Reduced bone tunnel enlargement post hamstring ACL reconstruction with poly-L-lactic acid/hydroxyapatite bioabsorbable screws

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Abstract

Bone tunnel enlargement following anterior cruciate ligament (ACL) reconstruction can complicate revision surgery. This study compared postoperative tibial tunnel widening in patients who underwent arthroscopically assisted, single-incision, four-strand hamstring ACL reconstruction using a poly-L-lactic acid/hydroxyapatite blend (PLLA + HA) bioabsorbable interference screw for tibial fixation, with those in whom a plain poly-L-lactic acid (PLLA) screw was used. Thirty-four patients (13 with PLLA + HA tibial interference screw fixation and 21 with plain PLLA tibial interference screws) underwent a spiral CT scan to assess maximum tibial tunnel cross-sectional area at an average of 28.7 months follow-up. An assessment of tunnel wall sclerosis adjacent to the screw (cortication) was also made. The two groups were well matched for age, sex and graft diameters.

Mean tibial tunnel enlargement in patients with PLLA + HA screws was 29.9% at average 30.9 months follow-up compared with 46% in patients with plain PLLA screw at an average 26.5 months follow-up ($p=0.03$). The tunnel wall adjacent to the screw appeared corticated in only 21% of patients with PLLA+HA screws ($p=0.02$) compared with 73% of patients with PLLA screws.

The blending of HA with PLLA appears to reduce postoperative tunnel widening, and the reduced tunnel wall sclerosis seen postoperatively may indicate improved screw incorporation.

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1. Introduction

Many surgeons routinely use bioabsorbable aperture interference screw fixation for hamstring ACL reconstruction. Initial pull-out force and material stiffness for this type of fixation have been shown to be similar to titanium screws when used on similar types of graft material [1], and satisfactory clinical results have been documented in the literature [2]. Bioabsorbable screws have the advantage of reduced MRI interference [3] and do not require removal at revision surgery. Nevertheless, as with metal screws, the problem of postoperative tunnel enlargement still exists [4,5], and whilst several studies have shown that this does not affect clinical outcome, it may severely complicate revision surgery [6].

We reviewed the literature, and were unable to find any studies directly comparing the degree of tunnel enlargement post hamstrings ACL reconstruction with different bioabsorbable screw materials. It is however known that tibial tunnel cross-sectional area may enlarge by up to 36% at 12 weeks post op [4] with poly-L-lactic acid (PLLA) bioabsorbable screw fixation. Some authors have also been concerned about the fate of the space occupied by the bioabsorbable screws following their hydrolysis [2,7]. Computerised tomography (CT) evaluation of bone tunnels following fixation with polyglyconate (PGA) screws has shown that a sclerotic rim forms around the tunnel [7], and magnetic resonance imaging (MRI) studies have shown that the tissue that replaces the screw is either fibrous or fatty, but not bone [8].

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A development in bioabsorbable screws has been the addition of hydroxyapatite (HA) to PLLA during the screw manufacturing process. It has been suggested that this may enhance biocompatibility. Animal studies using poly-L-lactic acid/HA blend (PLLA+HA) screws in the context of ACL fixation have shown new bone growth attaching to and encapsulating the screw as early as 4 weeks after surgery [9]. The effects in humans are unknown but it has been hypothesised that there may be reduced bone tunnel enlargement and better screw integration.

The purpose of this study, therefore, was to assess whether the addition of HA to bioabsorbable screws acts to reduce bone tunnel enlargement post hamstrings ACL reconstruction.

2. Material and methods

2.1. Patients

We retrospectively reviewed the records of the 674 patients who underwent arthroscopically assisted, four-strand, semitendinosus and gracilis (STG) ACL reconstructions at our clinic during 2001. Of these, 101 patients were found to be living within the local region (as defined by telephone code) and between 24 and 36 months post surgery. These patients were written to and invited to undergo a Spiral CT scan to assess tibial tunnel cross-sectional area (CSA). Thirty-four patients responded, 13 with PLLA + HA screws (BioRCI-HA®, Smith and Nephew, Andover, MA) and 21 with PLLA screws (BioRCI® Smith and Nephew, Andover, MA). We changed from using PLLA screws to PLLA + HA screws during 2001. The series was therefore essentially sequential and thus there was a significant difference in the duration of follow up. The average follow-up in the PLLA group was 30.9 months (range, 26.5–34.9 months), while the average follow-up in the PLLA + HA group was 26.5 months (range 25.2–30.5 months). Patients were otherwise well matched for age, sex and graft diameters (Table 1).

2.2. Surgical technique

The surgery was performed in the same centre by 4 surgeons using a standardised, single-incision, four-strand STG “arthroscopic” technique. Femoral fixation was by a combined suspensory (Endobutton-Acufex, Smith and Nephew, Mansfield, MA) and aperture (bioabsorbable interference screw) technique in all cases. The tibial tunnel was drilled to the same diameter as the measured graft diameter, and tibial fixation was with a 10-mm diameter screw (either PLLA or PLLA+HA) in all cases, irrespective of graft size.

Table 1

<table>
<thead>
<tr>
<th>Patient demographics</th>
<th>PLLA (n=21)</th>
<th>PLLA + HA (n=13)</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>27.4</td>
<td>26.9</td>
<td>p=0.88</td>
</tr>
<tr>
<td>Sex</td>
<td>M 76.2%, F 23.8%</td>
<td>M 76.9%, F 23.1%</td>
<td>p=0.81</td>
</tr>
<tr>
<td>Graft diameter (mm)</td>
<td>8.2 (SD 0.51)</td>
<td>8.2 (SD 0.65)</td>
<td>p=0.82</td>
</tr>
</tbody>
</table>

2.3. Computed tomography technique

Spiral CT scans (LightSpeed, GE Milwaukee, Ohio) were supervised and reported on by a single radiologist (PM) who was blinded to the type of screw fixation used. A standard protocol was used consistently throughout the study. Initial volume acquisition was with 1.25 mm cuts from 20 mm above the femoral tunnel to 20 mm below the tibial tunnel. Reconstruction along the axis of the tibial tunnel was then performed with 15 cuts, 1.0 mm thick (Fig. 1). Twenty 1.0 mm cuts were then taken perpendicular to the axis of the tibial tunnel.

2.4. Data analysis

Tunnel CSA was obtained by tracing the circumference of the tunnel wall on the scans taken perpendicular to the axis of the tunnel (Fig. 2), using the cursor on the scanner console.
A minimum of fifteen reference points was used and the console computer automatically calculated the CSA of the enclosed shape. We considered this method of tracing around the circumference of the tunnel more accurate than the ‘‘best-fit’’ circle method previously described by Fules et al. [10] because tunnel enlargement may be eccentric [4]. The maximum cross-sectional area was defined as the largest CSA of all of the cuts, and was used in the statistical analysis. The increase in tunnel CSA was calculated using a similar formula to that used in previous studies [5,10].

\[
\text{CSA increase} \, (\%) = \frac{\text{Follow-up CSA} - \text{Original CSA}}{\text{Original CSA}} \times 100
\]

A subjective, qualitative assessment of whether the bone adjacent to the screw appeared sclerotic (corticated) or not was also made. A two-tailed Student’s \( t \)-test for un-paired data was used to compare tunnel midpoint CSA’s and Fisher’s exact test analysis was used to compare tunnel cortication, with \( p = 0.05 \) for a 95% alpha level.

3. Results

The bioabsorbable screws were clearly identifiable in all patients and none appeared to have undergone significant reabsorption. In one patient in each group, the screw appeared to have broken.

3.1. Tibial tunnel CSA

The CT scans of the patients with PLLA screws showed a mean increase in tibial tunnel CSA of 46% (SD, 20.5). This compared with 29% (SD, 19.4) in patients with PLLA + HA screws (\( p = 0.03 \)). In the PLLA group, the tibial tunnels had enlarged more than 60% in 7 patients (33.3%) with one patient having greater than 100% tunnel widening. In the PLLA + HA only one patient (7.6%) had more than 60% enlargement.

3.2. Tunnel cortication adjacent to the screw

Tunnel wall cortication adjacent to the screw was seen in 16 of the patients with PLLA screws (71.4%). This was significantly more than in the PLLA+HA group (3 patients, 23.1%, \( p = 0.02 \)).

4. Discussion

Although many studies have shown that bone tunnel enlargement does not appear to adversely affect graft laxity or failure rates, revision surgery may be severely hampered by the presence of large tunnels [6]. Tunnel widening is generally cavitatory, frequently maximal in the mid-zone of the tibial tunnel and occurs in the plane of movement of the joint [11,12]. The aetiology remains uncertain but is likely to be multi-factorial with both biological and mechanical factors playing a part. There are many potential mechanical factors including tunnel malposition [13] and graft-tunnel micro-motion [4]. Early aggressive rehabilitation has also been suggested as another possible factor, potentially exacerbating micro-motion before the graft has been ‘‘ligamentised’’ or incorporated [6]. There are several biological hypotheses including the release of cytokines (such as interleukin-6, tumour necrosis factor alpha and nitric oxide) into the tunnel [5,12]. The liberation of toxic products into the tunnel (such as metallic particles) causing cell necrosis, or even thermal necrosis from drilling has been proposed as causing an immune or inflammatory response [4], and the presence of vascularised periligamentous tissue around the graft on MRI has been correlated with tunnel enlargement [14]. Previous authors have reported that the presence of cyst-like formations at the bioabsorbable screw site has to be regarded as a normal feature of the screw degradation process [3] and that the tissue replacing the screw is either fibrous or fatty, but not bone [8]. Others have suggested that the immunogenicity of allografts compared to autografts may cause less tunnel lysis and have commented that there is a need to optimise the biology around the graft in an effort to minimise tunnel widening [6].

To our knowledge, this study is the first to directly compare bioabsorbable interference screw type with bone tunnel enlargement following ACL reconstruction. We found that the interference screws containing both PLLA and HA appeared to cause less postoperative tunnel enlargement than pure PLLA screws. An acidic environment is created by the degradation of PLLA and the addition of HA has been shown to lessen this drop in pH [15]. This buffering effect maintains the pH closer to physiological norms at the surface of the implant, which may enhance its biocompatibility. Candrelli et al. [16] also found increased cell proliferation and adhesion with a PLLA/HA blend when compared with plain PLLA polymer alone. It may be that the improved biocompatibility of PLLA+HA screws was responsible for the reduced tunnel enlargement we observed.
This study does have some inherent weaknesses. It is retrospective and non-randomised and must be interpreted with some caution due to the small number of patients. No immediate postoperative CT scan was obtained and therefore the single assessment of tunnel CSA performed on patients at an average of 30±6 months after surgery does not provide a time-line of tunnel enlargement. The insertion of a large tibial interference screw has been shown to compress the graft and significantly enlarge the tunnel at implantation due to the greater compressive stiffness of the screw and graft compared to cancellous bone [6,17]. The material properties of the two types of screw could have resulted in differing degrees of immediate tunnel enlargement. However, the incorporation of HA into a polymer matrix has previously been shown to have a reinforcing effect on the mechanical performance of the matrix due to its higher modulus of elasticity and high compressive strength [9]. It is therefore unlikely that PLLA+HA screws produced less immediate tunnel widening at implantation than the PLLA screws. Several studies have also shown, with a variety of interference screw types, that maximum tunnel enlargement has occurred within the first 3–6 months after surgery, [4,5,17] with no further significant widening occurring between 6 and 24 months [4,5]. It would therefore seem reasonable to compare maximum tunnel CSA at 30±6 months follow up, although it is not possible to exclude late tunnel enlargement in either group.

In our study, it was noted that all the PLLA screws were still visible at follow up (average 30.7 months), confirming the slow degradation of PLLA screws found by previous authors [2,18]. All of the PLLA+HA screws were also visible at an average 27.7 months follow-up, compatible with the 2–6 years for absorption quoted by the manufacturer. Some authors have raised concerns that, following hydrolysis, the long-term fate of the space occupied by the bioabsorbable screws used for hamstring graft fixation is uncertain [2,7]. In a 2-year MRI follow-up of PGA interference screws used for hamstring graft fixation, Bach et al. [8] found that although screws had totally resorbed at 1 year, the tissue replacing them was found at 2 years to be either fibrous or fatty, but never bone. Fink et al. [7] also found no evidence of bony replacement of PGA screws for up to 3 years postoperatively. CT scans showed that a sclerotic rim had formed around the tunnel by 6 weeks postoperatively, which had further increased in density by 3 months. MRI studies with PLLA screws, albeit with small numbers (8 patients), have also shown that replacement of the screw by bone occurs in only 50% of cases [3].

The length of follow-up in this study was too short to assess PLLA screw substitution by bone. However, we too noted sclerosis of the tunnel wall adjacent to the screw with PLLA screws. The reduced appearance of cortication adjacent to the PLLA+HA screws in this study is encouraging and perhaps is suggestive of better screw assimilation. Although the PLLA+HA screws were associated with less tunnel widening at 26.9 months after surgery, further long-term follow up studies are needed to ascertain whether the addition of HA facilitates substitution of the bioabsorbable screw by bone.

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