THE DEVELOPMENT OF COMPOSITE STEM FOR HIP JOINT, AN APPLICATION OF COMPOSITE MATERIALS FOR MEDICAL IMPLANT DEVICE

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Abstract

The development program about a stem for Total Hip Arthroplasty (THA) is described. This stem is a tailor-made using PEEK carbon composite material.

First, design concept is explained, then material development, design database, stem shape design method, structural design method and structural verification test and animal test results are explained.

1. Introduction

As shown in Fig.1, artificial hip joint consists of a Cup, a Head and a Stem. A stem is a structural device to transfer the load from the head to the femur.

The purpose of this development program is to create an Artificial Hip Joint Stem with CFRP.

Today, THA has become a popular procedure for treatment of various hip diseases and more than 1.5 million surgeries are performed annually all over the world.

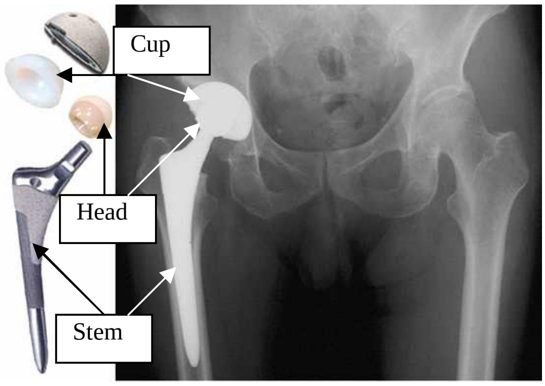

Fig. 1. Artificial Hip Joint System

However, all the stems are manufactured with metals, such as Ti or Co-chrome, or stainless steel alloys. Some of the issues associated with those metal materials including subsidence, stress shielding and fatigue fracture have been reported.

Recent 40 years, carbon composites has made progress and recently it is applied to structures of new large passenger aircrafts such as Boeing 787 or Airbus A350XBW, because of its reliability, high fatigue strength and design flexibility. Those properties are attractive not only for aircrafts, but for a stem of Hip Joint.

The biocompatibility of the material has been already proven. So, FDA approved PEEK carbon composite material on drug category in 2003 and the Japanese Ministry of Health Welfare and Labor approved it on implant device category such as Spinal Cage last year.

We have experiences of developing aircraft composite parts, so we planned to apply the material to a stem. The composite design, material database establishment, quality assurance and manufacturing method are based on the aircraft technology.

Some projects developing composite stem has been reported, but they were not successful [1][2].

Since 2003, our team, which consists of 2 universities and 4 companies, has been investigating and developing this composite stem.

This program was partially supported by NEDO (New Energy and Industrial Technology Development Organization) from 2005 to 2006.

This paper describes the results obtained by the NEDO program.

2 Design Concepts

The design concept of CFRP stem is shown in fig.2. It consists of 2 parts, Main spar and outer skin, and glued together with injected PEEK resin as shown in Fig.3.The role of the main spar is to carry loads from head. The outer skin is designed to fit the femoral medullary canal so that shear loading can be transferred without peaky hot stress spots.

2.1 Main Spar

Main spar is made of UD tape carbon PEEK composites. As shown in Fig.2 (b), there is a hollow cavity inside of it and the section area decreases along to the longitudinal axis of the spar. So, the shear stress along to the longitudinal axis, shown in Fig.4, is high in the proximal area. This contributes to improve "Stress shielding" on the femur. On the other hand, stress concentration occurs at the tip end of distal area of Ti stem, so this causes an adverse effects on "Stress shielding".

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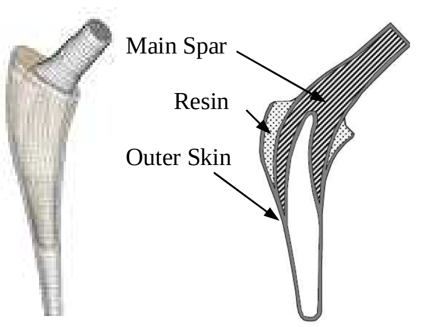


(a) External View (b) Cut View

Fig. 2. Composite Stem

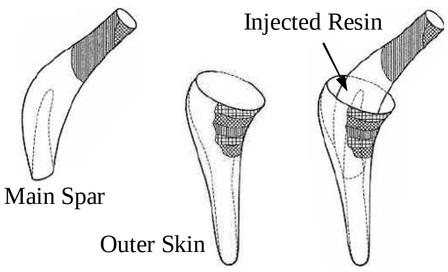


Fig. 3. Design Concept of the Composite Stem

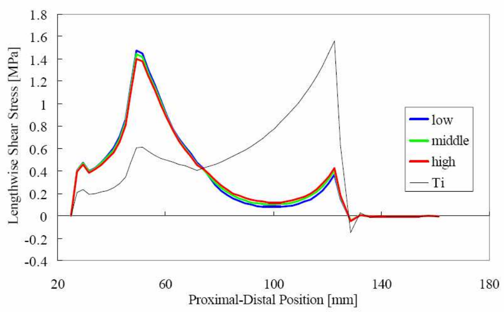


Fig. 4. Stress distribution of femur

2.2 Outer Skin

The outer skin is made of carbon fabric PEEK composites and its fiber directions are ±45 degrees along to longitudinal axis of stem so that this part can transfer torsional loading to femur.

The outer shape of it is designed from CT data of individual patients and maximizes "Fit & Fill" in the femur.

2.3 Advantages

The advantages over conventional metal stems are shown and explained in fig.5.

The higher fit and fill, longer fatigue life, and minimized stress shielding are the major advantages and those may contribute to extended life of the arthroplasty and to pain relief for patients.

By using automated manufacturing system, the composite stem can be supplied by a lower cost compared with the existing metal stem.

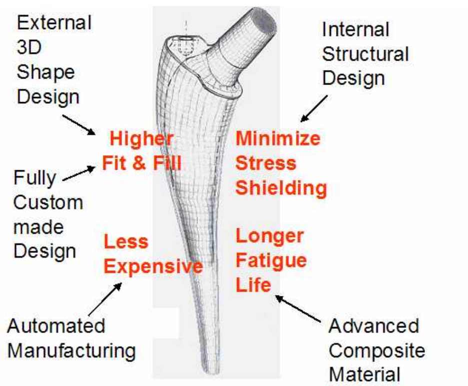


Fig. 5. Advantages of CFRP stem

3. Material Development

The material of Composite Stem is carbon fiber thermoplastic semi-preg, which is consisted of Toho Tenax "HTA carbon fiber" impregnated with PEEK resin. The UD tape form was used for the main spar, and 3K twill woven fabrics were used for the outer skin. To investigate the effects of cooling rate over degree of crystallization, several types of specimens were fabricated and tested. Test methods were the chemical, physical, inter laminar shear fatigue strength and wear test.

Those test results showed that there was no deference in the selected 3 conditions of cooling rates. The cooling rate at 4 degrees per minutes was selected as a standard cure condition.

Cooling Rate (℃／min)	Crystallization (%)
1	31.0
3.6	33.1
5	34.4
10	36.4
20	36.3

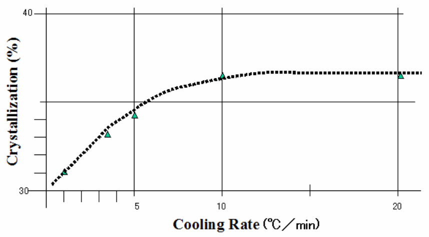


Fig. 6 Crystallization vs. cooling rate of PEEK

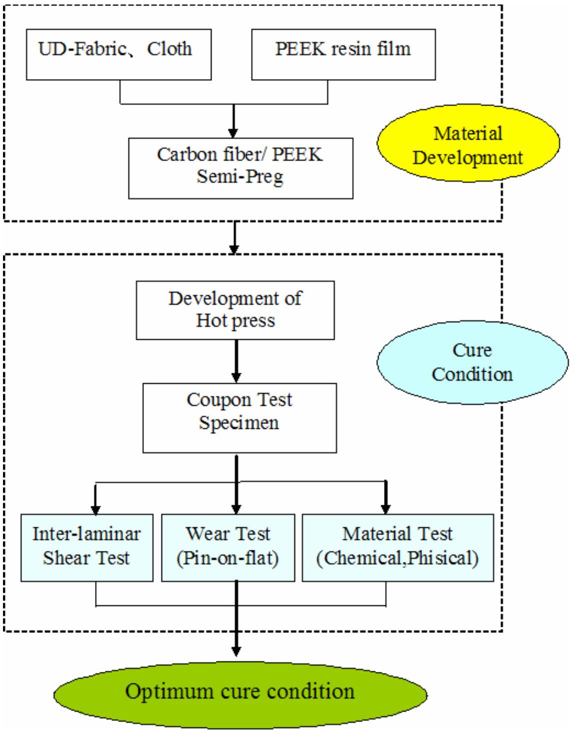


Fig. 7 Development process of PEEK/CFRP

4. Design database

Design database was established by a statistical analysis based on the data obtained from 3 types of tests shown in Fig.8.

Material design allowables were established mainly by static strength, because carbon composite material has high fatigue strength. But the neck portion of the stem is critical about inter laminar shear fatigue, so the fatigue test was carried out.

To fix the stem in the femur, the shear strength between the stem and the femur is important, so the in vivo strength test using rabbits was conducted.

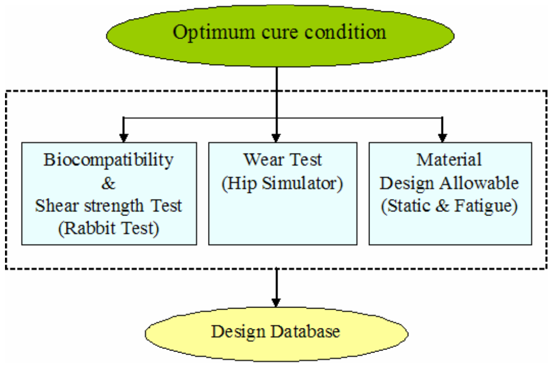


Fig.8 Acquisition of PEEK/CFRP Design Data

4.1 Material Design allowable

4.1.1 Static Strength

Coupon tests were conduced according to Mil-Handbook-17 and SACMA SRM was selected as the test specifications. This material design allowable is used only for the stem, so the test items can be very specific compared with those for aircraft designs. The test items and specifications are shown in Fig.9

Material	Test Item (Deg.)	Number of Specimen		Specifications of test methods
		RTD	HTW	
UD Tape	Tension 0	6	0	SACMA SRM 4R-94
	Tension 90	6	0	SACMA SRM 4R-94
	Compression 0	6	0	SACMA SRM 1R-94
	Inter-laminar Shear 0	30	6	SACMA SRM 8R-94
Fabric	Tension 0/90	6	0	SACMA SRM 9R-94
	Compression 0/90	6	0	SACMA SRM 3R-94
	Tension ±45	6	0	SACMA SRM 7R-94
Laminate	OHC	30	6	SACMA SRM 3R-94
	OHT	30	0	SACMA SRM 5R-94

Fig. 9 Coupon test items and specifications

Generally, strength of composites is weak in a so-called Hot and Wet condition (HTW). The Stem environment condition is 100% wet and 37 degree C. So, the water ingress test was carried out. HTW test specimens of UD tape inter-laminar shear test and laminar OHC test were treated based on the results shown in Fig.10. Weight fraction of ingress water is very low, compared with epoxy resin.

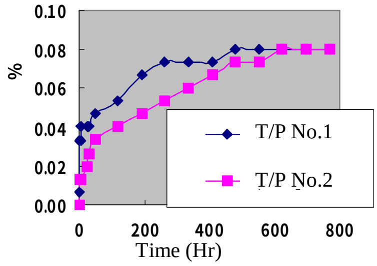


Fig.10 Water ingress of PEEK/CFRP

For elastic and non-critical strength test items, 6 specimens were selected, but 30 specimens were used for critical test items such as OHC and Inter laminar shear tests.

Coupon test results are shown in Fig.11.

From those data, strain base design allowables were calculated by statistics and shown in Fig.12.

Those allowables are almost similar or better than those of the carbon epoxy pre-preg for aircrafts.

Test Items		UD Tape				Fabric			Laminate	
		Tension 0	Tension 90	Comp. 0	Inter-Laminar Shear,	Tension 0/90	Comp. 0/90	Tension ±45	OHC	OHT
RTD	Modulus GPa	141	10	127		36	36	14	50	54
	Strength MPa	2540		1300	122	537	396	256	298	457
Wet	Strength MPa				105				278	

Fig. 11 Coupon test results

Items	Properties	
	UD Tape	Fabric
E_1 (GPa)	141	36.0
E_2 (GPa)	10.0	35.8
G_{12} (GPa)	6.75	6.75
μ_{12}	0.34	0.05

(a) elastic constants

Items		Allowables
In plane	Tension	6,748 (μ)
	Compression	4,783 (μ)
Out of Plane	Inter laminar Shear	89.3 (MPa)

(b) design allowables

Fig. 12 Design allowables of PEEK/CFRP

4.1.2 Fatigue Strength

Inter laminar shear fatigue test of UD tape was conducted. The test apparatus is shown in Fig.13(a).

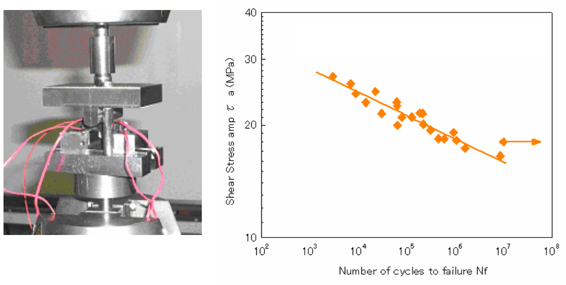
Test conditions are shown as follows.

1) Test method; ASTM D2344
2) Span to thickness ratio; 4.0
3) Constant amplitude
4) Frequency; 1.0 to 7.9 Hz
5) Stress ratio; R=0.1
6) Test machine; Electro-hydro servo type

Failure mode was very soft and no obvious clacking in the central portion was observed. So, the large stiffness degradation was used for the definition of failure.

Test results are shown in Fig.13 (b).

Shear strength is almost similar to the typical UD carbon epoxy pre-preg.



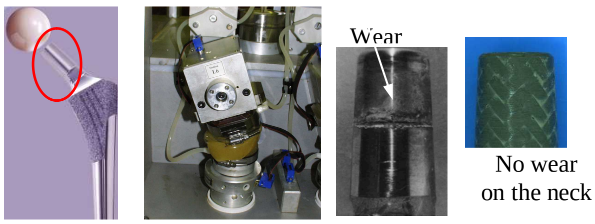
(a)test apparatus (b)fatigue test results

Fig. 13 Inter-laminar fatigue test

4.2 Wear test using Hip Simulator

The wear test on the neck portion of stem was carried out. A hip simulator is a wear test machine which simulates oscillatory angular motion along to 3 axis and synchronized oscillatory vertical loadings in the bood serum, as specified ISO14242.

After 1million cycles, observation of wear particles was conducted using SEM, neither carbon fibers nor PEEK resin powder was observed. Then, no wear was occurred on the composite neck.



(a)stem (b)simulator (c)metal (d)composite

Fig. 14 Hip simulator test

4.3 Shear strength test using rabbits

The in vivo shear strength test between the tem and the femur was carried out. As shown in Fig.15, a few grooves were introduced on the surface of test specimen. Those grooves were not machined and the carbon fibers were not cut. Hydroxyapatite powder coating was applied on the surface to obtain a good biocompatibility and accelerate bone growth on the surface of stem.

The test method is shown in Fig.16.

The purpose of this test is to get design data about the groove.

As shown in fig.17, push out force increased as number of grooves. From this chart, we can calculate specific shear strength of grooves .

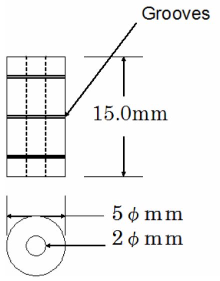


Fig. 15 Test specimen

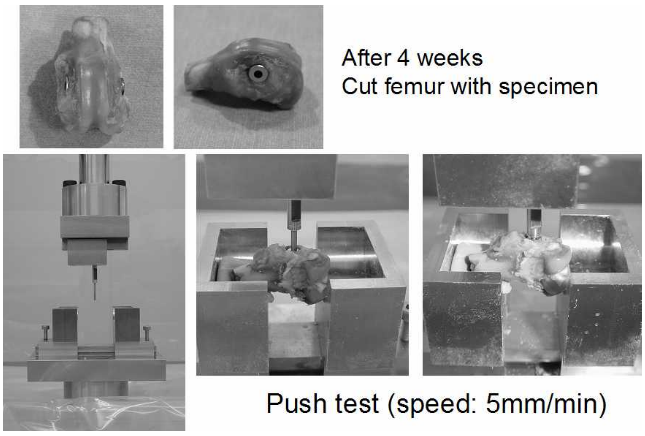


Fig. 16 Test steps

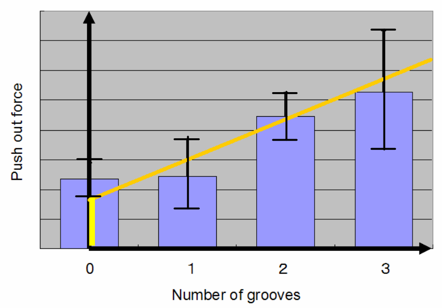


Fig. 17 Test results

5. Shape Design of Stem

The outer shape of stem is designed for individual patients. This is called " Custom design" using 3D digital computer system. This design steps are shown in fig.18.

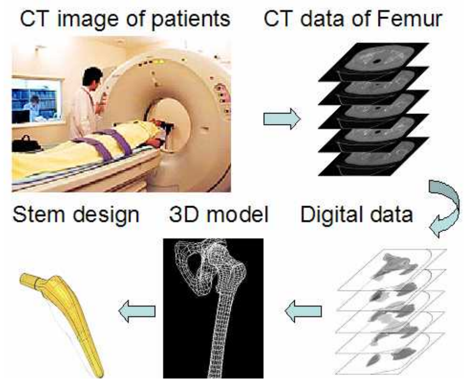


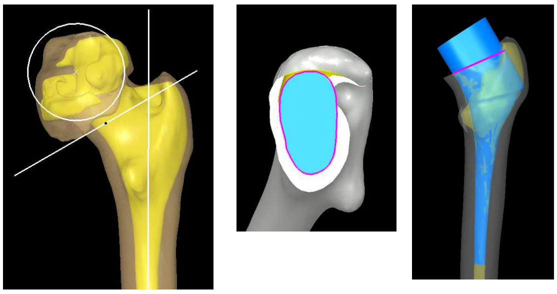
Fig. 18. Design process of stem shape

Each design step is explained as follows. The final goal is to complete a fully automated design system.

1) Design requirements
   (1) Threshold of CT images to create internal shape of femur.
   (2) Acceptable clearance between stem and femur
   (3) Stem length
2) CT data analysis
   (1) Definition of femur head center
   (2) Internal shape of femur
3) Initial input data (Shown in Fig.19)
   (1) Axis of geometry
   (2) Cutout position of the femural head
   (3) Open cut shape
   (4) Internal shape of the femur after head cut
4) Design parameter
   (1) Taper angle of the upper portion of the stem
   (2) Curvature of the insertion trace
5) Stem shape design (Automated process)
   (1) Outer shape of the femur
   (2) Insertion simulation (Fig.20)
   (3) Inspection and confirmation by a doctor

One of the examples of shape design is shown in Fig.21. It shows the comparison of "Fit" of existing custom made metal stem and composite stem. The results shows almost 20% higher "Fit".

Finally, as shown in Fig.22, installation test was carried out to confirm the results of shape design using a dried femur.



(a)Cutout position (b)Open cut (c)Internal shape
Fig.19 Initial input data

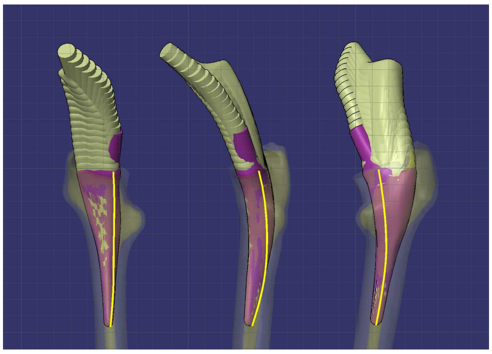


Fig. 20 Major design parameter

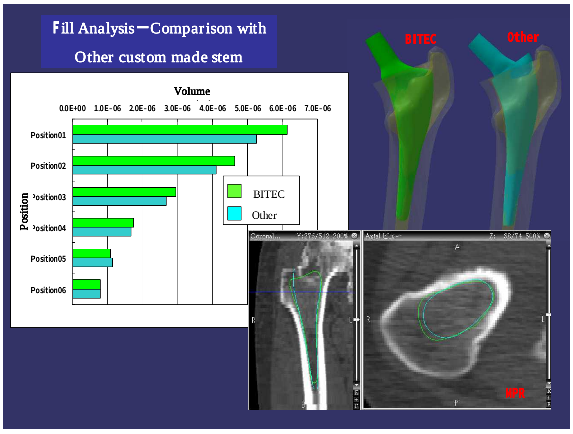


Fig. 21 Results of shape design, Comparison of 'Fit'

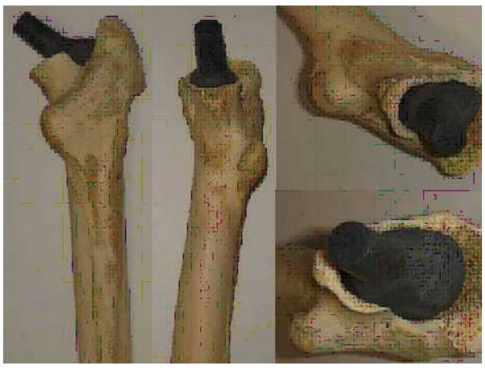


Fig. 22 Installation Test as Confirmation of Shape design using a dried femur

6. Structural Design of Stem

FEM analysis was conducted to get an optimum design. One example of FEM model is shown in fig.23. [3]

The most critical area was near the neck portion, but the maximum strain was well below the material design allowable. So the strength of the composite stem was high enough for the Hip Joint.

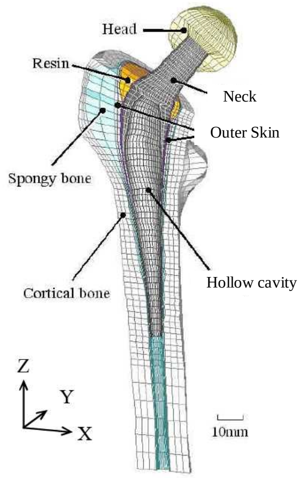


Fig. 23. FEM Model

7. Manufacturing of Structural test specimen

The composite stem was manufactured using a hot press. The maximum cure temperature was 380 degree C and the maximum pressure was 10atm as shown in Fig.24.

Fig.25 shows the specimen for the structural testing, the surface finish applied to the implantable grade is not applied.

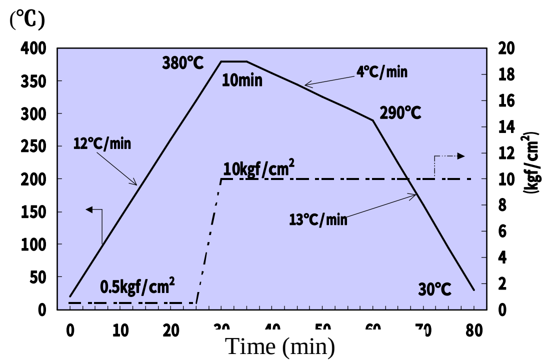


Fig. 24 Cure condition of composite stem

Fig. 25. Composite stem for structural testing

8. Structural Test

The structural in vitro testing was carried out using a dried femur.

8.1 Structural test and Verification

Fig.26 shows the test specimen and the dried femur with inserted composite stem. The composite stem is glued together with dried femur to simulate long-term fixitation.

The test set up is shown in Fig.27. As shown in fig.28, the measured strain was well agreed with the estimated value by FEM analysis. The error was only 4%. So, the analytical method was verified.

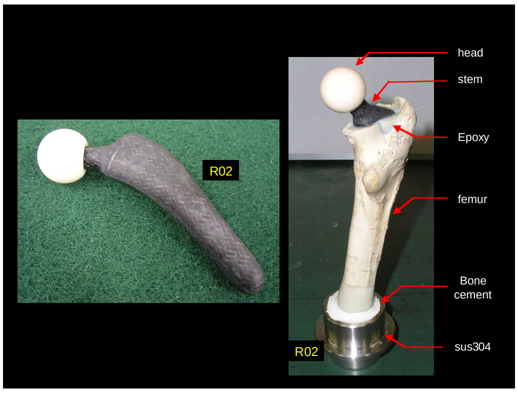


Fig. 26. Test Specimen with dried femur

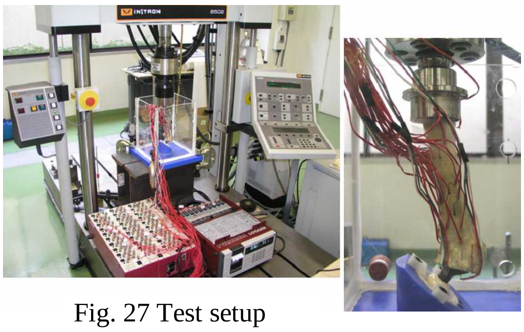


Fig. 27 Test setup

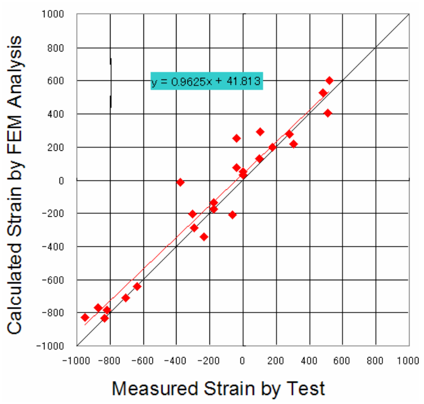
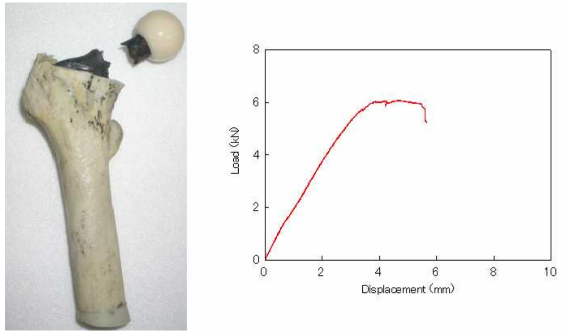


Fig. 28 Comparison of test and analysis

8.2 Static Test

As shown in Fig.29, the static test was successfully carried out. The test specimen was dipped and tested in 37 degree C normal saline solution. The maximum strength was over 6KN and 60% higher than the strength requirement of the femur. The failure location was the neck potion, shown in Fig.29 (a), and the failure mode was compression failure of the composites, as estimated by FEM analysis



(a)Failure Location (b)Load-Displacement chart

Fig. 29 Static test result

8.3 Fatigue Test

As shown in Fig.30, in accordance with ISO7206-4, the fatigue test was successfully carried out.

After 1 million cycles, no failure was observed.

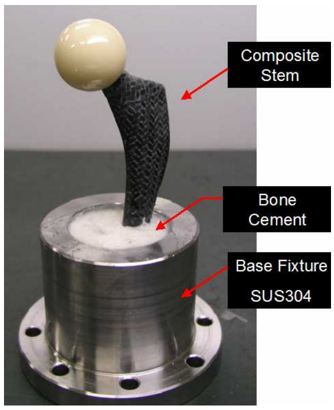


Fig. 30 Fatigue test apparatus of ISO7206-4

9.Animal Study using Sheep

In vivo test using sheep has been conducted at New South Wales University in Australia.

9.1 Stem design for animal study

The composite test specimen was designed based on the same design process of a composite stem for human being. When 55 kg of body weight of sheep was selected as a design requirement, loading of the stem for sheep is 50% of the one for human being.

As shown in Fig.32, distribution of UD tape section area of Main Spar along the longitudinal axis for both sheep and half of human being were almost same. As a result of this design policy, the shear stress of the stem bone interface and the normal stress of the femur are almost similar. So, the comparison of stress shielding could be observed by sheep test.

Fig.33 shows design of specimens. The diameter of ceramic head was 22mm and the stem length was 100mm. On the surface of stem, horizontal and vertical grooves were carved and hydroxyapatite coating was applied. Based on the CT data, as shown in Fig.34, 3 sizes, large middle and small, of stems were designed to fit for size variation of sheep.

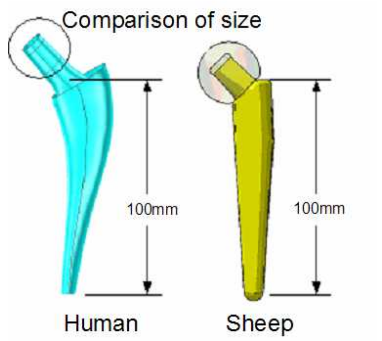


Fig. 31 Comparison of sheep stem vs human stem

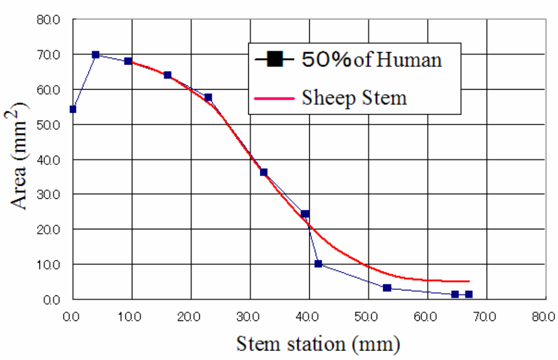


Fig. 32 Area distribution of UD plies

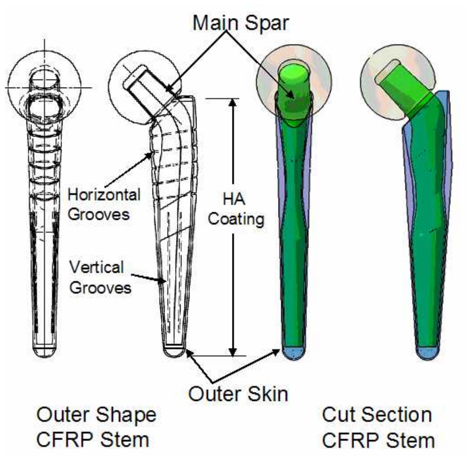


Fig. 33 Stem for sheep

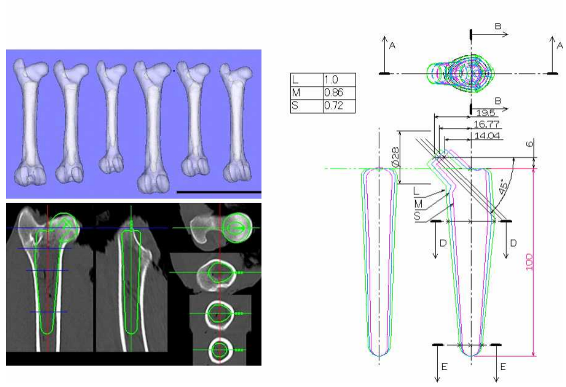


Fig. 34 Three types of Stem design

9.2 Fabrication of Stem

Animal test specimens were shown in Fig.35. Totally 30 specimens, 20 composite stems and 10 Ti stems, were manufactured for sheep test.

Ti stem is prepared as a control specimen and it has a same outer shape with composite stem.


(a) Composite stem (b) Ti alloy stem
Fig. 35 Stem for sheep

9.3 Sheep test

Factors of success about the in vivo animal study are considered as followings.

1) Shape Design
2) Material Surface Structure
3) Preoperative Planning
4) Instruments for surgery
5) Surgery technique
6) Postoperative Care

As shown in Fig.36, surgery of implanting was successfully conducted.

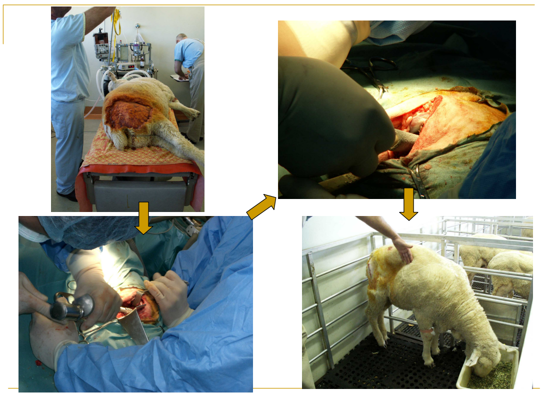


Fig. 36. Surgery of implanting stem into sheep

X-ray photograph about Ti stem implant results is shown in Fig.37. Bone growth at distal end of the stem and stress shielding at proximal area was observed as expected from the results of FEM analysis.

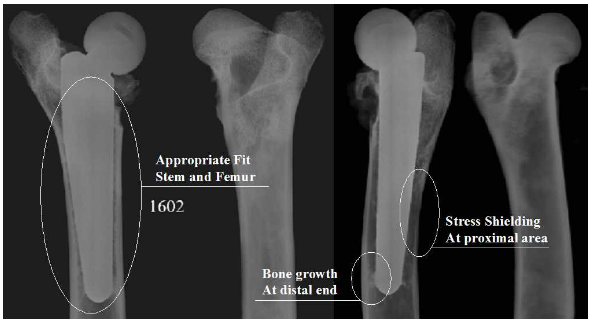


Fig. 37 Results of Ti stem implant by X-ray

CT images of implanted Composite Stem are shown in Fig.38. From those observations, good results were obtained.

However, some issues about instruments for surgery, surgery technique and postoperative care were considered and discussed.

Fig. 38 CT images of implanted Composite Stem

10.Conclusions

To develop the composite stem using PEEK carbon composite material for Total Hip Arthroplasty (HTA) following items were successfully investigated.

1) Design concept
2) Material development
3) Design database
4) Stem shape design method
5) Structural design method
6) Structural verification in vitro test
7) In vivo test using sheep

Acknowledgements

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