IMPLANTS FOR BONE-ANCHORED PROSTHESES - How they should be tested mechanically

A popular scientific summary of a Master's Thesis in Biomedical Engineering

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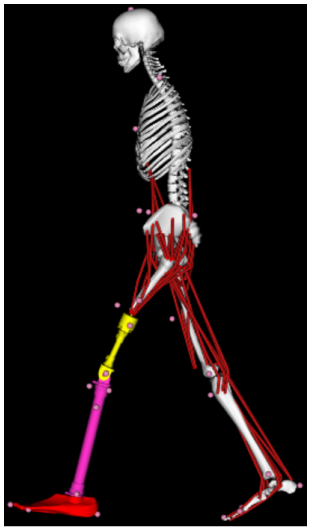
Bone-anchored prostheses is a relatively new technology, with the potential to improve the quality of life for many amputees. In order to make sure the implants used for anchoring last as long as they should, they need to be thoroughly tested. In this Master's Thesis, a standard for how this should be done has been developed.

Imagine that every step you take hurts and causes rashes and sores on your leg – this is the reality for many leg amputees using conventional prostheses. In some cases, the amputees are not able to use such a prosthesis at all, and this creates a major obstacle in their everyday life. For these groups of patients, *Integrum AB* provides an alternative solution called the OPRA implant system. This revolutionising system is based on a technique where the prosthesis is anchored directly to the remaining bone through insertion of a titanium implant. The implant gets firmly fixed when bone tissue grows into the surface of the implant – a phenomenon also known as osseointegration. Studies have shown significant improvements in quality of life for many patients treated with this technique, and it can give amputees back their ability to walk.

The implants used for anchoring the prostheses are built for lasting many years, and in order to make sure they do that they need to be thoroughly tested mechanically. Today there is no standard for how these tests should be performed, and therefore the aim of this Master's Thesis was to develop this. Through a literature study and review of international standards for other implants, it was concluded that the tests need to make sure that the implants can tolerate different types of loads put on them in everyday life, such as during walking or in case of a fall. Walking subjects the implants to repetitive loads during many years, while falling can cause a much bigger stress in the implant for a very short period of time. It is important to make sure neither of these situations causes the implants to break, and different types of tests simulating worst case scenarios are therefore needed.

To determine the requirements for the tests, a model was created using a software called OpenSim. This model, illustrated in the figure below, simulates a walking amputee fitted with an osseointegrated prosthesis. The software was used to study forces and moments acting on the implant throughout each step, and the simulated results were compared to measurements from amputees fitted with the OPRA implant. The comparison showed that the simulated results were consistent with the collected data to some extent, but due to limitations and assumptions in the OpenSim model it could not be used to determine the requirements for the test standard. This was instead done using the amputee data. There is however a lot of potential for further development of the model, which for example could be used for simulating different worst case scenarios.

The standard that has been developed during this Thesis is not a complete standard like the reviewed international ones, but rather a first attempt to establish a new and standardised test method for the OPRA implants. It constitutes a solid base for further development and completion, and can in the future lead to a new way of testing the implants. This project can act as a starting point for such work.



Master's Thesis in Biomedical Engineering:
Development of a Standard for Structural Testing of Implants in Transfemoral Osseointegrated Prostheses.