Comparison of Resorbable Mesh (Poly L-Lactide/Glycolic Acid) and Porous Polyethylene in Orbital Floor Fractures in an Experimental Model

Comparaison entre le treillis résorbable (poly L-lactide et polyacide glycolique) et le polyéthylène poreux en cas de fracture du plancher orbital dans un modèle expérimental

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Abstract

Background: Resorbable mesh and porous polyethylene are frequently used alloplastic materials for the treatment of the orbital blowout fractures. The literature lacks reports comparing their long-term effects on experimental models. **Objective:** Our aim was to radiologically and histologically evaluate the effectiveness and safety of porous polyethylene and resorbable mesh in a rabbit orbital blowout fracture model. **Methods:** Twelve New Zealand white rabbits (24 orbits) were randomized to 4 groups. In group 1, only orbital floor dissection was done. In group 2, following orbital floor dissection, a 10-mm defect was created without any extra procedure. In group 3, following a 10-mm defect creation, a 12-mm-round cut porous polyethylene was placed on the defect. In group 4, following a 10-mm defect creation, a 12-mm-round cut resorbable mesh was placed on the defect. Computed tomographic analysis was performed during follow-up period. Orbital floors were evaluated histologically at month 6. **Results:** No clinical complications were observed during follow-up period. In radiological evaluation, there was no statistically significant difference between groups regarding bone formation. In histological evaluation, the connective tissue was denser, and organized and better bone formation was observed in group 3 and 4 when compared with other groups. **Conclusion:** Although no significant radiological changes were present, porous polyethylene and resorbable mesh performed better histologically. They were effective and well tolerated for reconstruction of the isolated orbital floor defects.

Résumé

Historique : Le treillis résorbable et le polyéthylène poreux sont des matériaux alloplastiques souvent utilisés pour traiter les fractures isolées du plancher de l'orbite. Les publications ne contiennent pas de rapports sur les effets à long terme de ces matériaux dans des modèles expérimentaux. **Objectif :** Les chercheurs visaient à évaluer l'efficacité et la sécurité du polyéthylène

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poreux et du treillis résorbable sur le plan radiologique et histologique dans un modèle de fracture isolée du plancher de l'orbite chez un lapin. **Méthodologie** : Douze lapins blancs néo-zélandais (24 orbites) ont été répartis au hasard en quatre groupes. Le groupe 1 a seulement subi la dissection du plancher de l'orbite. Dans le groupe 2, après cette dissection, une anomalie de 10 mm a été créée sans intervention supplémentaire. Dans le groupe 3, après la création d'une anomalie de 10 mm, une coupe ronde de polyéthylène poreux de 12 mm a été placée sur l'anomalie. Dans le groupe 4, après la création d'une anomalie de 10 mm, une coupe ronde de treillis résorbable de 12 mm a été placée sur l'anomalie. Les chercheurs ont effectué une analyse tomodensitométrie pendant la période de suivi. Au sixième mois, ils ont évalué les planchers orbitaux à l'histologie. **Résultats** : Les chercheurs n'ont observé aucune complication clinique pendant la période de suivi. À l'évaluation radiologique, la formation osseuse ne présentait aucune différence statistiquement significative entre les groupes. À l'évaluation histologique, les tissus conjonctifs étaient plus denses et la formation osseuse était organisée et de meilleure qualité dans les groupes 3 et 4 que dans les autres groupes. **Conclusion** : Malgré l'absence de modification significative à la radiologie, le polyéthylène poreux et le treillis résorbable donnaient de meilleurs résultats sur le plan histologique. Ces matériaux étaient efficaces et bien tolérés pour la reconstruction des anomalies isolées du plancher orbital.

Keywords

blowout fracture, experimental, resorbable mesh, porous polyethylene

Introduction

There are various reconstruction options for the treatment of the orbital floor fractures. Among these alternatives, the autologous materials including bone, fascia, periosteum, cartilage, fat, and so on, or alloplastic materials including porous polyethylene, poly L-lactic acid, titanium plate, and so on, are the commonly used alternatives.¹⁻⁵ In larger defects, autologous bone may be advantageous since it provides construction of skeletal support and the osteoblasts inside the graft have osteoinductive effects.⁶

Alloplastic materials are better suited for smaller orbital floor defects. They became popular with no donor site morbidity, lower complication rates, and easy availability. Porous polyethylene (Medpor; Porex Surgical Inc, Newman, Georgia) and resorbable mesh (poly L-lactide/D-lactide) are 2 alloplastic materials used for this purpose. Porous polyethylene has a microporous architecture. It is stabilized with vascular and soft tissue ingrowth.^{7,8} Although it is a nonabsorbable material, it becomes a part of body network by this ingrowth. Since it does not induce a foreign body reaction, it also forms a barrier for infections.⁹ Poly L-lactide is an alloplastic material which has supportive characteristics and absorbed over time. It is resorbed completely with time.

There are limited experimental studies in the literature which evaluate the effectiveness of alloplastic materials in the surgical management of orbital fractures.^{10,11} These studies either evaluate each alloplastic material individually or give their combined comparison over a short-time evaluation. In this study, our aim was to evaluate the histologic and radiologic changes of porous polyethylene and resorbable mesh use in a rabbit orbital blowout fracture model.

Methods

This study was found to comply with the ethical guidelines and approved by the ethics committee of Gazi University (G.Ü. ET 08.033—07.04.2008). The whole study was conducted in accordance with the principles of the Guide for Care and Use

of Laboratory Animals. A total of 12 male New Zealand rabbits were included in this study. Orbits of each animal were undertaken separately, making 24 in total and then divided into 4 equal groups. During the study, the rabbits were maintained in appropriate separate cages. They were regularly given water and fed on a standard laboratory feed. All procedures were conducted by the same surgeon under sterile conditions. Following the surgical procedure, the rats were put in individual cages. To reduce the pain, analgesics were given when necessary (flunixin 1 mg/kg—Fluvin, Vilsan Pharmaceuticals, Ankara, Turkey).

A standard surgical procedure was performed for every patient under 10% ketamine HCl (45 mg/kg Alfamine-IM, Ege-Vet Ltd, Izmir, Turkey) and Xylazine HCl (5 mg/kg Rompun-IM, Leverkusen, Germany) anesthesia. Following the corneal reflex and extremity withdrawal response test, the surgical site antisepsis was supplied with 10% povidone-iodine solution and covered with a sterile drape. Subciliary incision was done in all groups. Following dissection of the muscles and the areolar tissue, periosteum was elevated and orbital floor was dissected.

Groups are summarized in Table 1. In group 1 (n = 6), only orbital floor dissection was done. In group 2 (n = 6), following orbital floor dissection, a 10-mm defect was created without any extra procedure (Figure 1). In group 3, following the same surgical procedure undertaken in group 2, a 12-mm-round porous polyethylene sheet which was 0.85 mm in thickness (Medpor) was placed on the defect. In group 4, following the creation of the same sized defect, a 12-mm-round resorbable mesh plate (Inion, Tampere, Finland) was placed on the defect (Figure 2). In all groups, at the end of surgical procedure, periosteum and skin were sutured with 5/0 Monocryl (Ethicon Inc, Somerville, NJ). Surgical site was disinfected with 10% povidone-iodine after skin closure. Flunixin (1 mg/kg Fluvin-IM) was used for the pain control. Six months after the surgery, all rabbits were killed with high-dose anesthetic agent Xylazine HCl (100 mg/kg Rompun-IV, Leverkusen, Germany).

Table 1. Summary of Groups.

Group	Surgical Procedure
1	Orbital floor dissection only
2	10-mm orbital floor defect without any implant
3	10-mm orbital floor defect with porous polyethylene sheet
4	10-mm orbital floor defect with resorbable mesh plate

Figure 1. Orbital floor dissection and creation of the defect.

Clinical Evaluation

Following surgical procedure, animals were evaluated daily on a routine basis. All patients were assessed for any complication including infection, extrusion, implant displacement, and eye movements. Before sacrifice of animals, force duction was assessed for each orbit.

Radiologic Evaluation

Radiological assessment of the orbital floor was done by means of computed tomography (CT) in months 1 and 6 postoperatively (Figures 3 and 4). Both CT image sets were evaluated according

to the presence of bone formation at the injury sites (0 = no bone formation, 1 = sparse bone formation, 2 = adequate bone formation), orbital fat herniation (0 = herniation between 0 and 2 mm, 1 = 2 and 4 mm, 2 = 4 and 6 mm), and the status of maxillary sinus for potential complications such as hemorrhage or infection (0 = empty, 1 = filled). Orbital fat herniation was determined by measuring the distance in millimeter of protruding fat tissue from the orbital floor to maxillary sinus, if present.

Histologic Evaluation

Following sacrifice of the animals, the orbital floor bone was taken out together with the implant and the surrounding soft tissue, for the histological evaluation. Tissue was fixed with 10% neutral formalin for 72 hours at room temperature. After fixation, bone tissue was embedded in decalcification solution (formalin–nitric acid solution; 37%-40% formaldehyde, 80 mL distilled water, 10 mL nitric acid). Solution was changed every week until tissue was decalcified. With routine histological procedures, paraffin blocks were created. Then 4- to 5- μ m-thick sections were cut with a microtome and stained with hematoxylin and eosin after this procedure sections were evaluated under the light microscope (Leica Camera G, SM 4000B, Wetzlar, Germany). Images were observed with Leica Q-Vin version 3 program. Evaluation of the bone formation at the injury site, neovascularization, fibrous tissue formation, and hemorrhagic infiltration were performed for every single group.

Statistical Analysis

SPSS for windows 11.5 was used for the analysis of the data. Group pairs in months 1 and 6 were analyzed with Wilcoxon test and comparison of data in same groups was done with Mann Whitney U test. A P value of less than .05 was statistically significant.

Results

Clinical Evaluation

All animals completed the postoperative follow-up period successfully without a complication. During the routine clinical

Figure 2. Preparation of porous polyethylene (A), resorbable mesh (B), and implant placement on the defect (C) area.

Figure 3. Computed tomography (CT) image of a group 3 rabbit, in which the orbital defect was treated with porous polyethylene. Figure shows the orbit (asterisk) and the bony defect (arrow head). Note slight herniation at the surgical site (arrow).

Figure 4. Computed tomography (CT) image of a group 4 rabbit, in which the orbital defect was treated with resorbable mesh. Figure shows the orbit (asterisk) and the bony defect (arrow head). Note relatively prominent herniation at the surgical site (arrow).

evaluations, none of the animals had restricted eye movements, infection, or implant extrusion. Forced duction test showed unrestricted movement of each orbit in upward, downward, lateral, or medial gaze.

Radiologic Evaluation

Both 1- and 6-month radiologic CT evaluations revealed increased and statistically significant bone formation for each group when compared to group 1 ($P < .05$). However, there was no statistically significant difference between groups 2, 3, and 4 in terms of bone formation at neither 1-month nor 6-month

Table 2. Orbital Fat Herniation Scores for Months 1 and 6 (mm) in Groups.

N	Group 1 (1/6 months)	Group 2 (1/6 months)	Group 3 (1/6 month)	Group 4 (1/6 month)
1	0/0	0/0	0/1	1/1
2	0/0	0/1	0/1	2/2
3	0/0	0/0	1/1	2/2
4	0/0	0/1	0/0	1/1
5	0/0	0/0	1/1	1/3
6	0/0	0/0	0/0	1/2

Table 3. Histologic Findings.

Group #	Hemorrhagic Infiltration	Connective Tissue	Vascularization	Bone Formation
1	+	Loose+	—	—
2	++	Loose++	—	—
3	—	Loose++	+	Localized small bone trabeculations
4	—	Organized++	+	Large area of bone trabeculations

Note: Hemorrhagic Infiltration was significant in Group 1 and 2, $P < .05$. Vascularization was significant in Group 3 and 4, $P < .05$.

radiological evaluation. Computed tomography examinations revealed a statistically increased herniation in group 4 when compared to groups 1 and 2 ($P = .019$; Table 2). There was no statistically significant difference in terms of herniation depicted between other groups. Computed tomography evaluation did not reveal a statistically significant difference for the status of sinuses between the groups.

Histologic Evaluation

Histologic findings are summarized in Table 3. Hemorrhagic infiltration was present in groups 1 and 2. Connective tissue was observed in all groups, which was loose in the first 3 groups and organized only in the fourth group. Enhanced vascularization and bone formation were present in groups 3 and 4 (Figures 5–7).

Discussion

Orbital blowout injuries can lead to enlargement of the orbital volume and orbital fat herniation. It is important to maintain the integrity of the orbital floor in order to obtain a functional result and a good aesthetic outcome. Various autogenous, alloplastic, and allogeneic materials have been used for the treatment of orbital blowout injuries.^{1–6} Since with autogenous bone and cartilage grafts a part of the body is incorporated with the recipient bone, they are less likely prone to infection and are preferred in wider defects. However, autogenous tissues have

Figure 5. Histologic section of group 1 shows trabecular bone tissue (#), minimal hemorrhagic infiltration at the periosteum elevation site (red arrow), loose connective tissue rich from fatty cells on the opposite side (black asterisk; A and B). Histologic section of group 2 shows wide gaps over the trabecular bone (red star), more prominent hemorrhagic infiltration (black arrow), and loose connective tissue consisting of fatty cells (black asterisk) compared to group 1 (C and D). Hematoxylin and eosin (H&E) bars: A-C, 200 µm; D, 500 µm.

the disadvantage of donor site morbidity risk. Moreover, shaping and fitting hard bone to the defect might be difficult.

Orbital floor fractures could be under the form of “pure” or “impure.”¹² Pure fractures are associated with isolated orbital floor fractures, whereas impure fractures are associated with the neighboring bone fractures, like frontal, zygomatic, orbital rim, and maxillary buttress fractures. In the current study, the defects were surgically created simulating pure blowout defects. As their causal mechanism is different from the clinical cases, only isolated fractures were studied in our model.

The critical size skull bone defect is controversial and 4 to 8 mm has been accepted in the literature.¹³⁻¹⁶ Seymour et al, Betz et al, Dougherty et al, and Schellini et al created 5 mm, 8 mm, 8 mm, and 15 mm × 6 mm orbital floor defect, respectively, in rabbit orbital defect model.¹⁷⁻²⁰ In the present study, 10 mm size defect was created in order to place relatively large-size implants.

Coronal CT is the gold standard for the evaluation of the orbital blowout fractures.²¹ We used orbital CT to evaluate orbital bone defects and its change with time. The position of porous polyethylene and resorbable mesh was determined indirectly by examining the orbital floor integrity. Bone healing was evaluated with CT of bone defect at months 1 and 6, postoperatively. There was no statistically significant

difference between groups except fat herniation. In group 4, orbital fat herniation was statistically more significant when compared with the other groups. However, clinical evaluation was insignificant for any complication. No correlation was detected with clinical evaluation and radiologic assessment for fat herniation. This clinical and radiological discrepancy led us think that the relatively limited spatial resolution of CT might have caused a pseudo appearance. In the current study, we also observed ossification in histologic specimens at the 6-month evaluation. However, radiologically, no statistically significant difference for the bone formation was detected. This result led us think that although present, routine CT failed to demonstrate very thin bone formation. Micro-CT with its inherent increased spatial resolution is known to be more sensitive in showing ossification. In our study, we did not have the opportunity to use micro-CT, and this can be cited as a limiting factor. Thus, experimental studies conducted with micro-CT could deliver an answer for the presence of fat herniation and ossification.

Porous polyethylene is a synthetic material which has microspores reside within. It has different sizes and thicknesses. After implantation, vascular ingrowth occurs and it incorporates with the normal tissue, therefore eliminates the need for fixation with screws or plates.⁹ High infection rates

Figure 6. Histologic section of group 3 shows variety of blood vessels, organized connective tissue (#) containing collagenous fibers (co) and cell nuclei (green arrow) indicating increased vascularization (red arrow) at the edge of trabecular bone (black arrow), localized small bone trabecula (yellow arrow), and Porous Polyethylene Implant (PPI) structure (*). Hematoxylin and eosin (H&E) bars: A and D, 200 µm; B and C, 50 µm.

Figure 7. Histologic section of group 4 showed an increased vascularization (red arrow) at the edge of trabecular bone (black arrow) similar to group 3. Connective tissue consisting of collagen fibers (co) and cells was more organized (#) and tightly structured together with trabecular bony structures (yellow arrow) expanding to a wider area compared to group 3. Hematoxylin and eosin (H&E) bars: A and D, 200 µm; B and C, 50 µm.

have been reported in comparison with nonporous materials, before vascular ingrowth.²² If injury involves the extraocular muscles, this situation may cause restriction in the eye movements with the ingrowth of the orbital tissue into the porous polyethylene implant.⁸ No infection or restriction in the eye movements occurred during the follow-up period. Thus, porous polyethylene was considered safe in our model.

Resorbable mesh is composed of poly L-lactid and D-Lactid acid. Although these materials are widely accepted as biocompatible and not causing any foreign body reaction, there are some reports related to the local tissue reactions.²³⁻²⁷ Uygur et al reported scar tissue formation through the holes of resorbable mesh which was causing eye movement restriction. In the current study, we did not observe any clinical or histological inflammatory reaction. In group 4, fat herniation was seen radiologically in higher rate, but no clinical complication was detected, including restriction in the eye movement. We thought that soft tissue herniation from the hole of the resorbable mesh could have caused a change in CT images. Resorbable mesh was considered safe in our model without complication. However, possibility of herniation through the holes, as reported in the literature, should be kept in mind when using resorbable mesh.

Both implants were observed to have higher vascularization histologically in comparison with the control group. Bone formation was also higher in implant groups. In porous polyethylene group, there were small bone trabecules seen; on the other hand, bone trabecules were more prominent and larger in the resorbable mesh group. Although there was no clinical or radiological correlation, further studies are needed to investigate this outcome.

In current clinical practice, it is widely accepted that both alloplastic materials can safely be used in surgical management of orbital fractures. However, this understanding is not well documented on experimental models in the literature. Among those limited experimental reports, some either evaluate each alloplastic material individually or give their combined comparison over a short-time evaluation. Lee et al compared resorbable mesh and porous polyethylene for fibrovascular growth over a 6-week follow-up period.¹¹ He detected vascular growth only in porous polyethylene. However, in our study, following 6-month period, we did document higher vascularization and bone formation for both materials. Therefore, the above presented study confirms the effectiveness and safety of both alloplastic materials following their comparison in an experimental study, including histological and radiological workup over a 6-month period.

Conclusion

In this long-term comparative study, porous polyethylene and resorbable mesh were evaluated in an animal model. Both implants were histologically found to enhance vascularization and bone healing at the orbital floor, whereas increased herniation was only observed with resorbable mesh group. Limitation

in spatial resolution of routine CT presumably prevented any radiologically significant finding to be detected. Although this animal model does not completely represent a human orbital fracture setting, findings of this article can form a histological basis for future studies aiming to compare the effectiveness of different implants in humans.

Declaration of Conflicting Interests

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