Direct Skeletal Fixation - a new treatment paradigm in combat amputees?

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Ten years of combat operations in Iraq and Afghanistan saw coalition soldiers increasingly exposed to improvised explosive devices (IEDs) either whilst driving in vehicles or on foot\(^1,2\). These devastating weapons became increasingly powerful and were soon a leading cause of serious injury.

Early devices were comparable to legacy landmines in terms of power and injury profile. Acute amputation was performed in cases where the limb was deemed to be non-salvageable\(^7\). Reconstruction sometimes failed for reasons of infection, non-union or chronic pain, and for these patients late amputation was necessary. Both of these cohorts tended to be left with relatively standard below knee amputations.

As the power of the IEDs increased, so their effect became more devastating. The zone of injury extended above the knee, into the thigh musculature and in some cases higher, involving the junctional area of the groin, the pelvic floor and intraabdominal structures\(^4,5\). Improvements in trauma care from point of wounding to definitive care led to an increase in unexpected survivors with an unprecedented numbers of soldiers surviving into rehabilitation centres and eventually wanting to walk again\(^6\).

The most severe effects of IED’s were seen in those soldiers exposed to dismounted blast. Improvements in body armour helped mitigate some of the effects of blast but as the power of the IED’s increased, so did the severity of injury. A pattern of devastating lower limb injuries associated with upper limb fractures, burns and soft tissue injury was commonly seen. Traumatic amputation either through or above the knee was treated at the point of wounding with field dressings and tourniquets. Resuscitation and, once stable, surgical debridement followed, usually within an hour of injury. All necrotic tissues were debrided, haemostasis was assured, fractures stabilised and the soft tissues splinted with topical negative pressure dressings.

Aeromedical evacuation back to definitive care allowed second look surgery to be performed by the receiving orthoplastic team usually within 48 hrs of injury. Soft tissue damage was severe with progression of wounds and extension of zone of injury being the norm. Once the wounds and systemic inflammatory response had been controlled, the residual healthy femur was usually short and the soft tissues often fragile with split skin grafts giving early coverage to allow closure of the wounds. Despite huge advances in prosthetics and socket fitting, the combination of short residuum and poor quality soft tissue coverage led to problems when these patients began to mobilise\(^7\).

Difficulty in obtaining a stable socket fit often led to soft tissue breakdown and the ever-present risk of heterotrophic ossification led to patients failing to achieve their goal of mobilising independently.

This patient group were exceptionally well motivated, well informed and living in the modern IT world had access to scientific literature from all over the world. They were keen to see if there was another way. In 2014, patients and their Rehabilitation Consultants began to ask questions: Was Osseointegration safe after blast? Could these soldiers, that had survived such severe injuries, realise a dream and walk?

Osseointegration is not new, its roots can be traced back many decades to the pioneering work of Professor Per-Ingvar Branemark\(^8\). He discovered that implants made of pure titanium formed a stable interface within living bone tissue. This discovery facilitated advances in several areas most...
notably dentistry. Branemark’s early pioneering work in Sweden led to the first amputation prosthesis being used in 1990. Osseointegration is now becoming more widely accepted with teams performing surgery in Europe, Australia and America. Ongoing work has developed the hypothesis that Osseointegration may provide a solution to the complex issues of traditional socket mounted prosthesis, particularly in those patients with a short residuum or poor soft tissues. Several published studies have demonstrated improvements of quality of life, mobility, ‘donning and doffing’ and even proprioception11 but always with the caveats of infection, loosening and fracture.

As with all things, the implants have evolved and the latest designs to come to market have moved away from the early screw type fixation to press fit, highly porous-coated metal alloy devices similar to those used in arthroplasty. Metal alloy devices have similar to press fit, highly porous-coated surface used to encourage osseointegration the dual cone coated surface used to encourage Osseointegration the dual cone and locking screw. Courtesy of the Osseointegration group of Australia.

There are three main Osseointegration systems in use. The OPRA (Osseointegrated Prosthesis for the Rehabilitation of amputees) system reports 100 cases from a single centre in Sweden and 11 cases from a single centre in England. This stem reports a good safety profile with implant survival of over 10 years. The OPRA protocol currently mandates a slow pace of rehabilitation and a two stage operation.

The ILP (Integral Leg Prosthesis-Endo-Exo Femur prosthesis) system reports 89 cases from Germany and two cases from the Netherlands. Implant survival has been reported out to over 12 years. The OPL (OGAP-OPL Osseointegration Group of Australia Osseointegration Prosthetic Limb) system from Australia (Figure 1) reported the clinical outcomes in 50 unilateral trans femoral amputees with a mean age of 49.9 years. Although 27 patients had some form of complication, they demonstrated statistically significant improvements in recorded outcome measures.

A Bazian review of published case series performed for NHS England in 2016 showed a substantial improvement in quality of life for the majority of patients. Mobility was also shown to increase with the majority of patients becoming daily prosthetic users.

The most common complication was superficial infection treated with oral antibiotics with relatively few patients needing intravenous antibiotics or hospital treatment. Periprosthetic fracture or implant failure did occur but in low numbers. At the time of publication, the Bazian group concluded that low quality evidence indicated that the OI prosthesis did improve the quality of life for amputees and appeared to be safe with a low incidence of deep infection.

The severity of soft tissue injury combined with bacterial and fungal infections had left our injured personnel with few options for reconstructive orthopaedic surgery, significant infection rates had become associated with late arthroplasty surgery.

Encouraging results from the Sydney group led to a combined decision by the then Surgeon General and the Rehabilitation team at Defence Medical Rehabilitation Centre (DMRC) Headley Court to send a wheelchair bound non-ambulant bilateral above knee amputee patient to Australia for OI surgery. The patient had reached the end of their prosthetic pathway and was still wheelchair bound. Successful surgery was performed in 2014. The results were excellent and a further 6 patients (Total 14 femurs) have undergone the surgery using the OGPL-OPL system. All patients were selected via a specialist OI MDT clinic. Inclusion criteria included being a bilateral Above Knee amputee with no active infection. Single stage implantation with concurrent stump refashioning and stoma preparation was performed. Post operatively patients were managed with progressive early weight bearing (20kg at three days) progressing at 5kg per day as pain allows. At a mean of 21.1 months from time of surgery, we have had no deaths, episodes of sepsis, loosening or osteomyelitis. Across the whole cohort, a total of nine courses of oral antibiotics have been prescribed. One patient sustained a proximal femoral fracture after a fall and three patients have undergone stump refashioning. (X-Ray examples are seen in Figures 2 and 3.)

Although the initial results appear encouraging, it is our opinion that Osseointegration surgery should not be considered a definitive procedure with secondary procedures being common.

The stoma or implant skin interface is the main cause for concern - it is difficult to imagine that current systems do not run a significant risk of deep bone infection in the future. Following surgery, these patients continue to undergo regular surveillance of their implant. As this technique becomes increasingly employed in the amputee population, we believe there needs to be a consensus on outcome measures and an international database should be used to compare stems across the globe.

References

References can be found online at www.boa.ac.uk/publications/JTO or by scanning the QR Code.
References


