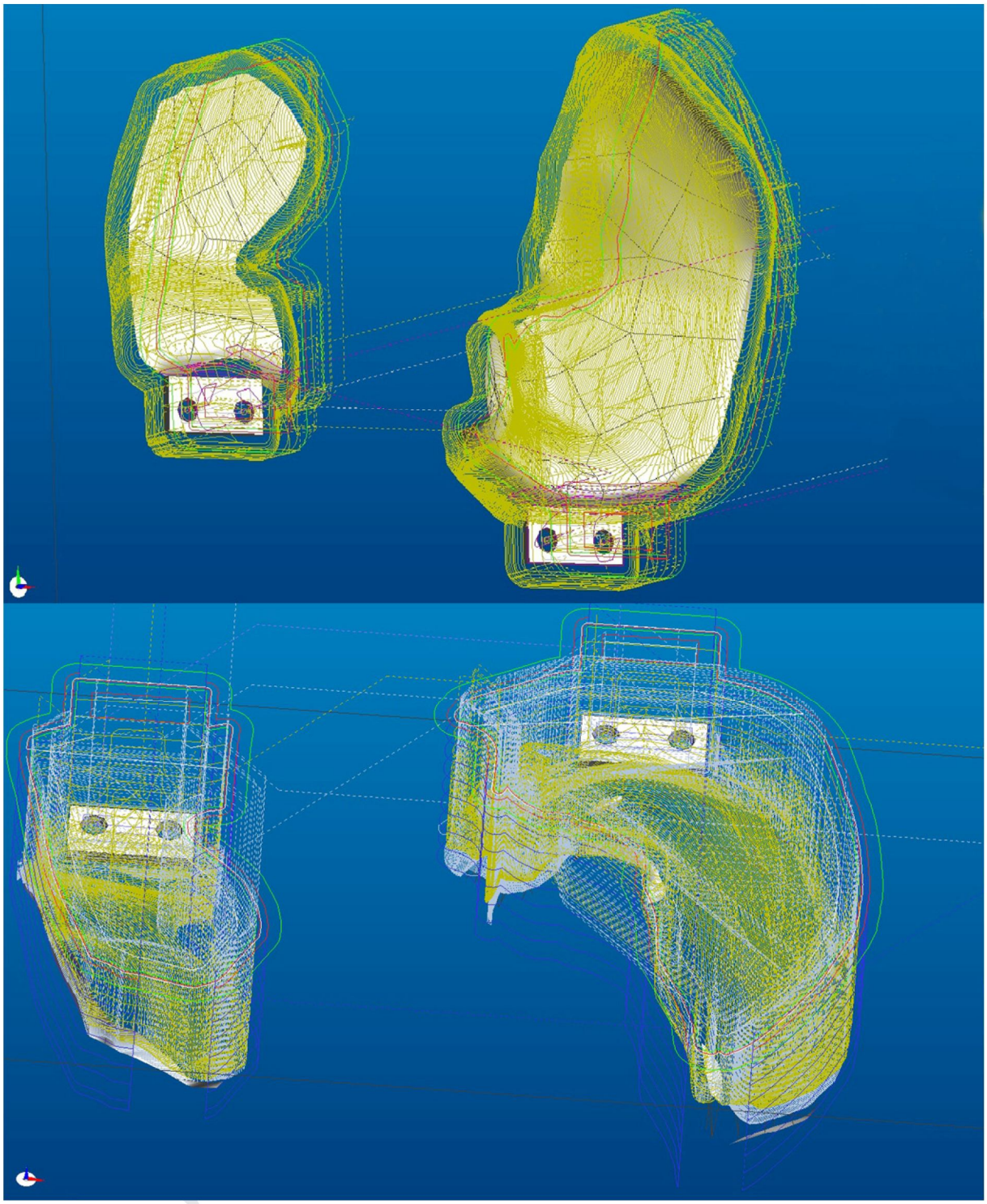

**Fig. 4.** Computer aided manufacture (CAM) – the milling strategy. The design of burr traces in UHMW-PE block encoded for numerical milling machine. Each line represents one trace of the burr.

10-year results with the hip endoprosthesis demonstrate exceptional high survivorship (Hinrichs et al., 2001). The authors concluded that the acetabular component can be recommended for further implantation. More detailed argumentation was revealed by Reynolds et al. (2012). The average total penetration was 0.339 ± 0.204 mm, and the mean annual penetration rate was 0.037 ± 0.022 mm. The paper demonstrated a 74% reduction in total penetration of highly cross-linked polyethylene when compared with historical controls using conventional polyethylene at an average of 9 years. It supports the belief that highly cross-linked polyethylene [i.e. UHMW-PE] does retain its wear resistance over an extended period.

The perfect orbital reconstruction material remains controversial (Chang and Bernardino, 2004). It should be cheap, biocompatible, readily available, and easy to manipulate and insert during surgery. It should allow fixation to the orbital rim (Potter and Ellis, 2004). Numerous materials have been used, including lyophilized

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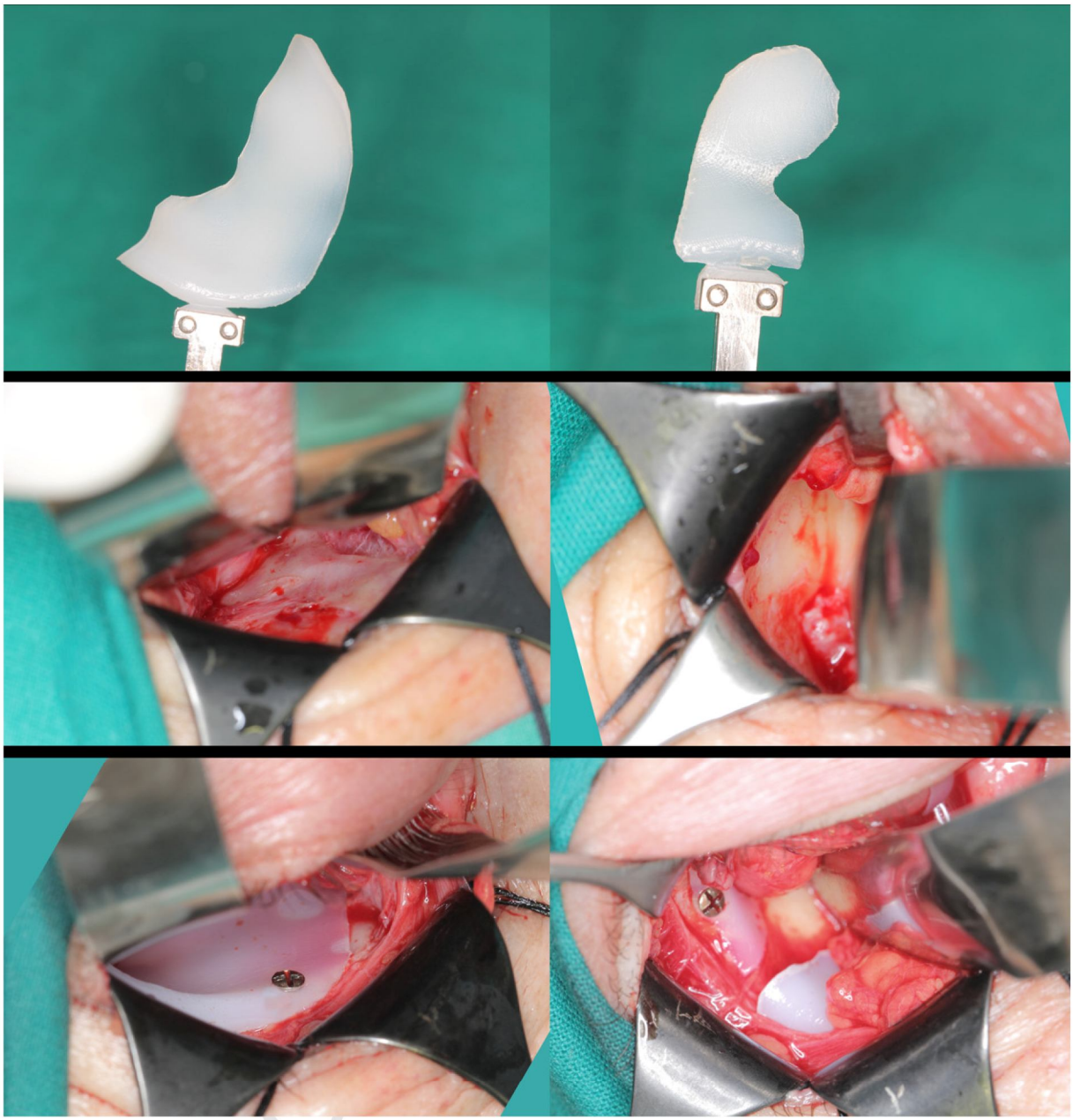

**Fig. 5.** Clinical application. Left column of images – orbital floor and medial wall implant. Right column – lateral wall implant. In the top – final versions of UHMW-PE patient-specific implants just before placing in the orbit. In the middle – exposed dislocated orbital walls. In the bottom – implants inserted and fixed with two screws.

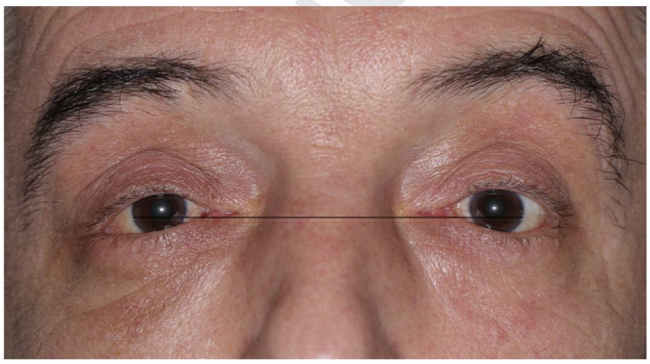

**Fig. 6.** Patient 6 months after treatment. Right eye globe position was re-established upward and medially (more iris is exposed in the lower aspect, and more sclera is revealed in the lateral part of the palpebral fissure).

dura, silastic, polyethylene or polydioxanone sheets, hydroxyapatite blocks, titanium mesh, ceramic inlays, and autogenous bone grafts (Hoffmann et al., 1998; Potter and Ellis, 2004; Ellis and Tan, 2003; Habal, 1992; Goldberg et al., 1993; Hammer and Prein, 1993; Howaldt and Zubcov, 1994; Kelly et al., 2005; Lee et al., 2005; Ropke and Bloching, 2004). More flexible materials are unable to withstand the dynamic stresses of large defects. Resorbable implants may be prone to foreign-body reaction, implant exposure, and result only in fibrous connective tissue remains after resorption (Hoffmann et al., 1998, Buchel et al., 2005). The disadvantages of autologous bone grafts include limited contourability and donor site complications. In addition, graft resorption can occur (Glassman et al., 1990, Kline and Wolfe, 1995; Marin et al., 1998). Titanium mesh has had a long track record in the reconstruction of large orbital floor defects and correction of globe malposition (Potter and Ellis, 2004, Glassman et al., 1990; Ellis and

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Tan, 2003). Some of the advantages of titanium mesh plates include availability, biocompatibility, easy intraoperative contouring and rigid fixation. Disadvantages are difficulties with ease of insertion. Any rough edges on the mesh tend to catch prolapsed orbital fat. Additionally, removal of the titanium mesh after the healing period is challenging, due to the presence of a scar tissue that grows through the mesh perforations. It can also be difficult to apply subtle intraoperative contours to the mesh, particularly if the deep orbital cone is affected or scarring renders the identification of stable posterior landmarks difficult (Hammer and Prein, 1995; Parsons and Mathog, 1988; Schön et al., 2006).

The described UHMW-PE implants are pre-formed, custom made and can be tailored to specific intra-operational needs. The material is radiolucent on CT scans and MRI images, causing no interference with postoperative imaging, although a combination with embedded or covering radio-opaque component may be useful for X-ray imaging follow-up (Liu et al., 2004).

The next desired feature, as previously mentioned (Ozturk et al., 2005), is thinness of polyethylene implants (<0.3 mm). We propose a patient-specific implant that is thin or has variable thickness and is made from durable biocompatible polymer. The extremely high molecular weight polymer and density of the resin make it possible to manufacture implants as thin as 0.2 mm. Depending on the reconstruction strategy, 1.0 mm or 0.5 mm-thick implant versions can be made. Furthermore, variable thickness patient-specific implants may be designed (0.2–4.0 mm). Thicker implants can be used for eye globe position correction in severe enophthalmic cases. Such implants could have high tensile strength (tensile stress at yield of UHMW-PE is similar to cortical bone) and ensure that position of the globe remains stable. This would be necessary in cases with a high score on the orbital destruction intensity scale (Kozakiewicz et al., 2011). On the other hand, thinner implants could be utilized to cover fracture lines and minor orbital wall defects. Therefore, the orbital volume would be minimally modified by the volume of the implant.

In delayed and multiple surgery cases, functional results of orbital surgery are worse than in simpler cases, yet in long-term follow-up partial subsidence of diplopia is noticeable. The results of treatment depend on the initial level of diplopia and severe initial diplopia may require thicker implants to correct. Larger orbital wall displacements require a greater reduction. What is obvious in such cases is that a surgeon needs accurate tools i.e. patient-specific implants. A surgeon should not be afraid of significant eye globe repositioning due to variable thickness implants as this ultimately results in precise enophthalmos correction.

Enophthalmos in posttraumatic cases is determined by the degree of orbital cavity enlargement, herniation of orbital fat into the sinuses, fat atrophy, loss of ligament support and scar contracture. Reconstruction can be achieved with bone grafts harvested from calvaria or iliac crest and using biomaterials (Clauser et al., 2008). Adequate hard tissue reconstruction is fundamental for the correction of enophthalmos. Long-term outcomes of standard polyethylene implants used for reconstruction of orbital floor defects revealed persistent enophthalmos in 7–11% of cases and diplopia in 6–17% (Hoşal and Beatty, 2002, Ozturk et al., 2005). Such results show that there is a need to find new treatment methods for such cases. Patient-specific alloplastic implants appear to be a useful alternative with promising results.

The advantages and disadvantages of the proposed implant material and method should be summarized.

Advantages:

1. Ability to accurately reconstruct the original shape of the orbital walls
2. Excellent structural support combined with a thin implant
3. Reconstruction of large orbital floor defects – the material is rigid
4. CAD model of the implant can be used as an intra-surgical navigation tool
5. Precisely located perforations prevent movement of the implant in site, after the healing period (for example: perimeter line perforation or one margin perforation)
6. Easy correction using scissors/scalpel
7. Less complications
8. Possibility to easily and precisely modify regional implant thickness during CAD design
9. Rounded edges and smooth alterations from thin to thick parts of the implant
10. There is an antioxidant-(vitamin E)-enriched UHMW-PE polymer available that may be beneficial for patients to be irradiated.

Disadvantages:

1. Inability to change the size or curvature of the implant during surgery (it is necessary to manufacture a larger implant than actual dimensions of the defect)
2. A fixing screw is required to stabilize the implant during the first phase of healing (for larger defects)
3. Time expenditure for design and production (pre-op)
4. The implant is translucent on X-ray imaging.

## 4. Conclusion

Ultrahigh molecular weight polyethylene implant prepared using CNC milling appears to have many advantages as a material for precise reconstruction of orbital wall defects. The implants produced are durable and accurately reconstruct the anatomy of thin orbital walls. Furthermore, they do not exhibit the complications of autogenous bone grafts and allow successful therapy of posttraumatic diplopia and enophthalmos.

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## References

Buchel P, Rahal A, Seto I, Iizuka T: Reconstruction of orbital floor fracture with polyglactin 910/polydioxanon patch (ethisorb): a retrospective study. J Oral Maxillofac Surg 63: 646–650, 2005

Chang EL, Bernardino CR: Update on orbital trauma. Curr Opin Ophthalmol 15: 411–415, 2004

Clauser L, Galiè M, Pagliaro F, Tieghi R: Posttraumatic enophthalmos: etiology, principles of reconstruction, and correction. J Craniofac Surg 192: 351–359, 2008

Ellis III E, Tan Y: Assessment of internal orbital reconstructions for pure blowout fractures: cranial bone grafts versus titanium mesh. J Oral Maxillofac Surg 61: 442–453, 2003

Frodel JL, Lee S: The use of high-density polyethylene implants in facial deformities. Arch Otolaryngol Head Neck Surg 124: 1219–1223, 1998

Glassman RD, Manson PN, Vanderkolk CA, Iliff NT, Yaremchuk MJ, Petty P, Defresne CR, Markowitz BL: Rigid fixation of internal orbital fractures. Plast Reconstr Surg 86: 1103–1111, 1990

Goldberg RA, Garbutt M, Shorr N: Oculoplastic uses of cranial bone grafts. Ophthalmic Surg 24: 190–196, 1993

Habal MB: Bone grafting the orbital floor for posttraumatic defects. J Craniofac Surg 3: 175–180, 1992

Hammer B, Prein J: Reconstructive surgery in the area of the orbit. Klin Monatsbl Augenheilkd 202: 458–459, 1993

Hammer B, Prein J: Correction of post-traumatic orbital deformities: operative techniques and review of 26 patients. J Craniomaxillofac Surg 23: 81–90, 1995

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He D, Li Z, Shi W, Sun Y, Zhu H, Lin M, Shen G, Fan X: Orbitozygomatic fractures with enophthalmos: analysis of 64 cases treated late. J Oral Maxillofac Surg, in press, corrected proof, http://dx.doi.org/10.1016/j.joms.2011.02.041.

Hinrichs F, Boudriot U, Held T, Griss P: 10-Jahres-Ergebnisse einer Monobloc-Huftendoprothesenpfanne mit mehrlagiger Reintitangitterschale zur zementfreien Implantation. Z Orthop Ihre Grenzgeb 139: 212–216, 2001

Hoffmann J, Cornelius CP, Groten M, Pröbster L, Pfannenberg C, Schwenzer N: Orbital reconstruction with individually copy-milled ceramic implants. Plast Reconstr Surg 101: 604–612, 1998

Hoşal BM, Beatty RL: Diplopia and enophthalmos after surgical repair of blowout fracture. Orbit 21: 27–33, 2002

Howaldt HP, Zubcov A: Orbital reconstruction with tabula externa for correction of post-traumatic enophthalmos. Fortschr Kiefer Gesichtschir 39: 64–66, 1994

Hwang K, You SH, Sohn IA: Analysis of orbital bone fractures: a 12-year study of 391 patients. J Craniofac Surg 20: 1218–1223, 2009

Jasty M, Rubash HE, Muratoglu O: Highly cross-linked polyethylene: the debate is over-in the affirmative. J Arthroplasty 20: 55–58, 2005

Kashkouli MB, Pakdel F, Sasani L, Hodjat P, Kaghazkanani R, Heirati A: High-density porous polyethylene wedge implant in correction of enophthalmos and hypoglobus in seeing eyes. Orbit 30: 123–130, 2011

Kelly CP, Cohen AJ, Yavuzer R, Jackson IT: Cranial bone grafting for orbital reconstruction: is it still the best? J Craniofac Surg 16: 181–185, 2005

Kirby EJ, Turner JB, Davenport DL, Vasconez HC: Orbital floor fractures: outcomes of reconstruction. Ann Plast Surg 66: 508–512, 2011

Kline Jr RM, Wolfe SA: Complications associated with the harvesting of cranial bone grafts. Plast Reconstr Surg 95: 5–20, 1995

Kozakiewicz M, Elgalal M, Loba P, Komunski P, Arkuszewski P, Broniarczyk-Loba A, Stefanczyk L: Clinical application of 3D pre-bent titanium implants for orbital floor fractures. J Craniomaxillofac Surg 37: 229–234, 2009

Kozakiewicz M, Elgalal M, Loba P, Broniarczyk-Loba A, Stefanczyk L: Treatment with individual orbital wall implants in humans – 1-year ophthalmologic evaluation. J Craniomaxillofac Surg 39: 30–36, 2011

Liu JK, Gottfried ON, Cole CD, Dougherty WR, Couldwell WT: Porous polyethylene implant for cranioplasty and skull base reconstruction. Neurosurg Focus 16: 3, 2004

Lee S, Maronian N, Most SP, Whipple ME, McCulloch TM, Stanley RB, Farwell DG: Porous high-density polyethylene for orbital reconstruction. Arch Otolaryngol Head Neck Surg 131: 446–450, 2005

Loba P, Kozakiewicz M, Elgalal M, Stefanczyk L, Broniarczyk-Loba A, Omulecki W: The use of modern imaging techniques in the diagnosis and treatment planning of patients with orbital floor fractures. Med Sci Monit 17: 94–98, 2011

Marin PC, Love T, Carpenter R, Iliff NT, Manson PN: Complications of orbital reconstruction: misplacement of bone grafts within the intramuscular cone. Plast Reconstr Surg 101: 1323–1329, 1998

Ozturk S, Sengezer M, Isik S, Turegun M, Deveci M, Cil Y: Long-term outcomes of ultra-thin porous polyethylene implants used for reconstruction of orbital floor defects. J Craniofac Surg 16: 973–977, 2005

Parsons GS, Mathog RH: Orbital wall and volume relationships. Arch Otolaryngol Head Neck Surg 114: 743–747, 1988

Potter JK, Ellis E: Biomaterials for reconstruction of the internal orbit. J Oral Maxillofac Surg 62: 1280–1297, 2004

Reynolds SE, Malkani AL, Ramakrishnan R, Yakkanti MR: Wear analysis of first-generation highly cross-linked polyethylene in primary total hip arthroplasty: an average 9-year follow-up. J Arthroplasty 27: 1064–1068, 2012

Rhim CH, Scholz T, Salibian A, Evans GR: Orbital floor fractures: a retrospective review of 45 cases at a tertiary health care center. Craniomaxillofac Trauma Reconstr 31: 41–47, 2010

Ropke E, Bloching M: Materials used in reconstructive surgery of the orbit. Klin Monatsbl Augenheilkd 221: 985–991, 2004

Schön M, Metzger C, Zizelmann C, Weyer N, Schmelzeisen R: Individually preformed titanium mesh implants for a true-to-original repair of orbital fractures. Int J Oral Maxillofac Surg 35: 990–995, 2006

Sclafani AP, Thomas JR, Cox AJ, Cooper MH: Clinical and histologic response of subcutaneous expanded polytetrafluoroethylene Gore-Tex and porous high-density polyethylene Medpor implants to acute and early infection. Arch Otolaryngol Head Neck Surg 123: 328–336, 1997

Tabrizi R, Ozkan TB, Mohammadinejad C, Minaee N: Orbital floor reconstruction. J Craniofac Surg 21: 1142–1146, 2010

Ticona Engineering Polymers, 8040 Dixie Highway, Florence, KY 41042, USA. http://www.ticona.com/products/uhmw-pe [accessed 9.03.2011]

Wajih WA, Shaharuddin B, Razak NH: Hospital Universiti Sains Malaysia experience in orbital floor reconstruction: autogenous graft versus Medpor. J Oral Maxillofac Surg 69: 1740–1744, 2011

Xu JJ, Teng L, Jin XL, Ji Y, Lu JJ, Zhang B: Porous polyethylene implants in orbital blow-out fractures and enophthalmos reconstruction. J Craniofac Surg 203: 918–920, 2009

Zimmerli W, Waldvogel FA, Vaudaux P, Nydegger UE: Pathogenesis of foreign body infection: description and characteristics of an animal model. J Infect Dis 146: 487–497, 1982



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