



## Development of Bioerodable PDO (Polydioxanone) Plate for Nasal Septum Deviation under Controlled Environment

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### Abstract

*A bioabsorbable plate is a flexible polydioxanone polymer plate. PDO is a synthetic, absorbable monofilament suture manufactured in a controlled environment from paradiioxanone polymer. In rhinoplasty and septal surgery, a resorbable PDO plate is connected to the nasal septal cartilage to assess its mechanical stability as the cartilage fragment heals. In this circumstance, the PDS plate can help support the healing cartilage, allowing for adequate repair without compromising the contour or stability of the nose. Septorhinoplasty is the most common procedure for reshaping the nose with bioerodable plates. Bioabsorbable plate is made using a solvent casting technology, making it cost-effective, robust, easy to use, and with a long shelf life. Cartilage grafts are frequently used in rhinoplasty and septal surgery. The use of an absorbable scaffold material to support the reimplanted cartilage during healing can improve the outcome if the cartilage is thin or deviated.*

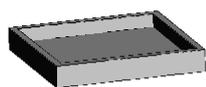
**Keywords:** Bioabsorbable, nasal septal cartilage, polydioxanone and controlled environment.

### Introduction

Bioerodable medical implantation was the subject of the present work. Polydioxanone (PDO) is a common material used to make biodegradable medical implants. PDO is colorless, synthetic polyester that has been utilized in medical devices since 1980. Bioerodable polymers have got a lot of attention in recent decades because of their potential use in the fields of environmental protection and physical wellness. PDO is made by polymerizing p-dioxanone rings with an organometallic catalyst in the presence of heat. PDO polymer is a biodegradable and

non-antigenic polymer that has been reported to cause minimal tissue reactivity after absorption following implantation. Within 180 days, PDS plate absorption was measured. By modifying the nose with surgery, a bioabsorbable medical implant can help with nasal correction and respiratory problems. A deviated septum is a condition in which the top of the cartilaginous ridge bends to the left or right, obstructing the nasal channel affected. Sinus drainage can get clogged as a result of the disorder. Breathing problems, headaches, runny noses, and sleeping problems are all common complaints. The bioerodable plate is made in a partial vacuum

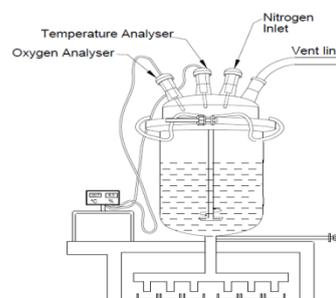
environment with inert gas accumulation, such as Nitrogen purging and oxygen removal. The solvent casting technique implies that it is more simple, long-lasting, and simple to utilize. The nose skin and soft tissue envelope are strong and tight, while cartilage is sparse and fragile. The majority of persons who suffer from a deviated septum have one nasal tube that is significantly smaller than the other. Breathing difficulties, frequent nose bleeds, facial pain, and a deformed nose are all symptoms of a deviated septum. Rhinoplasty is a surgical technique that includes changing the underlying structure of the nose. This surgery is done for a variety of reasons, including improving the patient's nose aesthetic look and treating nasal tube functional problems that affect inhalation and expiration. The nasal structure is supported by the flexible Plate until cartilage regrowth and scar tissue solidify the cartilage pieces bonded to the PDS Plate. The bones and cartilaginous structure of the nose are repositioned during surgery. Excessive scarring as a result of aggressive resection might also result in nasal valve narrowing. A new bioabsorbable polymeric plate that promotes tissue growth while minimizing long-term problems is also required. A major advantage of a biodegradable device over a non-degradable device is that it does not require a second operation for implant removal, reducing the number of hospital visits, healing time and hospital costs while also avoiding a long-term immune reaction.



**Fig.1** Mould shape

### Material and Methods

Various procedures can be used to create the bioerodable plate. Here, a partial vacuum environment is created by inserting purge Nitrogen ( $N_2$ ) gas and lowering down the  $O_2$  levels inside the chamber. Nose surgery can be performed using injection molding technique. The solvent casting technique will be used to pour it into the mould to make a plate (fig.1). The process works well with hygroscopic polymers, making them flexible, long-lasting, and stable. The solvent is added to the polydioxanone granules and the solvent is poured into the jar. The temperature for dissolution is roughly  $20^\circ C$ . The oxygen level was tested. The solute and solvent entry is located on the left side of the  $N_2$  gas chamber. In a controlled setting, a huge glass jar is placed in the center and mixed at 50-60 RPM for 15 minutes. The solution is drained from the bottom of the vessel and the required amount based on size is put into the mould. The bioerodable plate is made by dissolving PDO in a concentrated mixture of Hexafluoroisopropanol and dichloromethane or by using PDO alone. The plate separates from the mould as a result of phase separation. On the plate surface F mark is printed and after drying, the plate is packaged and sealed in a tyvek pouch. The ethylene oxide is employed to ensure sterility level of  $10^{-6}$ . The product is stored after Secondary packaging.



**Fig.2** Chamber having constant  $N_2$  purging and oxygen and temperature monitored

**Result and discussion**

PDO is hygroscopic in nature, therefore regular purging of N<sub>2</sub> in the solution creates an oxygen-free environment in the present invention, as shown in table 1. The bioabsorbable plate formulation in the desired model is made by dissolving PDO at a predetermined concentration in a 50:50 mixture of hexafluoroisopropanol and dichloromethane. By using the solvent casting method, a controlled amount of solution is poured into the glass mould with care to ensure that no air bubbles are trapped inside. As a result, a thin film was formed rather than a firm plate. Although the appearance and thickness were

accomplished, the tensile strength was low. The end result has proven to be unsatisfactory. Following the above unfavorable results, a new trial was conducted with a different solvent ratio. Hexafluoroisopropanol and dichloromethane are used in the formulation (10:90). The result, which was similar to the above technique, was the production of a firm perforated plate with good texture and a size of 40 X 50 mm. Additionally, the plate is sealed in a tyvek bag and treated with ethylene oxide to obtain a sterility assurance level of 10<sup>-6</sup>. The bioerodable plate has an opaque white appearance and a thickness of 0.25 mm. A tensile length was also discovered to be between 40 and 50 N, which is suitable for the operation.

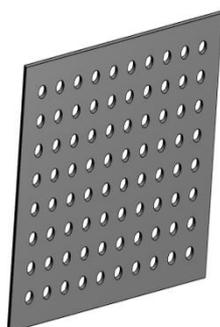
The following observations are listed in Table No. 1

**Table No. 1**

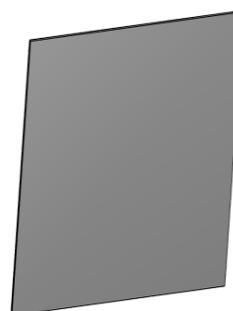
Sr. No.	Solution Concentration (gm)	Visual Perception
1.	0.2	A very thin, flexible film is created, but it is not strong enough
2.	0.5	
3.	0.7	
4.	1.0	A rigid plate of adequate strength is created
5.	1.5	A rigid plate is created, and flexibility is reduced

For the surgical operation, a hard perforated bioerodable plate with sufficient results is sought. Bioerodable is a biodegradable device that does not require a second operation to remove the implant, reducing the patient's number of hospital visits, healing time, and

hospital costs while also preventing a long-term immunological reaction. The thickness of the plate, produced by solution casting, ranges from 0.15 mm to 0.5 mm. Within 182 to 238 days, the PDS plate was completely absorbed or digested.



**Fig. 3** Perforated plate



**Fig. 4** Non Perforated plate

The analytic data for PDS flexible plate is shown in the table no. 2 to 4 for consideration the different parameters.

**Table No. 2**

PDS Flexible Plate		
Sr. No.	Parameters	Value by Optimization
1	Absorption Duration/ Degradation Data	182 to 238 days
2	Glass Transition Temperature (T <sub>g</sub> )	(-)10°C to 0°C
3	Melting Temperature (T <sub>m</sub> )	110°C to 115°C
4	Inherent Viscosity at 30°C	1.5 to 2.2 dl/g
5	Thickness of the plate resulting from casting of solution	0.15 to 0.05 mm

Based on the analytic data for manufacturing the PDS plate the appearance should be tested with visual test method that confirms white to off-white colour and granules in shape. The inherent viscosity should be found 2.0. The Coulomb's Determination test conducted for the water which gives a value 0.36. The gas chromatography

method conducted for the residual monomer dioxanone and residual solvent toluene was observed 0.16 ppm and less than 2 ppm, respectively.

With different batches and test speeds, the mechanical properties of PDS plate testing have varying tensile strength.

**Table No. 3**

Sr. No	Batch No.	Test speed (N/mm <sup>2</sup> )	Tensile strength (N)
1	PDSTr03	100.00	30.38
2	PDSr	250.00	13.89
3	PDSr	250.00	24.83
4	Trial	250.00	39.60

**Table No. 4**

PDS Flexible Plate (Product = RESOMER X 206 S)						
Sr.No	Property	Test Method	Unit	Value	Min. Specification	Max. Specification
1.	Appearance colour	Visual Test	N.A	conforms	White to off-white	
2.	Appearance Shape	Visual Test	N.A	conforms	chips or granules	
3.	Identity NMR	NMR-spectroscopy	N.A	conforms	Corr. to ref. spec.	
4.	Inherent Viscosity (30°C, 0.1%, HFIP)	Inherent Viscosity	dl/g	2	1.5	2.2
5.	Water	Coulomb's Determination	% (w/w)	0.36	< = 0.5	
6.	Residual monomer dioxanone	Gas chromatography	% (w/w)	0.16	< = 0.6	
7.	Residual Solvent toluene	Gas chromatography	ppm	< 2	890	
8.	Tin	ICP-MS	ppm	42	50	
9.	Sulfated ash	Limit Test	N.A	N.A	< = 0.1 % (w/w)	

## Conclusion

The PDS plate appears to be an excellent transplant for supporting and stabilizing recovering cartilage in the septum and other areas of the nose. PDS is a suitable and safe material for sophisticated functional and cosmetic nasal restoration. PDS plates are created using a solvent casting technology,

which makes them more flexible, stable, simple, and long-lasting. The strong plate is made with enough radial strength. PDS plates are highly biocompatible, have a low risk of infection, and can be thinly sliced. It can provide support and remodeling to the cartilage region while also maintaining nasal aesthetics.

**References**

1. Joanne rimmer, Louisa M. Ferguson and Hesham A. Saleh. Versatile Application of the Polydioxanone Plate in Rhinoplasty and Septal Surgery. Arch Facial Plast. Surgery. 2012 ; 14 (5): 323-330.
2. Miriam Boenisch and Gilbert J. Nolst Trenite. Reconstruction of the Nasal Septum using Polydioxanone plate. Arch Facial plast. Surgery. 2010; 12 (1) : 4-10.
3. Gwang Jin oh, Jaeik choi, Taek- Kyun kim, Jae-yong Jeong , Joo Halk Kim, Sunje Kim and Sang-Ha oh. Feasibility of a polydioxanone plate as an adjuvant material in rhinoplasty in Asians. Arch Plast. Surg. 2019; 46 (2) : 152-159.[ Google scholar]
4. Justin Morse, Jacqueline Harris, Scott Owen, Justin Sowder and Scott Stephan. Outcomes of Nasal Septal Perforation repair using combined temporoparietal fascial graft and polydioxanone plate construct. JAMA Facial Plastic Surgery. 2019; 21 (4).
5. Joana A Martins, Antonina A Lach, Hayley L Morris, Andrew J carr. Polydioxanone implants: A systemic review on safety and performance in patients. November-2019.
6. Daniel J. Tweedie and Stephenlo. Reconstruction of the Nasal Septum Using Perforated and Unperforated polydioxanone foil. Arch Facial Plast. Surg. 2010; 12 (2): 106-113.