Author’s response to reviews

Title: Comparison of pre-bent titanium mesh versus polyethylene implants in patient specific orbital reconstructions

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Version: 2 Date: 29 September 2013

Author’s response to reviews: see over
Dear Editor,

thank you for quick review. We have revised our manuscript as your reviewers suggested. There are also some minor editions. All changes are tracked back by Word track changes feature.

In response to suggestions:

Decent English language has been used. However, there are many grammatical errors that should be corrected by a native speaker.

Manuscript was corrected by native speaker

It is surprising that the author is describing about a new a new method but Rimell JT et al J Biomed Mater Res. 2000;53(4):414-20. et al already described it 2000. This paper is even not mentioned in the introduction. This may contribute to the good quality of the Journal and may let the reader feel a relation of the papers published.

We are glad for pointing this article concerning material processing attempt, and we added it in our manuscript as suggested. In our manuscript we use a different material and method of forming implants from UHMW-PE, not laser sintering.

Our 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 for us. 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 F648 for moulded forms made of UHMW-PE moulding material for surgical implants made by subtractive method [i.e. milling] nor additive [i.e. laser sintering].

The aim of this study was to compare UHMW-PE implant with titanium mesh, but there was not mentioned, how the authors controlled the position of the implant. Do they use navigation?

We have used navigation in a few cases. The main positioning method is to find reference area in the orbit and compare to virtual model of the orbit. Lower orbital rim [relatively long concave surface] in anterior aspect and posterior ledge [orbital process of palatal bone] in the posterior aspect are the reference areas. There is only one possible position of placing the implant in the orbit thanks to its individual and stiff shape of the implant. Operator only has to find the stable alignment of the implant in reference areas to the bone surface because there is this only one planed position.

Lacking information:
But lacks a final clinical photo a final proper clinical photo to describe the success of individually manufacture UHMW-PE implant.

Such photo of individual CAM UHMW-PE implant is in fig. 3C and final clinical position is in figure 3D demonstrated.

It’s difficult for the reader to understand. I wonder how the autor could measure the success of the treatment without radiographic proof. As well known the ultra-high molecular weight polyethylene sheets have not a radioopacity.

The measure of success was aesthetic and functional outcome. We have measured field of view affected by binocular vision before and after operation. Clinical improvement (lower percentage of Binocular Single Vison Loss) was considered success. What is more all operated patients had post-operational CT. Of course in cases treated with UHMW-PE it was not possible to see the implant itself, but reduced orbital hernia, correct position of extraocular muscles, negative postoperative forced duction test – all of these factors suggested successful operation result. Additionally in cases of Ti-mesh we can definitely evaluate the shape and position with post-op CT. Missing information was added in manuscript.

Who accurate was the production of the CAD models?

Accuracy was 0.05 mm. Miling mashine was: 5-axis milling machine Speed Hawk 650 (OPS-Ingersoll Funkenerosion GmbH, Burbach, Germany; www.en.ops-ingersoll.de)

Who bent the titanium meshes

Author – MK, preoperatively. Changed in manuscript

Which approach was used?

Transconjunctival approach was used in all cases [manuscript in the text]

Why is the follow-up time selected 6 month?

Polyethylene sheets starts to resorb after one year. Please provide the one year results.

The used in study ultra high molecular weight polyethylene is non-resorbable material. Wear of UHMW-PE in hip joint prosthesis is described at 0.04mm/yr [Thomas, G. E. R., et. al.. (2011). The seven-year wear of highly cross-linked polyethylene in total hip arthroplasty: a double-blind, randomized controlled trial using radiostereometric analysis. The Journal of bone and joint surgery. American volume, 93(8), 716–22. doi:10.2106/JBJS.J.00287]. We strongly believe that orbital implants placed subperiostally are not subjected to such tensions as acetabulum in hip joint prosthesis and thus wear of those implants is not significant. We believe 6 month follow-up is sufficient long-term to evaluate the relatively stable results. At that time post-op swelling and temporal dysfunction disappear.

More detailed are required in the figure legend.

We analysed figure legends and added previously lacking information.
I felt that the paper took too many assumptions on the reader. A clearer explanation and approach is required.

Whole manuscript was revised. More detailed descriptions were added. The lack of open minded and critical analysis is stated by the analysis of references in which 6 references are self references by Kozakiewicz M. We are glad for pointing this out. All of those self-references describe method designed by Kozakiewicz M. and used in submitted manuscript. We have done more article research, added new points to discussion section as well as new references.

1. In material-methods: How was the random assignment performed? First all the cases were treated by application the model+TiMesh and later on all the cases were treated by UHMW-PE.

2. I don’t understand the sentence “Classification of maxillofacial fractures according to H. Wanyura.” It would better use some international classification for example issued from AO CMF foundation. Classification used in manuscript is widely used in Poland. We added detailed descriptions of each type of fracture to meet international standards. Suggested AO CMF foundation classification does not reflect difference between low and high energy zygomatic complex fractures

3. 0.6 mm cuts: do you mean slice thickness ?, please provide kVp and mAs to the radiological protocol

Corrected

4. (Synthes, http://www.synthes.com/MediaBin/International%20DATA/036.000.607.pdf) should be (Synthes, CITY, Switzerland) please check

Corrected

5. « Medmont M600W Automated Perimeter »: please check company, city, country

Corrected

“patients were operated under general anaesthesia: by the same surgeon? Please specify

Yes, by the author MK. Also corrected in manuscript

6."In first group flat titanium 0.4mm thick mesh was shaped on solid individual model [Ti-Mesh] [7, 12], in next group virtual analysis of intact (mirrored) and
affected orbital wall were used to superimposition to give superior and inferior surfaces for CAM individual milling from ultrahigh molecular weight polyethylene [UHMW-PE][13] were used to reconstruct affected lower or lower and medial wall of the orbit.” Sentence too long, please modify

Corrected

7. « Statgraphics Centurion XVI » please check the correct spelling
Corrected, also we added information about company developing this software.

8. In Results section: please check the sentence: “The older was the patient was…”
Corrected

9. In Discussion:
“Autologous calvarial bone grafts, porous polyethylene, and polydioxanone (PDS) were most widely used for orbital reconstruction. »: please provide with a reference

10. “Ocular motility was reduced most with lyophilized dura and PDS.”: please provide with a reference

11. “Preoperative and postoperative rates for diplopia and enophthalmos varied among the materials”: please provide with a reference

12. “Those results reveal continued inadequate evidence to exclusively support the use of any one biomaterial or implant for orbital reconstruction. » please provide with a reference

All 4 points above are a result of citation copy-paste error, which was later overlooked during editing. Whole paragraph was deleted, conclusions and references were complemented.

13. “Within the last few years CAD and CAM in reconstruction of orbital fractures becomes commonly used technique » please check English editing
Corrected

14. « depending sex, » : please use word gender
Corrected