Intraosseous transcutaneous amputation prosthesis

An alternative to limb amputation in dogs and cats

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Full-limb amputation frequently constitutes the standard of care for certain appendicular neoplasias and irreversible vascular or neurological compromise in both humans and small animals. An estimated 113,000 new human amputations are performed each year in the USA (Source: Agency for Healthcare Research and Quality, US Department of Health and Human Services), while an estimated 156,000 new human amputations (approximately 390 per 1,000,000 people) are performed each year in the EU. Precise incidence and epidemiological data for small animal amputations have not been reported, although incidences of some of the common causes for amputation have been reported. For example, an estimated 6,000-8,000 new cases of canine osteosarcoma per year are identified in the US alone (Source: National Canine Cancer Foundation) representing a significant therapeutic challenge to the veterinary industry.

High incidences of other traumatic, neoplastic and congenital or developmental skeletal diseases make limb amputation one of the most commonly performed procedures in small animal practice, although much as for human medicine, it is considered a salvage procedure, with the only absolute indication being irreversible vascular compromise. Outcome following veterinary amputation is widely accepted as being positive, although detailed assessments of lifestyle or activity levels have not been reported for populations or case series of patients post-operatively. Anecdotally, a number of factors may predispose to relatively poor clinical outcomes following limb amputation in small animals, including increasing body weight, conformation (chondrodystrophic breeds), concomitant diseases (e.g. polytrauma, osteoarthritis, neurological or cardiovascular disorders) and thoracic limb (as compared with pelvic limb) amputation. Anticipated lifestyle (and corresponding owner expectations) should also be considered, with amputation being less readily accepted by very active, performance or working animals.

Figure 1. Radiograph in mediolateral projection of amputated distal antebrachium with an early version of the exoprosthesis attached.

A range of "limb salvage" techniques have been described, aimed at restoring comfortable limb function in spite of significant tissue defects (such as en bloc tumour resection, fracture non-union or following severe trauma), and include cortical bone allografts, free or microvascular bone (and soft tissue) autografts, bone transport techniques, distraction osteogenesis and metallic or other synthetic bone endoprostheses. Such techniques are well established in the human medical field and most have also been reported in individuals or small case series in the small animal veterinary literature. These techniques are highly challenging and necessitate an experienced surgeon, a compliant patient and committed owners to reliably achieve successful outcomes. Challenges associated with such techniques include availability and biocompatibility of allograft and endoprosthesis materials, implant loosening or failure associated with lack of integration of endoprostheses or allografts, and the prolonged therapy and multiple procedures required for bone transport techniques. Most significantly, these techniques can only be applied when the neurological and vascular supply to the limb distal to the tissue defect can be reliably maintained, and as a result these techniques are seldom applicable distal to carpus or hock. In spite of a range of technological and surgical advances, complications still exceed 50% in many studies.

Stump socket prostheses applied following partial limb amputation are common in human medicine and are available commercially for the veterinary market. Use in dogs has been reported as far back as 1906 in Frederick Hobday's book entitled Surgical Diseases of the Dog and Cat. However, weight bearing may subject un-acclimatized stump tissue to forces normally transmitted via the skeleton, resulting in stump morbidity such as abrasions and pressure sores. Such exo-prostheses typically require custom manufacture and regular refitting or adjustment, may be difficult and uncomfortable to maintain, and experiences within the small animal veterinary field have sometimes been disappointing - either because of poorly manufactured or fitted devices or because of poor owner or patient compliance. However, significant advances have been made in this arena in recent years, most notably by the Lacerta Rehabilitation group at The University of Salford, whereby several successful stump socket-prostheses have been fitted to dogs at different levels of amputation in both the fore-limb and hind-limb.[1]

Transcutaneous prostheses have been in development since the 1960s in the human surgical field, with initial applications including cosmetic dental and aural prostheses. However, in the long-term, such implants almost inevitably fail due to problems at the skin-implant interface, specifically epithelial downgrowth, marsupialisation and resultant infection and/or peri-prosthetic soft tissue necrosis. Such problems have been particularly experienced during attempts to adapt existing technology to the appendicular skeleton in both human and veterinary medicine. Additional problems have also been experienced such as implant loosening, fracture and ultimate failure associated with load transmission between the ground, the implant and the skeleton.

Figure 2. Coal with the external skeletal fixation apparatus attached to his antebrachium to transfer load from elbow to ground whilst bypassing the endoprosthesis to allow 5-6 weeks for integration before attachment of the new external foot..

ITAP - design and application

The Intraosseous Transcutaneous Amputation Prosthesis (ITAP) was initially developed by the Centre for Biomedical Engineering at the Institute of Orthopaedics of University College London under the umbrella of Stanmore Implants Worldwide Ltd., a world-leader in custom prostheses for limb salvage and complex joint replacement. The priority in designing the ITAP was to circumvent challenges associated with the skin-implant interface, providing a durable, low-maintenance transcutaneous handle for attachment of exoprostheses directly to the skeletal system. To this end, ITAP was specifically designed to closely mimic the anatomy of the deer antler, a rare natural circumstance where skin integrates directly with underlying bone to create a resilient, infection-resistant seal between the skin and the antler. This seal persists when the antler has matured and is dead bone attached to living bone of the skull through the skin. Antlers are used for fighting and as such sustain high levels of loading. This natural scenario was identified as an ideal biomimetic model for development of skeletally integrated exoprostheses for amputees.

ITAP implants are custom designed and manufactured for individual patients (currently with a turn-around of approximately 2 weeks) and comprise a titanium alloy intraosseous stem, a perforated subcutaneous umbrella flange for skin in-growth, and a distal extracutaneous peg for exoprosthesis attachment. The stem and flange are coated with hydroxyapatite to provide a porous surface with osteointegrative capacity. The extracutaneous peg is highly polished or coated by plasma-assisted vapour deposition with 'diamond-like coating' to limit bacterial adherence. An experimental caprine model[2,3] and on-going human clinical applications demonstrated excellent integration at the skin-ITAP interface with minimal epithelial downgrowth and mechanical competence of the osseointegration to allow long term functional loading.

We have now applied ITAP successfully in both canine and feline patients, in thoracic or pelvic limbs, representing the first application of this technology to a weight-bearing limb segment in any species. Since then ITAP has been applied to other skeletal locations including the humerus in human patients. The owners of each patient operated have at each stage been offered all contemporaneously available treatment options including amputation and euthanasia and they gave fully-informed consent, knowing that the procedure involved application of a novel device in an unproven clinical scenario. All patients operated have been afflicted by distal limb

Figure 3. Appearance of skin bonded firmly to the metallic umbrella of the endoprosthesis at the time of removal of the external frame. The metallic peg protruding from the skin now has a permanent seal against breakdown or infection.

disease which was considered unsuitable for previously-described limb salvage procedures. All patients have also been affected by significant orthopaedic disease or traumatic injury of at least one other limb (and in some cases, all three limbs) which was considered severe enough to be a major contraindication to full limb amputation.

Case example

We recently treated "Coal", an 8 year old male 37.7kg American Bulldog with a carpal synovial cell sarcoma. No evidence of lymphatic or distant metastasis was identified. Amputation and custom press-fit ITAP implantation was performed at the level of the distal radial metaphysis. The ITAP was protected for 6 weeks post-operatively (to allow for osteointegration) by application of a walking external skeletal fixation frame (Figures 2 and 3). Custom exoprostheses were manufactured and developed based on clinical findings, finite-element analysis and kinematic observations.

The ITAP successfully incorporated into parent bone, as documented by clinical examination and radiographic evidence of peri-implant osseous modeling over several months post-implantation. The skin-implant interface was visibly and palpably resilient with no complications observed. Limb use was considered excellent throughout the post-operative period. Initial challenges associated with abaxial motion of the elbow, which had been evident at initial presentation, were addressed by exoprosthetic design and hydrotherapy. Now only minor gait abnormality is evident, consistent with the lack of a functional carpal joint, as might be anticipated following pancarpal arthrodesis.

Video footage and further information about Coal can be found at: www.vetpulse.tv/in-practice/fitzpatrick-referrals/115_noel-fitzpatrick-coal-long

Exoprosthesis design

Exoprosthesis development is the subject of ongoing kinetic, kinematic, finite-element and computer modelling endeavour. Functional outcome and bone-response-to-implant parameters are reliant on a suitable weight-bearing, shock-absorbing and practical "foot" component. Initial exoprosthesis development was derivative in that a human blade-type foot was manufactured for one of our earliest patients. However loading was not appropriate for the canine thoracic limb and stress-concentration contributed to failure of the initial implant at the weakest point. With the goals of protecting the ITAP from eccentric loading, shock absorption at foot-fall to avoid bone-implant interface stress, and durability, the second iteration involved use of two metallic cylinders with compressible rubber positioned more caudally than the foot-fall position of the initial blade design. Subsequently, computer modelling and finite element analysis were employed to facilitate design of a more robust and practical exoprosthesis. These iterations of design initially involved an arc of Delrin™ which would deflect on loading, then application of Kevlar on rubber impregnated with air-bubbles and shock-absorbing foam-beads and latterly, various deformable polymers shaped to direct the limb in the normal sagittal axis of the gait pattern.

Our current goal is to use kinematic gait analysis to define the design characteristics of the optimal exoprosthesis. The final design will likely change over time as we build the knowledge base for the kinetics and kinematics of these implants used in various species, breeds and anatomical locations. The crucial objectives are to facilitate normalised gait in the saggital plane without circumduction or transverse-plane limb deviation, stress-shielding of the ITAP and the bone-implant interface, impact absorption for maximum comfort at various speeds and appropriate direction of forces relative to the bone-implant vector trajectory. We have also investigated "quick-release" mechanisms if the foot were to become trapped, so as not to jeopardise the bone-ITAP construct and reduce risk of fracture. Our most recent design, developed in conjunction with the Lacerta Rehabilitation group at The University of Salford, allows for semi-constrained motion at foot-fall to accommodate stance on uneven ground, has a detachable component that can be changed readily as it wears out and has a wear-surface which permits running on varied terrain surfaces.

Outcomes, discussion and conclusions

The positive outcome documented in Coal is by no means exceptional. Limb usage with the ITAP and exoprosthesis in place has been reliable across our patients, and quality of life is excellent in spite of the more advanced surgical procedure. Long-term histopathological assessment from the ITAP of a patient operated for a carpal osteosarcoma (collected at the time of euthanasia for distant metastasis 12 months post-operatively) has documented excellent integration at both bone-implant and skin-implant interfaces, with no evidence of marsupialisation or infection, supporting the evidence from the experimental studies by the UCL team at Stanmore.

The encouraging clinical findings in our patients has also provided support for human applications of ITAP. The first human upper limb ITAP was implanted in late 2007. Through a close working relationship between the human and vet teams working with the ITAP technology this has proved to be a magnificent example of the philosophy of 'one-medicine', for which the core ethos is cross-pollination of ideas between medical practitioners of any discipline, human and animal, allowing better outcomes for all patients through shared experiences. As veterinary surgeons, the rare opportunity to collaborate with colleagues in the human medical field at the forefront of medical science has been a privilege and an exciting new vista. Furthermore, it has allowed us to offer to a select group of patients, a technology which holds genuine benefits over the existing alternatives. We believe that as veterinary professionals, we have a responsibility to offer the gold-standard of care to our patients. It is for the owners to decide if they wish to avail of such technological advancements or not. We also believe it is our responsibility to strive for better treatments for our patients where existing options are suboptimal.

As with any veterinary procedure, the ethical implications must be considered. We believe that a procedure should not be performed because it can be done, but rather because it should be done. Application of technology for technology's sake is neither ethical or acceptable in our opinion, but embracing advanced technology and facilitating a symbiosis between mechanical and biological interfaces is not only morally forthright in our view, but is the cornerstone of all clinical advancements, which are fundamental to progress in veterinary surgery. Indeed no progress can be made in any arena unless we embrace change and innovation. Our resounding caveat is that such procedures should only be performed where the potential benefits gained by the procedure significantly outweigh the potential risks and short-term disadvantages. Cosmesis and owner recalcitrance to accept amputation where it is ethically the right decision are clearly inappropriate determinants when evaluating a potential ITAP candidate. Both conventional limb amputation and existing limb salvage techniques will remain the most appropriate options for many patients, but it seems likely that ITAP can provide a viable and positive alternative for a select group of patients.

The jury is still out on the acceptance of limb-spare technology in small animal veterinary surgery, either from the paradigm of veterinary practitioner acceptance or acquiescence by insurers. However, the fact remains that there are cases which would benefit from these procedures and when each and every one of us took our professional oath, we "solemnly swore to use our scientific knowledge and skills for the benefit of society through the protection of animal health, the relief of animal suffering, the conservation of animal resources, the promotion of public health and the advancement of medical knowledge." We vowed to "practice our profession conscientiously, with dignity and in keeping with the principles of veterinary medical ethics," and we accepted that we have a "lifelong obligation to the continual improvement of our professional knowledge and competence." Surely the advances outlined in this manuscript are appropriate targets for our professional ardor and aspirations when we uttered these words in rooms full of fellow professionals that share this responsibility?

Figure 4. Coal walking on a more recent version of the exoprosthesis which is shock-absorbing and semi-constrained so that it behaves more like his normal foot. Exoprosthesis development is in constant evolution.

We would be pleased to give advice or to discuss ITAP (as well as other limb salvage treatment options using endoprostheses) with any veterinary surgeon who may have a potential candidate for these procedures in any country.

References

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