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Review Article

Carbon fiber reinforced polyamide12 as a biomaterial for implant

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Abstract

Femoral heads of different designs were prepared by using stainless steel alloys, cobalt alloys, titanium alloys, alumina, zirconia and ultra high molecular weight polyethylene. Due to various issues like early failure, corrosion, increased ion metal levels in blood, machining difficulty and cost, there is always scope for research for new material for hip prosthesis. In this paper, suitability of Carbon Fibre Reinforced Polyamide 12 for femoral head has been reviewed. This framework quantifies CF/PA 12 material characteristics like biocompatibility, cost effectiveness, failure mechanism, corrosion and wear with respect to its use as femoral head. In this review, the adequacy of CF/PA 12 as a femoral head is discussed considering essential parameters.

Keywords: *Carbon fiber polyamide, inflatable bladder molding, selective laser sintering, hip arthroplasty, hip implant*

1. Introduction

Hip arthroplasty is a reconstructive procedure that has improved the management of those diseases of the hip joint that have responded poorly to conventional medical therapy. The hip is one of the body's largest joint. It is a ball-and-socket joint. The socket is formed by the acetabulum and the ball is the femoral head, which is the upper end of the femur (thighbone). The bone surfaces of the ball and socket are covered with the articular cartilage, a smooth tissue that cushions the ends of the bone and enables them to move easily.

The most common cause of chronic hip pain and disability is arthritis. Osteoarthritis, rheumatoid arthritis and traumatic arthritis are the most common forms of this disease. Hip replacement is an excellent alternative for patients suffering from arthritis or hip fracture. In a hip replacement, the damaged bone and cartilage is removed and replaced with prosthetic components (THR, AAO, 2015).

According to shape and design constraint, hip joint techniques can be classified mainly into three. These are (i) Hip Arthroplasty, (ii) Femoral Stem, (iii) Total Hip Arthroplasty (THA)(Princetonorthopaedic,2015).

a. Hip Arthroplasty Technique

This is the replacement of only acetabular part over the femoral head. The acetabular part can be fixed and femoral head can move. Shape of this prosthesis is like hollow hemisphere.

b. Femoral Stem Technique (Hemiarthroplasty)

This is a technique where artificial femoral stem can be inserted into marrow cavity of the femur with / without any cementing. Here only femoral head can be replaced and acetabulam can be moved over the fixed ball.

c. Total Hip Arthroplasty Technique

This is the technique where acetabulum cup and femoral head both can be replaced. One million of people undergo total or partial hip replacement every year (Uwe Holzwarth *et al*, 2012). Various materials hip implant are available for hip replacement like metal on metal (MOM), metal on polyethelene (MOP), ceramic on ceramic (COC) etc. Variations in the usage of hip implant over few years is shown in the figure1.

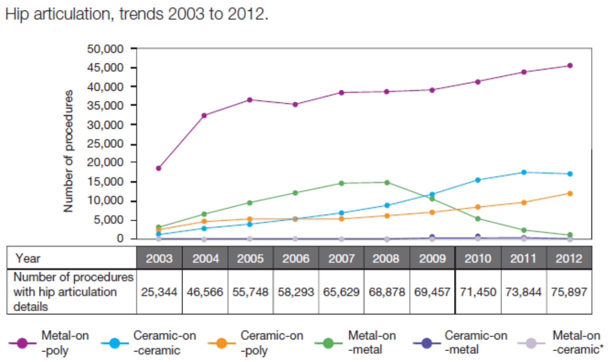

Fig 1 Hip articulation trends, 2012 adapted from (NJR, 2013)

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Metal on Polyethelene hip implant usage has been noticably increased since year 2003, as compared to other other types like metal on metal (MOM), metal on ceramic (MOC), ceramic on ceramic (COC), ceramic on polyethelene (COP),etc.

Although hip implant offer wide range of benefits like relief from pain, cost effectiveness, lifespan etc. they do come with some disadvantages like loosening, metallosis etc. which are mentioned below.

Table1 Advantages and limitations of current hip prostheses (THR, AAO, 2015)

Prostheses	Advantages	Disadvantages
Metal on Polyethelene	Large volume of evidence to support use Cost effective Predictable lifespan	Polyethelene debris leading to aseptic loosening
Metal on metal	Potentially longer lifespan than polyethelene due to reduced wear Larger femoral head - therefore lower dislocation rates	Metallosis Potential carcinogenic Effect of metal ions
Ceramic on Ceramic	Low friction Low debris particle Inert substance	Expensive Require expert insertion to prevent early damage Can produce noise on movement

A total hip replacement may require surgical correction or revision for any number of reasons. Compared with implants, made of other materials, all-metal joints had a substantially higher overall failure rate. After five years, 6.2 percent of metal-on-metal hips had failed, whereas only 3.2 percent of ceramic hips and 1.7 percent of metal-on-plastic implants had (A.Tylor *et al*). Various issues with current surgical implants are as follows.

Table 2 Issues with current surgical implants (M. Navarro *et al*, 2008,Sumit Patnaik *et al*, 2005)

Surgical Implants	Issues
Stainless Steel 316 L	Early failure, subjected to corrosion in long term
CoCrMo Alloys	Cobaltism (Increased ion metal levels in blood)
Pure Titanium & Ti alloy	Expensive and difficult to machine
Ceramics	Failure due to brittleness

Most recently, in last two decades, there has been considerable interest in biomaterials like PGA (Polyglycolic acid), PLA (Polylactic acid),PEEK(Polyether ether ketone),PA (Polyamide) etc[5,7]. Development of these materials has stabilized the femoral stem technique. Development of medical grade polymer and various other apatite materials are under research for hip joint prosthesis development. PA (polyamide) based femoral head have been introduced in the proposed work, as a relatively new alternative for enhanced acetabular fixation during hip prostheses.

Comparison of mechanical properties of hip implant material is mentioned below.

Table 3 Mechanical strength comparison for hip implants (M. Navarro *et al*,2008, Sumit Pramanik *et al*, 2005)

Hip implant material	Elastic Modulus (GPa)	Yield Strength (MPa)	Ultimate Strength (MPa)
Bone	14-21	NA	60-110
Co Cr Mo Alloy F75	220-230	275-1585	600-1785
Ti grade 4	105	692	785
Ti4Al6V	110	850-900	960-970
Stainless steel 316 L	205-210	170-750	465-950
NiTi	20-70	50-300	755-960
Ti6Al7Nb	105	921	1024

2. Material characteristic required for implant

The human body is a complex system, so there is a lot to consider when implanting artificial parts (M. Navarro *et al*, 2008). Different aspects for selection of implant material are

1) Mechanical properties of material (Hendra Hermawan).
2) Biocompatability (Hendra Hermawan, Melissa Campbell *et al*, 2008, Akiko Abe *et al* 2013).
3) Processing/ Manufacturing (Hendra Hermawan, M. Navarro *et al*,2008, Akiko Abe *et al* 2013).
4) Stress shielding (I. Sridhar *et al*,2010, Habiba Bougherara *et al*,2011).
5) Failure due to fatigue (A.Tylor *et al*, Charlotte Davies *et al* 2010).
6) Cost(Sagar Desai,2011).

2.1 Mechanical properties

Mechanical properties of material are behavior of the material that measured under the effect of external forces. Mechanical characteristics of bone and A with 68% wt long carbon fibers and 32% wt polyamide 12 using compression molding in different layup configuration was fabricated and tested for flexural and interlaminar resistance using standard testing methodology. The result obtained showed that moduli varies according to molding configuration. The moduli obtained ranged between 8 and 36 GPa and mechanical strengths between 134 and 565 MPa. Thus the moduli which were obtained for a THP stem made of these composites correspond to those reported for dense bones (5-30 GPa). At the same time, the mechanical strength of these composite stems proved to be significantly above that of dense bones (100-200 MPa), showing that in extreme physiological conditions the composite stems of the invention would be subjected to stresses considerably below those leading to their failure (Martin N Bureau *et al*,2006, www.ncbi.nlm.nih.gov/pubmed).

Tensile, compressive and interlaminar shear properties of carbon reinforced polyamide composites obtained by different fabrication techniques. Different fabrication processes has an impact on voids formed during synthesizing process with varying content of carbon fibre volume fraction. With increasing content of carbon fibre in the CFPA composite, flexural modulus and flexural strength gets improved (E.C Bothelho *et al*, 2003).

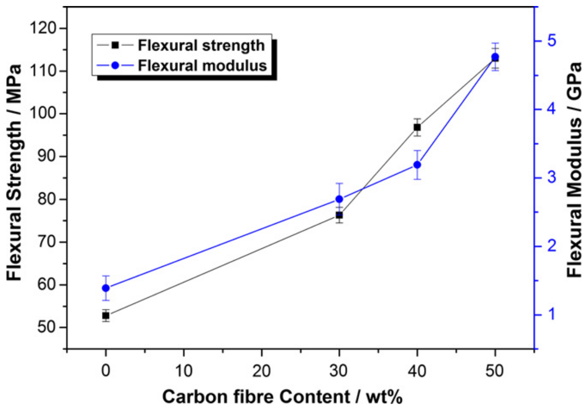

Fig 2 Void content impact on flexural strength and flexural modulus

2.2 Biocompatibility

Biocompatibility of CF/PA 12 using compression molding, was assessed on the basis of cytotoxicity testing consisting of qualification of survival rate of living cell after their exposure to extracts obtained from the tested materials. The results showed that CF/PA 12 composites did not significantly affect the cellular viability and it was concluded that the composite do not possess biocompatibility problems(, Habiba Bougherara *et al*,2011, Martin N Bureau *et al*,2006).

Biocompatibility of SLS nylon 12 (PA12) as a scaffold material was evaluated by performing cytotoxicity test and implantation test in subcutaneous tissue according to ISO standards. Both in vitro cytotoxicity test and in vivo implantation test demonstrated that 3 dimensional SLS object have excellent biocompatibility and can be used as a tissue scaffold material for clinical applications (Akiko Abe *et al*, 2013).

Periprosthetic bone remodeling in the presence of Carbon fiber polyamide 12 (CF/PA12), CoCrMo and Ti alloy implants was predicted and compared. The results showed that in terms of bone remodeling, the composite hip implant is more advantageous over the metallic ones as it provides a more uniform density change across the bone and induces less stress shielding which consequently results in a lower post-operative bone loss (-9% with CF/PA12 implant compared to -27% and -21% with CoCrMo and Ti alloy implants, respectively)(arthritis.org,2015).

CF/PA12 material is cytocompatible, on which immature oestoblastic cells can adhere, spread, proliferate and regularly differentiate (Dimitrievska *et al*, 2008).

2.3 Processing

Though there are a few different ways of making CF reinforced products like molding, compression molding, filament winding, & vacuum bagging[Ronald Hillock}. CF/PA 12 composite parts are fabricated majorly using two techniques:Inflatable bladder molding and selective laser sintering(Chunze Yan *et al*, 2011, Melissa Campbell *et al*, 2008).

2.31 CF/PA 12 composite by inflatable bladder moulding (Chunze Yan *et al*, 2011)

Braids composed of commingled carbon and polyamide 12 (PA12) fibers were used for this process. This particular braiding architecture combines filament winding and weaving. Carbon fibre wt fraction used was 0.683 and volume fraction was 0.,55. The upper and lower limit for the temperature was set by the thermal degradation temperature of PA12 and its thermodynamic melting temperature, respectively of 250 and 178^{0}C. Six overlaid braided sleeves of CF/PA12 yarns were placed around a silicone bladder mandrel. The assembly was then placed in a steel mold and inserted into a press equipped with heated/cooled platens. Once the desired molding temperature (above the melting point of the thermoplastic matrix of the composite) was reached upon heating, the bladder was inflated at a given pressure using nitrogen gas and the pressure was maintained for a given period of time,forcing the fabric against the steel mold cavity, which depending on the molding conditions squeezed out the excess resin between a resulting threshold level equating to 70% of the average initial static failure load. The failure mechanisms observed in the fatigue investigation with corresponding AE data matched that of the static testing very well (Dimitrievska *et al*,2008).

2.4 Cost

Implant cost depends upon various steps like 1. Manufacturing or synthesis of raw material 2.Casting or molding of intermediate form 3. Machining or finishing 4. Packing and sterlisation.

Following table indicates the fabricating price for various implants using above mentioned steps (Dimitrievska *et al*, 2008).

Table 4 Hip prostheses cost analysis

Process	Manufacture of raw material	Casting or molding	Machining & finishing	Packing & sterlisatio n
Material				
Forges CoCr	$41/pound	$80/piece	Labor charges	$5/part & $20/box
Cast CoCr	$25/pound	$60/piece		
Forged Titanium	$16/pound	$30/piece		
Cast titanium	$12/pound	$100/piece		
Polymer	$9/foot	$30/piece		

Manufacturing cost comparison analysis is done in the table no4. It shows that polymer is the most economical material and can be one of the best suited materials for implant.

Conclusion

The principal conclusion that is derived from the review analysis is that, there is wide variance in device selection that cannot be explained with limited material parameters. But still, with above mentioned framework, CF/PA 12 is suggested as a more suitable material for hip implant than metals and ceramics.

Future Scope

There is a need for more clinical trials including economic evaluations and comparing different prostheses with long-term follow up. Overall, significant work needs to be done under the guidance of practicing clinicians to optimize the economic and technical factors surrounding total hip replacement while improving the outcome.

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