LONG TERM BEHAVIOUR OF A HIGH DENSITY COLLAGEN BONE ANCHOR

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Introduction
The concept of bone anchors constructed of High Density Collagen (HDC) was introduced at this meeting last year1. The healing of tendon to bone in an animal model during the critical first six months was found to be equal to that produced with a standard metallic anchor. Collagen is being investigated as a material for making anchors to avoid the drawbacks of the materials in the current range of available anchors. Metallic anchors may permanently obscure radiological investigations and risk dangerous migration. Degradable synthetic polymeric orthopaedic devices can suffer unpredictable rates of hydrolysis, residual cysts and when used around joints may fragment causing locking symptoms3,4.

To realise the potential advantage of HDC as an anchor material, a demonstration of the long term degradation characteristics is required. This study presents the long term results of a study of HDC bone anchors in a loaded sheep patella tendon reconstruction model.

Methods
HDC was prepared from purified fibrillar bovine collagen by dehydration and gluteraldehyde cross-linking. The anchors consisted of a hollow cylinder of HDC. They were pre-threaded with a loop of braided 2 polyester suture, which was prevented from pulling back through the cylinder by a terminal PMMA washer. The assembled devices were gamma sterilised.

Skeletal mature cross bred merino wethers were used with the approval of our institutional Animal Care and Ethics Committee (permit 96/7). Six animals were sacrificed immediately following surgery (time zero). Bilateral procedures were performed on the time zero subjects, but only the right knee was treated in the other animals.

The surgical procedure entailed dividing and reattaching the patella tendon at the tibial insertion. The tibial tuberosity was denuded of all tendon, insertion fibrocartilage and periosteum with a high speed burr. A pair of holes were drilled 5 mm medial and lateral to the centre of the tuberosity. The anchor devices threaded with braided 2 polyester were inserted into the saline flushed holes and loaded to 10lb. Half the animals at each time point received 2 test collagen devices and the other half received 2 Mitek Rotator Cuff Anchors. A whip stitch of alternating 2 and 4 mm bites was applied to each edge of the tendon. A modified Robert Jones bandage was applied from the hoof to the groin and removed at 3 weeks. Animals were sacrificed for histological and mechanical testing at 0, 6, 12, 26 and 104 weeks.

Isolated patella - patella tendon - tibia constructs were mounted in a custom jig for testing in axial tension on a Mechanical Testing Systems’ MTS 858 Minibionix servohydraulic mechanical testing machine. A strain rate of 100mm/min was applied. The peak load, stiffness, energy to failure and mode of failure were analysed with two way ANOVA. Two animals were sacrificed for qualitative histological studies at 6, 12, 26, 52 and 104 weeks. Both routine paraffin embedded decalcified and glycolmethacrylate imbedded undecalcified histological methods were used.

Results
The peak load, stiffness and energy to failure of the repairs with both the devices increased rapidly to twelve weeks and gradually thereafter. There was no significant difference in peak load or energy to failure between the two anchors at any time point. Both approached the strength of the intact non-operated side by 26 weeks.

The mode of failure changed with time. After 26 weeks avulsion of the insertion was not observed.

Histologically, no difference was observed between repairs with the two devices at the level of the tendon healing to bone. The initial hypercellularity of the tendon interface decreased with time. Although areas of fibrocartilagenous differentiation could be identified from 6 weeks it still had not formed a mature direct tendon insertion at 24 months. By 12 weeks bone could be seen filling over the base of the anchors. Newly formed woven and lamellar bone were present in direct apposition to the surface of both bone anchors without evidence of fibrous encapsulation or bone resorption. From 6 weeks onwards continuous collagen fibres could be seen crossing from the HDC to the bone. At 12 weeks some scalloping of the surface of the HDC was visible with the occasional osteoid vesicle near the scalloped surface. Little difference was noted at 26 weeks. The HDC was still largely intact at 104 weeks. There was no evidence of fibrous encapsulation or cyst formation at any stage.

Discussion
Healing of tendon to bone is not altered by using a biological material in the underlying anchor rather than metal. The main difference seen between the two anchors was the interaction with bone. While there was outweigh of bone to the Mitek, there was incorporation of surface collagen fibres into adjacent trabeculae and a gradual remodelling of HDC into bone.

The ideal implantable device would maintain its mechanical integrity during its required functional life and then resorb to be completely replaced by the original tissue. In clinical practice, the unpredictability of both healing and degradation necessitates a large temporal margin of safety. While the HDC has maintained its strength for an ample time it is still present at 104 weeks.

In this model the HDC anchor supported as good healing of a flat tendon to bone as a standard metallic device while having the advantage of being slowly replaced by bone. A mature direct insertion had still not reformed at 104 weeks.

References
1Harrison, J.A. et al. ORS 45(2), 518, 1999

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