MANUFACTURE OF AN ARTIFICIAL HIP JOINT USING A COMPOSITE MATERIAL

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SUMMARY

The principle advantage of a polymer composite material as an artificial hip joint replacement, as opposed to the traditional metallic prostheses, is its relatively low stiffness. 'Stiffness matching' of prosthesis and bone leads to an ideal integral system which, under load, bends as one, thus inhibiting bone absorption.

A particulate composite has been developed which has a Youngs modulus of 25GPa, which is similiar to that of cortical bone. The material consists of an acrylic-based polymer matrix with a high proportion of inorganic filler particles(86% wt.) of two sizes: approximately 4um and 50nm in diameter.

A prototype hip joint was designed, and made using a simple 'transfer moulding' process, followed by an elevated temperature cure.

Severe surface defects were apparent upon removal of the prototype from the mould. It is suspected that these defects resulted due to curing inhibited by presence of oxygen and inadequate venting. Shrinkage cavities also existed on the surface, and cracks due to 'constrained shrinkage' during curing. On microscopic examination other defects were identified, including resin-rich and resin-free regions.

Mechanical testing, of all prototypes, was carried out: it was noted that failure resulted from moulding defects. Scanning electron microscopy showed crack initiation occuring at moulding defects.

A complete presentation of moulding defects, with micrographs, and a conceptual analysis of why these defects occured during transfer moulding is given.

INTRODUCTION

Total hip replacement (THR) is the most frequently performed major orthopaedic procedure today. Traditional artificial hip joint replacements consist of a metallic prosthesis held 'in situ' by a polymeric bone cement(figure 1). The metal ball at the top of the prosthesis fits into a matching socket. The polyethylene socket is attached to the pelvis to complete the joint.

Although the hip joint prosthesis has proved a great success, it does have a limited 'in-service' functioning period. It has been reported in the literature(1,2) that 10% of prosthesis fail after 10 years.

Prosthesis failure is usually due to loosening of the metallic femoral component of the THR . Bone absorption , which is essentially due to 'stress shielding', is a major contributory to prosthesis loosening. 'Stress shielding' is the term given to the phenomena whereby the stiff metal component, implanted in what was a quite flexible system, disrupts the stress distribution as a result of its implantation. The concept of an 'isoelastic' prosthesis proposes that a component which has the same stiffness as the initial bone structure when implanted would maintain the original, physiological stress distribution, thus inhibiting bone absorption.

This paper reports on the manufacture of an isoelastic prosthesis, specifically from the aspect of moulding difficulties encountered. The material used in the design is a particulate composite, which has a stiffness similiar to that of cortical bone. A metal insert , embedded in the composite femoral component, is attached to the metallic acetabular ball.

This is designed so as to facilitate gradual stress transfer to the cortical bone in order to stimulate bone growth. Three insert designs, [mark 1], [mark 2] and [mark 3], were proposed. Figure 4 shows the geometry of the femoral component and insert[mark 1]; the ball was not included in these prototypes.

Moulding of the particulate composite femoral component was unsatisfactory, resulting in a number of defects. This paper examines those defects and shows how they contributed to prototype failures.

MATERIAL

The material is a new composite invented by ICI, consisting of an acrylic-based polymer matrix with a high proportion of inorganic particles(86% wt.) in two size ranges, approximately 4um and 50nm in diameter. It was designed to have a Young's modulus of 25GPa which is typical for cortical bone.

Mechanical and environmental assessment of the material have proven satisfactory in relation to the specified purpose, [3].

MANUFACTURE

The present design envisages a pre-moulded composite stem with attached acetabular head to be inserted and held by a press-fit, using no bone cement.

Initial prototypes were made by hand moulding. This consisted of compacting the composite material, in its dough form, into the cavity of a mould and around the metal insert.

The mould was made up of two halves(figure 2), with a cavity geometry similiar to that of the upper femur. A simple test head was used instead of the complex acetabular ball.

A preliminary transfer moulding technique was then devised. The protocol for transfer moulding the hip joint stem prototypes was as follows:

1 - spray release agent was applied to the head of the metal insert before it was put into the mould ;

2 - the mould halves were then clamped together and the

reservoir(pot) was screwed on top of it, a thin sheet of polyethylene (0.15 mm) was placed between the reservoir and the upper half of the mould ;

3 - the mould, reservoir and plunger were heated to a temperature *Tm* ;

4 - approximately 220g of the composite, in a dough form, was heated in a microwave oven to an average temperature of about *Td* ;

5 - the mould and plunger were placed on the Instron ;

6 - the hot composite was dropped into the reservoir and the plunger put on top ;

7 - the composite was then transfer moulded at a cross head-speed S ;

8 - after transfer moulding, the reservoir was unscrewed and cooled down in cold water immediately ;

9 - any flash present was removed and the transfer port closed ;

10 - the mould was then placed back in the oven at a temperature CT for a time Ct ;

11 - when sufficient time was allowed for complete cure, the mould was taken out of the oven and let cool down for at least 2 hours before opening ;

12 -the prototype was removed.

Figure 3 illustrates the equipment used. The parameters involved in transfer moulding, i.e. whether or not a gasket was used, T*m*, T*d*, S, CT, and Ct, were varied systematically (see table 1).

SIMULATION

Mechanical simulation testing of prototypes was carried out. This is described in detail elsewhere, [4]. A purpose built testing rig and a suitably designed femoral model allowed relatively accurate simulation of the actual post-operative hip joint system. Failure of the prototype prosthesis was defined by cracking of the composite material at what would be the resectioned femur plane.

The two moulding techniques had been used in the manufacture of the original prototype,[mark 1]. Fatigue life of hand moulded prototypes showed typical S-N curves i.e. as the maximum fatigue load increased the number of cycles to failure decreased. At the physiological load of 3kN(maximum load) no cracking occured after a total of 100,000 cycles. However upon testing of prosthesis prototype[mark 1] which had been manufactured via the transfer moulding technique no typical S-N behaviour could be recognized. Sporadic failure occured, and none of the transfer moulded prototypes[mark 1] lasted for as many cycles to failure as the hand moulded prototypes[mark 1]. This was disappointing since the transfer moulding technique had been employed in order to improve the structural integrity of the composite and to increase the efficiency of manufacture. It was noted that failures had initiated from defects in the composite stem.

Subsequent prototype designs, [mark 2] and [mark 3], were manufactured using the hand moulding technique. These more complex insert designs resulted in cracking of the composite during manufacture. It is suspected that this was as a result of shrinkage occurring around the insert.

DEFECTS

The principle types of structural defects were recognized as;

a. resin free regions
b. resin rich regions
c. internal shrinkage cavities occurring along the length of the prosthesis and perpendicular to the mould joint.
d. presence of small voids throughout the composite
e. surface shrinkage cavities
f. inadequate curing of matrix
g. composite/insert interface voids at the insert tip
h. severe cracking of the composite stem at the distal(lower) end.

The first four moulding problems outlined above were common to both transfer and hand moulding manufacture. (e) and (f) were major problems encountered with respect to the transfer moulding technique. (g) and (h) were found to be related to insert geometry since they occured only for the more complex designs [mark 2] and [mark 3].

Figures 6 to 8 show features of inclusions of free resin , regions of dry filler content and internal shrinkage cavities. Figure 9 shows a typical surface shrinkage cavity. Figure 10 shows a crack initiation site at the edge of the surface shrinkage cavity in figure 9. Figure 10 shows a fracture which occured at an uncured region. All transfer moulded prototypes pocessed some degree of inadequate curing.

DISCUSSION

In general , moulding defects result from:

a. moulding parameters
   - no. of gates and gate location
   - temperatures of mould, composite, curing
   - transfer pressure used and time maintained
   - venting conditions

b. insert geometries

c. shrinkage of composite during cure(which is effectively a result of (a.))

d. material properties
   - matrix/particle cohesion
   - flow properties

Six prototypes[mark 1] in all were manufactured using the transfer moulding technique outlined above. The conditions i.e. Tm, Td, S, CT, Ct and whether or not a gasket was placed between the 'half moulds', were varied as stated in table 1. The different combinations of conditions were used in order to try to establish which parameters might affect the resulting manufactured design. Unfortunately no consistent observations can be concluded, except that all transfer moulded prototypes had intolerable defects, as described under 'Defects' above.

The macroscopic cracking of the femoral composite component evident upon removal from the mould, which occured in the case of insert[mark 2] and insert[mark 3], may be attributed to a combination of b.) insert geometry and c.) shrinkage of the composite. Figure 4 illustrates how insert[mark 1] geometry allows shrinkage to occur because of the simple conical, short design. Whereas figure 5 illustrates the restraint imposed on shrinkage due to the longer length of inserts, [mark 2] and [mark 3]. It is proposed that this restraint caused tensile residual stresses, resulting in cracking and complete breakage of the composite at distal regions.

The problems of inadequate curing(figure 11) and shrinkage cavities(figures 8 & 9) both seem largely to be influenced by the location of the gate and the venting used. It may be that a number of gates, located at more 'strategic' positions, would have been more appropriate for the particular mould cavity.

The venting system used was quite primitive and consisted of placing a gasket between the mould halves, leaving a gap at what would be the proximo medial i.e. above the gate location (see figure 2). It proved to be insufficient as could be seen from the uncured regions.

The microscopic 'structural' defects of resin free/particle rich and particle free/resin rich regions(figures 6 & 7) could be due to the inhomogeneous distribution of pressure intensity throughout the composite, causing greater concentrations of particulate content in some areas than in others. This could possibly be rectified by the right combination of composite temperature, gate location, cross head speed and maximum pressure applied.

The internal cavities observed(figure 8) are considered to be due to shrinkage and the flow pattern in the cavity around the insert. In the case of the internal cracks which existed along the length of the composite stem, the flash which was 'trapped' between the two half moulds prevented shrinkage occurring in that plane, whereas no restraint of composite existed in the plane perpendicular to that of the mould joint. Thus the non-uniform shrinkage resulted in a quite distinctive crack as described above. Other internal cracks could be recognized as following the path of the composite flow, suggesting that some degree of lamination effect existed.

The bad composite/insert interface ,at the insert tip, in the case of insert [mark 2] and [mark3], was attributed to the location of the gate, and the radius of the insert tip.

CONCLUSIONS

1.) This particulate composite material can be satisfactory for use in hip joint prostheses, as shown by simulation testing of prototype designs.

2.) Failure of prototypes resulted from moulding defects, thus limiting prosthesis life.

3.) Longer insert designs caused cracking of the composite during curing.

4.) The range of parameters varied, during transfer moulding(see table 1), had no marked effect on the quality of the resultant prototypes.

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REFERENCES

1.) Beckenbaugh, R.D. and Ilstrup, D.M.; J. Bone Joint Surgery 60A(1978) pg. 306

2.) Moreland, J.R., Gruen, T.A., Mai, L. and AmStutz, H.C.; "The Hip" Chapter 13 (1980) pg. 281

3.) Henn, G., Prendergast, P.J. and Taylor, D.; "Assessment of a particulate composite material for use in hip joint prostheses", Advanced Engineered Materials Published Parsons Press pg. 283

4.) O'Brien, B.; Design of an Isoelastic Prosthesis, MSc Thesis, 1991, Trinity College Dublin

Transfer Moulding Conditions(insert[mark 1])

Prototype no.	Gasket	Tm	Td	S	CT	Ct
1	no	85	85	20	85	90
2	no	85	85	20	85	90
3	no	85	85	20	85	90
4	yes	70	56	5	85	90
5	yes	75	56	5	85	90
6	yes	75	56	20	85	90
Hand Moulding Conditions						
	no	room t.	room t.	N/A	100	90

Tm = temp. of mould, reservoir and plunger before transfer[Celsius]

Td = temp. of composite before transfer[Celsius]

S = cross head speed[mm/min]

CT = cure temp.[Celsius]

Ct = cure time[min.]

Table 1

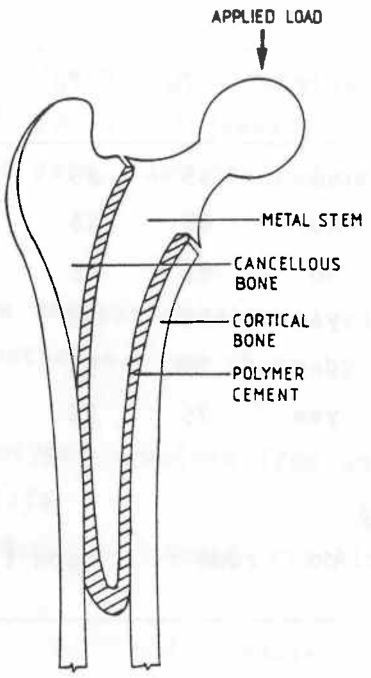

Figure 1. Schematic of the hip joint(post-operatively)

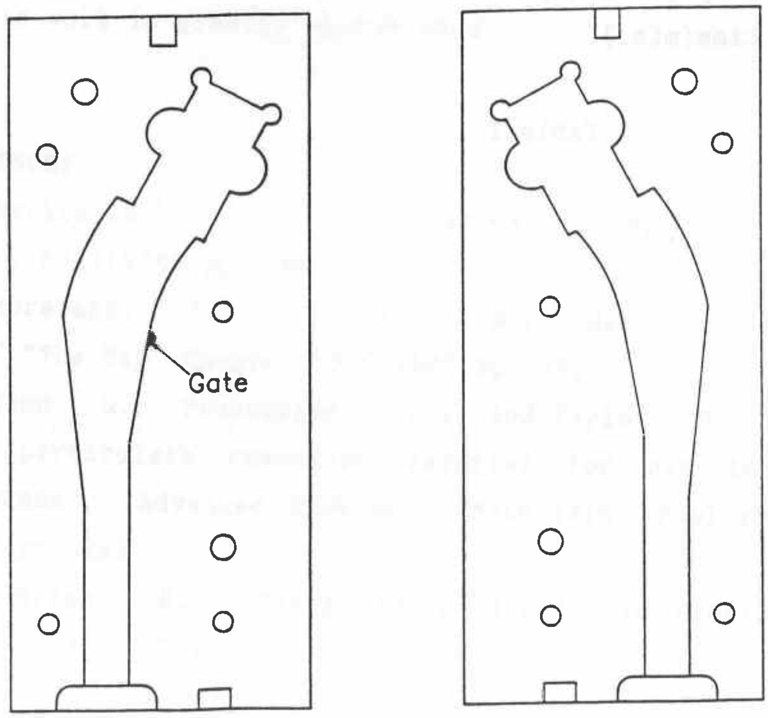

Figure 2. Diagramatic illustration of mould

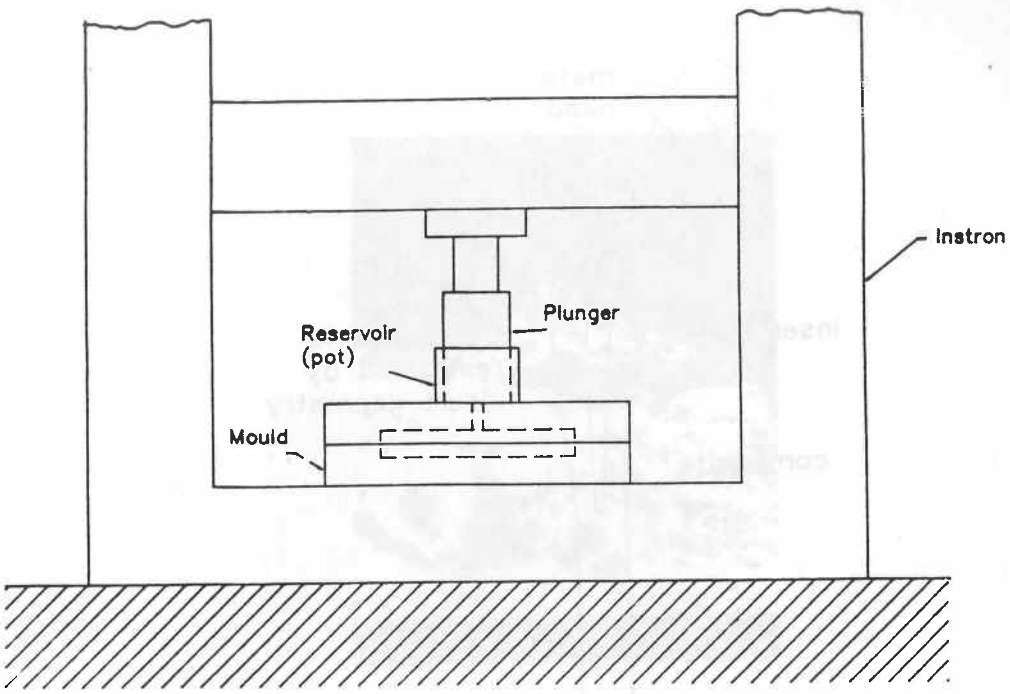

Figure 3. Diagramatic illustration of transfer moulding

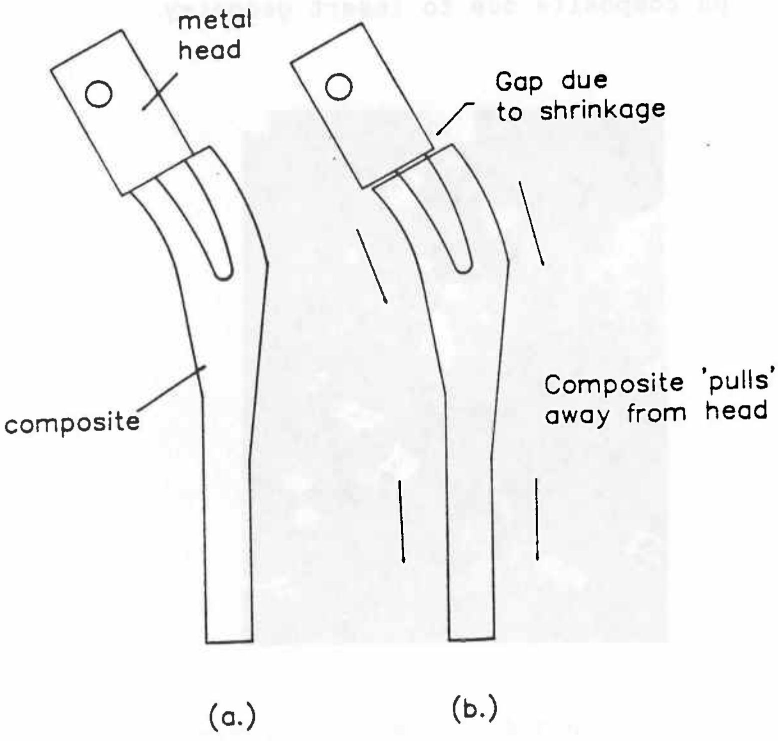

Figure 4. Prototype insert[mark 1]
a.) before shrinkage
b.) after shrinkage

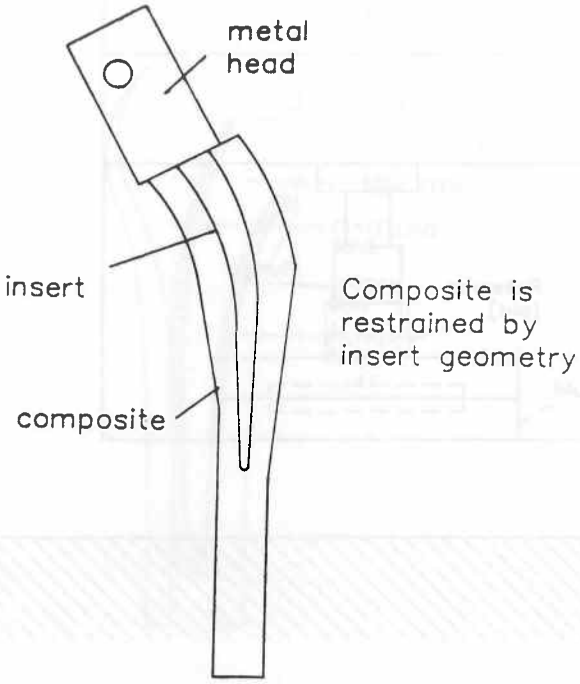

Figure 5. Prototype insert[mark 2] showing restraint on composite due to insert geometry

Figure 6. Particulate rich region

Figure 7. Resin rich region

Figure 8. Internal shrinkage cavity

Figure 9. Surface shrinkage cavity

Figure 10. Crack initiation site

Figure 11. Fracture at uncured region