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Dynamic Fatigue Testing of Customized Hip Implant: A New Experimental Model

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Abstract— Customized hip implant is a hip prosthesis specially developed for hip anatomy of a particular patient and manufactured in a single sample. Human activities exerted forces, which generate stresses that vary over time and resulting in fatigue failure of the hip implant. Therefore, customized hip implant should be checked against fatigue failure. The aim of this work was to develop a new experimental model for in vitro custom hip implants fatigue testing with minimum number of experiment by using Taguchi method for 147 patients. To this end, a fatigue testing machine was developed, based on a cam and follower mechanism. This machine is able to apply the hip contact force in typical physiological load conditions; including normal walking and walking up and down the stairs. Nine custom hip implants were developed by using Taguchi L9 orthogonal array for fatigue tests. Fatigue testing was carried out under similar conditions of the ISO 7206-4 fatigue testing. The results of fatigue tests showed that all hip implants are safe enough in terms of fatigue life. The nine hip implants have been tested for 1, 80,000 cycles and until then no failure has occurred in the hip implant. The strain recorded by the strain recording software shows that the fatigue life of experiment no. 8 hip implant is more as compared to experiment no. 5 hip implant. This study also shows that the Taguchi method is useful for fatigue testing of customized hip implant with a minimum number of experiments.

Keywords: Fatigue Testing, Orthogonal Array, Taguchi, ISO 7206-4, Hip Implant.

I. INTRODUCTION

Standard hip implants available are developed mostly according to the Western population. Therefore, these hip implants do not meet the need to the people of India and Asia Pacific. Technical errors may be occurring in THA due to the unavailability of hip implants of appropriate size for ethnic groups in India and Asia-Pacific. The hip implants may be oversize because of smaller build and stature of Indians and other Asian sub populations as compared to the western counterparts[16]. Closer fit and stability can be achieved by employing customized hip implant for respective femora [1, 2, 3].

fracture strength of customized hip implants should be tested for a full range of the life cycle loading. During normal activities and occasional traumatic events, such as stumbles and falls, a hip implant is loaded with several times to the body weight [6, 7]. There is an application of a million cycles per year of high magnitude load on the hip implant [4, 5]. Therefore, fatigue should be a main focus in pre-clinical testing and analysis. Fatigue failure of the hip implant may occur as a result of the forces exerted on the hip implant by human activities. So it is important to make hip implant resistant against fatigue failure.

The fatigue behavior of the hip implants, are often analyzed with the help of experimental tests. These tests are usually performed in accordance with the technical International Standards voluntarily applied by both manufacturers and the notified bodies on a voluntary basis. In order to evaluate the reliability of the prosthesis, the fatigue test is used[16,17]. It is carried out according to the ISO 7206-4 standard, in which the test apparatus and procedure are describes to assess the fatigue resistance of femoral stems. In this experimental work, fatigue tests were performed according to ISO 7206-4 under sinusoidal loading [18].

The aim of this work was to develop a new experimental model for in vitro customized hip implants fatigue testing with minimum number of experiment by using Taguchi methods for 147 patients.

II. MATERIALS AND METHODS

A. Taguchi method

The Taguchi method is used for fatigue testing of customized hip implant with a minimum number of the experiment for 147 patients. The total number of experiment required will be very high, if full factorial is run exploring every possible combination of values of each factor. An orthogonal array utilizes by a statistical approach developed by Taguchi [14, 15].This method is a form of fractional factorial design containing a well-chosen subset of all possible combination of test conditions. A balanced comparison of levels of any factor and significant reduction in the total number of required experiment can both be achieved by using Taguchi method.

	Horizontal Offset(HO) mm	Vertical Offset(VO) mm	Neck Shaft Angle(NSA) (degrees)	Weight (Kg)
Max	40	49	140	70
Min	20	29	124	56
Mean/Avg	30	39	132	63
Range	20	20	16	14

Table 1: Summary statistics of femoral geometric parameters, Age, Weight and Height of 147 patients.

Experiment No.	Horizontal Offset(HO) (mm)	Vertical Offset(VO) (mm)	Neck Shaft Angle(NSA) (degrees)
1	40	49	140^0
2	40	39	132^0
3	40	29	124^0
4	30	49	132^0
5	30	39	124^0
6	30	29	140^0
7	20	49	124^0
8	20	39	140^0
9	20	29	132^0

Table 2: Experimental layout using L9 orthogonal array

As shown in the (Fig.1), horizontal offset (HO), Vertical offset (VO) and the Neck shaft angle (NSA) are the most important geometrical parameters of customized hip implant. An anthropometric measurement of the hip joints of 147 patients was carried out by a computed tomography (CT) scan images. Horizontal offset (HO) was in the range of 20-40 mm with an average of 30 mm. The vertical offset (VO) was in the range of 29-49 mm with an average of 39 mm, and the neck shaft angle (NSA) was in the range of 124^0 to 140^0 with an average of 132^0, respectively. As shown in Table. 2 nine runs should be carried out as per L9 orthogonal array. Based on nine experiments, nine CAD models were developed by using Pro/ENGINEER software. In this way, these nine CAD models of hip implants are related to the hip joints of 147 patients (Fig.2).

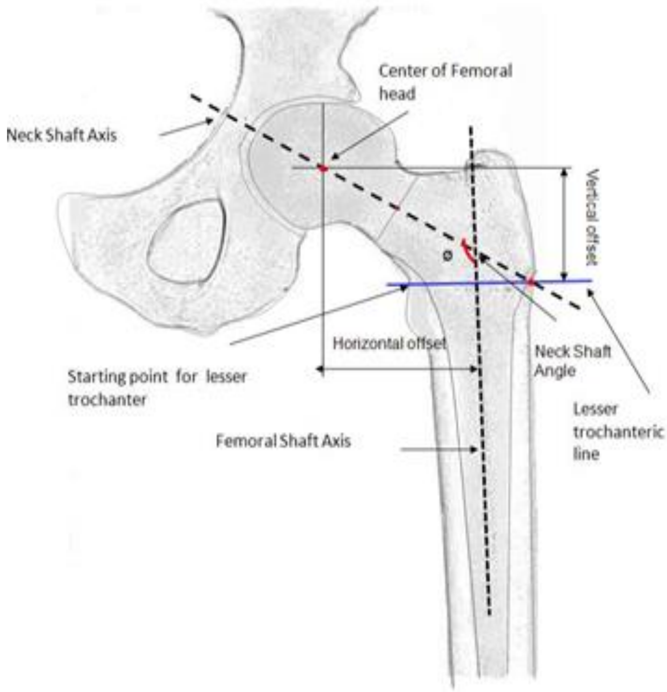

Fig. 1. Horizontal Offset (HO) in mm, Vertical Offset (VO) in mm and Neck Shaft Angle (NSA) in degrees.

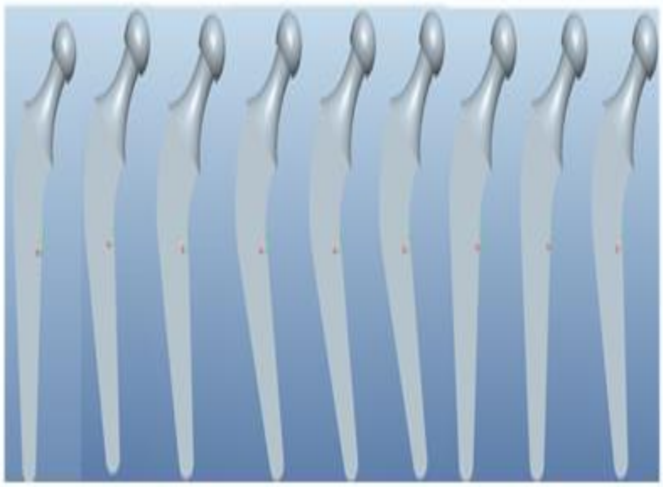

Fig. 2. Nine CAD models developed using Pro-Efrom L9 orthogonal array

As shown in Fig.3 nine rapid prototyping patterns were created from STL files of nine CAD models. Rapid prototyping patterns of hip implants have been used for casting of the 316l stainless steel hip prosthesis. Four unidirectional strain gauges (Tokyo Sokki Kenkyujo, Tokyo, Japan) were bonded to the highly stress area, that is, the neck region of hip implant for the measurements of the strains. Strain gauges were first linked to a data acquisition system. After that a data acquisition system was connected to a computer with strain recording software to record strain as shown in Fig.4

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Figure 3. Nine Rapid prototyping patterns created From stl files of CAD models of the hip implant.

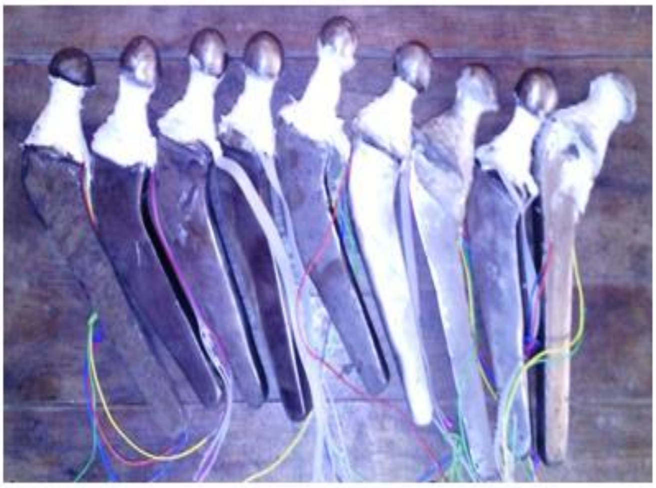

Fig. 4. Strain Gauges Attached At the Neck Region of the Nine Hip Implants.

B. *Fatigue Testing*

To apply the forces on the hip implant, similar to the gait cycle of human activities, A fatigue testing machine was design and developed on the basis of Cam and follower mechanism. A Cam may be defined as a specially shaped piece made up of metal or other materials to displace the follower may be either rotation or translation in an ascertained way. The cam profiles for Normal Walking, Up Stair and Down Stair is developed based on the resulting contact forces [8] as shown in Fig.5. For a revolution of the cam cycle, one gait pattern of forces will be applied to the hip implant. To apply other patterns of gait cycles, e.g. down stair, up stair etc., previous cam should be replaced by new one. The maximum force applied is 238%, 251% and 260% of maximum body weight of 147 patients of 70 kg, as shown in Table 1. i.e., 1634N, 1723N and1785N, respectively, for Normal walking, Up and Down stair. Load cells were used to measure the load on the hip implant.

The boundary conditions were applied as similar to ISO 7206-4 fatigue resistance test. As shown in Fig. 7 the hip implant is inclined at an angle of 10^0 and it is fixed up to 60 % of the distance between the centre of the head and stem tip. Also it is tilted at an angle of 9^0 in the medial-lateral direction. The load is applied in vertically downward direction. Hence the entire criterion given in the ISO 7206-4 protocol is successfully fulfilled as shown in Fig. 6.

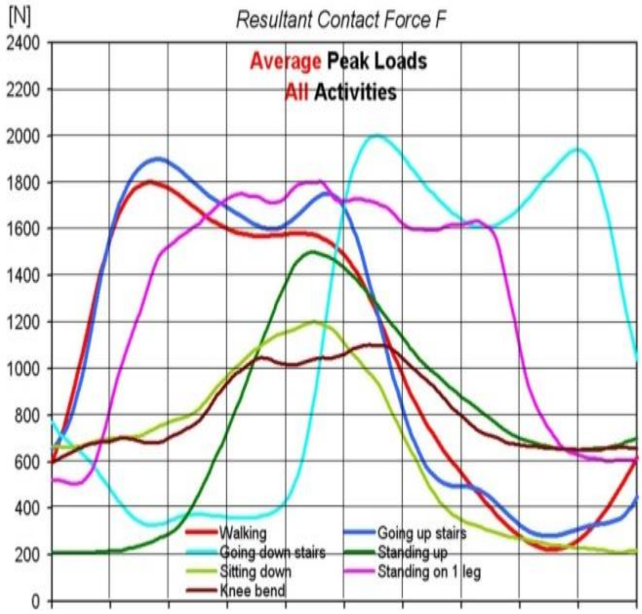

Fig. 5. Average peak loads' during 'high-impact activities' and 'low-impact activities'. Resultant contact Forces

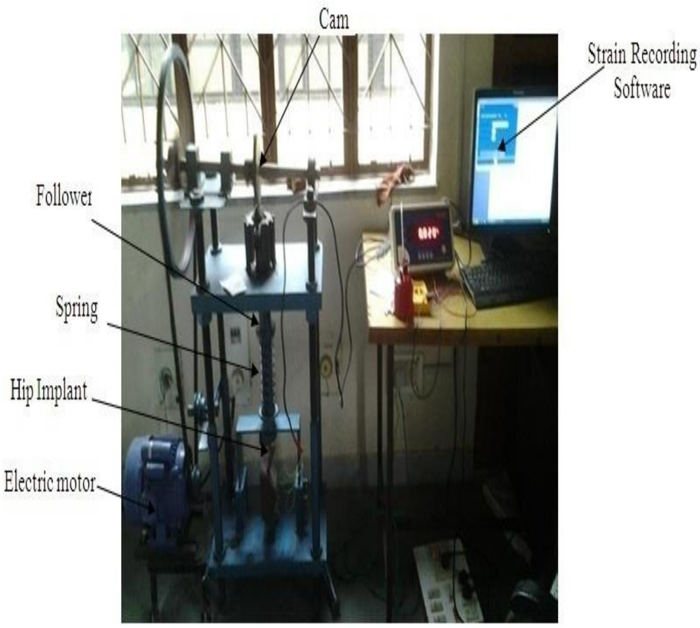

Fig. 6. In vitro experimental set up for fatigue testing of hip implant.

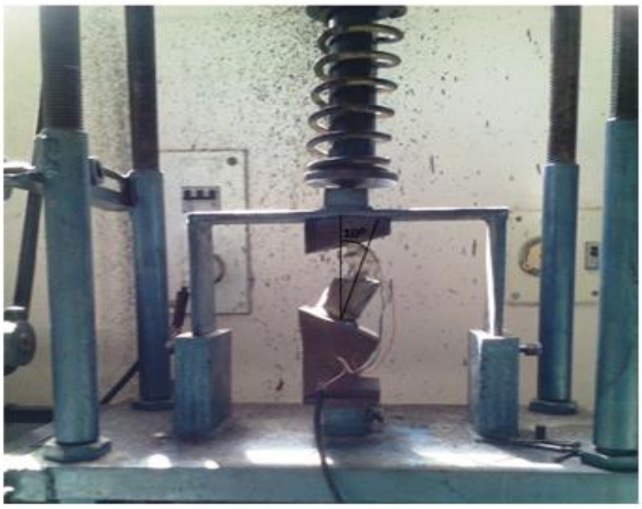

Fig. 7. Position of Hip Implant for Testing.

III. RESULTS

The fatigue life of hip implants for a physical activity of normal walking, up stair and down stair is tested in fatigue testing machine. The physical testing is carried out for this purpose is as per ISO 7206-4 norms. The results are within the acceptable limits. This shows that the hip implant satisfies the conditions set by ISO 7206-4. The induced strains developed in the neck region of hip implants during normal walking, up stair and down stair are found out from the strain recorded by the software as shown in Table 3. The nine hip implants have been tested for 1, 80,000 cycles and until then no failure has occurred in the hip implant. Therefore, based on which it can be assumed that the nine hip implants are safe for 1, 80,000 cycles. If patient travel for approximately 1000 cycles per day, it nearly accounts for the number of steps traveled by a patient without stoppages in approximately six months.

Expt No.	Normal Walking Strain	Up Stair Strain	Down Stair Strain
1	0.000402561	0.00045352	0.00049235
2	0.000437891	0.00047653	0.00052101
3	0.000486521	0.00048865	0.00052658
4	0.000427852	0.00046325	0.00047856
5	0.000488865	0.00054365	0.00054589
6	0.000348956	0.00039658	0.00042589
7	0.000347452	0.00039124	0.00041489
8	0.000335412	0.00042856	0.00042568
9	0.000390042	0.00043258	0.00040568

Table 3: Strain Recorded In the Strain Recording Software for Normal Walking, Up Stair and Down Stair.

IV. DISCUSSION

The aim of this work was to develop a new experimental model for in vitro custom hip implants fatigue testing with minimum number of experiment by using Taguchi methods for 147 patients. Hip contact forces during normal walking, up stair and down stair have been realized and evaluated in a new fatigue testing machine. The realization of hip contact forces as measured in vivo is of significant advantages for endurance testing of implants, particularly as a tool for pre-clinical testing of customized hip implants. The database of hip contact forces by Bergmann [9, 10], has been successfully utilize for endurance testing of the strength of hip implant. The successful trials of the new fatigue testing machine open up realistic prospect in the application of combined loading cycles, such as those recommended in Bergmann et al. [11], for preclinical testing purposes.

All nine hip implant were tested in identical boundary and loading conditions, but the strains developed in nine hip implants are different from each other because of the differences in the geometric parameters, i.e. horizontal offset (HO), vertical offset (VO) and neck shaft angle (NSA), as shown in Table 3. The hip implant of an experiment number 6, 7, 8 and 9 has minimum strain in it, whereas the strain in the hip implant of an experiment number 1,2,3,4 and 5 has maximum strain. From this, it can be concluded that, as the horizontal offset (HO) was increased and the neck shaft angle decreased, the strain in the hip implants increased. This is accurate, because the bending moment at any section is directly related to the moment arm, which is determined by the horizontal offset (HO) and neck shaft angle (NSA).From this Table.3 it can also be concluded that hip implant of experiment no.8 having less strain will survive for more number of fatigue cycles. Whereas, the hip implant of experiment no5. having high strain, will survive for less number of fatigue cycles.

In conventional design experiment techniques, large numbers of experiments have to be carried out, and these techniques are so complex that it is difficult to apply. The main advantage of Taguchi method is less time for experiments to reduce costs [14,15]. The purpose of this study is to fatigue testing of custom hip implants with a minimum number of the experiment, using Taguchi method for 147 patients. If full factorial is used exploring all likely combinations of the values of each factor, the total number of required experiment will be very high. A statistical approach developed by Taguchi uses an orthogonal array, which is a form of fractional factorial design containing a subset for all possible combinations of test conditions [14]. Using the Taguchi method, significant reduction in the total number of experiments can be achieved.

V. CONCLUSIONS

This paper presents a procedure for the fatigue testing of customized hip implant for a physical activity of normal walking, up stair and down stair. The physical testing is carried out for this purpose as per ISO 7206 norms on the new fatigue testing machine. All the hip implants are survived during fatigue testing. This shows that all the hip implant satisfies the conditions set by ISO 7206.The strain recorded by the strain recording software shows that the fatigue life of experiment no. 8 hip implant is more as compared to experiment no. 5 hip implant. This study also shows that Taguchi method is useful for fatigue testing of customized hip implant with a minimum number of experiments.

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