Determining Inspection Intervals For Lower Limb Prosthetic Components

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Abstract

Fatigue failure is the most common form of component failure in lower limb prosthetics. In this paper we look at two common prosthetic components and determine their fatigue life and recommend inspection intervals. A review of failed components is used to determine the conditions of a typical failure. Cracks are initiated in the two components which are cyclically tested with realistic loads. FEM analysis and crack growth analysis are used to build a model of the expected life of the components. This model is compared to the cyclic test results and manufactures testing. The model is then used to determine appropriate inspection intervals.

Keywords - Prosthetics, Fatigue, Crack Growth, FEM

Introduction

The majority of component failures in lower limb prosthetics are fatigue related. Usually the first indication of a failure in the components is when the amputee returns to the clinic with a broken prosthesis. Of failures presented to **REHAB*Tech*** only 6.9% had been removed prior to failure.

These failures can have many effects. In the worst cases causing the amputee to fall with possible subsequent injuries.

Modular lower limb prosthetic components are built from a variety of high tech materials with different functional requirements. Component selection is customised for each amputee. Taking into account the amputees weight and activity.

The best way to avoid fatigue failure is by regular inspection and in some cases replacement of components. The need for accurate component inspection times is required as to few and failure can occur between inspections. Too many and they become costly, both in time and money.

Inspection intervals when provided are a flat rate. Although a starting point they do not take into account the amputees activity, weight, environment and the age and history of the components.

There is an absence of any related analysis in determining the inspection intervals and expected life of lower limb components. This limited study looks at determining the expected life and inspection intervals for two commonly used components. The first a 30 mm Aluminium pylon as these are one of the more common failures. The other a Titanium pylon adapter. These have not been reported as failing and are probably being replaced too frequently.

Method

1. A review of failed components submitted to REHABTech was conducted to asses which components are likely to fail. The method of failure and the conditions of failure are used to set up a realistic fatigue test. Using new components a crack is initiated in the component were cracks have been found to initiate in failed components. As an assembled prosthesis this is then cyclically loaded on the **REHAB*Tech*** fatigue tester which simulates a realistic gait pattern. Any subsequent crack growth can then be monitored during testing.
2. The pylon and adapter were modeled using finite element analysis. This was conducted to determine the load paths between the two components. It also gave the stress distribution for the components to be used in crack growth analysis. The pylon adapter was also modeled with cracks of different lengths to help determine the stress intensity factor.
3. Using the results from the FEM analysis the analytical simulation of crack was performed. This used linear elastic fracture mechanics and strain life methods. AFGROW a commercial program was used for this. The crack models were run for different load spectrums simulating different amputee weights and activities. Load spectrums for comparison to fatigue testing and manufactures testing were also modeled.
4. Using information from the above steps inspection and replacement intervals for these components are then determined. This was done using a combination of damage tolerance and safe life fatigue design philosophies.

Figure 1, Pylon and a cut away of the pylon adapter

Results

In the fatigue test the pylon and pylon adapter reached 1.74 x 10^{6} cycles without fracture. A crack was found in the pylon with a length of 51 mm. The crack had not penetrated the pylon at this length. No crack developed from the initiated crack in the adapter. A very small (<0.2 mm) dark line was observed on the adapter from the initiation point which at first was thought to be a crack. However it did not increase in length during testing and may be damage due to the initiation process used and not a crack.

Pylon

To check the accuracy of the pylon model, it was checked against data supplied by USMC, for testing at ISO10328 loads. A life of 5.6 x 10^{6} cycles was predicted using FEM and AFRGOW. In tests conducted by USMC they reached 6 x 10^{6} cycles[1] when failure occurred. This is a 7 percent difference which is very good. A 10 percent variation is expected in the testing alone [2].
The pylon model was also checked with the fatigue test. The predicted life using the loads in the test is 2.03 x 10^{6} cycles. At 1.74 x 10^{6} the predicted length of the crack is 3.4 mm while we observed a substantially longer crack length of 25.5 mm. However as crack growth increases rapidly (see Figure 2) as length increases the error is less significant than it appears. The model predicts significant crack growth within a short time frame of 1.74 x 10^{6} cycles. In cycles this is a 15 percent difference.

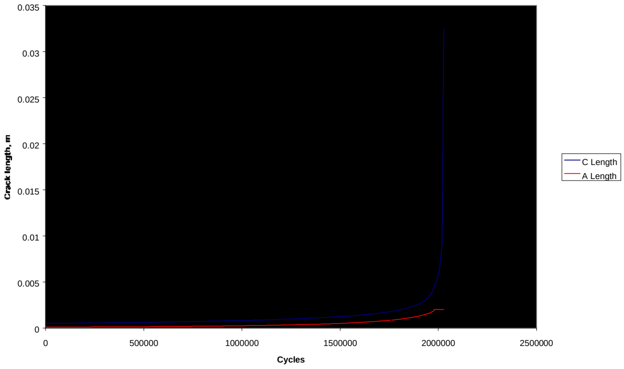

Figure 2, Crack growth for Fatigue test loads

The fatigue life of the pylon for different activity levels and amputee weights can be seen in Figure 3. The activity levels considered were AOPA levels K2, moderate activity, and K3, high activity, [3]. These values were used as a basis for determining the inspection intervals (Table 1).

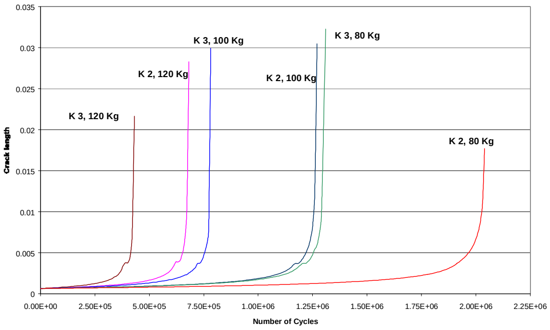

Figure 3, Damage Tolerance Life at different amputee weights and activity levels

Amputee weight/ Activity level	K3 cycles (days)	K2 cycles (days)
80 Kg	10^{6} (200)	1.5 x 10^{6} (300)
100 Kg	5 x 10^{5} (100)	10^{6} (200)
120 Kg	2.5 x 10^{5} (50)	5 x 10^{5} (100)

Table 1 Inspection intervals for the pylon

Pylon Adapter

Figure 1 is typical of the stress distribution for the pylon adapter. The stress distribution is what would be expected with higher stresses adjacent to the grub screw hole and the end of the slit. The high stress at the proximal end of the pylon adapter are a function of how the loads where applied. High stresses would be appropriate in this region but the magnitude of these stress at the proximal end is effected by how the loads were applied.
The stresses in the region of the grub screw are remote from the applied loads so should be more accurate.
The fatigue life of the pylon adapter turned out to be very interesting. From experience it was assumed it would have a very long life. When a crack had developed it propagated very quickly to failure. Even changing the grade of Ti 6AL 4V this still occurred. A life expectancy of less than 100 days once a crack occurred was common. However the time for initiation was effectively infinite. Even with a notch placed in the pylon adapter initiation still took a very long time. This suggests that the adapter has great resistance to crack initiation, but little resistance to crack growth. This is reflected in failed adapters. The majority being Aluminum which has lower resistance to crack initiation, or stainless steel in combination with stress corrosion.
This suggests the pylon adapter should be inspected along with other components. If any damage is present replace the pylon adapter. Total life of the adapter can be seen in Table 2 for different amputee weights and activity levels.
Comparing the analysis to test data. At the ISO10328 load level A136 USMC, titanium pylon adapters fail after 7.5 x 10^{6} cycles[1]. The analysis predicted 7.9 x 10^{6} cycles for the same test. Again this is a good comparison as variations between specimens in testing are usually around 10 % [2]. As expected the adapter did not failure during the cyclic testing conducted at 1.74 x 10^{6} cycles., with crack growth observed.

Amputee weight/ Activity level	K2	K3 cycles
80 Kg	infinite	6.2×10^8
100 Kg	1.0×10^8	4.5×10^7
120 Kg	9.2×10^6	7.4×10^6

Table 2 Total life of the pylon adapter

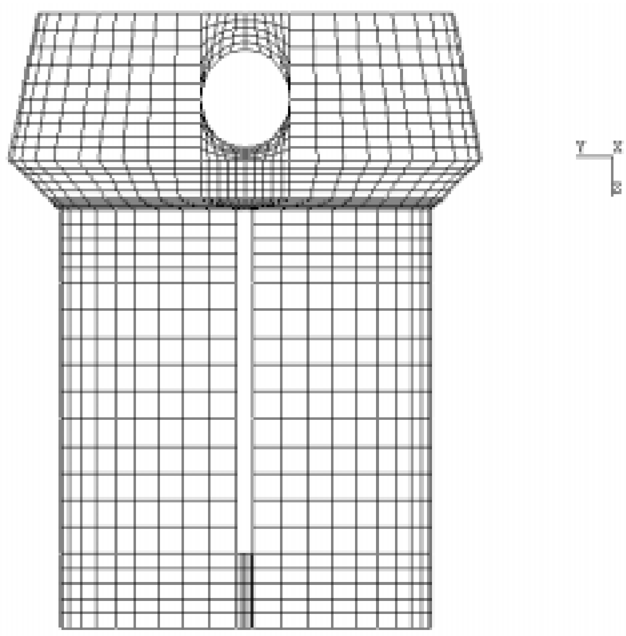

Figure 4, FE model of the pylon adapter

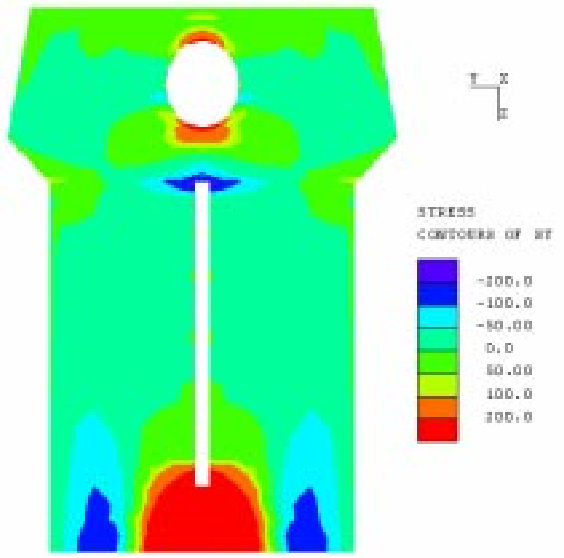

Figure 5, Stress distribution for the pylon adapter, loading at push off phase of gait.

Conclusion

Using the load scheme for a typical 80 Kg Trans tibial amputee with an activity level K3 a fatigue test, structural analysis and fatigue life predictions were made for the 30 mm Aluminium pylon and Titanium pylon adapter used in the prosthesis.

Both the pylon adapter and pylon were modeled using finite element analysis to assess their stress distributions. These results were then used to help determine the fatigue life of the components using linear elastic fracture mechanics (LEFM), safe life and damage tolerance fatigue management philosophies.

The results of the analysis were compared to the fatigue test of the components and ISO10328 testing conducted by the component manufacturers. Along with information of failures in use.

Using this information inspection intervals were derived along with best practice recommendations to ensure a safe working life for the components while maximising this life.

References

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