INTRODUCTION: In amputees the function of the external prostheses is often impaired by problems at the stump – socket interface, due to non-uniform pressure distribution leading focal points of increased stress, poor stump – socket fitting and infection. An Intraosseous Transcutaneous Amputation Prosthesis (ITAP) would overcome these problems by protecting the soft tissue – implant interface, whilst redistributing high stresses to bone. ITAP creates a breach in the skin’s protective barrier, and a soft tissue – implant seal is essential to prevent implant failure and infection. Deer antlers are natural analogues of ITAP and successfully overcome the problems associated with skin penetrating implants including infection, marsupilisation and avulsion. In this study, an ITAP device has been developed, with a soft tissue – implant interface, based on deer antler morphology. It is hypothesized that the structure and morphology of deer antlers can be extrapolated to develop a successful soft tissue seal around transcutaneous implants for use in ITAP.

METHODS: Eleven pairs of deer antler were used to evaluate the interface between the antler and pedicle, and the soft tissue seal around the antler-pedicel structure using hard grade resin histology and scanning electron microscopy (SEM). The findings were used to develop a biomimetic titanium alloy (TiAl6V) ITAP device, which was tested in vivo in a goat model. Three to five transcutaneous pins were implanted into the medial aspect of the right tibia of skeletally mature female goats. Four implant designs were tested, Machine Finished Straight (MFS), Hydroxyapatite (HA) Coated MFS, Machine Finished Flanged (MFF) and HA Coated MFF. The hydroxyapatite coating consisted of a 70μ thick plasma sprayed HA layer that was applied to the implant region abutting the sub-epithelium. The implants remained in situ for four weeks after which they were processed for routine hard grade resin histology. The resulting interfaces were analyzed quantitatively for epithelial downgrowth (marsupilisation) and epithelial/sub-epithelial layer attachment to the implant surface.

RESULTS: The histology of the deer antler showed there to be a small area of epithelial attachment, with negligible downgrowth, arrested by soft tissue adhesion to the underlying pedicle surface (Figure 1). There was a significant increase in pore size and frequency in the pedicle structure (abutting the soft tissues), compared to the external antler proper (p values < 0.05) (Figure 2). The flanged implant represented the porous pedicle bone and was designed to be analogous to the dermal attachment region of the deer antler. It was anticipated that this would increase dermal attachment and reduce downgrowth. The MFS ITAP implants were associated with significantly greater downgrowth and reduced epithelial and sub-epithelial layer attachment compared to all other implant designs (p < 0.05). The HA coating, and porous flange structure significantly reduced downgrowth and increased sub-epithelial layer attachment (p < 0.05) (Figure 3). Epithelial downgrowth was observed to decrease with increasing sub-epithelial layer attachment. The relationship was found to be significant at the 0.01 level (R squared = 0.185) (Figure 4).

DISCUSSION: The deer antler successfully overcome the problems associated with an ITAP device, creating a tight seal between the soft tissues of the skin and the antler bone. Perforating collagen fibres extend from the sub-epithelium into the bone, creating the seal between the dermis and the antler bone. This seal prevents epithelial downgrowth into the underlying soft tissues. The findings from the deer antler research enabled us to formulate the basis for the ITAP design. The ITAP implants developed, by artificially mimicking aspects of the antler including layering of porous and bioactive surfaces for tissue attachment, have been successful in minimizing downgrowth and actively encouraging epithelial and sub-epithelial soft tissue attachment. We modelled the design of a novel ITAP on the findings of the study of deer antler, as a biomimetic structure. As a result we have successfully developed an implant, which has the potential to revolutionize lower limb amputation prosthetic design in the future.