First-in-human implant of a new prosthesis for trans-femoral amputated patients

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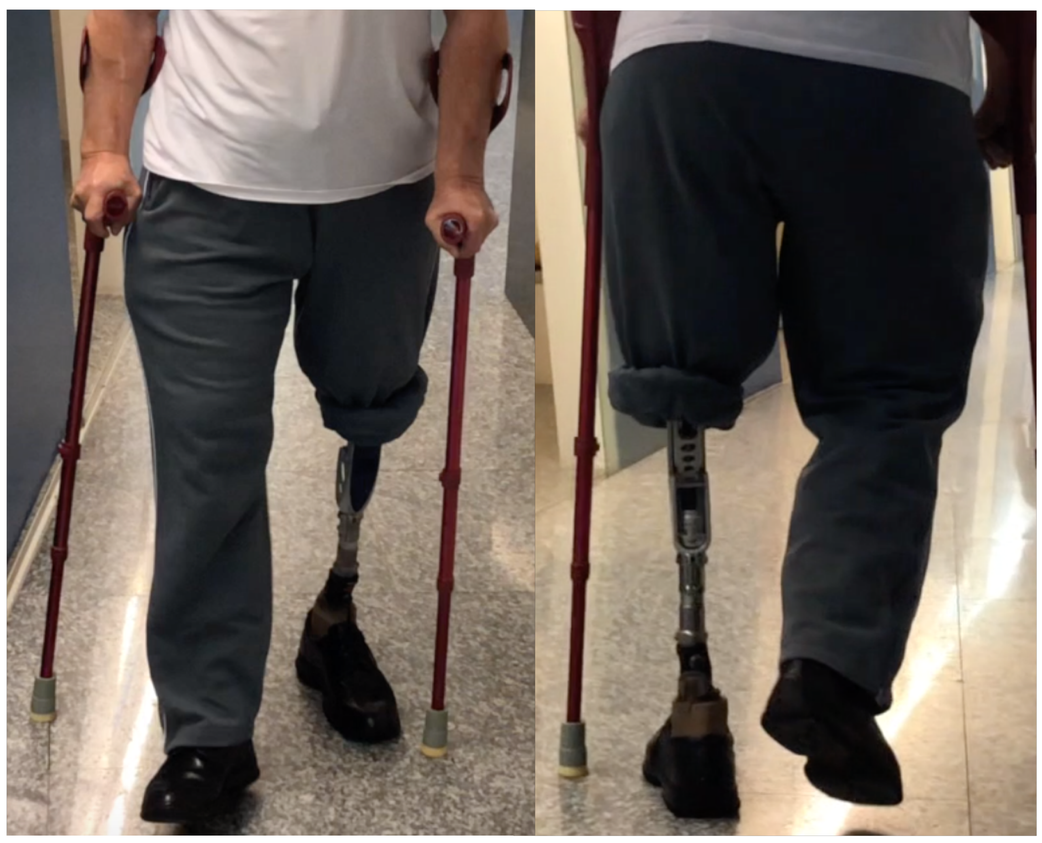
Introduction Patients with trans-femoral amputations use lower limb prosthesis whose attachment is realized by a stump-fitting socket to which the artificial limb is fixed. However, the performance of this fixation method is often reported as unsatisfactory. Some patients have complained about the restricted hip motion, pain, soft tissue irritation and break down, as well as the lack of appropriate control of the prosthetic limb. An alternative solution for trans-femoral amputated patient is attaching the artificial limb directly to the femur via a percutaneous implant with a risk of infections and implant loosening. To overcome these issues a new concept of device that combines the advantages of the trans-femoral fixation and the through-knee amputation was created and implanted.

Methods The new implant is composed by an intramedullary nail with a terminal base plate allowing weight-bearing with a more physiological pressure distribution and a better prosthesis fixation and control. The latter can be achieved using a less cumbersome socket adapted to the femur that perfectly engages the bulbous shape of the epiphyseal component of the implant. This phase-I study will evaluate the results of the implantation of this innovative device in 5 previously trans-femoral amputated patients. This will be carried out by evaluating the clinical, radiological and ergonomic outcome and health-related quality of life. Moreover, the risk of infection and implant mobilization will be monitored with a follow-up of 2 years.

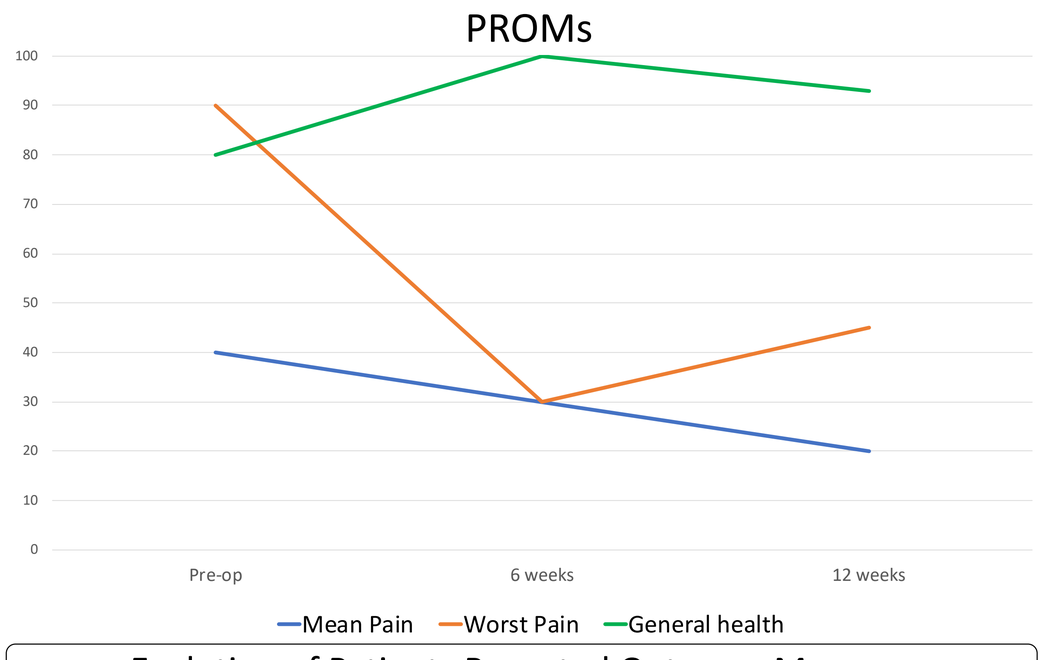
Model of the implant (left) and of the custom-made epiphyseal component (right)

Results The first patient was successfully treated without peri-operative complications during a 107-minute long surgery. After 6 weeks the patient was able to walk with crutches. After 3 months, the results are promising with an improvement of all the clinical scores, a good integration of the implant, and a significant increase of patient's quality of life. The Patient was moreover able to perform everyday activities without problems. This was achieved without adverse events or safety concerns. A second patients has been enrolled and will be treated on the 13th March.

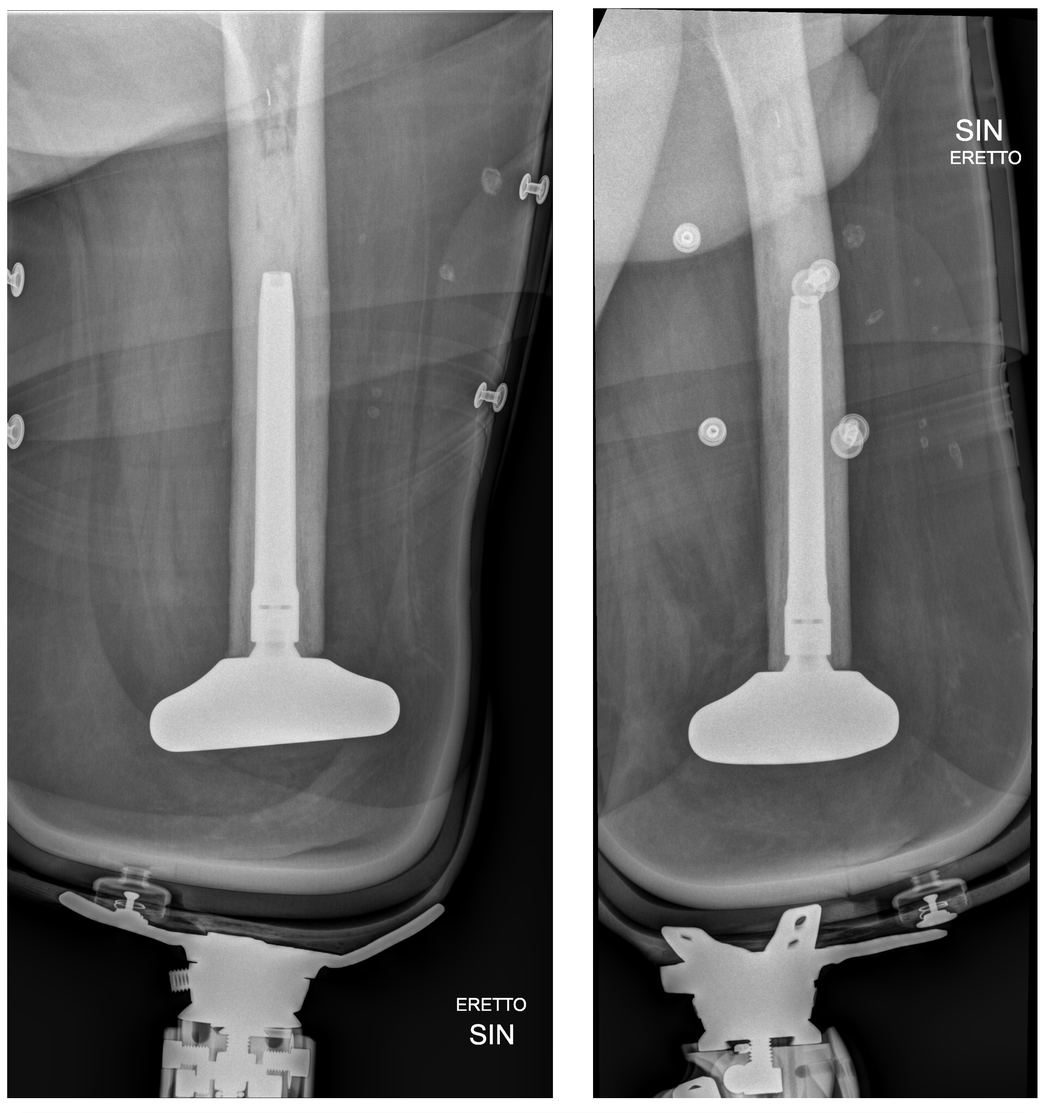
Conclusion The first-in-human implantation of the new device showed interesting results in terms of functional outcome and patients' satisfaction, without safety concerns after 3 months from surgery. This innovative implant could represent an affordable solution for the orthopaedic surgeon in order to improve the quality of life of trans-femoral amputated patients.



Clinical Status 6 weeks after surgery



Evolution of Patients Reported Outcome Measures



Antero-posterior (left) and lateral X-Ray (right) 12 weeks after surgery