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A new modification of the individually designed polymer implant visible in X-ray for orbital reconstruction

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ABSTRACT

Orbital reconstruction makes higher demands on symmetry and axial precision than other parts of the skull, because the position of the eye globe determines proper vision. The aim of this study is to evaluate titanium surface marking of polymers (UHMW-PE and PA6) to check implants position in CT examination and clinical application of such modified individual implant.

One hundred and twenty-four polymer blocks were prepared. New method of ultrasounds welding to connect the titanium markers to the polymer surface was developed and tested. Titanium marked polymer blocks were examined by CT to evaluate the quality of the cover. Then, two modified UHMW-PE individual implants were applied clinically and implant position was checked by CT.

The biggest titanium cover was in PA6 [25 ± 18% of processed surface] and for UHMW-PE [19 ± 12%] without significance [$p = 0.14$]. Both covers were visible in CT. Clinical application revealed proper reconstruction, uneventful post-operational outcome and well visible surface of the implants in CT.

The conducted tests make it possible to determine the suitability of ultrasonic technology for the deposition of titanium markers in polymer. The clinical use of modified individual implants allows to confirm the correct position of the implants because they are accurate visible in CT.

1. Introduction

Reconstructive surgery is the most dynamic field of medicine, where new technologies and materials open up many new opportunities for restoring the structure and function of damaged organs. Although autologous bone is still the golden standard for bone reconstruction (Tieghi et al., 2013), formable titanium meshes, allogenous and xenogenous materials, and polyethylene have changed surgical procedures. The requirements which are placed on these materials are biocompatibility, ease of application, being non-toxic, hypo-allergenic and non-carcinogenic, as well as long-time stability and visibility in imaging procedures. Additional properties of these materials used in orbital reconstruction include precision in cutting, forming and adapting, durability in supporting orbital contents and ease of being anchored in position (Ellis and Tan, 2003).

Orbital reconstruction makes higher demands on symmetry and axial precision than reconstruction of other parts of the skull because the position of the eye globe determines proper vision. Application of patient-specific implants milled from ultrahigh molecular weight polyethylene (UHMW-PE) is a promising way towards proper three-dimensional orbital wall reconstructions (Kozakiewicz et al., 2013, Kozakiewicz, 2013). The material allows for volume corrections of the orbit and is immune to intraoperational deformations. However, the UHMW-PE is invisible in radiological examination, which makes it difficult to assess the final position of the implant and influence the functional outcome (Wilde et al., 2013).

1.1. Objectives

The aim of this study is to evaluate the possibility of marking polyamide 6 (PA6) and polyethylene (UHMW-PE) surfaces with titanium particles in order to show these surfaces in computerized tomography examination and to assess potential clinical applications of modified patient-specific polyethylene implants, whose postoperative position can be confirmed by CT.

2. Material and methods

Medical grade powder UHMW-PE for surgical implants produced in accordance with ISO 5834-1 2007 type 1, ISO 5834-2 2006

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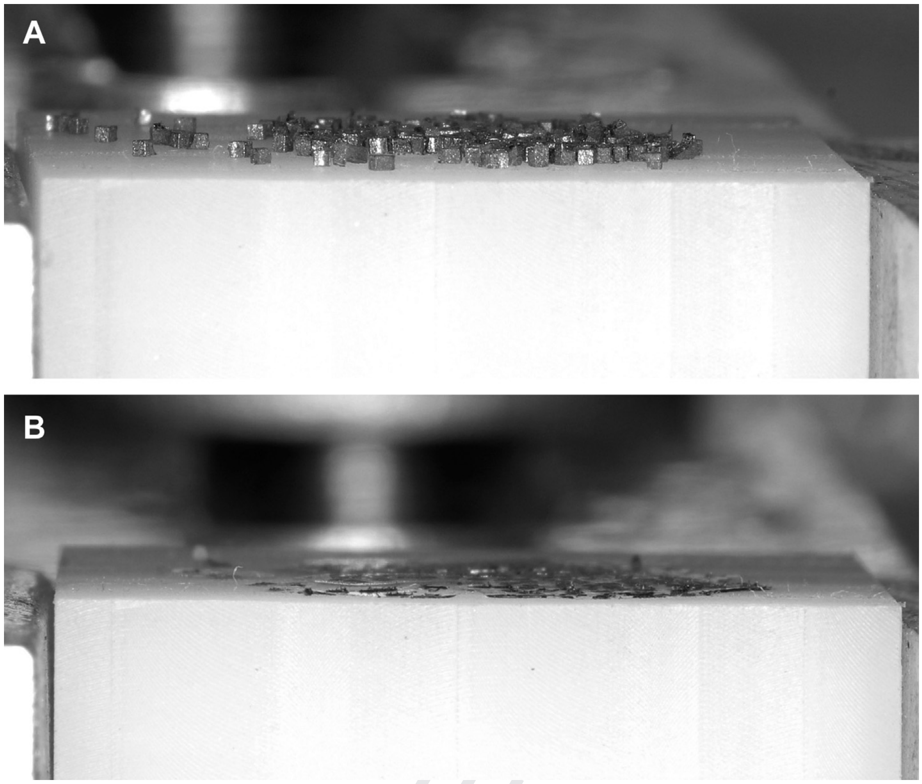

Fig. 1. The block of medical ultrahigh molecular weight polyethylene A – before and B – after welding titanium cubes on its surface. The 0.2 × 0.2 × 0.2 mm cubes of titanium grade 23 were ultrasonically inserted in the surface of the polymer block. A total penetration of the titanium cubes into the block surface was revealed.

type 1 and ASTM F648-07 type 1 standards (Ticona Engineering Polymers, Florence, USA; www.ticona.com) was chosen as the test material. This material is a linear polyolefin resin in powder form with a molecular weight of approximately 5 million mers calculated using Margolies' equation. The extremely high molecular weight of this resin yields several unique properties, including high impact strength and low friction coefficient, which results in self-lubricating, and thus non-sticking surfaces after processing. Med-iTECH, Quadrant Deutschland GmbH (Vreden, Germany; www.meditechpolymers.com) produced the final solid material from raw powder, which was certified for medical use. After that, the substrate resin was processed by compression moulding and ram extrusion. The moulded forms were annealed under nitrogen atmosphere at 110 °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 F648 for moulded forms made of UHMW-PE moulding material for surgical implants.

Nylon 6 (polycaprolactam, polyamide 6, PA6) is a polymer developed by Paul Schlack at IG Farben to reproduce the properties of nylon 6.6 without violating the patent on its production. Nylon 6 has good biocompatibility with human tissues, probably due to its similarity to collagen protein in its chemical structure. It has been widely used in the biomaterials application of surgical sutures for nearly half a century (Xu et al., 2010). PA6 has several advantageous properties: resistance to heat, chemicals, wear, fungi, bacteria, mould and mildew, resilience to abrasion, flexibility, durability, and low friction (Xu et al., 2010; Mehrabanian and Nasr-Esfahani, 2011).

One hundred and twenty-four blocks (20 mm × 20 mm × 10 mm) were prepared, sixty-two of which were made of UHMW-PE and sixty-two of PA6. The OPS-INGERSOLL SPEED HAWK 650 machine was used to prepare the blocks (http://www.en.ops-ingersoll.de). The polyamide and polyethylene blocks were divided into two groups, each consisting of 31 blocks. A block of certified medical titanium alloy grade 23 was chosen for the production of the marker cover. Ti6Al4V ELI (grade 23) alloy is very similar to Ti6Al4V (medical grade 5), except that Ti6Al4V ELI contains reduced levels of oxygen, nitrogen, carbon and iron. ELI is an abbreviation for Extra Low Interstitials, and these lower interstitials provide improved ductility and better fracture toughness for the Ti6Al4V ELI material. Titanium rods of a square cross-section of 0.2 × 0.2 mm were precisely cut electromechanically, with cooling, the length of 0.2 mm thereby obtaining the shape of an equilateral cube. The process was performed in Mitsubishi FA 20S wire erosion machine (http://www.mitsubishi-world.com). The sonotrode machine SIRIUS Model USP ENERGY (http://www.siriuselectric.it/en) was used to connect titanium particles with

Table 1
Summary statistics for ultrasound welding titanium to polymers surface. In vitro experiment. Data as % of total surface covered by titanium. Q5

	UHMW-PE		PA6	
	P I	P II	P I	P II
Average titanium cover ± SD	19.36 ± 12.35%	5.35 ± 3.85%	7.46 ± 5.70%	25.17 ± 18.11%
Minimum	1.65%	0.40%	0.70%	0.50%
Maximum	44.15%	12.40%	18.05%	58.45%
Range	42.50%	12.00%	17.35%	57.95%
Stnd. skewness	1.31	1.02	1.54	0.25
Stnd. kurtosis	−0.50	−1.28	−1.01	−1.67

Abbreviations: UHMW-PE = ultrahigh molecular weight polyethylene; PA6 = polyamide 6; P I = Parameters I i.e. less starting force, pressure and amplitude but longer welding time; P II = Parameters II i.e. more force, pressure and amplitude but shorter welding time.

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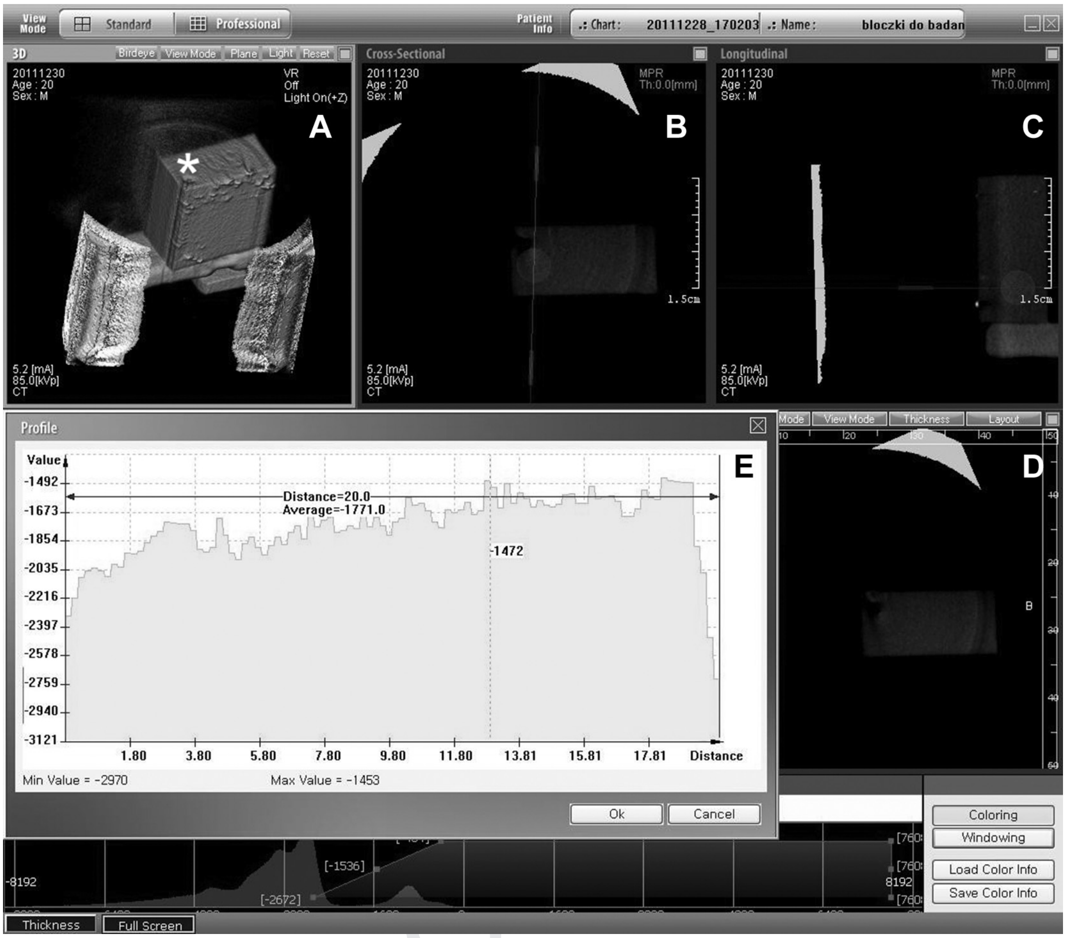

Fig. 2. Ultrahigh molecular weight polyethylene after welding using parameters II. Cone beam computerized tomography of the block with one surface covered with titanium cubes. A – three-dimensional image reconstruction; asterisk indicates the polymer block. B, C, D – two-dimensional multilane image reconstructions (MPR) in axial, coronal and sagittal planes; there is a visible titanium layer on one surface of the polymer block in each plane. E – profile of intensity of radio-opacity along the surface marked with titanium (value – Hounsfield units, distance – length of the block surface, i.e. 20 mm).

the polymer blocks. The titanium-made horn was rectangular in shape and the flat surface was larger than the block area.

A makeshift nest was made for the purposes of the study in order to immobilize the sample during the welding process. Irregularly shaped titanium chips and cubes were used for welding during preliminary trials. Due to their flat surfaces, titanium chips lacked energy hubs for their connection to PA6 or UHMW-PE blocks. As a result, they were eliminated from further testing, and only titanium cubes were used. All the blocks were numbered and parameters to connect titanium to PA6 and UHMW-PE were established by trial and error. Tests were performed for a group of UHMW-PE and PA6 blocks using two different welding parameters established in a series of preliminary experiments with titanium chips and cubes. Two groups of parameters were selected, one for the best connection between titanium and PA, the second for the best connection between titanium and UHMW-PE. Subsequently, PA6 and UHMW-PE were tested in these two parameter conditions. The first group of blocks of UHMW-PE and PA6 was subjected to welding using the following parameters (lower force parameters, longer time): welding amplitude: 26.0 μm; starting force: 550 N; welding force: 750 N; pressure: 650 N; welding time: 0.5 ms; welding path: 0.28 mm. The second group of blocks of UHMW-PE and PA6 was subjected to welding using the following parameters (higher force parameters, shorter time): welding amplitude: 29 μm; starting force: 800 N; welding force: 1000 N; pressure: 1000 N; welding time: 0.3 ms; welding path: 0.28 mm. The surface covered with titanium particles was inspected by an optical microscope in magnification of 10×.

Next, the blocks were examined by cone beam CT (Vatech PAX Uni 3D, Vatech, http://www.vatechamerica.com) to evaluate their radio-opacity and utility in clinical conditions. The parameters of cone beam CT visualisation were: current 5.2 mA, voltage 85.0 kVp, single scan width 0.125 mm, window width 3500 HU, window centre 100 HU. In the computer analysis the blocks were virtually cut every two millimetres to create ten transverse sections. The sections which showed PA6 with a titanium connection and UHMW-PE with a titanium connection were measured and calculated as a percentage of the titanium-covered surface area in the total block surface.

A statistical analysis (Statgraphics Centurion XVI) was performed using *t*-test to compare average UHMW-PE (polyethylene) and PA6 (polyamide) implant surface areas covered with titanium. The significance level was established as $p < 0.05$.

2.1. Clinical application

In this study, two patients with orbital floor fractures were operated on using individual UHMW-PE implants modified with titanium cubes (approval of the Ethics Committee: RNN/740/12/KB). There were no previous reports on PA6 implantation, which is

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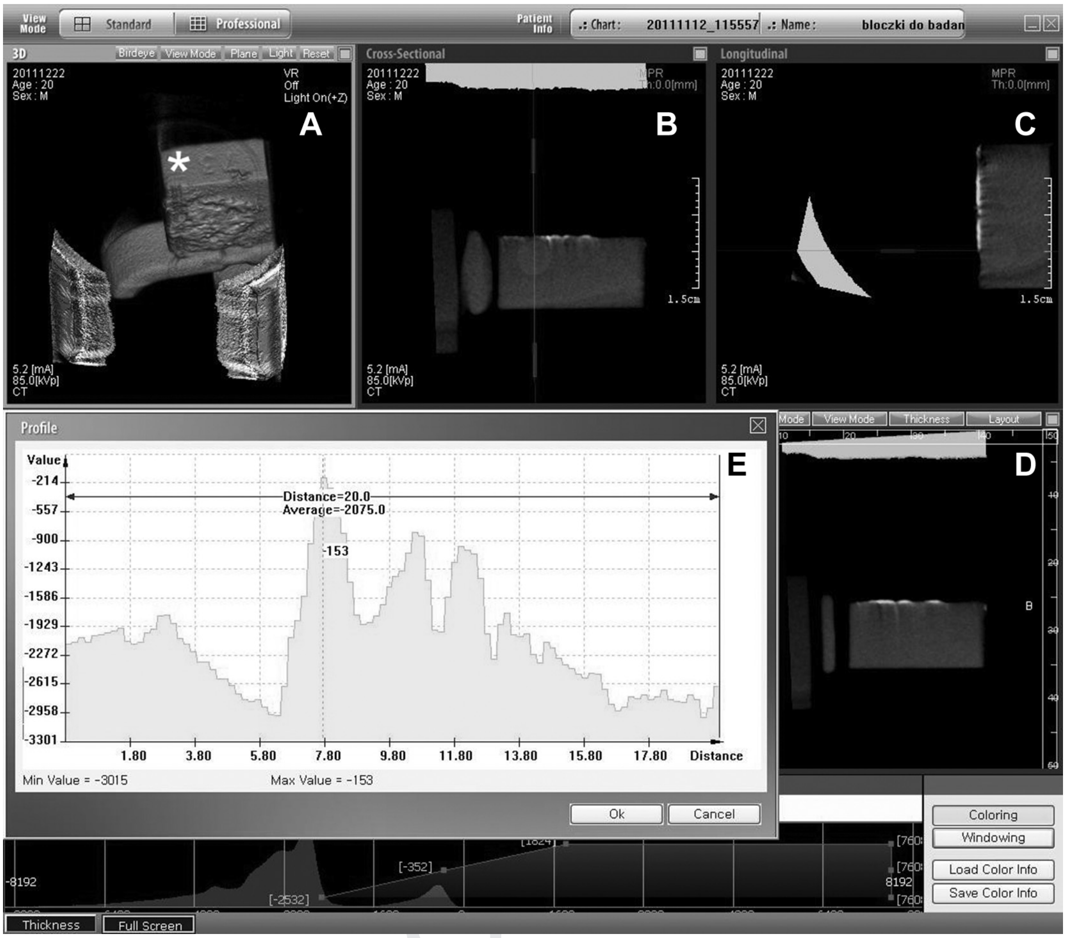

Fig. 3. Ultrahigh molecular weight polyethylene after welding using parameters I. Cone beam computerized tomography of the block with one surface covered with titanium cubes. A – three-dimensional image reconstruction; asterisk indicates the polymer block. B, C, D – two-dimensional multilane image reconstructions (MPR) in axial, coronal and sagittal planes; there is a visible titanium layer on one surface of the polymer block in each plane. E – profile of intensity of radio-opacity along the surface marked with titanium (value – Hounsfield units, distance – length of the block surface, i.e. 20 mm).

why the authors did not seek the Ethics Committee's approval for that polymer's implantation in humans.

A 30-year old male patient was admitted to the Department of Maxillofacial Surgery due to a blow-out fracture of the right orbital floor and malposition of the globe with consecutive diplopia. Next, a 28-year old man was admitted for re-operation of the orbital floor and release of adhesions from his previous post-traumatic reconstruction of the orbital wall using titanium mesh, performed five months earlier. This patient also had malposition of the globe and consequent double vision. The preoperative investigation included maxillofacial and ophthalmologic examinations and computed tomography. CTs were performed by means of Multi-slice VCT, GE Lightspeed 64-slice scanner using 0.6 cuts, a gantry tilt of 00 and a 512 × 512 matrix.

The first digital step to prepare an individual implant was segmentation of the bones of the orbital region from DICOM files imported into the specialist software Geomagic Studio 12 (Geomagic Corp., Morrisville, USA). The intact orbit was mirrored and superimposed onto the contralateral side, i.e. the injured orbit. The unaffected upper rim and wall were indicated as reference surfaces for superimposition. Then, the left-right reference (symmetrical) surfaces on the orbital rim were detected in Geomagic Qualify (Geomagic Corp., Morrisville, USA). Subsequently, the volume of interest (the injured orbital wall to be implanted) from the virtual model data was translated to the CAD program SolidWorks (Dassault Systèmes SolidWorks Corp., Waltham, USA) in order to design the implant for the milling machine. Before being approved, the virtual implant was inspected by a maxillofacial surgeon. Next, the file was imported to the CAM program Pathtrace Edgecam (Edgecam, Berkshire, UK) to choose the type of tools and milling strategy. The direction of the bur movement was designed from the central part to the periphery of the implant surface. The milling program was exported to the milling machine Speed Hawk 650 (OPS-Ingersoll Funkenerosion GmbH, Burbach, Germany; www.en.ops-ingersoll.de) of X650 Y550 Z500 mm working space to manufacture the implant. Once released from the milling machine, the implant was cleaned and its borders were rounded thermally. Simultaneously, a model of the fixed orbit was built from resin. The assumption for the model design was that its inner (intraorbital) surface should be the same as the outer surface of the implant (outside of the orbit). Then the milled implant fits accurately to the orbital wall. It was later used for quality control of the modified implant.

The individual UHMW-PE implant prepared was modified by the welding of titanium cubes. A manual sonotrode had to be used in the process because there was no possibility to fix the implant in the same way as the blocks in the study. Moreover, the authors decided to use a manual, rounded, flat surface 4 mm diameter sonotrode since the welding process requires a perpendicular direction of the appliance to the implant surface. Lower starting force, pressure and amplitude were used but longer welding time created a perfect permanent connection between titanium cubes and the

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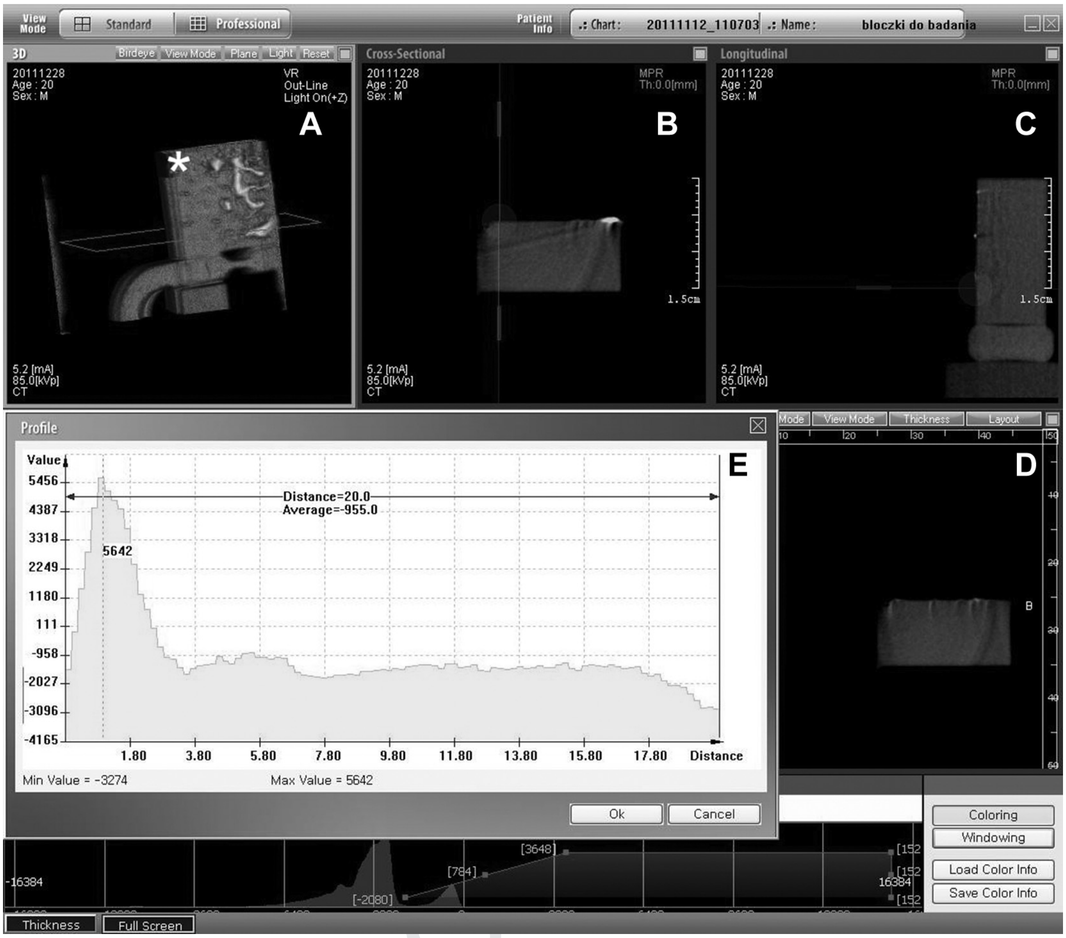

Fig. 4. Polyamide 6 after welding using parameters II. Cone beam computerized tomography of the block with one surface covered with titanium cubes. A – three-dimensional image reconstruction; asterisk indicates the polymer block. B, C, D – two-dimensional multilane image reconstructions (MPR) in axial, coronal and sagittal planes; there is a visible titanium layer on one surface of the polymer block in each plane. E – profile of intensity of radio-opacity along the surface marked with titanium (value – Hounsfield units, distance – length of the block surface, i.e. 20 mm).

polyethylene implant. However, this process requires precision and attention because high temperature in the plastification area may deform the shape of the implant. That is the reason why breaks between each ultrasonic welding procedure and constant inspection are necessary. This is extremely important because the welding process may distort the implant if unattended. Finally, to check the proper shape of the cube-covered implant, the researchers tried fitting it on the rapid prototyping model.

Once the patients' consent had been obtained, surgeries were performed in general anaesthesia and the subjects received perioperative antibiotic prophylaxis. The transconjuctival approach was used to approach the inferior orbital walls and the rim region. The herniated orbital tissue was reduced and adhesions released. Individual UHMW-PE implants modified on the surface by titanium cubes were inserted in an appropriate pre-planned position and fixed to the lower orbital rim by titanium screws (1.5 mm diameter and 4.0 mm length). The postoperative CT and ortoptic examination revealed proper implant placement, an appropriate position of the globe and reduced visual disturbances. In both cases the postoperative course was uneventful.

3. Results

The result of the welding of titanium cubes with the polymer blocks is presented in Fig. 1. A total penetration of the block surface by titanium cubes was revealed.

The results for UHMW-PE and PA6 covering with titanium using higher or lower welding parameters are shown in Table 1. The best cover of UHMW-PE with titanium cubes was obtained under the optimal parameters for UHMW-PE, i.e. (parameters I) lower starting force, pressure and amplitude but longer welding time ($t = 6.0298$; $p < 0.0000001$). In the case of PA6 and titanium, more covered surface was obtained under the optimal parameters for PA6 – i.e. (parameters II) more force, pressure and amplitude but shorter welding time ($t = -5.1920$; $p < 0.000003$). PA6 had a greater surface coverage than the UHMW-PE block using the best parameters for each material, with no statistical significance ($t = -1.4750$; $p < 0.1454$). Fig. 2 presents cone beam CT scans with a visible cover of the surface of UHMW-PE blocks with titanium cubes using parameters II. It was the least coated block surface of that experiment. Fig. 3 presents cone beam CT scans with a visible cover of the surface of UHMW-PE blocks with titanium cubes using parameters I. It was a considerable block surface cover with titanium cubes. Cone beam CT scans revealed the smallest surface cover of PA6 blocks with titanium cubes using parameters I (Fig. 4). The largest block surface cover with titanium cubes, visualized in cone beam CT (Fig. 5), was obtained for PA6 blocks using parameters II.

A microscopic examination revealed very clearly that the cubes were evenly and homogeneously welded to the polymer blocks. The plastification area was visible in the form of a ring surrounding the titanium marker and was much larger than the titanium cubes,

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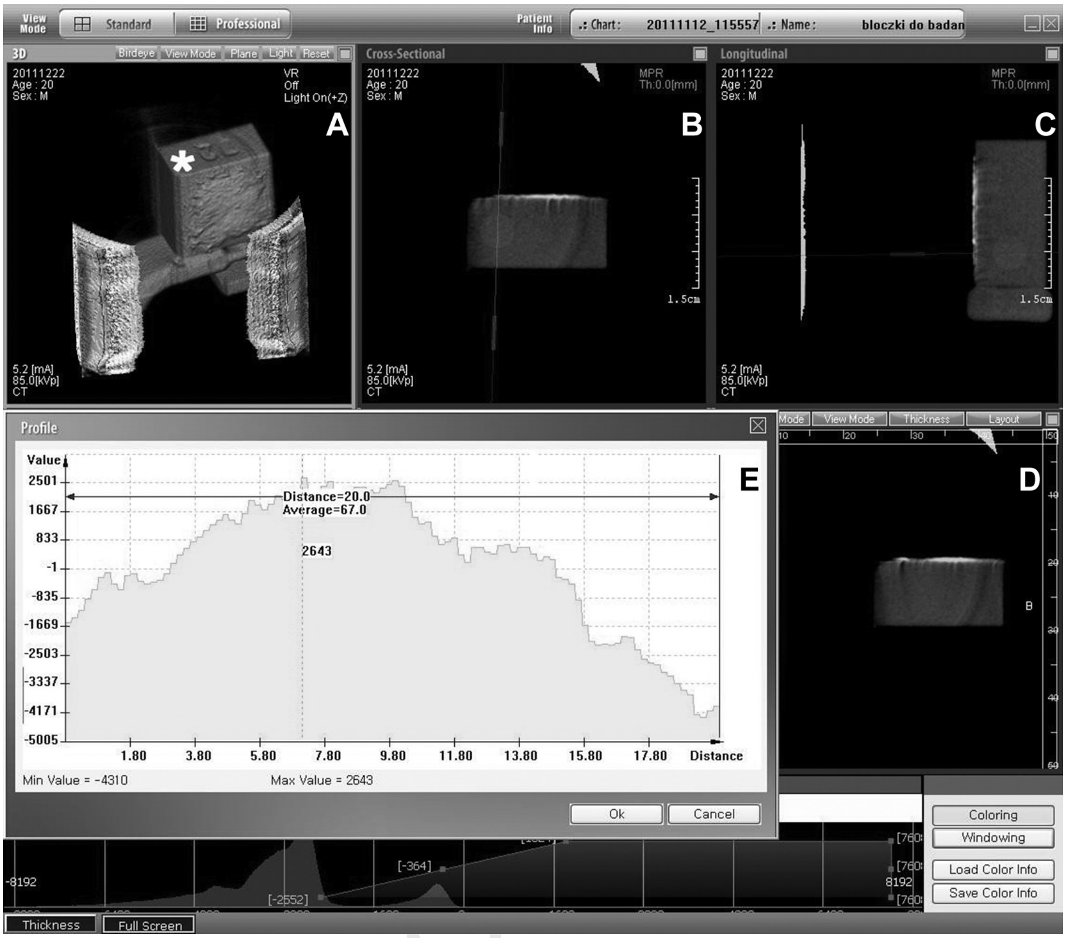

Fig. 5. Polyamide 6 after welding using parameters I. Cone beam computerized tomography of the block with one surface covered with titanium cubes. A – three-dimensional image reconstruction; asterisk indicates the polymer block. B, C, D – two-dimensional multilane image reconstructions (MPR) in axial, coronal and sagittal planes; there is a visible titanium layer on one surface of the polymer block in each plane. E – profile of intensity of radio-opacity along the surface marked with titanium (value – Hounsfield units, distance – length of the block surface, i.e. 20 mm).

which demonstrates that the latter were welded to the surface of the block and could not be removed from the sample by non-invasive methods (Fig. 6). In the case of titanium chips, lack of plastification region of the surrounding material was caused by the flat chips adhesion to the block, with no connection to UHMW-PE or PA6 surfaces. That is why the chips could be easily removed mechanically from the surface of the block (Fig. 7). It was observed that the best connection was obtained as the sharp edges of the titanium cubes touched the surface of the polymer.

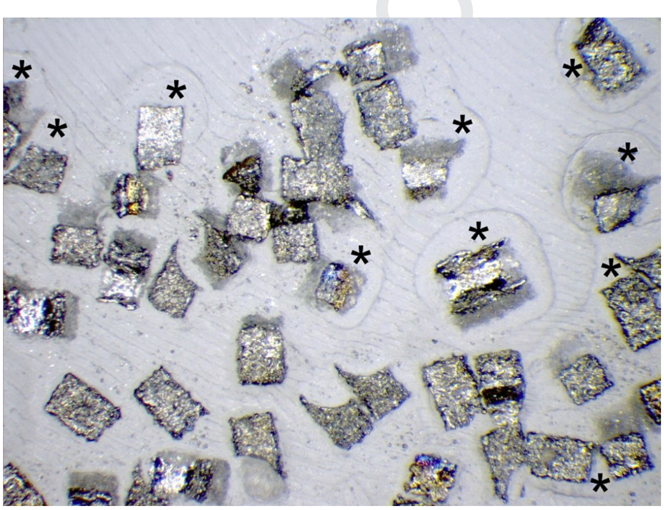

Fig. 6. A visible UHMW-PE surface with welded titanium cubes. Asterisks indicate plastification areas of UHMW-PE around the welded titanium cubes.

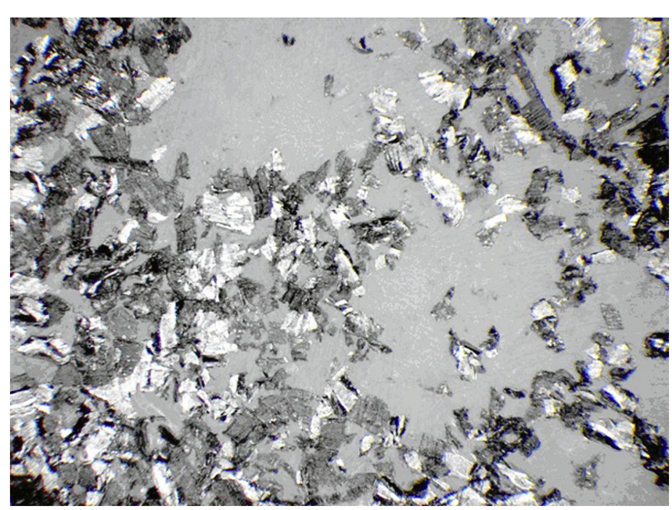

Fig. 7. A visible UHMW-PE surface following the connection with titanium chips. Lack of visible plastification areas of UHMW-PE around the titanium chips.

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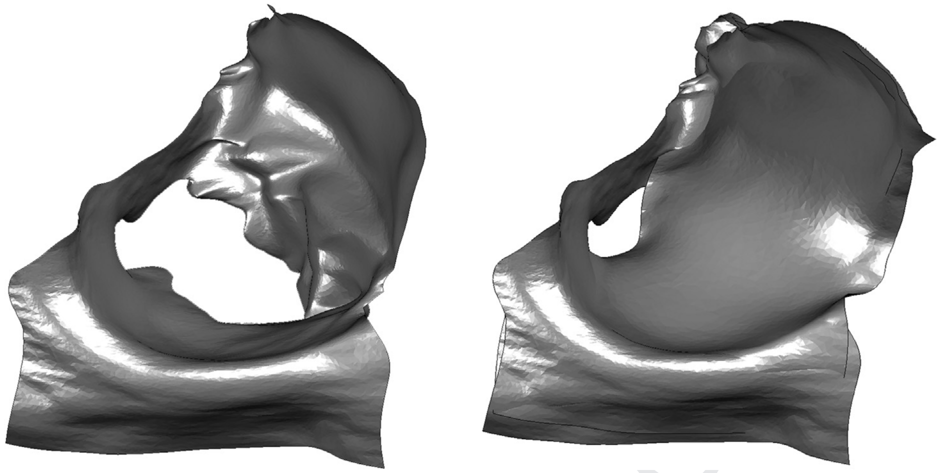

Fig. 8. Processing of computerized tomography. On the left: segmented lower and medial orbital walls with a large bone defect. On the right: superimposition of intact orbital walls (after mirroring) on the affected one to reconstruct the orbit.

In clinical application, orbital reconstruction yielded satisfactory results (Figs. 8–11). The proper aesthetic position of the globe and correction of enophthalmos and diplopia were achieved (Fig. 12). The implant made of UHMW-PE modified with titanium cubes was clearly visible in the CT scan, giving the opportunity to evaluate its position in relation to the surrounding bony structures (Fig. 13). The patients were followed up postoperatively for 12 months, and no adverse effects were revealed. Functional outcomes were stable.

4. Discussion

The goal of surgical orbital reconstruction after an injury is to restore the motility and accurate position of the globe. It is obtained by removing herniated tissues from the fissure fracture and reconstructing the bone defect. It must be emphasized that the most important issue in orbital reconstruction is to obtain the correct shape of the space and proper support for the eye globe (Shetty et al., 2009). Residual diplopia, sometimes at a significant level, is one of the most frequent complications following orbital surgery (Kozakiewicz et al., 2011; Mustafa et al., 2011). Obviously, double vision can be reduced by extraocular muscle surgery (Loba et al., 2012), but if a simple correction of the implant position in the orbit during primary surgery is possible and the location is confirmed by CT imaging, residual diplopia and enophthalmos can usually be avoided. In order to achieve this, a radio-opaque surface of an implant is required.

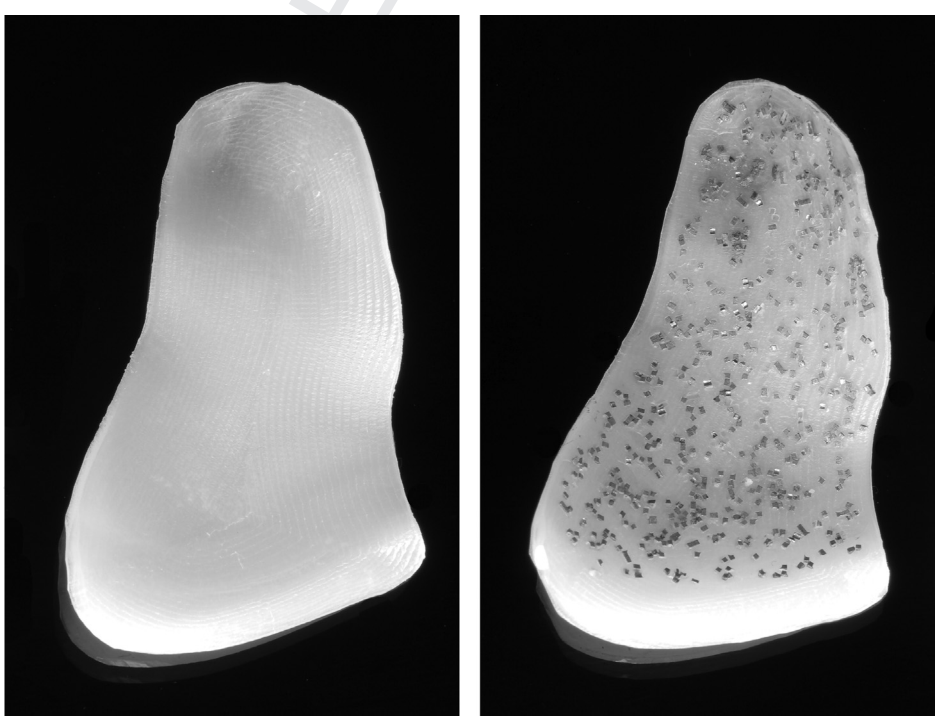

Fig. 9. Patient-specific ultrahigh molecular weight orbital implants. On the left: an implant just after computer-aided manufacturing, i.e. computer numerical control milling. On the right: the same implant after ultrasound titanium cube marking.

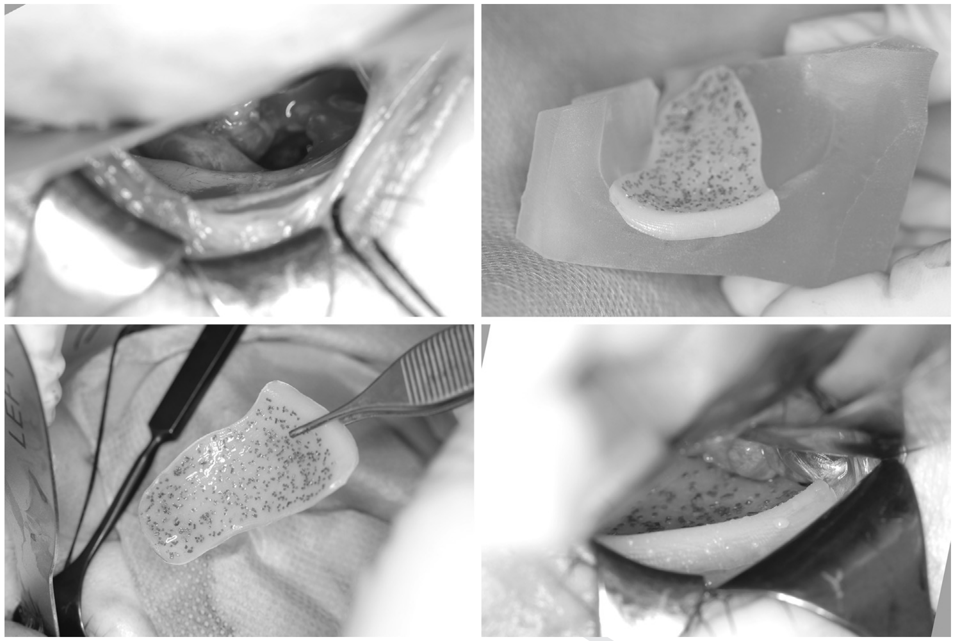

Fig. 10. Individual volumetric reconstruction of the right orbit. Top left: transconjuctival approach, an exposed bone defect of the orbital floor. Top right: a modified individually designed implant on the biomodel, the manufacturing quality controlled by perfect fitting to the orbital rim and walls. Bottom left: insertion of the implant into the orbit. Bottom right: the implant in proper position after reconstructing the affected walls.

The choice of material for orbital reconstruction remains controversial (Chang and Bernardino, 2004). Numerous materials are available at present (Baino, 2011; Metzger et al., 2006), including lyophilized dura, polyethylenes or polydioxanone sheets, hydroxyapatite blocks, titanium mesh, ceramic inlays, autogenous bone grafts etc. There is an ongoing search for the best alloplastic material to restore the skeleton – chemically inert, biocompatible, non-allergenic, non-carcinogenic, sterilizable, easy to handle, stable, radio-opaque, cost-effective, and permitting tissue ingrowth (Potter et al., 2012). Professional literature describes methods of treatment of orbital wall defects using individually formed titanium mesh (Schön et al., 2006; Kozakiewicz et al., 2009). However, the method employing an individually shaped volumetric polyethylene implant is more accurate, because of the possibility of shaping the implant in three-dimensions and the use of varying thickness of the implant depending on the need to support orbit tissues. It is a real three-dimensional implant versus titanium mesh, which is, in fact, just a flat material without a significant volume.

Still, many authors report that titanium mesh offers excellent results in orbital reconstruction because of its biocompatibility and ensures good integration with adjacent bone, which translates into a low infection rate and rare postoperative migration of implants (Schön et al., 2006; Kozakiewicz et al., 2009). Characterized by significant tensile strength and malleability, the material is easy to form but also easy to deform in the operating field (Kozakiewicz and Szymor, 2013). Titanium is visible in X-ray examination as well (Yi et al., 2012). On the other hand, modern surgery should be based on thoughtful preoperative planning and especially on restoring the original shape, volume and function (Yi et al., 2012). It seems that titanium mesh, despite its advantages, cannot accurately imitate lost orbital volume due to its constant and low thickness (Kozakiewicz et al., 2013). Furthermore, complications may arise when titanium mesh is used, such as its transfer in the

Fig. 11. The patient affected with a right orbit blow-out fracture. The right globe is dislocated downward.

Fig. 12. The patient after treatment. The level of pupils is normalized.

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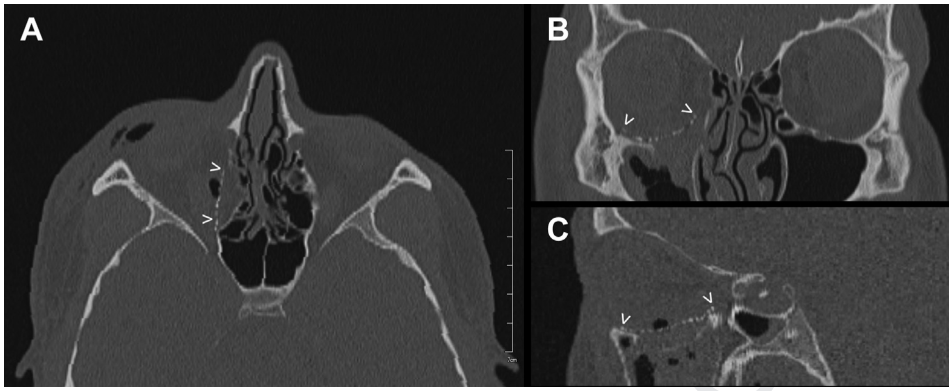

Fig. 13. Postoperative computerized tomography reveals a clearly visible position of the implant thanks to titanium cube marking by ultrasound technique. A – axial view, B – coronal view, C – sagittal view. Arrows indicate implant position in the right orbit.

direction of the optic nerve (Shetty et al., 2009). Not without significance is also the psychological aspect of using titanium, which is sometimes not tolerated by the patient (Maier, 2009).

Although no single alloplast fulfilling all the criteria of an ideal material has been developed to date, high density porous polyethylene (HDPE) – a large, porous, biocompatible, synthetic material – appears to be suitable for maxillofacial skeletal reconstruction (Deshpande and Munoli, 2010). The tested material, UHMW-PE, has been used in medicine for more than 60 years. Solid polyethylene was applied for the first time in 1947 as a substitute for cartilage or bone. Porous HDPE was developed in the early 1970s and has been in mass commercial use since 1985 as Medpor (Porex Surgical, College Park, GA) or Biopore, available in the Indian market since 2006 (Deshpande and Munoli, 2010). Another type of polyethylene, ultrahigh molecular weight polyethylene (UHMW-PE), is used in orthopaedic applications. UHMW-PE is applied as the liner of acetabular cups in total hip arthroplasties, in the tibial insert, as a patellar component in total knee arthroplasties, and as a spacer in intervertebral artificial disc replacement (Navarro et al., 2008). Porous high molecular weight polyethylene implants (Medpor, Synpore) are used for orbital reconstruction as they are easy to handle, shape, contour, position, fix, and can be used with other autogenous and alloplastic implants. The material is well tolerated, resists infection, is non-antigenic and promotes tissue ingrowth. Its porous structure allows fibrovascularization, which not only protects the implant from infection but also prevents its migration (Ram et al., 2010). According to Ye et al. (2006), the use of polyethylene implants offers a chance to achieve a more optimal orbital reconstruction than by applying other alloplastic materials, and to position the implant in a more predictable manner. Ye et al. (2006) recommend the use of polyethylene implants, especially in large bone defects. Three-dimensional patient-specific shaping is still a challenge in the case of HDPE, but the use of UHMW-PE individual implants for orbital wall reconstruction has already been ophthalmologically assessed and deemed a predictable method (Kozakiewicz and Szymor, 2013).

In our department rapid prototyping (Kozakiewicz et al., 2009) and individual orbital implants are used in daily practice (Kozakiewicz, 2013). These implants are made of ultrahigh molecular weight polyethylene (UHMW-PE), a material which has a lot of advantages, but also some drawbacks, such as lack of visibility in X-ray examination. This is why we devised a method of connecting polyethylene and titanium. Our promising ultrasonic welding technique involves the use of high frequency sound energy to soften or melt the thermoplastic at the joint. Parts to be joined are held together under pressure and then subjected to ultrasonic vibrations. The ability to weld a component successfully depends on the design of the equipment, mechanical properties of the material to be welded and the design of the components. Since ultrasonic welding is very fast (weld time is typically less than 1 s), it is a widely used technique, though not in surgery.

An ultrasonic welding machine has four main components: a power supply, a converter, an amplitude modifying device (commonly called Booster) and an acoustic tool known as the horn (or sonotrode). The power supply changes mains electricity at the frequency of 50–60 Hz into a high frequency electrical supply operating at 20, 30 or 40 kHz. This electrical energy is supplied to the converter. Within the converter, discs of piezoelectric material are sandwiched between two metal sections. The converter changes the electrical energy into mechanical vibratory energy at ultrasonic frequencies. The vibratory energy is then transmitted through the booster, which increases the amplitude of the sound wave. The sound waves are then transmitted to the horn. The horn is an acoustic tool that transfers the vibratory energy directly to the parts being assembled, and it also applies welding pressure. The vibrations are transmitted through the work piece to the joint area. Here the vibratory energy is converted to heat through friction, which softens or melts the thermoplastic, and joins the parts together. To improve the quality of the implant through radio-opacity we devised a method of welding using a sonotrode to connect UHMW-PE implants with titanium particles.

In our study the most satisfactory results are achieved when welding cubes with polyethylene or polyamide. In the case of irregularly shaped materials, which may have a flat surface, it is impossible to obtain either effective or repeatable welds. What is necessary is to adhere to the principles of concentrating energy on the welded components. It follows that titanium chips are not suitable energy hubs to weld UHMW-PE or PA6. The lack of proper weld triggers the possibility of drop-out of incorrectly welded titanium chips, which could move inside the patient's orbit. Nylon (PA6) was also tested, although there are very few reports in the literature about the use of this material. In 2002 Wang et al. described the unique procedure of connecting hydroxyapatite with polyamide (Wang et al., 2002). Su et al. also used a material which was created by connecting polyamide with bioglass. In their studies polyamide creates a porous scaffold with interconnected spaces in order to provide sufficient room for cell migration and adhesion, and the ingrowth of new bone tissue. They suggest the possibility of using this material in the future both in orthopaedics and maxillofacial and reconstructive surgery (Su et al., 2012).

In both investigated alloplasts the covered surfaces are well visible in CT examination, which is the first choice method for implant follow-up in the orbit.

The authors applied the method of connecting UHMW-PE with titanium cubes to create an ideal implant which has the advantages of the currently used UHMW-PE implant and is visible in X-ray examination. Thanks to that, the treatment of the fractured orbit is accurate and yields good results. Moreover, the operating time is shorter and the 3D reconstruction of the lost bone tissues is excellent, which is especially significant in difficult large bone defects. Compared to traditional UHMW-PE implants, the main benefit of using cube-covered ones is the possibility of imaging them in postoperative CT. The planning and manufacturing time may be quite long and labour-intensive, but the good result of the treatment compensates for this inconvenience.

5. Conclusion

The tests conducted make it possible to determine the suitability of ultrasonic technology for the deposition of titanium markers in polymer. The clinical use of modified individual implants allowed us to confirm their correct position because they are clearly visible in CT.

Conflict of interest

The authors have declared no conflict of interest.

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