Mechanical Properties and the In Vivo Response to Porous Polyurethane: An Evaluation to Provide an Effective Subdermal Barrier against Infection.

INTRODUCTION: Percutaneous osseointegrated prosthetics are currently being considered to provide amputees with a prosthesis that will give them mobility and improve their quality of life. However, these prostheses permanently disrupt the skin which places the implant at a high risk of infection. For this methodology to succeed, the skin and underlying soft tissue need to integrate with the porous polyurethane device creating a subdermal barrier to infection. Current techniques utilize a titanium implant which limits the ability of the skin to fully integrate and attach to the implant. A material is needed which more closely resembles the mechanical properties of skin to facilitate a more robust integration. Porous polyurethane provides flexibility and functionality which may allow such an attachment. The aim of this study is to provide insight into the mechanical properties of porous polyurethane, human skin, pig skin, and titanium; (2) the hardness properties of porous polyurethane, human skin, pig skin, and titanium; and (3) the tissue integration into the porous polyurethane.

METHODS: Human cadaver and pig carcass skin specimens were prepared, including both epidermal and dermal layers. Pig is the animal model which will be used to evaluate efficacy of porous polyurethane and titanium osseointegrated implants and is used as a comparable measure in this study. The porous polyurethane (CarboSil Polymer Technology Group, Berkeley, CA) was fabricated with a pore size ranging from 300-500 µm and a porosity of ~85-90%.

Specimen Preparation: The test specimens were punched using an ASTM D 412 die into 16 human and 32 pig test specimen strips. Due to the nature of the skin and comparable interest of this experiment, skin specimens were cut and categorized by whether they were parallel to the nature of the skin and comparable interest of this experiment, skin specimens were cut and categorized by whether they were parallel to Langer lines (10 human, 14 pig), perpendicular to Langer lines (6 human, 7 pig), or parallel with bone shaft tissue deep to the dermal layer of the specimen (11 pig). Three polyurethane samples were punched using the D412 die.

Tensile Test: Using an Instron Tensile Machine, the specimens were secured with freeze clamp devices (Fig 1 Right). Each specimen was given a 5 N tensile load after which the cross-sectional area was measured using a digital caliper. Specimens were then pulled at a rate of 1/3 mm per second until the specimen failed. Load and position were acquired by Instron. The modulus of elasticity was calculated, averaged, and compared for each specimen. Titanium values reported are according to ASTM F 136 grade 5.

Hardness Test: Using a Type OO durometer, tests were performed in accordance with the ASTM D-2240 standard procedure (Fig 1 Left). Each specimen was placed on a hard surface, and was folded in half to double the thickness as suggested by standard to improve accuracy. Hardness values were averaged and compared.

In vivo Response and Integration: A pilot study to determine in vivo response and tissue integration of the porous polyurethane was performed in three New Zealand White Rabbits. Porous polyurethane implants were circular measuring 10mm by 30mm (h x d). An incision was made on the dorsum and a subcutaneous pocket was created into which the implant was placed. Four weeks from surgery, the animals were euthanized and the implants were carefully harvested, fixed in 10% NBF, embedded in paraffin, and stained with H&E. The durometer hardness test was performed on the skin over the implanted porous polyurethane implants at time of surgery and at four weeks after surgery.

RESULTS: It was observed that the modulus of elasticity of human and pig skin were very comparable with little deviation which provided an accurate baseline comparison (Fig 2). As a result, all human and pig skin values were combined. The polyurethane samples were ~2 magnitudes lower than the skin samples, and the titanium ASTM values, were over 3 magnitudes higher than the skin samples.

DISCUSSION: We have shown that polyurethane, compared to that of titanium, will provide greater functionality in osseointegrated implants by more closely representing the mechanical properties of skin. The porous polyurethane had a favorable tissue response with infiltration and vascularization throughout the implant. Osseointegrated implants that utilize polyurethane will allow for skin and soft tissue attachment, which as a whole will have flexibility and mechanical properties similar to skin. Ultimately, this will result in a subdermal barrier that will prevent microbial invasion, subsequent infection, and improve the lifetime of the implant within the patient. In future studies we will investigate the porous polyurethane implant upon injury, evaluating the strength of the skin attachment.

ACKNOWLEDGEMENTS: The project described was supported by grant R01HD061014 from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NIH/NICHD). The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH/NICHD.