

HIGH DENSITY POROUS POLYETHYLENE IMPLANTS IN FACIAL DEFORMITY

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ABSTRACT

Objective: A prospective study to assess the overall acceptance, safety and efficacy of Biopore™ (porous high-density polyethylene implants) implants as an onlay implant in facial deformity. **Material and Method:** Eight patients (six males and two females) ranging from 17 to 30 years of age requiring correction of facial skeletal deformity with augmentation by alloplastic material. Follow up ranged from 6 - 24 months. **Results:** Types of deformity and defect corrected include four patients with chin deficiency, two with Nasal bridge defect, one orbital defect and one with infra-orbital rim defect. Total of eight implants were placed. Complications include temporary nerve paresthesia in case of augmentation genioplasty and inappropriate reconstruction of infra orbital rim requiring re-intervention. **Conclusion:** Within the limits of the present study, it can be concluded that the Biopore implants are an effective alternative to autogenous grafts in correction of facial defects and deformity. The implants were found to be 100% successful including one patient requiring implant revision. Advantages include biocompatibility due to vascular ingrowth in the implant due to its adequate pore size and wide variety of shapes and sizes availability. Disadvantages though not observed in the present study, include the chance of extrusion of implant.

KEYWORDS: High-density porous polyethylene, Alloplast, Biopore™, Facial skeletal augmentation.

INTRODUCTION

Porous high-density polyethylene (pHDPE) is an alloplastic material developed in 1970s, comprised of polyethylene resins as straight chain aliphatic hydrocarbons. It is an inert material with very low tissue reactivity. It also causes minimal inflammatory foreign body reactions, forms no capsules, and yields no observable systemic or cytotoxic effects.^[1-5] It is relatively non-compressible, somewhat flexible, and can be carved easily with a sharp instrument after being submerged in hot sterile saline (80 to 100°C) for several minutes with permanent results and applied directly onto the facial skeleton as an onlay implant owing to its excellent biocompatibility. Pieces can be sutured or screwed together when necessary. The material is biologically inert and characterized by large pores averaging 200 µm in diameter.^[1] This property allows for significant tissue ingrowth, excellent implant fixation, very low resorption, and low likelihood of infection or exposure.^[6] pHDPE is effectively used in facial skeletal reconstructions and in different reconstructive interventions like nasal dorsal augmentation; augmentation of malar, paranasal, and mandibular

contours; microtia reconstruction; and orbital floor and socket reconstruction.

Polyethylene has been used as an implant material for more than 60 years. HDPE became commercially available as MEDPOR (Porex Surgical, College Park, GA) in 1985. Biopore™ (PHDPE) implants have been available in the Indian market since 2006 (www.biopore.in). [Fig.1]

The aim of the study was

1. To evaluate the safety & efficacy of porous polyethylene implant in facial deformities as an augmentation onlay implant to achieve the desired esthetic & function.
2. To evaluate the short and long-term complications, if any like allergic reactions (immediate or delayed), rejection (immediate or delayed), infection (acute or chronic), dehiscence or loosening and bone resorption.

MATERIALS AND METHODS

This study was undertaken in eight randomly selected patients reporting to the department of Oral & Maxillofacial Surgery, Punjab Government Dental College & Hospital, Amritsar between December 2010 to May 2013. The institutional ethical committee approved the study. Patients were explained about the surgical process, advantages and disadvantages of HDPE. Furthermore, informed consent was obtained from all the patients. In each case, powder free sterile latex gloves were used to avoid contamination of the implant with talc. Before final placement of implant, it was soaked in gentamycin solution 400mg diluted in 50ml normal saline.^[7] The augmentation with Biopore implant was carried out by following the three manoeuvres described by **Yaremchuk (2003)** viz. wide periosteal exposure, screw fixation of the implant to the underlying bone and “in-place” contouring of the implant. In all cases, the implant was fixed to the underlying skeleton with 10-12mm titanium screws.^[8]



Fig. 1: (Chin Implant).

1. Inclusion criteria

- Patients in the age group of 15 years or above irrespective of sex, caste, religion and socioeconomic status.
- Patients requiring facial augmentation of chin, mandibular angle and inferior border, skeletal nasal base, cheek or orbit.
- Patients who were declared fit for surgery under local or general anaesthesia.

2. Exclusion criteria

- Medically compromised patients
- Presence of any active or acute infection.
- Patients who refused their consent for the study.

3. Preoperative assessment

Preoperative assessment was aimed at history, clinical (extraoral & intraoral) and systemic examination.

- Routine blood investigations
- Measurements on soft tissues and study models were taken so as to select an implant of adequate size and shape (wherever applicable).

Radiographs

- Augmentation Genioplasty - Standard PA view mandible, Lateral cephalogram.
- Rhinoplasty - PA view maxilla in Water's position, Lateral cephalogram.
- Infra-orbital Rim Reconstruction - PA view maxilla in Water's position
- Orbital Floor Reconstruction – NCCT Scan / MRI.

4. Selection of graft

Extended preformed implant for the defect was selected according to judged requirements. Its dimensions were altered during surgery.

RESULTS

Of the total eight patients, there were six males and two females. Sites involved in the surgery were Chin, Nasal Dorsum, Orbital Floor and Infraorbital Rim. Clinical assessment for restoration of function, aesthetics or any complication was evaluated postoperatively on first day, third day, at first week, third week, sixth week and after three months. Post-operative radiograph was done after three months to evaluate any loosening of screw or underlying bone resorption. Moreover, follow up period ranged from 6 – 24 months. Patient's and doctor's ratings of overall acceptance, was recorded on 100 mm Visual Analogue Scale (VAS) on 2nd day, 7th day, after 6 weeks and after 3 months. The VAS was anchored at each end as “completely dissatisfied” and “completely satisfied”.

All 8 patients were satisfied by the results of surgery. They represented remarkable improvement in facial esthetics. [Fig.2 - Fig.6] No major complication such as mobility, infection, dehiscence, extrusion of implant was noted at follow-up. Transient paresthesia was noted in genioplasty patients, which resolved automatically within 6 weeks. The infraorbital rim reconstruction patient required revision of graft (smoothing) at 3rd week.



Fig. 2 & 3: (Preoperative Pictures of Nasal Deformity).



Fig. 4 (Intraoperative Picture)



Fig. 5 & 6: (Postoperative Pictures).

DISCUSSION

Augmentation of the facial skeleton can be done by orthognathic surgery, autografts, allografts and alloplasts. Autografts were traditionally regarded as 'gold standard' for facial reconstruction as they have relative resistance to infection, no host response, incorporation by host into new bone and lack of late extrusion of graft. But disadvantages such as donor site morbidity, resorption, and difficulty in carving and

additional operative time have caused decline in use of autografts.

To overcome the disadvantages of traditional orthognathic surgery and autografts, various artificial graft materials were developed, and methods for efficacious use of the graft materials were proposed. It was Rousset, in 1828 who initialized use of artificial materials with gold.^[9] Following that Joseph used Ivory for this purpose in 1900. These materials are not used anymore due to poor tissue tolerance. Since 1950, silicon

rubber, polyamide, Gore-Tex started to be used with their specific reactions. Furthermore, in 1953, Brown used silicon (smooth surface, solid implant) which usually surrounded by fibrous capsule, was predisposed to be extruded by host tissue within a long time, and also there was absence of proper vascularization.^[9] Additionally, extrusion risk was decreased by using polyamide mesh as it allowed fibrous tissue ingrowth within several months and caused fixing of the implant. Despite these advantages, severe inflammatory reactions resulted in the recipient body. Later on, Gore-Tex or Polytetrafluoroethylene (PTFE) (porous) was developed which was not accompanied by extrusion or degradation; however; its elasticity was not enough to be shaped properly for some areas such as nose and it was not fixed in the host tissues as it lacked tissue ingrowth capability.^[6] Further, Proplast was another alloplast available for reconstruction but caused antigenic reactions in host body and had increased risk of infection.^[2] Lately, MEDPOR™ Biomaterial has been used in over 250,000 surgical procedures and referenced in over 350 published articles since 1985. It was introduced by Porex Surgical, Inc., Newnan, GA but now has been acquired by Stryker Craniomaxillofacial, Kalamazoo, MI 49002 USA. BIOPORE™ (PHDPE) is available in the Indian market since 2006.

PHDPE is relatively non-compressible, somewhat flexible, and can be carved easily with a sharp instrument and applied directly onto the facial skeleton as an onlay implant owing to its excellent biocompatibility. Additionally, its pieces can be sutured or screwed together when necessary. Although, high-density polyethylene is similar in hardness to cancellous bone at room temperature, it demonstrates excellent thermoplastic abilities and can be bent & moulded easily after being submerged in hot sterile saline (80 to 100°C) for several minutes with permanent results. Most importantly, it is biologically inert and characterized by large pores averaging 200 µm in diameter that allows for significant tissue ingrowth, excellent implant fixation, very low resorption, and low likelihood of infection or exposure. Thus, high-density polyethylene implants achieve optimal fixation through tissue ingrowth to underlying bone when implanted in a subperiosteal pocket. It can be sculptured before surgery, or fabricated implants are also easy obtainable in the market. In addition, increased tissue ingrowth also increases its resistance to infections. PHDPE is effectively used in facial skeletal reconstructions and in different reconstructive interventions like nasal dorsal augmentation; augmentation of malar, paranasal, and mandibular contours; microtia reconstruction; and orbital floor and socket reconstruction.

In our study greater percentage of male patients required facial augmentation. The male patients constitute 75% of the sample size. It is in contrast to studies done by **Niechajev** with female predominance 57%.^[10] The study done by **Deshpande and Munoli** exhibited equal

distribution.^[11] The age of the patients in the study group ranged from 17 years to 30 years, with mean age 21.3 years. **Niechajev** in his study demonstrated median age of 29 years. The study comprised of four patients with deficient chin, two patients with depressed nasal dorsum, one with blow out fracture of orbital floor and one with depressed infra orbital rim (post trauma defect).

The patients with deficient chin were treated with onlay Biopore implants. Augmentation in three patients was done intraorally and in one case extraorally as the defect was extending up-to the body region of mandible. The patients with depressed nasal dorsum were operated with external rhinoplasty approach. Biopore Nasal Arch (Catalogue No. 5030) was used for both the patients. The implant was inserted as a columellar strut between the medial crura and sutured into place high and low to the medial crura with 3-0 Vicryl, followed by placement of dorsal implant. [Fig.2 - Fig.6]

The orbital floor reconstruction patient had enophthalmos, hypoglobus, diplopia in upper gaze and paresthesia of infraorbital nerve following trauma. Patient reported to our department 4 weeks after trauma along with MRI. Inferior rectus muscle entrapment and herniation of orbital fat into the maxillary sinus were visible in MRI. The defect was 1.2cm x 1.5cm. According to clinical and MRI findings, lifting of herniated orbital fat and nerve decompression was planned under general anaesthesia. The orbital floor was exposed via subciliary incision and orbital floor reconstruction was done using 1.5mm thickness Biopore Implant (Catalogue No. 2080), which was carved and contoured intraoperatively according to requirement.

The patient with depressed infraorbital rim had chief complaint of epiphora. The nasolacrimal duct was found to be patent. Further, clinical examination showed eversion of punctum due to inappropriate support of lower eyelid owing to deficient bony support. So infraorbital rim reconstruction was planned. The infraorbital rim was exposed intraorally, Biopore infra orbital rim implant was carved and contoured according to requirement and was finally fixed to the underlying skeleton with titanium screws. Unfortunately, it required implant smoothing of a sharp point which was carried out at 3rd week. During the surgery, there was bleeding evident from the implant itself which indicated fibrovascular growth and is supported by Sclafani. Patient experienced significant but not complete reduction in epiphora. Though we were not satisfied, the patient was reasonably content with the outcome of the surgery.^[2]

In our experience, the implant was easy to work with. The implant was quite effective in reconstruction of chin, orbital floor and orbital rim as the implants were placed subperiosteally and rested on rigid surfaces. In nasal dorsal augmentation, complications viz. mobility, infection and extrusion of implant, have been reported by

Niechajev, Romo & Skouras et al, owing to inability of the recipient site to allow fixing of the implant with underlying skeleton with screws.^[10,12,13] In our experience, there was some mobility of the implant initially which got fixed by the 3 weeks without any further intervention. The final fixation of the implant to the surrounding tissues occurs only after fibrovascular ingrowth of the implant, which according to **Sclafani, Romo, Silver** reaches near completion in 14 days and completes within 21 days.^[14]

The criteria for successful graft was: Restoration of aesthetics and function, Absence of pain and swelling in the operated area beyond 10 days, Absence of extrusion or dehiscence of graft during study period, No signs of pus or edematous discharge during study period, and no mobility on manipulation. The implants in all eight patients satisfied all the criteria mentioned above. Esthetic and functional recovery was achieved in all cases. The only complication worth mentioning was paresthesia. As during the surgical procedure wide subperiosteal dissection is required and injury to the neurovascular bundle may occur from pulling force applied during retraction of tissues, it may have led to paraesthesia. However, the effect was transient. In our study, paraesthesia resolved in all patients by 1 month postoperatively. The follow up period ranged from 3 months to 1 year.

CONCLUSION

In conclusion, PHDPE implant is safe, effective and a successful alternative to autogenous grafting within the limit of present study. Although, PHDPE comes quite close to fulfil the criteria of an ideal implant, it has increased risk of infection as well as incidence of implant mobility & extrusion as compared to autogenous graft. To analyse the long term clinical success and safety of this material, studies with larger sample size and longer period of follow up are recommended.

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