THE STRENGTH OF ARTIFICIAL LIGAMENT ANCHORAGES

A COMPARATIVE EXPERIMENTAL STUDY

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This study aimed to compare the holding strength of various commercially-available anchorage devices for artificial ligaments, so that surgeons might make a reasoned choice. Tensile tests to failure were performed on screws, bollards, toggles and staples which had been implanted into cadaveric bones.

The holding strength of all devices correlated significantly with the local thickness of cortical bone, so it is recommended that anchorages should be placed away from the joint line, into diaphyseal bone if possible. A new trans-cortical grommet was developed which, when used around an AO screw, had significantly greater holding strength than the other devices.

Although there has been much work on artificial ligaments and clinical use of a range of devices (Amis 1986), little has been published on the design or properties of their anchorages. This has probably arisen because the anchorages have been considered to be less important than the implants themselves, and also because it has been claimed that biological ingrowth means that the anchorages do not need to function for long (Jenkins et al. 1977; Bolton and Bruchman 1985).

The late realisation that the tissue response to implants within the knee varies greatly, and cannot be relied on to integrate fibrous implants into the host tissues (Rushton, Dandy and Naylor 1983), means that in some cases the ligament anchorages must continue, in the long term, to withstand the forces which arise from normal activities (Morrison 1969). Otherwise failure of anchorage will occur and this inevitably means failure of the entire procedure. This paper presents, for the first time, comparative data on the performance of some ligament fixation devices, so that the surgeon may make a reasoned choice.

MATERIALS AND METHODS

A study was made of all the ligament fixation devices commercially available in Britain in 1986 and known to the author. Comparisons were made with Sherman-type bone screws and with a new "grommet" device designed and developed by the author. All implants were donated by the manufacturers and initially used in accordance with either the manufacturers' instructions or the

methods demonstrated by the originators of the devices. Tests were made in cadaveric bone; the devices are described below:

Sherman bone screw. This stainless steel, self-tapping, cortical bone screw had a thread of 3.7 mm outer diameter and 2.5 mm core, with a pitch of 1.3 mm. The screw was used in a pre-drilled hole of the core diameter through both cortices of the bone, with its tip just protruding.

Gore/AO screw. This was a modified AO cortical bone screw. The threaded part was the standard 4.5 mm outer diameter, 2.7 mm inner diameter, 1.8 mm pitch screw. It also was placed through both cortices after pre-drilling to 3.2 mm diameter and tapping. The screw head had been machined down to give a cylindrical seating and securing flange for the end loop of the Gore-tex implant (Bolton and Bruchman 1985).

Richards staple. This cast, cobalt-chrome alloy staple had barbs on the outward-facing surface of each leg, and an array of seven spikes, each 2 mm long and 1 mm in diameter, on the undersurface of the crossbar. The spikes were designed to prevent slippage of implants trapped against bone. The legs of the staple were approximately 2 mm square and were hammered into pre-drilled holes 2 mm in diameter and 14 mm apart, the correct spacing being ensured by a drilling jig. The crossbar was grasped in an introducer tool while the staple was inserted.

Bollard. This single-cortex device was designed for anchoring carbon fibres in cancellous bone (Strover 1985) and was made from a carbon fibre/polysulphone composite. The bone was prepared using a special 4.7 mm diameter drill, 22 mm long, with an integral counterfacing cutter, then the 20 mm long bollard was partly inserted. The carbon fibre (40 000 filaments of Grafil type X-AS) was wound one-and-a-half times round the bollard and held under tension while the bollard was driven home, trapping the fibres beneath its head. The shank of the bollard had been cut longitudi-

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nally into four segments or "legs"; hammering in a central rod splayed them out, making it difficult to extract or rotate the bollard. Finally, the tail end of the implant was secured to the periosteum by four interrupted sutures of 2-0 Dexon, in some cases.

Bollards can also be used to anchor implants with end loops, by placing the shank through the loop before it is driven home. This has been used in metaphyseal and diaphyseal bone, as well as in the cancellous bone for which the bollards were originally designed.

Toggle. This device was used to secure an implant at the entrance to a bone tunnel, by passing it through the end-loop of the implant and bridging across the hole (Strover 1985). The toggle was moulded from a carbon fibre/poly-sulphone composite, with a central depression so that the implant loop would not stand too high from the bone surface. It was 22 mm long and designed to bridge a 4.6 mm hole, which was countersunk to accommodate the central dip in the toggle. It has been recommended that the toggle should be set into a trough, cut into the cortex on either side of the hole, so that it will not protrude subcutaneously over the anteromedial aspect of the upper tibia.

Grommet. This stainless-steel implant was designed for use with a standard 4.5 mm AO cortical bone screw. It had a cylindrical body 9 mm in diameter and 15 mm long, cannulated to accept the screw. The grommet penetrated one cortex; it was stabilised by the screw tip engaging the far cortex and had a flange 1 mm thick to secure the implant loop. This device was implanted by drilling a 9 mm hole through the first cortex, then plugging a drill guide into the hole, drilling the far cortex with a 3.2 mm drill, then using a guide to tap the far cortex, after measuring the correct screw length. Thus, after the grommet had been placed, the screw tip was directed to the hole in the far cortex.

Each implant was tested in various locations around the knee, because cortical thickness varies, tending to increase with distance from the joint line. Since cortical bone has a compressive failure strength of approximately 150 MPa (Reilly and Burstein 1974) and cancellous bone fails at approximately 5 MPa (Van Audekercke and Martens 1984), it was expected that the local cortical thickness would control the failure strength of some devices, while the presence or absence of cancellous bone would affect others.

Cadaveric knees were obtained at post mortem and stored at -20°C until needed, when they were thawed rapidly, a procedure which has been shown not to change mechanical properties significantly (Sedlin and Hirsch 1966). The bone shafts were mounted into steel tubes using polymethylmethacrylate bone cement and the ligament anchorages were inserted. The bones were then mounted in a Tensometer type E tensile test machine, using adjustable mounting fixtures which ensured that the pull on each anchorage was in the correct direction

Fig. 1

The apparatus for tensile testing. The position of the bone is adjusted to put the loading cable on the axis of the test machine. Part of the epicondyle has been cut away so that the cable will not be deflected when load is applied. The pointer will indicate the onset of implant migration.

Fig. 2

Fig. 3

Bone screws failed by sideways migration of the head following compressive failure of the cortex, the tip remaining in the far cortex. Figure 2 - This screw has been pulled well beyond the point of failure and is being extracted. Figure 3 - Bone screws were bent by the forces needed to cause bone failure where the cortex was more than 3 mm thick. Gore/AO screw on the left, Sherman screw on the right.

Fig. 4

Test results. ● - Sherman screws, ○ - Gore/AO cortical screws. Failure loads are related to cortical thickness.

Fig. 5

Broken Richards staples after forcible extraction from bone by a wire loop. There were brittle fractures of the cast cobalt-chrome alloy after small deformations, when the cortex was 4 mm or more in thickness. The staples came out intact from bone with a thin cortex.

Fig. 6

Test results for Richards staples, related to cortical thickness. ○ - tests using rope, with fraying failure; ● - tests using wire loop, when staples were either pulled out or fractured.

(Fig. 1). This was normally across the bone surface towards the joint line, except for the toggles, which were loaded through the bone tunnel which they had bridged. Grooves were cut through the proximal flare of the tibia or the femoral condyles, so that the load could be applied parallel to the bone surface, rather than have a component of the force which would tend to pull the anchorages out. All anchorage types were loaded at a crosshead speed of 20 mm per minute using a loop of 2.5 mm multi-strand steel cable which, when placed around the crossbar of the staples, represented implants folded back over the staple and secured by suturing. Bollards were loaded via a normal carbon fibre implant, as described above, and the staples by an 8 mm diameter nylon rope, which was chosen as a compromise between the axial fibres of an autogenous tendon and the braided structure of some artificial ligaments.

A graph of load against crosshead motion was drawn on a chart recorder integral with the test machine; a stationary pointer fixed beside the device being tested revealed its movement as the load increased. Failure was defined as occurring when the load caused 1 mm of anchorage movement in the bone, or when the artificial ligament slipped relative to the anchor. The peak load was also recorded, as was the mode of failure. Each bone was used for several tests, keeping drill holes well apart. The bones were then sawn lengthwise and the thickness of the cortex recorded at each anchorage site.

RESULTS

Sherman screw. Sideways load applied beneath the screw head caused compressive failure of the adjacent cortex, resulting in a slot being cut as the screw moved (Fig. 2) and its tip pivoted in the far cortex. The screws were bent, where they emerged from the bone, if the cortex was thicker than 3 mm (Fig. 3), but then proceeded to fail in the same way. The failure load results are related to the cortical thickness in Figure 4.

Gore/AO screw. This failed in the same way as the Sherman screw, again bending if the cortex was more than 3 mm thick (Fig. 3), then cutting through the bone. The failure load results are shown in Figure 4.

Richards staple. When loaded through nylon rope, failure occurred by slippage from beneath the crossbar, with fraying by the spikes. If the cortex was less than 2 mm thick, the staple became tilted and lifted as the rope slipped.

A wire loop tilted and then extracted the staple if the cortical thickness was less than 4 mm. The staple was damaged when the cortex was 4 mm or more thick, usually by bending and brittle fracture of the legs (Fig. 5). The holding strength was again related to the cortical thickness (Fig. 6), the wire loop tending to sustain higher forces at higher cortical thickness.

Bollard. The carbon fibres slipped at relatively low forces, the bollard rotating within the bone, with

extraction and tilting (Fig. 7). Suturing the end of the implant to the periosteum, recommended as a means to prevent premature slippage, made no significant difference. Either the centre of the bundle of carbon fibres slipped out of the sutures, or the sutures disrupted the periosteum. The wire loop caused bollards to fail by tilting and extraction (Fig. 8), at significantly higher forces than the carbon fibre failures (Fig. 9).

Examination of bollards after testing showed that the legs had rarely splayed out properly. The pin driven

in to cause this usually deviated from the central axis, so that only two adjacent legs were splayed and extraction normally broke one of them (Fig. 10).

Toggle. Toggles failed when either the cortical shell collapsed or the toggle itself bent, so that the toggle was pulled into the interior of the bone (Fig. 11). The strength test results (Fig. 12) suggested that failure occurred at a lower load if the bone had been excavated to accommodate the toggle, but there were not enough specimens to make a valid comparison.

Fig. 7

Fig. 8

Figure 7 - Section to show bollard in bone after testing with carbon fibre. The bollard has tilted, rotated and been partially extracted as the implant pulled and slipped around it. The legs have not splayed out widely within the bone. Figure 8 - Bollards failed by tilting and lifting when loaded by a wire loop.

Fig. 9

Test results for bollards. ● - test with carbon fibre, when end of implant was secured to periosteum with sutures, ○ - test with carbon fibre, end of implant unsecured; □ - test with cable loop.

Fig. 10

Appearance of bollards after testing. Deviation of the central pin meant that the legs did not splay out equally. One leg was often fractured in testing.

Fig. 11

Collapse of the cortex sometimes allowed the toggle to sink into the cancellous interior of the bone without damage to itself. This was the most common mode of failure; other toggles sustained damage caused when they were pulled into the bone.

Fig. 12

Tests on toggles. ○ - failure by toggle pulling into the bone intact; ● - failure by bending of the toggle, which allowed it to pull into the bone with less cortical damage.

Grommet. The diameter of the grommet was optimised so that the anchorage had similar strength to that of the whole bone, giving failure loads significantly greater than those obtained by the other anchorages for cortical thicknesses of 2 mm or more (Fig. 13). When the cortex was thin, the bone usually failed locally, allowing the grommet to migrate sideways in the same manner as the bone screws. Fractures sometimes occurred when the cortex was 3 mm or more thick, but only at forces in excess of four times body weight (Fig. 14).

Fig. 14

Fracture separation of the distal femur caused by loading grommet to approximately five times body weight, the fixation remaining secure. The fracture section shows that the grommet had penetrated one cortex, with AO screw stabilisation in the opposite cortex. The most common failure mode was sideways migration of the grommet.

The results of all the tests are shown in one graph for comparison (Fig. 15).

DISCUSSION

It is accepted that an isolated bone screw is not capable of withstanding sustained heavy loads *in vivo* without it migrating within the bone, so fracture fixation devices normally use an array of screws to share the load and reduce the localised stresses. Thus the failure mode seen with the screws could have been predicted, and the larger forces needed to cause failure with the Gore/AO screw than with the Sherman screw could be accounted for by the increased core diameter spreading the load to a larger area of bone.

Fig. 15

Comparison of the results of strength test for all the fixation methods examined, showing the benefit of placement in thicker cortical bone. The grommet had a significantly greater fixation strength than the other methods, when used away from the joint line. The toggle is a convenient device if fixation close to the joint line is necessary.

Although the staple used a single cortex, with legs which were intended to be stabilised by cancellous bone, the test results (Fig. 6) showed that the fixation strength was dependent on the cortical thickness. The staple tilted at the cortex and its movement was scarcely affected by the deeper cancellous bone. Since the staple was least strong where the cortex was thinnest, yet the bone was widest in such areas (near the joint), superior fixation could have been obtained there by lengthening the legs of the staple.

The ability of the staple to secure an implant

beneath the crossbar appeared to be optimal since, if the cortex was thinner than average, the rope did not slip until the staple itself was partly extracted.

When carbon fibres were used to load the bollard, they slipped at low loads, having low friction characteristics. The finding that this behaviour was not changed significantly by suturing the end of the implant to the periosteum was unexpected but, since slippage occurred at approximately 250 N, it is not surprising that the sutures were carried away. Since the carbon implant will only be held securely by fibrous tissue ingrowth, and evidence has been presented to show that this takes six months to mature (Amis, Campbell and Miller 1985), these implants should be protected from excessive loads for several months postoperatively.

The low failure forces seen with the bollards might have been caused by the use of cadaveric bone aged 60 years or more, since it is known that cancellous bone loses strength rapidly with age (Weaver and Chalmers 1966), but a theoretical analysis based on normal bone strength suggested that the bollards would rotate under a load of only 110 N and that much of the rotation resistance above this level must have derived from friction against the cortical bone. Although the bollard could be fixed more securely if its legs were longer and splayed out further, this would not increase the friction holding the carbon fibres.

When loaded by a loop, which could not slip, the bollard had an anchorage strength similar to that of the AO screw and the staple. Its mode of failure and the area of bone loaded were similar to those of the staple, so this was not surprising. Although the bollard was designed for fixation into cancellous bone, the increasing strength with cortical thickness (and thus distance from the joint line) showed that cancellous bone played little part, since its strength decreases with distance from the joint line (Ducheyne et al. 1977).

The toggle was a convenient method of fixation for implants with end loops that also had to pass through the bone. The strength of the toggle appeared to have been optimised, so that some failed in bending while others were pulled into the bone undamaged, but this was matched to a relatively weak cortical shell (1 to 2 mm). The toggle could be made stronger by thickening the central crossbar, to increase the bending strength, or by enlarging the ends, which would increase the force required to pull it through the cortex. The few tests performed with a toggle inset into the bone surface suggested that, as expected, it failed at a lower force than that seen with the bone intact. Although this procedure made the toggle less prominent subcutaneously, the author is not aware of clinical problems with this, and recommends that the cortical shell be left intact.

The grommet anchorage was designed to be strong and easily inserted. Experience showed that a single hole device was easiest to insert, so multi-legged staples, for example, were discounted. Furthermore, the hole should

be rounded, avoiding sharp corners which would act as stress raisers (Clark et al. 1977). The Gore/AO screw was as strong as the bollard and staple, despite concentrating the loads onto a smaller area of cortex, because its bicortical fixation prevented tilting. Its disadvantage, however, was the need for a complete range of screw lengths before an implant could be used.

The standard AO screw would have the same advantages as the Gore/AO screw, be available in many hospitals and, of course, be familiar. Unfortunately, the unmodified head and neck were not suitable since the sharp threads would cause damage to the implant, while the head would protrude excessively. The solution was to make a grommet, with a diameter large enough to countersink the screw head within it to the level of the bone surface, which would provide a smooth outer surface for the implant loop. With the large diameter of the grommet penetrating the cortex, loads would be transferred to the bone over a larger area, so a correspondingly larger force would be needed to cause failure. This lengthened sleeve would also protect the screw against bending. The remaining aim was to optimise the diameter of the grommet because, although a large diameter would raise the load that would cause localised bone failure, too large a diameter would weaken the bone excessively, and could lead to fracture. A diameter of 9 mm was found to be a good compromise, allowing both modes of failure to occur, but at significantly greater forces than those sustained by the other types of anchorage. Both clinical and animal trials of the grommets are being performed.

Conclusions

1. Although some fixation devices were designed for use in cancellous bone, these tests have shown clearly that it is the local thickness of the much stronger cortical bone which determines the holding strength of these devices.
2. Since the thickness of the cortical shell increases with distance from the joint line, it seems that ligament anchorages should be placed as far from it as possible, subject to constraints such as those imposed by incision and length of implant.
3. Many of the artificial ligaments which are commercially available are significantly stronger than the 1.7 kN average strength of the natural anterior cruciate ligament, yet failures still occur in vivo. Since the forces imposed on ligaments in sport and trauma are unknown, it would seem prudent to employ anchorages which are at least of similar strength to the implants. At present, this can only be achieved by the grommet device which is described above.

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The new grommet device is available for experimental use from the author at Imperial College, London.

This article was accepted before a conflict of interest policy had been adopted.

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