We split 100 porcine flexor tendons into five groups of 20 tendons for repair. Three groups were repaired using the Pennington modified Kessler technique, the cruciate or the Savage technique, one using one new device per tendon and the other with two new devices per tendon. Half of the tendons received supplemental circumferential Silfverskiöld type B cross-stitch. The repairs were loaded to failure and a record made of their bulk, the force required to produce a 3 mm gap, the maximum force applied before failure and the stiffness. When only one device was used repairs were equivalent to the Pennington modified Kessler for all parameters except the force to produce a 3 mm gap when supplemented with a circumferential repair, which was equivalent to the cruciate.

When two devices were used the repair strength was equivalent to the cruciate repair, and when the two-device repair was supplemented with a circumferential suture the force to produce a 3 mm gap was equivalent to that of the Savage six-strand technique.

The restoration of normal function following injury to a flexor tendon remains a challenge. Adhesions readily form between the injured tendon and the surrounding soft tissue, tethering the tendon, limiting excursion and resulting in a poor functional outcome.

The most effective way of counteracting formation of adhesions is to promote early mobilisation, thereby increasing excursion and improving function. Early movement is, however, associated with an increased rate of rupture of the tenorrhaphy. Studies have investigated ways to increase the strength of tendon repairs by increasing the number of strands bridging the repair site and adding supplemental circumferential sutures. These measures significantly increase the strength of the repair, but multistrand techniques require extensive dissection and are both laborious and technically demanding.

Our aim was to develop a device that could be used to create repairs equivalent in strength to multistrand procedures while requiring minimal soft-tissue dissection and being quick to perform.

Materials and Methods

Design and construction of the device. In order to achieve the aims of simple insertion with minimal dissection we chose to create a device using barbs. The barbs were produced by making a pattern in two dimensions which was used to guide a laser around a length of nitinol tubing. Nitinol is an extremely flexible alloy of nickel and titanium. The excess material was removed and each of the barbs was manually primed by deflection from the central core, resulting in the device shown in Figure 1b. A double-ended suture was then attached to enable easy insertion into the tendon undergoing repair. The length of the device enabled the use of at least 10 mm of each divided tendon end for repair. Each barbed section was 12 mm long, this length being determined by constraints of manufacture. The barbed sections were joined by a junctional segment devoid of barbs to ensure that the barbed sections were implanted well into the divided end of the tendon, with minimal chance of their protruding from the repair site. The choice of a diameter of 3 mm for the device was arbitrary, being the largest size that we felt would allow the insertion of two of these implants into the tendon without breaching the surface.

Repair technique. The needle at one end of the device is inserted into one of the ends of the divided tendon (Fig. 2a) and passed along its length for 20 mm. This suture is pulled through until half of the device is embedded in the tendon, a process that requires a little more force than is necessary when using normal braided suture material. The excess suture is then cut flush with the surface of the tendon.
(Fig. 2b). The suture at the opposite end of the device is then passed into the other end of the divided tendon and, once the position is checked, the repair is tensioned (Fig. 2c); the remaining suture is then cut and a supplementary circumferential suture is placed. If the repair is over-tensioned the device must be cut and the individual segments advanced through the tendon substance until free. The repair may then be performed again, or abandoned and a suture undertaken. In our experience this does not often occur, as the resistance to pulling the device into the tendon is such that accidental over-tensioning is unlikely.

**Testing protocols.** We harvested 100 profundus tendons from the central two rays of adult porcine forelimbs within two hours of being killed, wrapped them in saline-moistened gauze and then froze them at -25°C. Before repair and testing, the tendons were thawed as previously described by Giannini et al. This method of preservation has previously been validated for use in testing the linear load to failure of repairs of porcine flexor tendons. The tendons were randomised then thawed into five groups, each of which was repaired using a different technique. Half of each group was supplemented with an additional circumferential suture. During the experiments, tendons were kept wrapped in saline-soaked swabs. The conventional suture techniques used have been previously published. The five groups were: group 1, Pennington modified Kessler (PMK); group 2, cruciate four-strand repair; group 3, savage six-strand repair; group 4, one device per tendon; and group 5, two devices per tendon. The tendons were divided using a scalpel at the level of the metatarsophalangeal joint, a location consistent with the literature and approximately equivalent to a laceration in zone II. In order to guide suturing, a transverse line was marked on the surface of the tendon at the point of division, and two additional marks were made 5 mm and 10 mm on either side of this point, as measured with a vernier caliper (Mitutoyo Corporation, Kawasaki, Kanagawa, Japan). The control core repairs were performed using 4/0 braided polyester suture with locking loops 10 mm from the cut end of the tendon. The circumferential repair used the type B peripheral crisscross stitch, as described by Silfverskiöld and Andersson, using 6/0 monofilament nylon with bites 5 mm from the repair site. All repairs were performed by a single surgeon (KMH) using 2.5× loupe magnification. Tensile testing was carried out in a Zwick Tensiometer (Zwick GmbH & Co. KG, Ulm, Germany) with a 2.5 kN load cell and an interclamp distance of 60 mm. The tendons were secured in pneumatic clamps with coarse sandpaper grippers, subjected to a preload of 1 N and the maximum and minimum diameters of the tendon were measured both at the repair site and 1 cm on either side of it using a vernier caliper. The cross-sectional area of the tendon at these points was calculated using the formula for the area of an ellipse \( \text{Area} = \pi \text{rmin} \times \text{rmax} \). The average of the cross-sectional areas for the tendon at sites 1 cm proximal and distal to the repair was considered to be the ‘normal’ cross-sectional area. The percentage bulking was calculated using the following equation:

\[
\text{Percentage increase in Bulk} = 100 \times \left( \frac{\text{Area}_{\text{repair}}}{\text{Area}_{\text{normal}}} \right)
\]

The tendons were subsequently subjected to linear loading to failure at a rate of 10 mm/min. All testing was observed under 2.5× loupe magnification, and when a gap of 3 mm was present at the repair site this was recorded digitally on the test curve. The maximum force applied to the construct prior to failure was defined as the maximum force sustained by the repair as measured from the force...
versus displacement curve. The stiffness of the repair was calculated by measuring the slope of the elastic region of the force versus displacement curve using the Qtiplot 0.9.1 (ProIndep Serv S.r.L.; Craiova, Romania) scientific graphics package.

**Statistical analysis.** Prior to testing, a power analysis was performed with the G*Power 3.0.4 program (Heinrich-Heine University, Düsseldorf, Germany)\(^1\)\(^4\)\(^1\)\(^6\) using the results from the work of Thurman et al.,\(^1\)\(^5\) who studied two-, four- and six-strand repairs in a model of linear load to failure. This permitted calculation of the effect size, which is a measure of the strength of the relationship between two variables in a statistical population, and which is required for power analysis using the a priori method. Analysis was performed using an effect size of 1.159, which was calculated using the results for ultimate tensile strength, and showed that to achieve a power of 0.975 a minimum of three tendons was required in each group. This small number of tendons is an indication of the large improvement in strength gained by increasing the number of strands crossing the repair site.

The data were tested for normality using the Shapiro-Wilk W test and deemed non-parametric. Further analysis was performed using the Kruskal-Wallis one-way analysis of variance (ANOVA),\(^1\)\(^4\)\(^1\)\(^6\) with post hoc comparison using the Dwass-Steel-Critchlow-Fligner method of all-pairwise comparisons. A p-value of < 0.05 was considered statistically significant.

**Results**

The results are summarised in Table I.

**Bulk of the repair site.** There was no significant difference between the repairs performed as a core repair alone (p = 0.058) or with the addition of a circumferential suture (p = 0.336).

**Force to produce a 3 mm gap** (Fig. 3a). The force to produce a gap of 3 mm in tendon repairs using one device without an additional circumferential repair was not statistically different from that of the two-strand PMK (p = 0.8395), and was less resistant to gapping than the cruciate (p = 0.0009) and Savage (p = 0.0009) repairs. When a supplemental circumferential stitch was added, repairs with the device were not statistically different in resistance to gapping from the cruciate repair (p = 0.998); they were more resistant than the PMK (p = 0.0063) and less than the Savage (p = 0.0016).
Table I. Traditional repair techniques. Results of experiments (SD)

<table>
<thead>
<tr>
<th></th>
<th>PMK*</th>
<th>Cruciate</th>
<th>Savage</th>
<th>One device</th>
<th>Two devices</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Core repair</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bulk (%)</td>
<td>123.09 (17.36)</td>
<td>137.88 (23.84)</td>
<td>125.35 (12.7)</td>
<td>140.83 (32.27)</td>
<td>152.53 (24.79)</td>
</tr>
<tr>
<td>Force to produce a 3 mm gap (N)</td>
<td>7.29 (1.46)</td>
<td>23.06 (3.22)</td>
<td>44.07 (11.43)</td>
<td>8.79 (3.37)</td>
<td>29.95 (11.32)</td>
</tr>
<tr>
<td>Maximum force applied to the construct prior to failure (N)</td>
<td>26.23 (1.89)</td>
<td>41.66 (6.94)</td>
<td>75.08 (9.87)</td>
<td>25.61 (8.51)</td>
<td>58.39 (14.54)</td>
</tr>
<tr>
<td>Stiffness (N/mm)</td>
<td>2.8 (0.48)</td>
<td>3.58 (0.53)</td>
<td>8.67 (1.03)</td>
<td>2.46 (0.56)</td>
<td>5.32 (1.77)</td>
</tr>
<tr>
<td><strong>Core and circumferential repair</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bulk (%)</td>
<td>156.8 (14.38)</td>
<td>143.84 (19.35)</td>
<td>143.88 (11.44)</td>
<td>140.81 (22.98)</td>
<td>142.54 (35.56)</td>
</tr>
<tr>
<td>Force to produce a 3 mm gap (N)</td>
<td>36.06 (9.33)</td>
<td>55.78 (7.33)</td>
<td>82.37 (9.26)</td>
<td>55.45 (8.44)</td>
<td>79.65 (5.61)</td>
</tr>
<tr>
<td>Maximum force applied to the construct prior to failure (N)</td>
<td>52.65 (9.03)</td>
<td>79.11 (14.73)</td>
<td>105.97 (9.96)</td>
<td>64.36 (7.29)</td>
<td>96.26 (9.58)</td>
</tr>
<tr>
<td>Stiffness (N/mm)</td>
<td>7.13 (1.15)</td>
<td>8.48 (1.04)</td>
<td>14.27 (1.39)</td>
<td>8.35 (0.90)</td>
<td>11.19 (0.96)</td>
</tr>
</tbody>
</table>

* PMK, Pennington modified Kessler

The addition of a second device in the repairs produced significantly more resistance to gapping than the PMK (p = 0.0009) and significantly less than the Savage (p = 0.0407) repair. Adding a circumferential stitch to the repairs with two devices created structures that were not statistically different from the Savage technique (p = 0.9816), and were more resistant to gapping than the PMK (p = 0.0009) and cruciate repairs (p = 0.0009).

Maximum force applied to the construct prior to failure (Fig. 3b). The maximum force of repairs using one device per tendon without a circumferential repair was not statistically different from the two-strand PMK (p = 0.9816), and was less than the cruciate (p = 0.0049) and Savage (p = 0.0009) repairs. With a supplemental circumferential stitch, repairs with the device had a significantly lower maximum force than the cruciate (p = 0.0329) and Savage repairs (p = 0.0009).

With two devices per tendon and no circumferential stitch, the maximum force was greater than the cruciate (p = 0.0133), less than the Savage (p = 0.0407) and significantly greater than the PMK repair (p = 0.0009). The addition of circumferential suturing increased the maximum force across all repairs, with the cruciate (p = 0.0499) and the PMK (p = 0.0009) less than the device and the Savage repair significantly greater (p = 0.0407).

Stiffness (Fig. 3c). There was no significant difference in the stiffness of tendons repaired with a single device compared to those repaired by the PMK (p = 0.4529), and they were significantly less stiff than the cruciate (p = 0.0037) and Savage (p = 0.0009) repairs. When supplemented with circumferential sutures the device was comparable to both the PMK (p = 0.0735) and the cruciate repairs (p = 0.9959) and significantly less stiff than the Savage repair (p = 0.0009).

Two-device repairs were less stiff than the Savage repairs (p = 0.0049), but significantly stiffer than the PMK (p = 0.0028) and the cruciate (p = 0.0265) procedures. Additional circumferential suturing maintained the Savage repair (p = 0.0028) stiffer than that using two devices per tendon, whereas the PMK (p = 0.0012) and cruciate (p = 0.0022) repairs were less stiff.

Discussion

The aim of this device is to simplify repair of a tendon in order to reduce the time, exposure and levels of skill required. Barbs were chosen for fixation, as these are already used in vivo to gain purchase in various other tissues, such as in bone anchors and meniscal darts, and require minimal time to use. Mounting the flexible device on a suture facilitates placement into the tendon. Although we found the device harder to pull into the tendon than a braided polyester suture, there was very little buckling of the tendon and minimal manipulation of the ends was required. During insertion there was minimal damage to the substance of the tendon, and the surface showed no evidence to indicate the presence of the device. As the suture exits the tendon some distance from the tenorraphy the number of punctures on the surface of the tendon is minimised, thereby reducing the focus for adhesion information. This technique also allows less invasive surgery, as the only part of the tendon that requires exposure is the site of the division. The introduction suture may be brought out of the tendon through an intact flexor sheath, thereby reducing local trauma, expediting the procedure and removing the need to open the sheath for access, although it might still be necessary to vent the pulleys to allow the repaired tendon to pass through.

The locking configuration of multistrand repairs transmits the applied forces to the tendon in discrete areas of its substance. These strains have been shown to result in the death of the tenocytes around the suture material. The barbed device increases the number of contact points between the repair and the tendon, reducing the applied strain at each point and avoiding the need for a large knot or locking suture, which may adversely affect healing through the formation of an acellular zone near the repair. Another concern with traditional repair techniques is the excessive amount of suture material placed on the tendon surface, which may compromise gliding and increase the work of flexion, thereby negating the benefits of increased strength. The barbed device leaves no material on the surface of the tendon.
We found the tendon to be relatively undamaged after failure, with the device either breaking along its length or pulling out of the substance of the tendon. When the device pulls out it removes some of the substance from the core of the tendon but leaves the surface intact, which could easily be repaired by suturing. When the device is fractured along its length, a tenotomy would be required at the tip to allow advancement through the substance of the tendon for removal. The tendon would then be amenable to repair using traditional techniques.

As flexor tendons are subject to considerable bending forces as well as tension, an exceedingly flexible metal was required. Nitinol is a shape memory material designed by the Naval Ordnance Laboratories in 1962. It is a group of alloys that comprise roughly 55% Ni to 45% Ti that possess many interesting properties. The mechanism that underpins its function is the transformation between its two crystalline forms when subjected to stress or a change in temperature. At a high temperature the molecular structure of the alloy is an austenite, which is simpler than the structure at low temperatures which is called martensite. Shape memory materials such as nitinol are able to undergo an instantaneous and reversible change from one crystalline structure to the other on heating and cooling; the martensitic transformation. This means that an object formed of a shape memory alloy can be deformed while in the low-temperature martensite phase, but when heated will transform to the austenite phase and resume its previous shape. A similar phenomenon occurs in superelasticity, but instead of heating being necessary to cause a phase change the applied stress of deformation causes such change, so that the material immediately returns to its original shape after the stress is released. This superelastic behaviour occurs in a narrow temperature range. We chose a form of nitinol called SE 352 because it acts superelastically at body temperature and is not affected by creep and stress relaxation. It is also exceedingly biocompatible, and has a similar inflammatory response to prolene when used in tendons.

Although nitinol is very flexible it is difficult to gauge how well it will survive cyclical deformations in vivo, and it will be necessary to perform cyclical and in vivo testing to determine the long-term survivability of the device.

Our results show that repairs performed using this device are at least as strong as two-strand techniques, and in certain configurations as strong as four- and six-strand procedures. The repair is simple, takes very little time, and with
practice the core repair takes approximately two minutes and leaves a smooth tendon surface. It should be noted that these are early results. We aim to continue development as well as performing cyclical testing and in vivo studies. We are concerned that the use of two devices per tendon may potentially be detrimental to tendon healing, both by introducing excessive amounts of foreign material and by subjecting the already tenuous intra-tendinous blood supply to excessive pressure. Our next step is to optimise the size and configuration of the bars, as by lengthening them, and possibly by increasing their number, we hope to increase purchase within the tendon and therefore to create repairs equivalent to four-strand procedures using only one device. Once the design has been optimised we can then proceed to testing the device in a more rigorous cyclical fashion.

Supplementary material
A further opinion by Ms S. Fullilove is available with the online version of this article on our website at www.jbjs.org.uk

Manufacture of the device was funded by Xircon Ltd (Galway, Ireland). Testing was performed in laboratories owned by Creganna Medical Devices Ltd (Galway, Ireland). The first author has intellectual property rights to the device, but no financial interests in the parent company (Xircon). No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References