
Reliability Approach in Implant Fatigue Design

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Today, the hip prosthesis is validated following Standards. For the stemmed femoral components, the Standard ISO 7206-4 requires to test 6 components at 230daN during 5×10^6 cycles without crack. For the neck region of stemmed femoral components, the Standard ISO/FDIS 7206-6 (draft) requires 6 tests at 534daN during 10×10^6 cycles without crack.

On one hand the implantation of hip prosthesis advances because more and more people are implanted and people of all ages. The implanted people have tendency to load more and more the prosthesis because they want to be able to continue a "normal" life: then there is a modification of the use of prosthesis in comparison with some years ago. On the other hand, there is the risk-benefit ratio.

The objective of this study is to establish a statistical distribution of the uses of hip prosthesis in order to define at best a minimum value of strength required for a good fatigue design. To define this strength, the Stress-Strength approach will be applied. This approach will allow defining the validation proceedings of hip prosthesis for the new Standards in progress. After to establish the distribution of the uses for a hip prosthesis, for a given risk level, the required strength can be defined, knowing the dispersion of this strength.

The strategy to have the distribution of the uses is :

- to obtain the loads for each activities divided by the dynamic coefficient and the weight of the person,
- to know the breakdown of the activity time and the activity type of implanted population by age group, sex, profession group, weight on a number of years,
- to search a relation between the dynamic coefficient (ratio between maximum load and the weight) and weight.

After to verify the validity of the combination of the data, the distribution of the uses could be established to particular population group, for examples:

- young people (lower than a certain age),
- old people (above a certain age),
- the people with a certain weight, etc