Outcomes following femoral lengthening

AN INITIAL COMPARISON OF THE PRECICE INTRAMEDULLARY LENGTHENING NAIL AND THE LRS EXTERNAL FIXATOR MONORAIL SYSTEM

M. Laubscher, C. Mitchell, A. Timms, D. Goodier, P. Calder

From The Royal National Orthopaedic Hospital, Middlesex, United Kingdom

Aims
Patients undergoing femoral lengthening by external fixation tolerate treatment less well when compared to tibial lengthening. Lengthening of the femur with an intramedullary device may have advantages.

Patients and Methods
We reviewed all cases of simple femoral lengthening performed at our unit from 2009 to 2014. Cases of nonunions, concurrent deformities, congenital limb deficiencies and lengthening with an unstable hip were excluded, leaving 33 cases (in 22 patients; 11 patients had bilateral procedures) for review. Healing index, implant tolerance and complications were compared.

Results
In 20 cases (15 patients) the Precice lengthening nail was used and in 13 cases (seven patients) the LRS external fixator system. The desired length was achieved in all cases in the Precice group and in 12 of 13 cases in the LRS group. The mean healing index was 31.3 days/cm in the Precice and 47.1 days/cm in the LRS group (p < 0.001). This was associated with an earlier ability to bear full weight without aids in the Precice group. There were more complications with LRS lengthening, including pin site infections and regenerate deformity. Implant tolerance and the patients’ perception of the cosmetic result were better with the Precice treatment.

Conclusion
Femoral lengthening with the Precice femoral nail achieved excellent functional results with fewer complications and greater patient satisfaction when compared with the LRS system in our patients.

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Femoral lengthening by means of distraction osteogenesis has been successfully performed for more than 50 years since the pioneering work of Gavril Ilizarov. This has traditionally employed external fixation devices such as the Ilizarov frame (Smith & Nephew, Memphis, Tennessee) itself, or unilateral monorail systems such as the LRS rail (Orthofix, Verona, Italy). These types of devices are not well tolerated by patients around the femur when contrasted to their use in the tibia.

To reduce treatment times, various hybrid techniques have been developed, including lengthening over an intramedullary (IM) nail, lengthening followed by IM nailing and lengthening followed by plating. These techniques allow for earlier removal of the fixator while reducing the likelihood of fracture within the regenerate bone. These hybrid techniques, however, do not address the other complications of external fixation systems, namely pin tract infections, soft-tissue tethering and joint stiffness. They can also give rise to other complications such as IM sepsis and fatigue failure of the implant.

For some years, fully implantable lengthening devices have been developed to try to address and reduce these complications. Bliskunov, during the early 1980s, described the first such device, which lengthened the femur using a ratchet mechanism through an articulated connection to the iliac wing. Two subsequent devices also made use of a ratchet mechanism for lengthening but without connection to the pelvis, namely the Albizza nail and the Intramedullary Skeletal Kinetic Distractor (ISKD; OrthoFix, McKinney, Texas). Both systems required a degree of axial rotation of the limb to achieve lengthen-
The Fitbone nail (Wittenstein Intens, Igersheim, Germany) employed an implanted electric motor controlled through transcutaneous electrical transmission to control lengthening.

The early generations of these IM nails were fraught with complications, mainly due to problems with the various distraction mechanisms used. These included painful distraction due to ratcheting (Albizzia and ISKD), mechanical failure, uncontrolled lengthening and failure to lengthen (ISKD). Some authors reported fewer complications, when comparing lengthening by external fixation over an IM nail with the ISKD device. A new IM lengthening nail, the Precice (Ellipse Technologies Inc., Irvine, California), became available in the United Kingdom in 2011. The fully implantable, telescopic rod has a magnetic drive actuator mechanism. This mechanism is controlled by an external handheld device, featuring a rotating static magnet activator, which is both accurate and mechanically reliable. To date, there have been no studies comparing the Precice nail with an alternative method of lengthening.

A new IM lengthening nail, the Precice (Ellipse Technologies Inc., Irvine, California), became available in the United Kingdom in 2011. The fully implantable, telescopic rod has a magnetic drive actuator mechanism. This mechanism is controlled by an external handheld device, featuring a rotating static magnet activator, which is both accurate and mechanically reliable. To date, there have been no studies comparing the Precice nail with an alternative method of lengthening.

Historically our unit has performed femoral lengthening by external fixation. In cases that involved simultaneous deformity correction and lengthening, the Taylor Spatial Frame (TSF; Smith & Nephew) was used. If the sole deformity was shortening, then a monolateral external fixator, the Limb Reconstruction System (LRS; Orthofix) was used. Since 2011 we have used the Precice nail for femoral lengthening without associated deformity. The aim of this study was to compare the outcome of ‘simple’ femoral lengthening in these two groups; those treated with the LRS external fixator and those with the Precice nail. We measured functional outcome, complications encountered, implant tolerance by the patient and attempted to assess the healing index (HI) radiographically.

Patients and Methods
This study was subject to an institutional Research and Development Department review (Research and Development registration number SE.14.038). We performed a retrospective review of all skeletally mature patients who underwent femoral lengthening between September 2009 and October 2014 (n = 84). Patients with nonunion, concurrent deformity correction, lengthening of congenital limb deficiencies, lengthening below an unstable hip and patients who had undergone previous lengthening procedures were excluded (n = 51).

No cases were lost to follow-up. This left 33 femoral lengthening procedures in 22 patients for review with 11 patients undergoing bilateral procedures. Patients who underwent bilateral femoral lengthenings were reviewed as separate cases, whether the lengthenings were simultaneous or consecutive. The first 20 consecutive Precice nail femoral lengthenings performed in our unit were compared to a preceding cohort of 13 cases of lengthening using the LRS external fixator. The Precice procedures were performed by one of the two consultant limb reconstruction surgeons (PC or DG). All the LRS operations were performed by the same consultant limb reconstruction surgeon (PC).

The characteristics of the study groups are summarised in Table I. In the Precice group two patients (four cases) had non-syndromic short stature. A total of four patients (seven cases) with skeletal dysplasia included Léri-Weill dyschondrosteosis, Robinow syndrome and two patients with spondylo-epiphyseal dysplasia (one patient only had one femur lengthened as part of this cohort). Three cases (three patients) of post-traumatic leg length discrepancy (LLD) were treated. The other causes for acquired leg length discrepancies included spinal dysraphism in two cases (two patients) and following treatment of adolescent Blount’s disease (one patient). The cause of limb length discrepancy was unknown in three cases (three patients). In the LRS group the diagnosis was short stature in six patients (12 cases). This was syndromic in two patients (one case of Turner’s syndrome and one of Klippel-Feil’s syndrome) and due to stunted growth following chemotherapy for leukaemia in one patient. The cause was unknown in three patients (six cases). One case of post-traumatic LLD was treated.

The mean length of follow-up was 14.7 months (6 to 30) in the Precice group and 28.8 months (10 to 53) in the LRS group.

Pre-operative clinical information was obtained from the hospital records. Pre-lengthening knee range of movement (ROM) was recorded on a proforma. All radiographs were
taken in a standardised fashion, including erect bipedal length and alignment views.

**Surgical technique - Precice group.** In 18 cases (14 patients) an anterograde Precice femoral nail was used. A total of 17 of these (13 patients) were piriformis fossa entry straight nails and in one case a trochanteric entry point IM nail had previously been used, so a trochanteric angled Precice nail was used. Two cases (one patient) had a narrow proximal femoral isthmus; in these a retrograde nail was used. The nails were inserted using the standard technique as advised by the manufacturers.\(^1\) Corticotomies were pre-drilled and completed with an Ilizarov osteotome using a low energy technique.\(^2,3\) The level of the corticotomy was approximately 55 mm distal to the lesser trochanter, except in retrograde cases where the corticotomy was placed at the junction of the distal metaphysis and diaphysis. No attempt was made to alter the mechanical axis and the corticotomy was anatomically reduced when inserting the nail.

Bilateral cases were performed sequentially as the manufacturers advice is for patients to be non-weight-bearing during the distraction phase. Once the desired length was achieved, patients were allowed to gradually increase their weight-bearing over a four to six week period from non- to full weight-bearing based on the regenerate consolidation seen on the radiographs.

**Surgical technique - LRS group.** The LRS monorail fixators were applied in a standard fashion in all cases.\(^2,4\) All frames included a proximal pin fixation clamp, with three half-pins at the level of the lesser trochanter. Distal fixation consisted of a central fixation clamp in the mid-diaphysis and a distal clamp at the flare of the metaphysis and diaphysis, both fixed with two half-pins. Bilateral cases were performed simultaneously. Patients were encouraged to weight-bear as tolerated on the device during the lengthening and consolidation phases. Fixators were applied along the anatomical axis. All the corticotomies were performed with a low energy technique similar to the Precice group.\(^3\) The level of the corticotomy was approximately 80 mm distal to the lesser trochanter between the proximal and middle pin clamps. Weight-bearing as tolerated was allowed from day one.

**Lengthening.** A latent period of six days was observed in both groups. Distraction was performed at a rate of 1 mm/day in three or four increments, but reduced if pain was unacceptable or where adjacent joint contractures developed. The mean rate of lengthening was calculated as the total length achieved in millimetres divided by the number of days until lengthening was complete.

The follow-up regime was similar in both groups. Patients were seen at two week intervals with radiographs to monitor lengthening. Once the desired length was achieved follow-up intervals were increase to four weeks until consolidation of the regenerate bone. Patients from both groups initially attended out-patients physiotherapy weekly to maintain hip and knee range of movement and were provided with a daily home exercise programme. The intensity of the physiotherapy was increased when ROM at the hip or knee was lost. Weight-bearing instructions differed between the two groups as described. We defined time to actual full weight-bearing as the witnessed ability to walk unaided with a normal gait pattern and recorded this moment.

All radiological measurements were performed by a single author (ML) who was not involved in the lengthening procedures, using McKesson PACS software (McKesson Corp., San Francisco, California) (magnification calibrated with the use of a calibration sphere and ruler). Radiographic union was defined on serial radiographs when corticalisation in the regenerate bone was observed in at least three cortices as described by previously.\(^2,5\) The Healing index (HI) was defined as total period with the fixator in place (in days), divided by the lengthening achieved (in cm) in the LRS group.\(^20\) In the Precice group the HI was modified, as suggested by previous authors\(^4,22\) as the period with the nail *in situ* (days) until adequate union was achieved that would allow removal of an external fixator. The presence of a nail *in situ* did not interfere with this evaluation.\(^4\) The increase in femoral length achieved and mechanical axis deviation (MAD; the deviation of the mechanical from the centre of the knee) were recorded.

Removal of either device was not considered a re-operation as it was part of the treatment regime. Further re-operations and all complications were identified from the hospital notes. At their latest follow-up all cases were reviewed by one of the senior authors (PC or DG). Knee ROM was measured and classified as ‘full’ if within 5° of pre-lengthening ROM or ‘reduced’ if decreased by > 5°.

All patients were interviewed at the completion of treatment either face-to-face in clinic, or by telephone and asked to complete a simple questionnaire. They were asked to recall their pain using the visual analogue scale (VAS) both during the lengthening and the consolidation phase of treatment and to rate their surgical scars on a scale from 0 to 10 (0 = best, 10 = worst). We asked whether they were able to perform their activities of daily living (ADL) while lengthening and to indicate whether they would opt to have the treatment again if given the choice.

**Statistical analysis.** This was performed using IBM SPSS v. 21 (IBM, Armonk, New York) software. An independent samples *t*-test was used to calculate *p*-values. A *p*-value of < 0.05 was considered significant.

**Results**

The groups were comparable with respect to age and gender (Table I).

The results of lengthening are summarised in Table II. The mean lengthening was 59.7 mm (50 to 70) in the Precice and 51.4 mm (25 to 68) in the LRS group. The mean rate of lengthening was greater in the Precice group (0.93 mm/day *versus* 0.83 mm/day with LRS). This was due to more patients in the LRS group having soft-tissue complications.
We had no cases of ‘inadequate’ regenerate in either group. The modified healing index in the Precice group was significantly shorter than seen in the LRS group (31.3 days/cm compared with 47.1 days/cm; \( p < 0.001 \)). This was mostly due to a shorter consolidation phase in the Precice group (mean 101 days, 42 to 213 versus LRS group mean 204 days, 97 to 329) where the regenerate seemed to form at a faster rate. There were no cases of premature consolidation or regenerate fractures in either group.

We encountered a change in MAD of > 2 mm in eight Precice cases, and regenerate deformity leading to a shift of > 2 mm in MAD in six of the LRS cases. There were no cases of a change in MAD of > 10 mm in either group.

Patients who had been treated by the LRS rail were permitted to weight-bear as tolerated, but no patients were actually able to bear full weight immediately. The Precice group were only permitted to weight-bear once lengthening had been completed and some regenerate was visible, increasing loading depending on the appearance of the regenerate. Overall however, the Precice group were actually able to achieve full weight-bearing without aids earlier than the LRS group (3.6 months, 2 to 7 versus 4.8 months, 3 to 7; \( p = 0.02 \)).

Complications and re-operations are summarised in Table III. All the pin site infections in the LRS group responded to oral antibiotics. No pins required removal or exchange. There were no cases of deep infection in either group. In one LRS case lengthening was abandoned after 70 days, 10 mm short of the 60 mm goal due to loss of knee ROM that did not respond to treatment. The same patient was diagnosed with a deep vein thrombosis (DVT) when lengthening was stopped which required anticoagulation with warfarin. Due to difficulty controlling his anticoagulation, and the associated increased bleeding risk, surgical release was not undertaken and his knee ROM remained reduced at final follow-up with an arc of movement from 0° to 90°. A total of two patients developed fixed flexion deformities at the knee and another four patients had reduced knee flexion following LRS lengthening which responded to a manipulation under anaesthetic with return to full pre-lengthening ROM. In the Precice group three patients required soft-tissue releases due to contractures. In all, two required releases of the ilio-tibial band (ITB) for hip abduction contractures and a third required both hamstring and ITB releases for a fixed flexion deformity (FFD) of the knee which did not respond to physiotherapy. Knee ROM at final follow-up had returned to the pre-lengthening range in all Precice cases and in 12 of 13 LRS cases. There were no implant failures with the Precice nail. A total of two out of 39 distal locking bolts backed out of the nail, both required removal after completion of lengthening due to soft-tissue irritation. In one patient the distracting pin clamp of the LRS seized which required manipulation and adjustment under general anaesthetic.

**Table II. Results of the study groups**

<table>
<thead>
<tr>
<th></th>
<th>Precice group (n = 20)</th>
<th>Orthofix LRS group (n = 13)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Planned lengthening achieved (%)</td>
<td>20 (100)</td>
<td>12 (92)</td>
<td></td>
</tr>
<tr>
<td>Mean lengthening (range)</td>
<td>51.4 mm (25 to 68)</td>
<td>59.7 mm (50 to 70)</td>
<td></td>
</tr>
<tr>
<td>Mean lengthening rate (range)</td>
<td>0.93 mm/d (0.67 to 1.09)</td>
<td>0.83 mm/d (0.55 to 1.13)</td>
<td></td>
</tr>
<tr>
<td>Preservation of knee ROM (%)</td>
<td>20 (100)</td>
<td>12 (92)</td>
<td></td>
</tr>
<tr>
<td>Mean HI (range)</td>
<td>31.3 d/cm (21.1 to 43.0)</td>
<td>42.1 d/cm (34.4 to 67)</td>
<td>( p &lt; 0.001 )</td>
</tr>
<tr>
<td>Mean time to full weight-bearing (range)</td>
<td>3.6 mths (2 to 7)</td>
<td>4.8 mths (3 to 7)</td>
<td>( p = 0.02 )</td>
</tr>
</tbody>
</table>

* independent samples \( t \)-test; ROM, range of movement; HI, healing index

**Table III. Summary of complications and re-operations**

<table>
<thead>
<tr>
<th></th>
<th>Precice group (n = 20)</th>
<th>Orthofix LRS group (n = 13)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Septic complications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pin site infection</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>Significant change MAD &gt; 2 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hip abduction contracture</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Knee fixed flexion deformity</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Loss of knee flexion</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Backing out of locking bolts</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Fusion of distraction device</td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>DVT</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Re-operations (excluding removal) (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iliotibial band (ITB) release</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>ITB and hamstring release</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Removal of locking bolt</td>
<td>2</td>
<td>NA</td>
</tr>
<tr>
<td>MUA knee</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Adjust LRS, replace distraction unit and MUA knee</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

MAD, mechanical axis deviation; NA, not applicable; DVT, deep vein thrombosis; MUA, manipulation under anaesthesia
The pain score during the distraction phase (4.4 versus 8.1; p < 0.001), the pain score during the consolidation phase (2.2 versus 5.3; p < 0.001), and the cosmetic scar rating (3.0 versus 7.5; p < 0.001) were all significantly better in the Precice group (Table IV).

### Discussion

The aims of limb lengthening are to achieve the desired length with the fewest complications and as rapid a return to normal function as possible. To compare external fixation and intramedullary implants is difficult due to the contrasting methods. We attempted to compare similar cases of ‘simple’ lengthening without concurrent deformity correction, despite various aetiologies. We feel that these cases would have been suitable to either treatment options and a comparison would be useful to inform future practice.

All cases in the Precice group achieved the desired length and 12 from 13 LRS cases. The mean modified HI was found to be significantly shorter (31.3d/cm versus 47.1d/cm, p < 0.001) in the Precice group. This shorter HI suggests that the regenerate formed more rapidly in the Precice group. The mean time to actual full weight-bearing was also significantly shorter in the Precice cases (3.6 months versus 4.8 months, p = 0.02). Although weight-bearing is partly dependant on the instructions from the treating surgeon and influenced by whether cases are uni- or bilateral, we feel that the ability to walk unassisted with a normal gait pattern is an indication of restoration of normal function to a limb which allows comparison between the groups.

We used the same low energy technique to perform the corticotomy in both groups. Some authors have expressed concern that intramedullary reaming might destroy endosteal blood supply which has been thought to be important for regenerate formation in distraction osteogenesis. It has been noted that preservation of the periosteum was key to producing bone. We speculate that the shorter HI in the Precice group is due to the bone grafting effect following intramedullary reaming. The inherent stability of the intramedullary device may also be a contributing factor. A histological study might help to compare the regenerate between the two techniques. Conclusions on the difference in regenerate should be interpreted with caution as all the corticotomies were not performed at exactly the same level which could influence regenerate quality.

One of the perceived problems with an intramedullary lengthening device is that the femur is lengthened along the anatomical axis, theoretically leading to medialisation of the knee joint. Previous authors suggested that the mechanical axis moves laterally by 1 mm for every 1 cm lengthened. This observation was not consistent with the results in our series. A change of the MAD of < 2 mm was considered inconsequential, as suggested by previous authors. This was due to the potential for errors in measurement and also because the mechanical axis would remain within the intercondylar eminence of the tibia (Fig. 1). We only encountered a change in MAD of > 2 mm in eight from 20 Precice cases. Paley et al have suggested that only a change of > 10 mm in the MAD is clinically significant. There were no cases with a change in MAD of > 10 mm in our series. An external fixation system allows lengthening along either the anatomical or mechanical axis of the femur. Mechanical axis lengthening with a monorail device requires very long pins at the distal fixation, which can easily bend leading to deformation of the regenerate into varus. For this reason we elected to lengthen along...
The anatomical axis. We encountered regenerate deformity leading to a shift of > 2 mm in MAD in six from 13 LRS cases, and none were clinically significant (Fig. 2). We did not routinely assess sagittal alignment of the whole limb, only the segment (femur) involved. With both devices the lengthening is in a straight line, not matching the anterior bow of the femur in the sagittal plane. As such, sagittal alignment would therefore likely to be affected in a similar fashion by both devices.

Despite advances in limb lengthening procedures, complications remain a problem. Early studies on the Precice nail have suggested high accuracy and few complications. In the Precice group we observed soft-tissue complications in three patients. These cases were all early in our series and all were lengthenings of > 60 mm. Subsequently we started performing prophylactic release of the ITB at time of insertion if the planned lengthening was > 40 mm. Anecdotally this appeared to be the length when patients complained most of muscle and joint tightness. We also instituted earlier and more regular physiotherapy. There were no further soft-tissue complications after introducing these measures. All cases in the Precice group regained full knee ROM.

An anteroposterior whole leg alignment radiograph of an 18-year old male patient with short stature during the consolidation phase of simultaneous bilateral femoral lengthening of 60 mm with the use of the LRS system. It demonstrates the typical varus angulation and translation deformity due to the cantilever effect of the soft tissue.

We only performed two supracondylar corticotomies in retrograde nailing cases with no knee contractures in either case, however the number is too small to draw any significant conclusions.

In two Precice cases, one of the locking bolts backed out during lengthening. The locking bolts are only proximally threaded to allow a thicker core and more strength. Some of the earlier generation lengthening nails reported high rates of uncontrolled lengthening or failure to lengthen. We did not observe this problem with the Precice nail and the mean rate of lengthening was 0.93 mm/day. We had one hardware complication in the LRS group. The distraction unit fused and the subject had to be taken to theatre for adjustment of the LRS and replacement of the distraction unit.

There are no validated patient reported outcome measures specific for limb lengthening. We have attempted to quantify the patients experience and implant tolerance with a number of observations. Patients were significantly happier with the cosmetic appearance of their scars in the Precice group (mean score 3.0 versus 7.5 out of 10, p < 0.001). We retrospectively asked all subjects to rate their pain. Previous authors found significant correlations between the mean contemporaneous scores and the single retrospective scores for pain with the VAS. Nevertheless we treat these findings with caution due to the risk of recall bias. Subjects experienced significantly less pain both during lengthening and consolidation (p < 0.001) in the Precice group. More cases in the Precice group indicated that they were able to perform their activities of daily living, including washing, dressing themselves and using the lavatory. All the cases in the Precice group indicated that they would choose to have the treatment again compared to only 68% of cases in the LRS group.

One potential issue with the Precice nail is the cost involved, being approximately 2.5 times more expensive than the LRS system. Although unable to provide a direct comparison, like other authors we can speculate that some of the increased cost is mitigated by fewer complications and re-operations. The difference in cost may be further offset by the savings due to shorter rehabilitation time after intramedullary lengthening. An accurate analysis is needed to assess the cost effectiveness.

We believe our study is the first in which femoral lengthening with a Precice nail has been compared to an alternative technique. We acknowledge that there are several limitations to our study. Firstly the two groups were not matched. However, variables such as age, aetiology and lengthening achieved were similar and we attempted to compare cases of lengthening with similar difficulty. Secondly all data were reviewed retrospectively. A pain diary might have been more accurate than the retrospective application of the VAS, especially in the LRS group who undertook the questionnaire much later, after completion of treatment, than the Precice group. Thirdly because the series was performed consecutively, the follow-up period in

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Fig. 2

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the Precice group is much shorter than the LRS group and does include the surgeons’ learning period for a new implant. This is however a preliminary study and at the time of writing only eight out of the 20 Precice nails had been removed as advised by the manufacturer. Late complications following removal of the device might still occur.

We conclude that we achieved a significantly lower HI and encountered fewer complications with a Precice nail femoral lengthening. Patients experienced better implant tolerance and were more satisfied with their treatment in the Precice group.

Take home message:
The Precice nail should now be the method of choice for simple femoral lengthenings.

Author contributions:
M. Laubscher: Conception and study design, Literature review, Data collection and analysis, Data interpretation, Writing.
D. Goodier: Performed surgeries, Revision of manuscript.
P. Calder: Conception and study design, Performed surgeries, Revision of manuscript.
A. Timms: Data collection and analysis.
C. Mitchell: Data collection and analysis, Data interpretation, Writing.

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References