Comparative study on prosthetic socket materials

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Abstract

Prosthetic socket materials must exhibit a good processing performance so that a variety of desirable shapes can easily be formed, thereby enabling more controllable and adjustable socket production process and socket compatibility with the human anatomy and movement mechanics. Additionally, they need to feature high strength and light weight, and must be comfortable for the patient to use. In this study, the properties and application potential of current prosthetic socket materials, such as thermoplastic sheets, low-temperature thermoplastic sheets, silicone-based materials, and resin-based composite materials, were compared. Additionally, the matrix used in resin-based composite materials was investigated by infrared spectroscopy.

Keywords: prosthesis, socket, thermoplastic sheet, resin-based composite material

1 Introduction

A prosthesis is an artificial limb that is produced and assembled to restore body form and function, and to compensate for the disability caused by limb amputation. For the >200 million amputees in China, receiving a prosthesis is an important step towards their rehabilitation and reintegration into society. The prosthetic socket that connects the stump to the prosthesis is a critical part of the prosthesis and determines its performance. The prosthetic socket enables transfer of force between the stump and the prosthesis [1-5]. The basic requirements of a prosthetic socket are its ability to bear loads, control the prosthesis, and suspend the prosthesis. The prosthetic socket material must exhibit a good processing performance to allow the facile production of a variety of desirable shapes, thus enabling more controllable and adjustable socket production process and socket compatibility with the human anatomy and movement mechanics. Additionally, it must possess high strength and light weight, and be comfortable for the patient to use [6-17]. However, studies on prosthetic socket materials are rare. In this paper, we compare the properties and application potential of four types of existing prosthetic socket materials.

2 Thermoplastic sheets

Thermoplastic sheets are widely applied in the fabrication of prosthetic sockets including temporary sockets, transparent sockets for experimental purposes, and long-term prosthetic sockets. Among the polymers used as raw materials for thermoplastic sheet production are polyethylene (PE), polypropylene (PP), and modified polyesters, e.g., polyethylene terephthalate glycolate (PETG).

Table 1 presents the properties of various thermoplastic sheet materials used for prosthesis socket fabrication. Low-density polyethylene (LDPE), synthesized via a high-pressure polymerization process, consists of long and branched chains, and has a low crystallinity, density, and strength, but good toughness. It can be used to manufacture flexible sockets. High-density polyethylene (HDPE), synthesized via a low-pressure method, exhibits less branching, a higher crystallinity and strength, a good processing performance, and excellent toughness. It is therefore used to produce temporary prosthesis sockets.

TABLE 1 Properties and performance of different thermoplastic sheet materials used for prosthesis socket fabrication

		LDPE	HDPE	PP-H	PP-C	PETG
Processing performance	Melting temperature of the crystalline part (°C)	100–120	125–138	160–175	150–175	>150
	Melt index (g/10 min)	0.25–27		0.4–100	0.6–100	
Mechanical properties	Elongation at break (%)	100–650	350–525	100–600	200–500	110
	Bending strength (breaking or yield strength) (psi)			6000–8000	5000–7000	10200
	Tensile modulus (×103 psi)	25–41	130–150	165–225	130–180	
	Shore D hardness	44–50	61–63	76	70–73	78
Thermal properties	Linear expansion coefficient (10−6/°C)	100–220	130–200	81–100	68–95	
	Thermal conductivity	8	11–12	2.8	3.5–4	
Physical properties	Relative density	0.917–0.932	0.94	0.9–0.91	0.89–0.905	1.27

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PP has also been used to fabricate prosthetic sockets (Figure 1) because of its higher melting point, strength, rigidity, and resistance to bending and fatigue when compared with PE. However, PP is more brittle than PE, especially at low temperatures. To reduce the brittleness of PP, the latter can be copolymerized with ethylene to obtain a polypropylene copolymer (PP-C). Despite the lower resulting strength and rigidity of PP-C when compared with those of the polypropylene homopolymer (PP-H), the brittleness of the PP material is greatly reduced. Thus, PP-C is usually selected for low-temperature applications. However, because the viscosity of the PP melt is sensitive to changes in temperature, the processing temperature needs to be strictly controlled and maintained at ~185°C during socket fabrication. Furthermore, because of the lower thermal conductivity of PP relative to that of PE, the heat generated during the grinding process cannot be easily released, thereby leading to the adhesion of debris to the polishing head. Therefore, low revolution speeds during the grinding process and a metallic grinding head for coarse grinding are necessary to ensure efficient heat dissipation.

FIGURE 1 PP prosthesis socket

Polyethylene terephthalate (PET) can crystallize into a configuration that reduces the transparency of the resulting product. To circumvent this issue, the resin can be modified accordingly to inhibit PET crystallization, thus generating products with good transparency. For example, modification of PET with cyclohexanediol affords non-crystalline PETG with good transparency. The resulting PETG can then be used for the fabrication of transparent prosthesis sockets for experimental purposes (Figure 2). As shown in Figure 3, the elastic modulus of PETG is higher than that of other thermoplastic sheets.

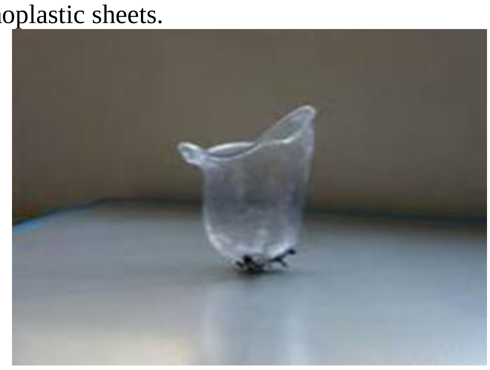

FIGURE 2 Transparent PETG prosthesis socket

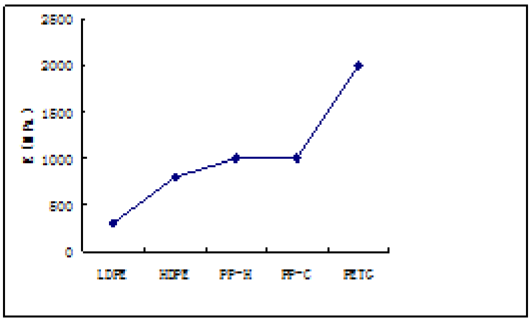

FIGURE 3 Elastic modulus of different thermoplastic sheet materials used for prosthesis socket fabrication

3 Low-temperature thermoplastic sheets

Plastic sheets have been widely used in the field of prosthetic products. However, socket production from ordinary plastic sheets is a complex process that includes the production and filling of the plaster female mold, modification of the plaster male mold, thermoplastic molding, and trimming of the products. In contrast, low-temperature thermoplastic materials can be shaped directly on the patients' bodies, and the product can be used directly after trimming, which greatly reduces the working and processing time. Low-temperature thermoplastic materials have a relatively low softening temperature and can be shaped in the temperature range from 55 to 75°C that human skin can withstand. Currently, the most frequently used low-temperature thermoplastic materials are polycaprolactone (PCL) and transpolyisoprene (TPI).

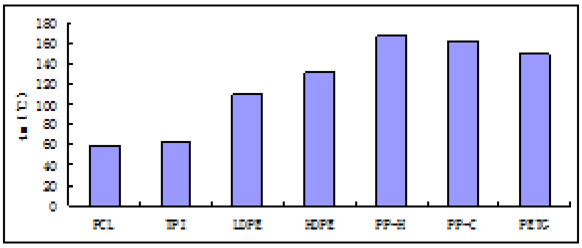

FIGURE 4 Melting temperature of different thermoplastic sheet materials used for prosthesis socket fabrication

PCL is a semi-crystalline polymer that can be synthesized via ring-opening polymerization of E-caprolactone in the presence of a catalyst. PCL has a crystalline melting temperature of ~60°C and a glass transition temperature of ~60°C. Its mechanical properties are similar to those of polyolefin, with a tensile strength of 13–30MPa and an elongation at break between 300 and 600%. TPI has a similar chemical composition, but a different configuration from that of natural rubber. Additionally, the good regularity of the molecular chains of TPI affords arrangement of the molecular chains with a high degree of ordering, resulting in a crystalline state. As a result, TPI loses its elasticity in the temperature region around room temperature, and can be used as a plastic. TPI has a low melting point of ~64 °C; hence, above this temperature, TPI has a soft, viscous flow appearance. Tables 1 and 2 compare the properties and performance of different low-temperature thermoplastic materials and ordinary plastic materials. Based on the melting temperatures given in Tables 1 and 2, the low-temperature thermoplastic sheets melt and deform more easily than ordinary plastic sheets at high temperatures. Hence, their application potential in the production of prosthetic sockets is limited. To better satisfy the requirements for successful application in the production of prosthetic sockets, some modifications are necessary to improve the mechanical properties of low-temperature thermoplastic sheets.

TABLE 2 Properties of low-temperature thermoplastic sheet materials

	PCL	**TPI**	**LDPE**	**HDPE**	**PP-H**	**PP-C**	**PETG**
Melting temperature (°C)	58–61	64	100–120	125–138	160–175	150–175	>150
Shore D hardness	50–55	50	44–50	61–63	76	70–73	78–80
Density (g/cm3)	1.145	0.96	0.917–0.932	0.94	0.9–0.91	0.89–0.905	1.27

4 Silicone rubber and silicone gel

Silicone rubbers and silicone gels have been widely used for the production of prosthetic socket inner liners because of their excellent biocompatibility, high temperature tolerance and chemical resistance, and lack of colour and odor, additionally, they do not promote bacterial growth or induce tarnish and corrosion of other materials [18, 19]. Their three main functions are as follows. First, they exert a skin-protecting effect, especially under poor skin conditions involving scars that are prone to damage owing to compression and friction. These types of wounds are difficult to heal and may even form ulcers. To prevent scar damage, an oily lubricant or softening scar drugs can be smeared on the skin surface of the stump to reduce friction between the scar and socket. Compression pressure can also be applied to the scar to soften the scar and prevent scar damage. Second, silicone rubbers and silicone gels exert a suspension effect. The silicone rubber stump sleeve can be rolled over and sleeved on the stump without the need for application of a lubricant on the skin. Additionally, silicone rubber sleeves generally show good adhesion to the skin, which can reduce both skin friction and shear force between the skin and internal wall of the socket, thus increasing the stump capability for prosthetic suspension. Third, silicone rubbers and silicone gels can improve the load-bearing capacity of the stump. Owing to the soft texture of silicone rubbers, they can adjust accordingly to protuberances of the stump bone and improve the load-bearing ability of the stump.

TABLE 3 Physical, mechanical, and chemical properties of silicone-based prosthesis products

Properties and performance	Index	Properties and performance	Index
Tensile strength (MPa)	≥7.00	Change in pH	≤1.5
Rupture strength (kN/m)	≥14.00	Heavy metal content (g/mL)	≤1.0
Elongation at break (%)	≥250	Residual content after evaporation (mg/mL)	≤0.05
Permanent deformation at break (%)	≤8	Consumption of KMnO4/mL	≤6.5
Shore A hardness	45–80	UV absorbance at 220 nm	≤0.3
Thermal aging	70°C for 72h		
Change of tensile strength (%)	≥−15		
Change of elongation at break (%)	≥−25		

Table 3 lists the physical, mechanical, and chemical properties of silicone-based prosthesis products. Because silicone-based prostheses cannot transfer force between the stump and prosthesis owing to the low material strength, a silicone rubber or a silicone gel prosthetic inner liner must always be used in combination with prosthetic socket materials.

5 Resin-based composite materials

Resin-based composites used for prosthesis socket fabrication are typically fibre-reinforced plastic materials. Among the most frequently used reinforcing fibres are glass, carbon, and aramid fibres. Commonly used base materials are, for instance, epoxy resin, unsaturated polyester resin, and poly (methyl methacrylate) (PMMA). The main features of resin-based composite materials are their high strength and light weight. Table 4 compares the performance of different resin-based composite materials and metallic materials.

The most commonly used prosthetic socket material is the modified PMMA-based fibre composite material. It is non-toxic and therefore does not induce strong skin irritation effects that are common for additives used in epoxy resin and unsaturated polyester. Additionally, the cured fibre–PMMA composite material is a thermoplastic and the shape of the products can be modified by annealing and subsequent processing. The composite material is typically prepared via a two-step process. The first step involves the formation of a prepolymer via bulk polymerization of methyl methacrylate monomers; the prepolymer is further modified to form the matrix of the prosthetic socket material. The second step involves the manufacture of the prosthetic socket using the base material and the fibre material via a composite processing technology.

TABLE 4 Performance of different resin-based composite materials and metallic materials

	Aluminium alloy	Titanium alloy	Steel	Glass fibre-reinforced composites	Carbon fibre-reinforced composites
Elastic modulus (MPa)	75	110	210	30	88
Tensile strength (MPa)	350	800	1100	720	900
Specific strength	125	178	141	343	600
Specific stiffness	27	24	27	14	59
Density (g/cm3)	1.145	0.96	0.917–0.932	0.94	0.9–0.91

FIGURE 5 Carbon fibre-reinforced plastic prosthetic socket

FIGURE 6 Shaping and molding process of prosthetic sockets based on carbon fibre-reinforced plastic materials.

Figures 5 and 6 show an example of a carbon fibre-reinforced socket and its molding process, respectively. Prosthetic sockets and orthoses produced via this process have a thin texture, light weight, and high mechanical strength. When resin-based composite materials are used to produce prosthetics and orthoses, the packing of the fibre material must not be too loose because only a tight fibre packing can ensure material capability to effectively withstand the desired load. Besides, the fibres should be oriented parallel to the direction of maximum loading so that the fibre material can withstand maximum loading. Furthermore, the high-strength fibre materials, e.g. carbon fibres, should have sufficient length and need to be laid on the weakest part of the composites to ensure effective material reinforcement. Processing and socket production technologies using resin-based composite materials are widely applied; however, studies on such materials have been rarely reported to date. In this paper, the base material of resin-based prosthetic sockets was investigated by infrared spectroscopy, and the results are shown in Figure 7. The peaks observed at 1730cm-1 corresponding to C=O stretching vibration and at 1150, 1190, 1240, and 1268cm-1 corresponding to C–C–O–C stretching vibrations are in good agreement with the characteristic bands of methyl methacrylate. Two characteristic peaks corresponding to amines and ether groups appeared at 1450 and 1600cm-1, respectively, and can be attributed to the modification of the PMMA prosthetic socket [20-29]. Figure 8 shows the molecular weight distributions of the base materials used for resin-based prosthetic socket fabrication. The preparation of the most stable base material will be reported in due course in the following study.

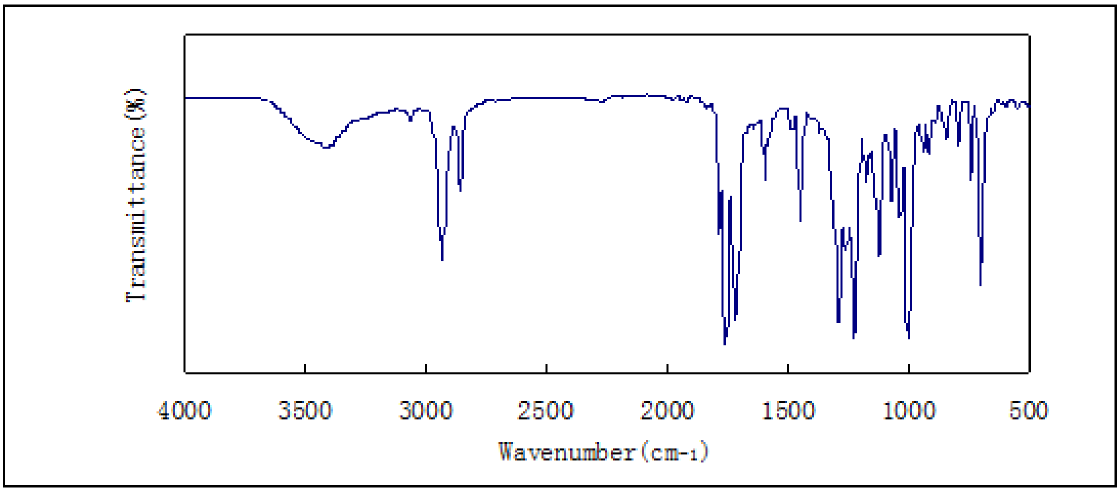

FIGURE 7 Infrared spectrum of the base material used for resin-based prosthetic socket fabrication

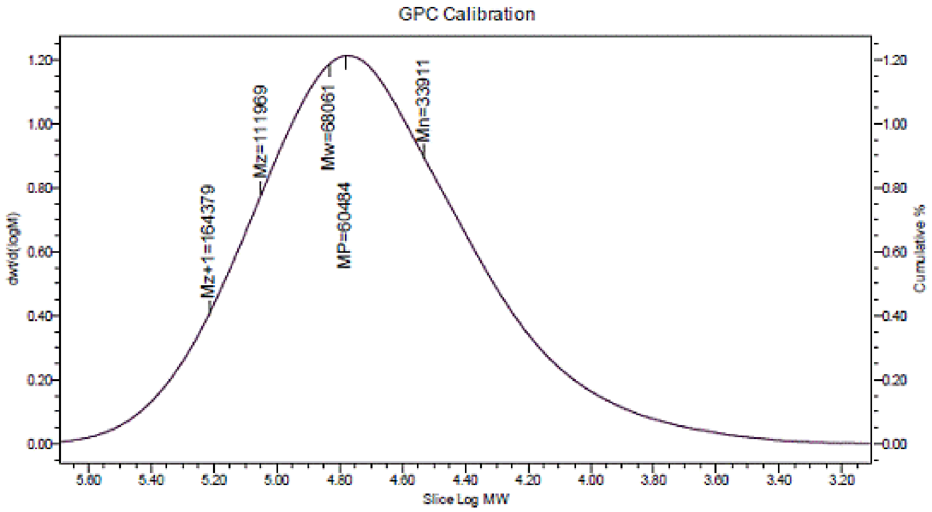

FIGURE 8. Molecular weight distribution of the base materials used for resin-based prosthetic socket fabrication

6 Conclusion

Currently, there are several gaps in the research of prosthetic socket materials and their modification for application. More specifically, several fundamental aspects relating to resin-based composite materials need to be studied including the reinforcement of the resin matrix, preparation of the prepolymer for resin matrix fabrication, effective shaping and molding of both the resin matrix and carbon fibres, and the curing process at room temperature. In-depth research of these aspects will assist standardization of the production process of prosthetic sockets and further improve the overall quality of prosthetic sockets.

References

[1] Biddiss E, Chau T 2007 Upper-limb prosthetics critical factors in device abandonment *American Journal of Physical Medicine & Rehabilitation* **86**(12) 977-87

[2] Randall D A, Williams T W, Albuquerque M J, Altobelli David E 2011 Prosthetic sockets stabilized by alternating areas of tissue compression and release *Journal of Rehabilitation Research and Development* **48**(6) 679-96

[3] Gerzeli S, Torbica A, Fattore G 2009 Cost utility analysis of kneeprosthesis with complete microprocessor control (C-leg) compared with mechanical technology in trans-femoral amputees *Eur J Health Econ* **10**(1) 47-55

[4] Silver-Thorn B, Current T, Kuhse B 2012 Preliminary investigation of residual limb plantarflexion and dorsiflexion muscle activity during treadmill walking for trans-tibial amputees *Prosthet Orthot Int* **36**(4) 435-42

[5] Fey N P, Klute G K Neptune R R 2012 Optimization of prosthetic foot stiffness to reduce metabolic cost and intact knee loading during below-knee amputee walking: a theoretical study *J Biomech Eng* **134**(11) 111005

[6] Postema K, Hermens H J, de Vries J, Koopman H F J M, Eisma W H 1997 Energy storage and release of prosthetic feet Part 1: Biomechanical analysis related to user benefits *Prosthet Orthot Int* **21**(1) 17-27

[7] Rouse E J, Hargrove L J, Peshkin M A, Kuiken T A 2011 Design and validation of a platform robot for determination of ankle impedance during ambulation *Annual International Conference of the IEEE Engineering in Medicine and Biology Society IEEE Engineering in Medicine and Biology Society 2011* 8179-82

[8] Ciobanu O 2012 The use of CAD/CAM and rapid fabrication technologies in prosthesis and orthotics manufacturing *Rev Med Chir Soc Med Nat Ias* **116**(2), 642-648

[9] Barr J B, Wutzke C J, Threlkeld A J 2012 Longitudinal gait analysis of a person with a transfemoral amputation using three different prosthetic knee/foot pairs *Physiother Theory Pract* **28**(5) 407-11

[10] McNealy L L, Gard S A 2008 Effect of prosthetic ankle units on the gait of persons with bilateral trans-femoral amputations *Prosthet Orthot Int* **32**(1) 111-26

[11] Yeung L F, Leung A K, Zhang M, Lee W C 2012 Long-distance walking effects on trans-tibial amputees compensatory gait patterns and implications on prosthetic designs and training *Gait Posture* **35**(2) 328-33

[12] Pailler D, Sautreuil P, Piera J B, Genty M, Goujon H 2004 Evolution in prostheses for sprinters with lower-limb amputation *Ann Readapt Med Phys* **47**(6) 374-81

[13] Hirons R 2012 Preparing our Paralympians: research and development at Ossur, UK Interview by Sarah A Curran *Prosthet Orthot Int* **36**(3) 366-9

[14] Hafner B J, Sanders J E, Czerniecki J M, Fergason J 2002 Transtibial energy-storage-and-return prosthetic devices: a review of energy concepts and a proposed nomenclature *J Rehabil Res Dev* **39**(1) 1-11

[15] Gauthier M A, Zhang Z, Zhu X X 2009 New dental composites containing multimethacry late derivatives of bileacids: Acomparative study with commercial monomers *ACS Appl Mater Interf* **1**(4) 824-32

[16] Winkler P A, Stummer W, Linke R, Krishnan K G, Tatsch K 2000 Influence of cranioplasty on postural blood flow regulation, cerebrovascular reserve capacity and cerebral glucose metabolism *Childs Nerv Syst* **16** 247-52

[17] Greenwald. R. M, Deanw R. C, Board J 2003 Volume management: Smart variable geometry socket (SVGS) technology for lower-limb prostheses *JPO: Journal of Prosthetics and Orthotics* **15**(3) 107-12

[18] Rotaru H, Baciut M, Stan H, Bran S, Chezan H, Iosif A, Tomescu M, Kim S G, Rotaru A, Baciut G 2006 Silicone rubber mould cast poly ethyl methacrylate-hydroxyapatite plate used for repairing a large skull defect *J Craniomaxillofac Surg* **34**(4) 242-6

[19] Min Cai,Yan Jing, Hongyan Shi, Renguo Song, Hongwen Zhang, Mengchao Zhao 2013 Polymethylmethacrylate Grafted onto

Surfaces of Silicone Rubber via Atom Transfer Radical *Polymerization Polymer Materials Science and Engineering* **29** (5) 23-32

[20] Barszczewska-Rybarek I M 2009 Structure property relationships in dimethacrylate networks based on Bis-GMA, UDMA and TEGDMA *Dental Mater* **25**(9) 1082-9

[21] Jin Z, Liu C, Zhang W 2006 Nano Carbon-poly(Methyl Metha Crylate) Composition Materials *Acta Polymerica Sinica* **2**(2) 320-4 *(in Chinese)*

[22] Li Y, Liu P, Wei Z, Wang Y, Yu H 2014 Preparation and Oil-Absorbing Properties of Poly(Lauryl Methacrylate) *Polymer Materials Science and Engineering* **29**(2) 5-8 *(in Chinese)*

[23] Mravljak M, Sernek M 2011 The influence of curing temperature on rheological properties of epoxy adhesives *Drvna Industrija* **62**(1) 19-25

[24] Jaruchattada J, Fuongfuchat A, Pattamaprom C 2012 Rheological investigation of cure kinetics and adhesive strength of polyurethane acrylate adhesive *Journal of Applied Polymer Science* **123**(4) 2344-50

[25] Du Q, Du Z, Li M, Sun X, Zhang C, Zou W 2013 Rheological Properties of Polyurethane Adhesive in Curing Process *Polymer Materials Science and Engineering* **29**(3) 31-4

[26] Huanqin Chen, Chunbao Huang, Huifang Shen, Kai Zhang 2014 Emulsion Grafting Polymerization of Chloroprene Latex with Methyl Methacrylate *Polymer Materials Science and Engineering* **29** (2) 141-44

[27] Bai R, Wei Z B, Zhang F A 2013 MMA solution polymerization in the channel of modified SBA-15 *Acta Polymerica Sinica* **2013**(7), 849-55 *(in Chinese)*

[28] Cai J, Chen T, Wang G. Z, et al 2012 The study on the reverse atom transfer radical polymerization of MMA catalyzed by acetylacetonate cobolt(II)complex supported by ionic liquid *Adv Mater Res* **2012**(1) 476-8

[29] Sun F, Wei Z, Zhang F 2014 Effect of Initiator Content on Methyl Methacrylate Solution Polymerization in the Channels of Mesoporous SBA-15 *Polymer Materials Science and Engineering* **30**(6) 29-32

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