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Rotational-guided growth

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Background: Rotational deformities of the femur and tibia are some of the most common orthopedic alignment problems in the lower extremity. In-toeing and out-toeing are common complaints seen by pediatric orthopedic surgeons as well. The idea of guided growth to correct axial rotation deformities in children is appealing. The purpose of this study was to investigate this concept and to test it in a large animal model taking advantage of the human like dimensions and biomechanics. **Method:** To generate axial-rotational growth we tether the growth plate on both sides at a fixed inclined angle on each side a cable with two screws. This construct was called the Percutaneous Progressive Derotator (PPD). Eight calves, two-month old, four male (50%) and the other four female, were used as models. The PPD device was implanted at the distal physis of the right metacarpal in an external rotation configuration, leaving the left side as control. The PPD device was left in for 3 months and was then removed. The total followed up was 2 years and 3 months. **Results:** The hypothesis that guided growth was possible in large animals has been confirmed. Rotation of 24° average were achieved in the right metacarpus of the growing cattle ($P < 0.001$), using the torque generated in the growth plate by the PPD.

Keywords: *Femoral anteversion, guided growth, in-toeing, limb torsion, limb malalignment, out-toeing, rotational deformities, tibial torsion.*

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Introduction



Rotational deformities of the femur and tibia are some of the most common orthopedic alignment problems in the lower extremity. In-toeing and out-toeing are common complaints seen by pediatric orthopedic surgeons as well.^{[1],[2],[3],[4],[5],[6],[7],[8],[9],[10]} Historically, such problems were treated by counseling parents about avoiding sitting in the reverse W position for internal femoral torsion and external tibial torsion. A variety of devices are available to impart rotational torque to the lower limbs such as Dennis Brown boots and bars for internal tibial torsion to twister cables for internal femoral torsion. While the majority of children were thought to “outgrow” their deformities (those who learned to compensate well and were asymptomatic), a small group presented with continuous complaints and were treated by osteotomy of the femur and/or tibia. Rotational deformity was associated with conditions such as miserable malalignment syndrome (internal femoral torsion combined with external tibial torsion). Lack of rotation in one direction at the hip often leads to complaints of back, hip, or knee pain due to alteration of gait and compensatory joint motion at these joints.^{[6],[9],[11],[12],[13]} Rotational deformity is also reported to lead to degenerative changes in the lower back, hip, knee, and patella-femoral and ankle joints.^[14]

Angular deformities of the lower limbs in children are often treated by guided growth (hemiepiphysiodesis) using staples or screw-plate devices. This has greatly reduced the number of osteotomies performed for frontal and sagittal deformities.^{[7],[8],[15],[16],[17],[18],[19],[20],[21],[22],[23],[24],[25],[26],[27]} When it comes to rotational deformities, osteotomies have been the only modality for correction.^[12] The idea of guided growth to correct axial rotation deformities in children is appealing. For frontal or sagittal plane angular deformity, the staple, screw, or plate device acts as a tether at one periphery of the growth plate. The screws of the plate or tines of the staple are on the opposite sides of the growth plate, oriented opposite to each other longitudinally. Conceptually, if the screws were not opposite to each other longitudinally but rather one more anterior and one more posterior such that the line connecting the screws is inclined toward the longitudinal axis, the screws would have to grow toward each

other before they could tether the growth on that periphery of the physis. If such a mechanism was placed on two opposite peripheries of the physis inclined in opposite directions, this would impart a rotational tether on the growth plate. This concept was recently shown to cause rotational growth in a rabbit model. [\[1\],\[2\],\[3\],\[11\],\[27\]](#) The purpose of this study is to investigate this concept and to test it in a larger animal model of more similar dimensions and biomechanics to a human.

Materials and Methods



To tether the growth plate on both sides at a fixed inclined angle on each side, a cable with two screws was used. Two 5 millimeter diameter cannulated screws were used. The stainless steel cable was 1.5 mm thick. A 1-mm cotter was used to lock the cable to the screw. This construct was called the percutaneous progressive derotator [\[Figure 1\]](#), [\[Figure 2\]](#), [\[Figure 3\]](#).

Figure 1: Photograph of the percutaneous progressive derotator implant components

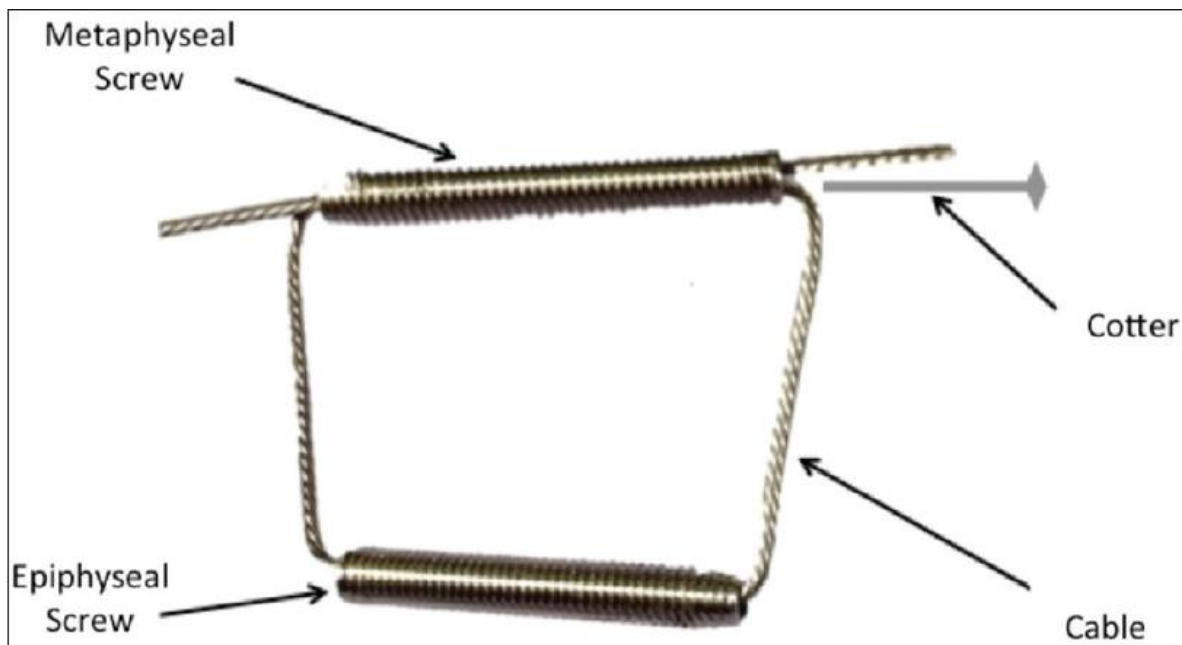


Figure 2: Torque generation between distal femoral physis and the percutaneous progressive derotator in a bone model, a: Physis distraction force, b: Cable resistance and r: Torque force

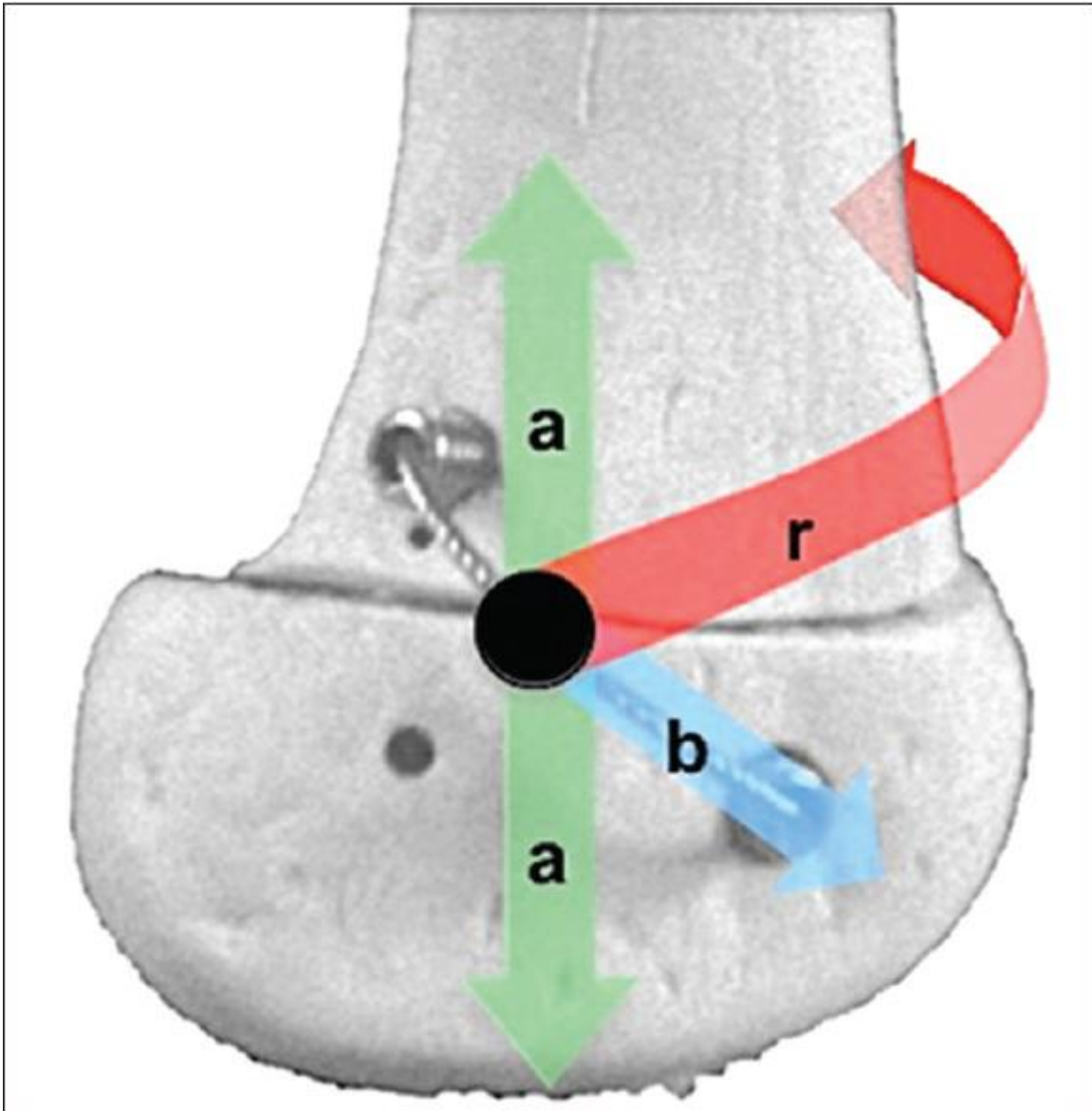
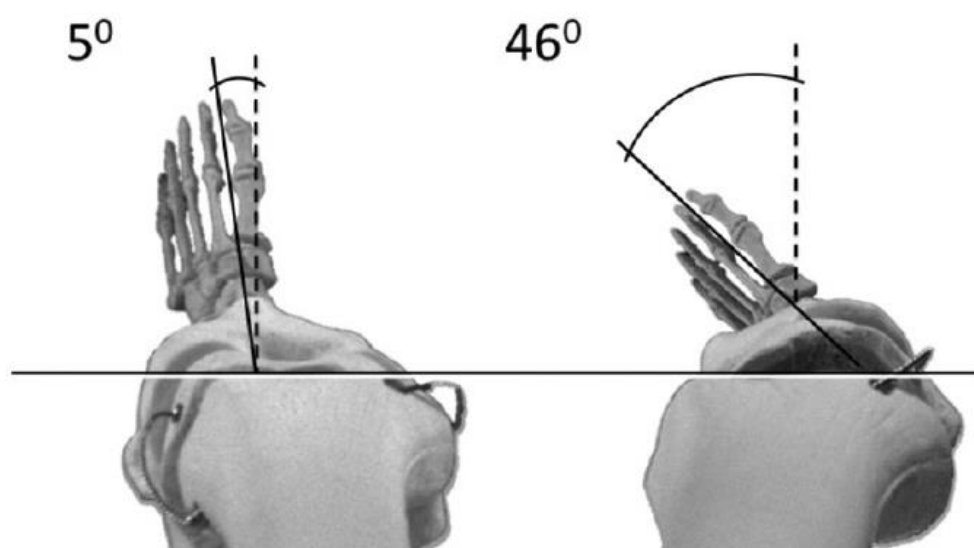
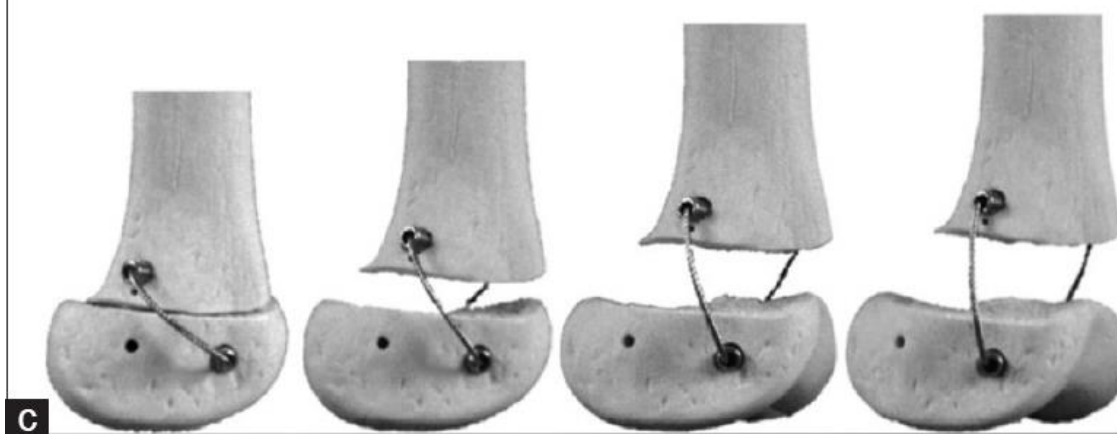
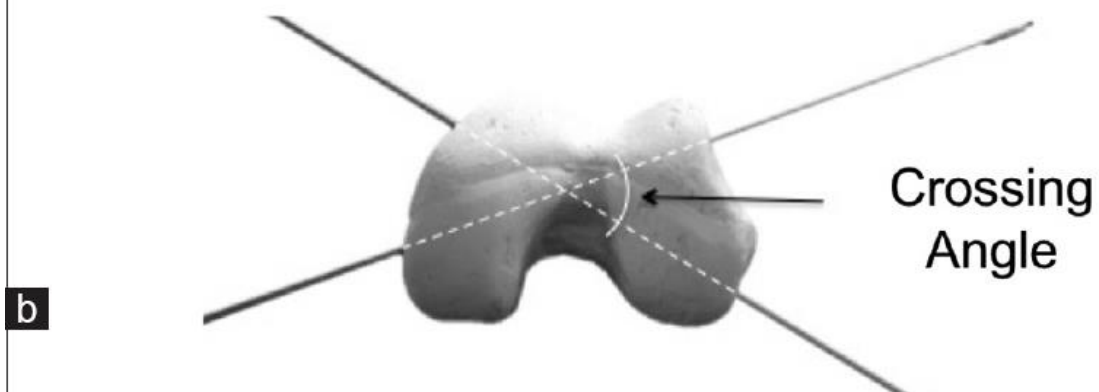
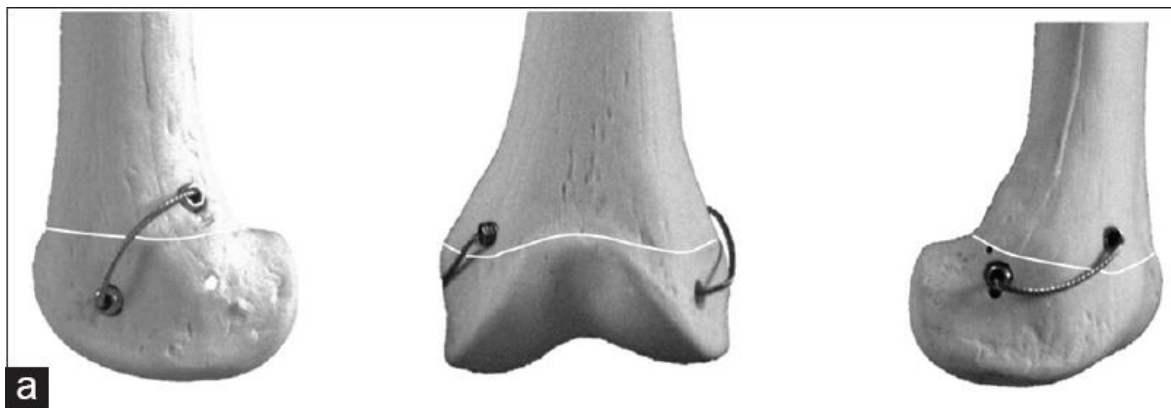


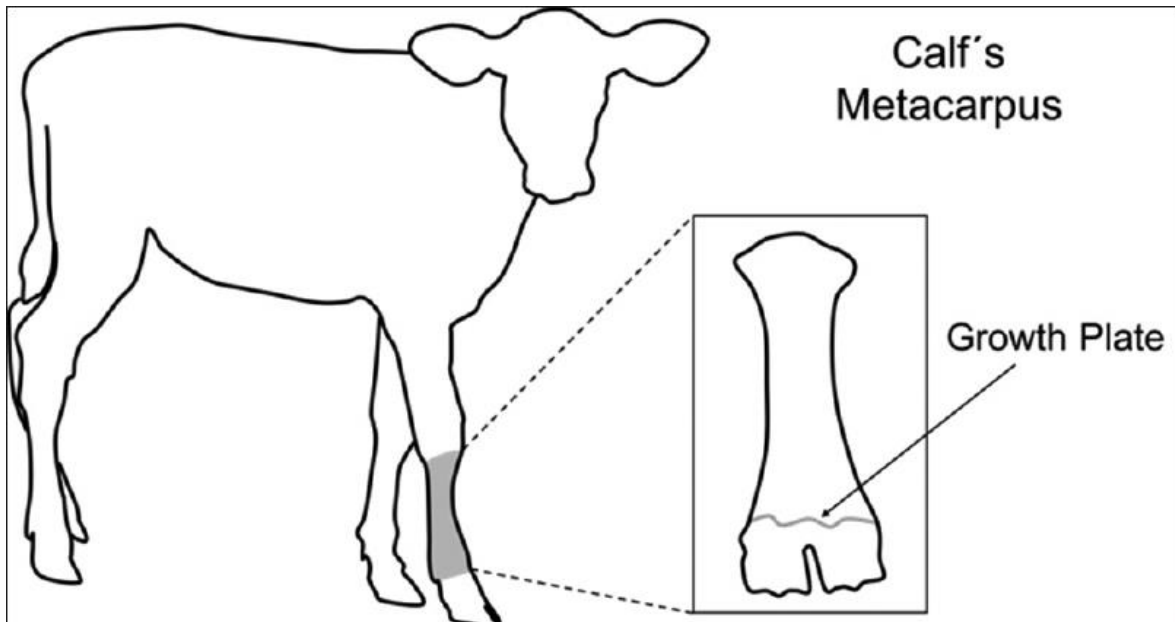
Figure 3: Multiple views of a bone model, percutaneous progressive derotator applied with a crossing angle of 50° between epiphyseal and metaphyseal screws. (a) Lateral, frontal and medial views, (b) Axial view with the guidewires left inside the screws, crossing angle is pointed. (c) Sequence of rotational changes during physeal distraction, (d) Upper view comparing, initial and final appearance of the lower-extremity bone model, before and after the simulated percutaneous progressive derotator guided growth. There is a 41° rotational change



Animal model

The calf metacarpal was chosen for the *in vivo* animal model. The average 5-month-old calf metacarpal size, measured at the level of its physis, is 6 cm wide, similar to that of a growing human knee. The calf metacarpal bears between 21 and 90 kg load which is similar to the load to the adolescent human knee [\[Figure 4\]^{\[7\]}](#) (60% of the weight is on the fore limbs,^{[\[28\]](#)} at the beginning of the study, the calf weight was on an average 70 kg and 300 kg at the final follow-up).

Figure 4: Calf's fore limb metacarpal



Methods

Eight 2-month-old calves, descendants from the same father and different mother, were used for this study. The mean age at surgery was 2.2 months (standard deviation [SD] = 0.35). Four of the calves were male (50%) and the other four were female. The mean calf weight was 69.5 kg (SD = 5.5).

The 16 metacarpals were studied as the unit of analysis. Randomly, the right metacarpal was chosen for experimentation, leaving the left side metacarpal as control group. The average metacarpal length was 18.1 cm (SD = 0.61) measured on X-rays. We examined the length of metacarpal bone before surgery to find whether the operated limbs differed from the nonoperated ones and found no difference ($t = 0.0$) ($P = 1.0$). The clinical shape and distribution of the initial rotation was assessed and found to be normally distributed ($P = 0.53$). The mean rotation was -8° (SD = 5.2). Rotation patterns were normally distributed ($P = 0.07$).

The PPD device was implanted at the distal physis of the right metacarpal in an external rotation configuration, leaving the left side as control.

To objectively measure the limb rotation, a special limb alignment goniometer was constructed [\[Figure 5\]](#). This goniometer is composed of two separate pieces; one is a 4-limb scaffold with a laser guide built in, and the other one is a modify protractor. The goniometer was mounted first over the end of proximal metacarpus. Two limbs of the goniometer were aligned to the midline of the lateral side of the metacarpus and the other two limbs to the medial side. The protractor was set at the distal end of the same metacarpus when the laser guide was on a red dot pointing the angle of rotation [\[Figure 5\]](#). In order to assess goniometer accuracy, three measures were taken by three different observers using this device including the author himself, which proved good interrater reliability. [\[28\],\[29\],\[30\],\[31\],\[32\],\[33\],\[34\],\[14\]](#)

Figure 5: Modified goniometer for rotational limb measurement, (a) on the left the proximal component with the laser guide built in, on the right the protractor, (b) Goniometer applied on the calf's right forelimb



a



Rotational baseline alignment was defined as the angle formed between the two lines following the bone's mayor transverse axis: one above the physis and the other below it. The goniometer was settled aligned to those lines. This measurement was repeated before surgery and then once a month until the 3rd month; at that time, the device was removed and biopsys of the physis were taken.

Standardized anteroposterior (AP) and lateral X-rays were taken in conjunction with limb rotation measurements. Lateral projections were taken with the film flat on the ground, with the X-ray tube pointing downward from 1.5 meter away. The calves lied in a right lateral decubitus position to have a lateral projection of the right metacarpus and then changed to left decubitus position to take the left-sided lateral X-rays. For AP projections, both metacarpus were positioned parallel to each other on the same radiographic film.

The PPD was inserted at a crossing angle between 35° and 55°. AP and lateral radiographs were obtained in a standardized fashion.

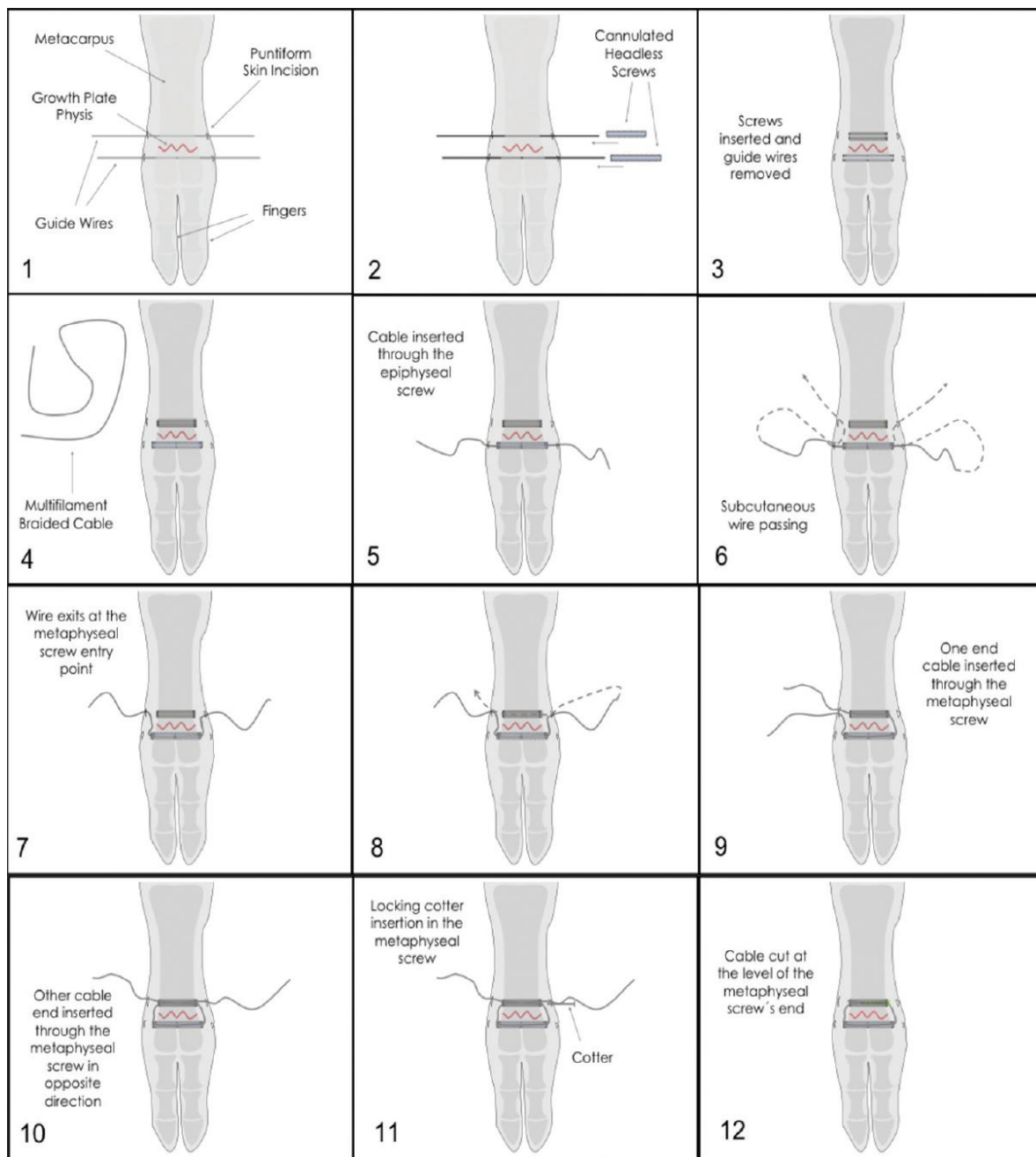
The PPD device was left in for 3 months and was then removed under local anesthesia (LA) before the screws came in line, provoking growth inhibition.

After the removal, the calves were followed clinically every month in order to check out postoperative complications. No further measurements were taken after implant removal and when they went to the slaughterhouse, the metacarpals were harvested.

The total follow-up period was 2 years and 3 months. Calves were allowed to live for 2 years in order to evaluate bone remodeling potential until bone maturation. The remaining growth period after implant removal was, on an average, 20 months.

After the calves were sacrificed and both metacarpals were harvested, computed tomography (CT) scan cuts were taken at the proximal and distal ends for rotational profile measurement on both the control and operated sides for comparison. The specimen was then dissected and coronal cuts were made to macroscopically examine the joint and bone structure.

Surgical technique [\[Figure 6\]](#)



Once in the operating room, calves received a dose of anesthetic (Cilazina), with a dose of antibiotic (Oxytetracycline LA) to prevent infection and a dose of Ivermectin to prevent myiasis.

Asepsis of the area with povidone-iodine solution was carefully done. After that, a circumferential local anesthetic with 10 ml lidocaine 2% without epinephrine was applied. Then, a hemostatic cuff was placed around the limb. After 10 min, two k-wires of 2 mm diameter each were inserted, one 1 cm proximal and one 1 cm distal to the physis. Intraoperative AP and lateral X-ray were taken in order to identify the physis and to check the correct guidewire position. Both wires were placed in parallel planes between each other and the physis.

In order to place the PPD in an external rotation configuration, the metaphyseal wire was inserted from the anteromedial to posterolateral aspect and the epiphyseal wire from the anterolateral to posteromedial aspect. A standard goniometer was used during surgery to measure the angle between the k-wires and make sure that the crossing angle was correct (range between 35° and 55°). AP and lateral radiographs were taken to verify the correct placement of the wires in order to check the absence of growth plate violation.

Four small incisions were made at the four points where each wire end exited the skin. A 4.5-mm cannulated drill bit was used to ream over the top of each wire. Once the drill bit was removed, two 5-mm self-tapping cannulated stainless steel screws were inserted. The screw length was measured to protrude a few millimeters from each side.

A 1.5-mm braided stainless steel cable was passed all the way through the epiphyseal screw's cannulation. The cable was then passed subcutaneously to enter the metaphyseal screw from either side. The two cable ends overlapped inside the metaphyseal screw. A locking cotter pin was inserted into the cannulation of the metaphyseal screw to lock the overlapping cable ends in place. At the end of the surgery, an X-ray was taken to check the correct placement of the PPD implant. The incisions were sutured, and the hemostatic cuff was removed [\[Figure 6\]](#).

Statistical analysis

Descriptive analysis for continuous variables was shown as mean and standard deviation. To evaluate rotational changes of the metacarpals, we performed repeated measures analysis of variance. The factors were type of treatment (treated and control) and repeated measures were times. The assumptions were evaluated with the tests of box for sphericity, Levene for equality of variances, and Kolmogorov–Smirnov for normality. Simple effects were calculated through an ANOVA table. Significance was defined as $P < 0.05$. All data analyses were performed with IBM SPSS software, version 19 (IBM SPSS, Chicago, IL, USA).

Goniometer accuracy was tested using the interclass correlation coefficients (ICCs). Three observers measured the metacarpal's rotational profile at each period: basal, 1st month, 2nd month, 3rd month, and after the 2-year follow-up and ICC calculated at each period was 0.88, 0.93, 0.89, 0.81, and 0.97, respectively. These values indicated a good interrater reliability.

Results



The hypothesis that guided growth was possible in large animals has been confirmed. Rotation of

24° average was achieved in the right metacarpus of the growing cattle, using the torque generated in the growth plate by the PPD.

One month after surgery, the mean rotation was 2° (SD 6). This change in rotation was found to be statistically significant (−8° vs. 2.6°). Comparing the initial rotation measures with those taken a month later, the external rotation was not clinically obvious at this time.

To determine the effectiveness of surgery in increasing rotation, the mean difference in rotation was examined, comparing the preoperative measurements with those of the 1st, 2nd, and 3rd month postoperatively. In summary, the corresponding rotation measurements were −8° (SD = 6); 2.6° (SD = 2.3); 9.1° (SD = 4.6), and 15.7° (SD = 7.6), respectively. After 2-year follow-up, the average rotation was −3.6° (SD = 5.3). [Table 1](#) summarizes the metacarpal's rotational profile of control and operated sides at each measurement interval. The discrimination between treatment and time is statistically significant; there is evidence that the effect of treatment is different over time, and hence it is studied in simple effects.

Table 1: Rotation changes over time summarized and ANOVA test for repeated measurements

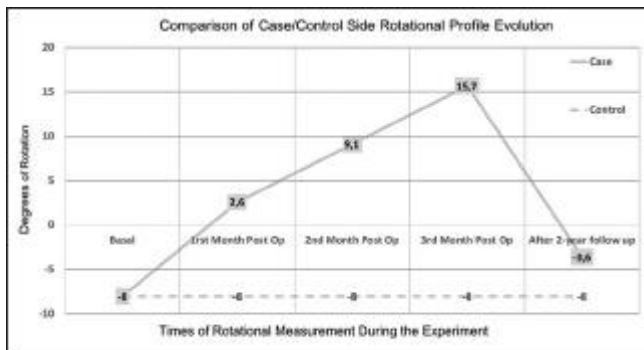
	Basal Media (SD)	1 st Month Media (SD)	2 nd Month Media (SD)	3 rd Month Media (SD)	24 th Month Media (SD)	ANOVA efecto (P)		
						Time	Treatment	Interaction
Treated	-8.2 (DS 5.7)	-8.2 (DS 5.7)	-8.2 (DS 5.7)	-8.2 (DS 5.7)	-8.2 (DS 5.7)	0,001	0,001	0,001

In case 6, the rotational value of the second month is assumed to be 1. Average between T2 and T4

[Table 2](#) shows the operated metacarpal's rotational profile of each individual in every measurement. **Rotational profile measurements evolution in each individual considering preoperative, 1st, 2nd, and 3rd month postoperative and after 2-year follow-up**

Individuals	Pre-op	1 st month post-op	2 nd month Post-op	3 rd month Post-op	2 years follow up
1	0	0	5	28	0
2	-15	3	10	15	-3
3	-10	0	5	10	-10
4	-3	3	18	20	-2
5	-5	5	15	15	-5
6	-5	0	Lost data	2	-5
7	-15	5	10	21	-10
8	-13	5	10	15	6
Average Rotation	-8	2,6	9,1	15,7	-3,6

From the variance analysis comparing the simple effects between treated and control groups, a significant statistical difference was observed regarding the treated group. ($P < 0.001$). [Graph 1] shows the marginal rotational measures in each group over time.



Graph 1: Rotational marginal measures for each group over time

[Table 3] shows the amount of longitudinal growth relative to rotation achieved. There is a proportional relation between growth in length and rotation; the more the bone grows, the more it rotates.

Operated metacarpus growth (cm) from the beginning to the 3 rd month	Total rotation achieved (degrees) From the beginning to the 3 rd month
2.5	28
1	30
1.5	20
3.5	23
3.5	20
2.5	7
2.5	36
2	28

Table 4: Amount of longitudinal growth relative to other side

Control metacarpus length (cm) 3rd month	Operated metacarpus length (cm) 3rd month	Total discrepancy (cm)
20.5	20	0.5
21.5	21.5	0
20.5	20.5	0
21	21	0
22	22	0
20	18.5	1.5
21	19.5	1.5
20	19	1

[Table 4] shows the amount of longitudinal growth comparing the operated metacarpus to the control side. No significant difference was found between the sides.

Control metacarpus length (cm) 3rd month	Operated metacarpus length (cm) 3rd month	Total discrepancy (cm)
20.5	20	0.5
21.5	21.5	0
20.5	20.5	0
21	21	0
22	22	0
20	18.5	1.5
21	19.5	1.5
20	19	1

Radiology results

In the sequence of X-rays (lateral and AP) taken monthly during the first 3 months of the experiment, a progressive change in the shape of the PPD was more noticeable on the lateral view. The rotational measurement on X-rays was difficult because landmarks are blurred, but seem to be greater compared to the ones obtained with the modified goniometer [Figure 7] and [Figure 8]. That is the reason why rotimeter values have been chosen as the standard method for rotational assessment.

Figure 7: Follow-up X-ray month to month. First column shows starting point X-ray; second column, 1-month control; and third column, 3-month postoperative control. First row, anteroposterior views; second row, lateral views



Figure 8: Full bone length lateral view X-rays showing the rotational profile of the same bone, comparing it before and 3 months after surgery. Rotation angle is measured



The periosteal sheath bone formation seen in calves is remarkable and responsible for wire entrapment and landmark blurring.

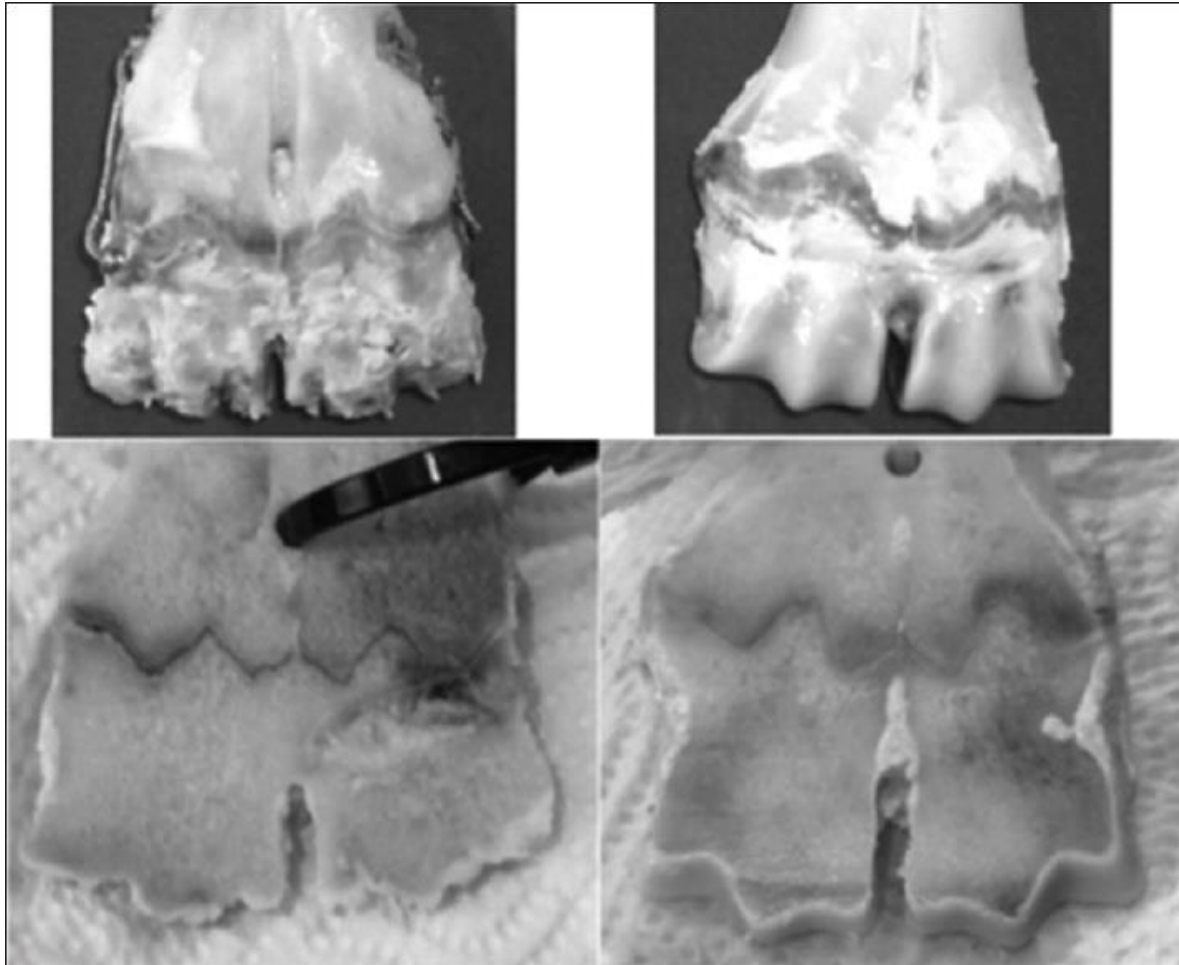
Length comparison between operated and control side, measured on X-rays, showed no statistical difference. No significant discrepancy was found.

Gross anatomy results

After 3 months since the experiment begun, one calf, not included in this series, was sacrificed, both metacarpals were harvested, and soft tissue was removed. Coronal cuts were made at their distal ends to study the physis.

In the control metacarpal, the physis shape seemed to be very irregular with high double-peak mountains separated with deep valleys. In the operated side, the physis looked less irregular, showing one peak with shorter mountains separated with shallower valleys [\[Figure 9\]](#).

Figure 9: Pictures in the row above show the dissected metacarpus comparing the operated side (left) and the control side (right). Below are the coronal cuts of each bone respectively. Notice the physeal topographic changes between the operated and the control metacarpus in the same animal



Histology results

Histological examination of the epiphysis and physis showed no significant difference in morphology comparing control and operated sides. In contrast, the metaphysis of the rotated side showed significant angio-hyperplasia and increased ossification [\[Figure 10\]](#) and [\[Figure 11\]](#).

Figure 10: 9353 control. Control sample photomicrograph (H and E, $\times 120$) of the metaphyseal area showing normal endochondral ossification trabeculae. It presents a normal bone marrow vascularization according to a normal endochondral ossification interface

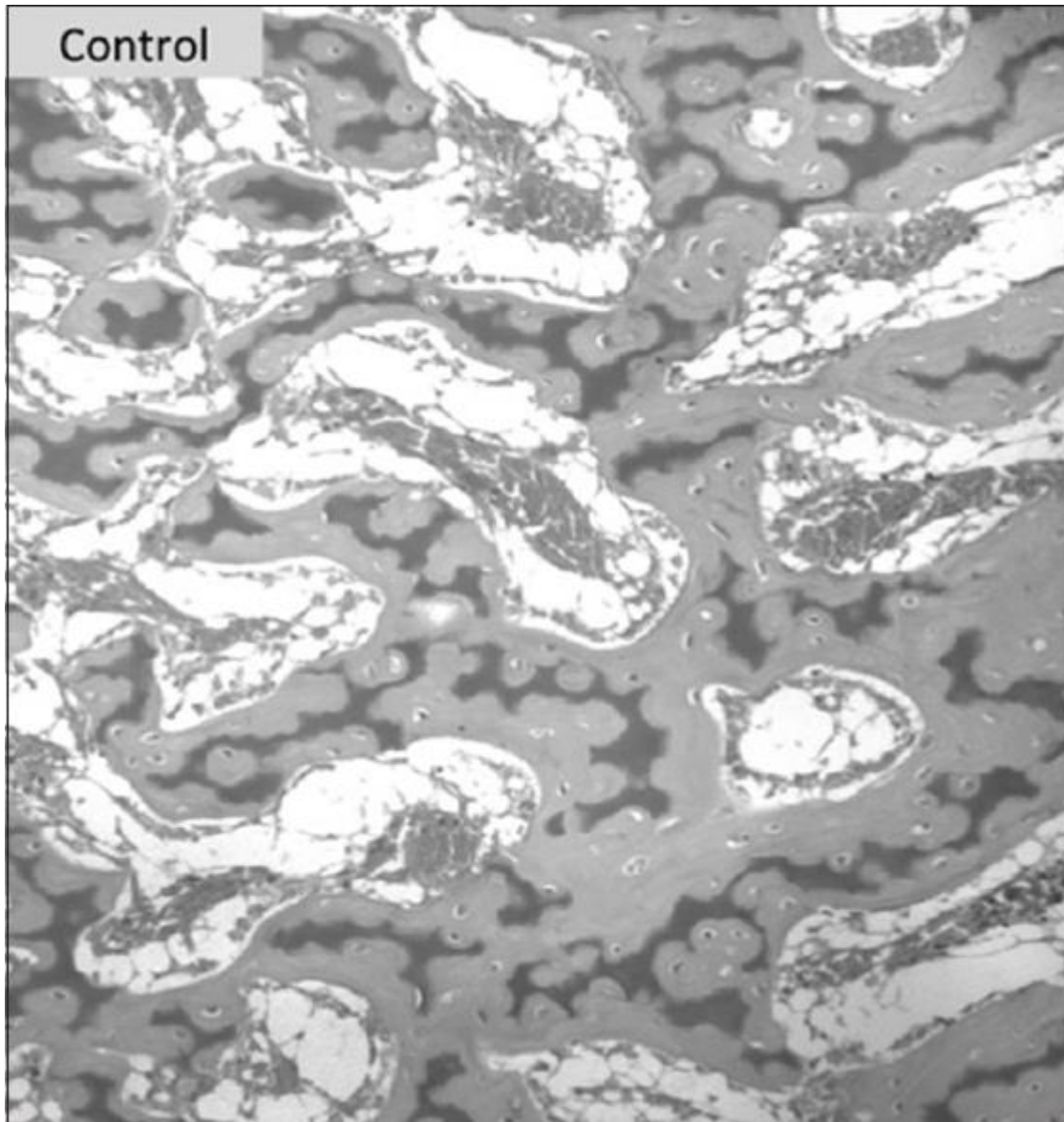
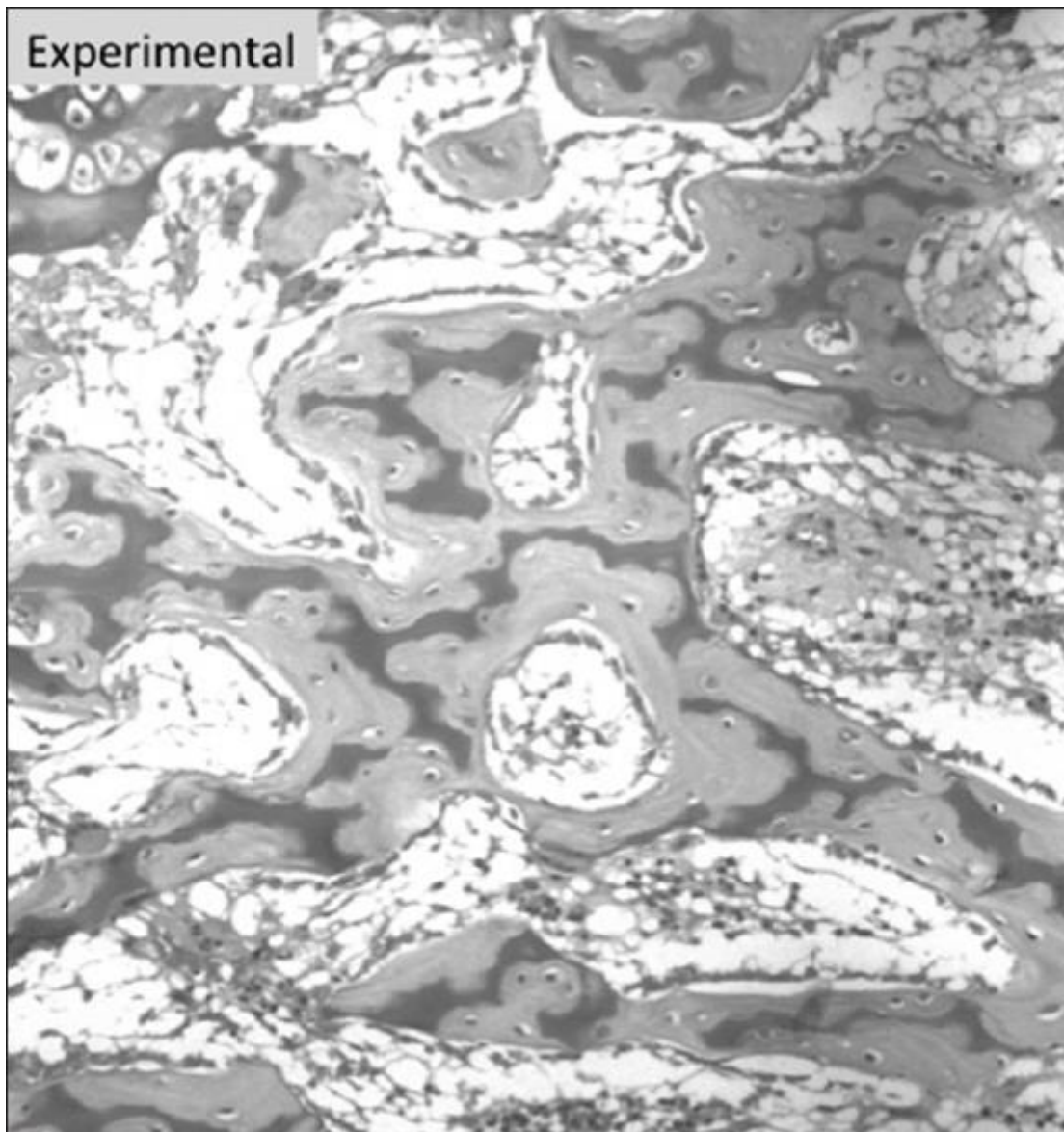
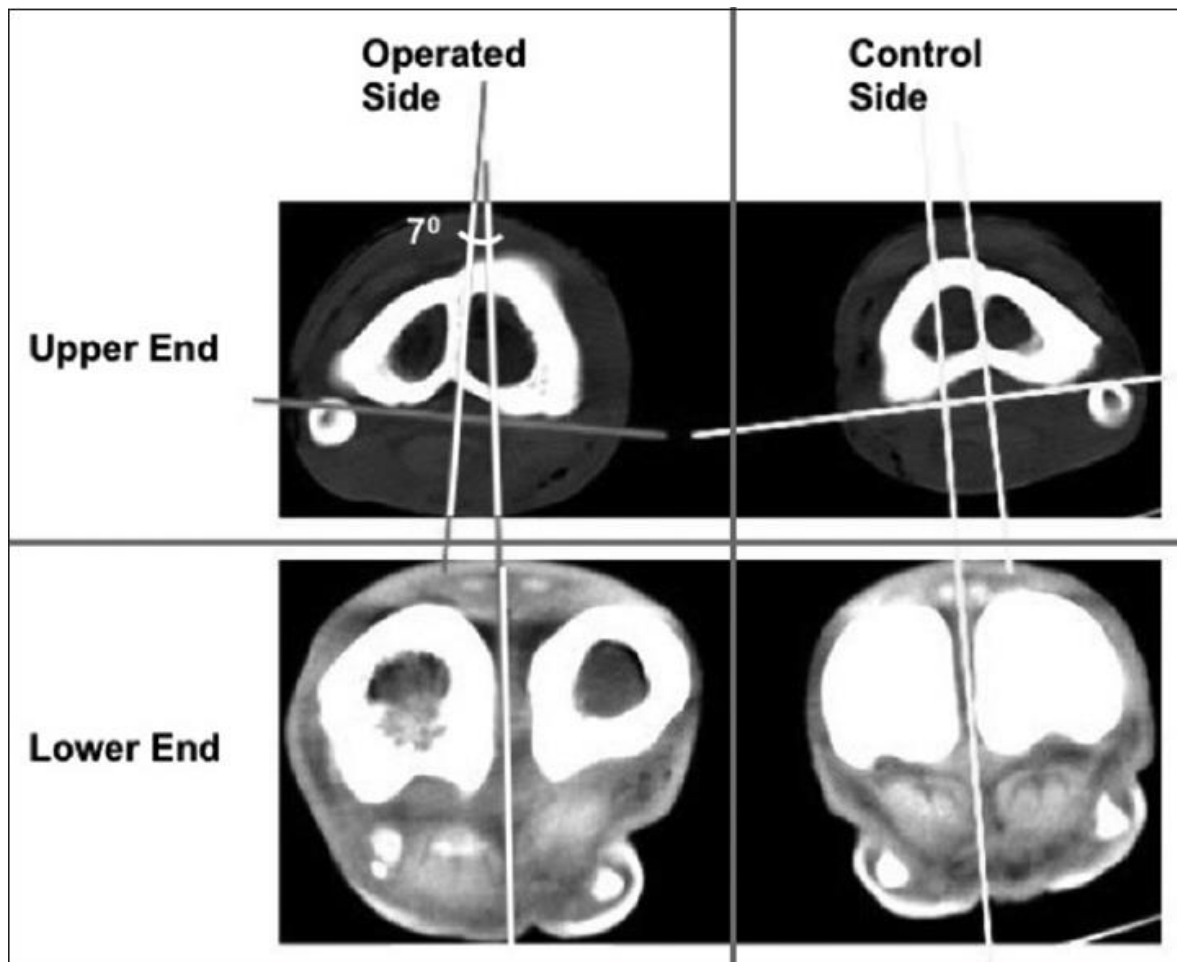


Figure 11: 9349 experimental. Experimental sample photomicrograph (H and E, $\times 120$) of the metaphyseal area showing interspersed endochondral ossification trabeculae and fatty marrow with significant angio-hyperplasia and increased ossification



All individuals were kept under clinical supervision for 2 years. After that, they were slaughtered and the limbs were harvested. Coronal CT slices were made at both ends of every metacarpus, and the rotational profile was measured and compared with the control metacarpus [\[Figure 12\]](#). It was observed that only some of the rotation obtained was maintained in only 25% of the operated bones.

Figure 12: One of the cases in which 70° of external rotation was maintained after a 2-year follow-up



Discussion



Rotational-guided growth has been proven by Arami *et al.*, 2013,^[4] Sevil-Kilimci, 2017, and Lazarus *et al.*, 2018,^[22] using small animal models (rabbits).

The aim of this article was to test the hypothesis that rotational-guided growth was feasible by using a percutaneous surgical technique, which demanded a larger animal model and a specific implant design.

At present, rotational deformities are corrected by means of an osteotomy. In general, osteotomies demand immobilization, several inpatient days, pain management, serious surgical complications, and rest until consolidation is confirmed before returning to previous activities. The percutaneous rotational-guided growth method shares the benefits of the modulated growth, plus the benefits of the mini-invasive surgery such as quick recovery, low rate of major complications, fast resumption to normal activities, and less scarring.

On the contrary to the aforementioned articles^{[4],[22]} which used two opposed oblique plates and four screws, the PPD implant used a multifilament wire and two cannulated screws to generate rotational growth. Perhaps, eight plates which are successfully used for coronal or sagittal bone deformities are not the best choice for rotational growth modulation. One thing to take note of is the dragging effect that might occur when a bulky plate shifts its position against soft-tissue resistance. The interface between the PPD wire and the soft tissue is minimal (1.5-mm diameter) compared to the body of a regular plate.

Contrarily to Lazarus *et al.*,^[22] who concluded that torsional growth modulation by oblique plating might result in shortening of the ipsilateral bone, we did not encounter significant growth inhibition, shortening, or axial deformities in the operated bone. On-time implant withdrawal and a progressive balanced stimulus seem to be variables of paramount importance.

The surgical technique was carried out in a percutaneous fashion, reducing unnecessary soft-tissue damage with insignificant scarring compared to usually applied surgical techniques. On an average, every 1 cm of longitudinal growth, 10° of rotation was gained.

The limitations of this study were the following: first, because of using large animals, CT scans for rotational measuring were not practical. It would have been ideal to had CT taken before surgery and 3 months after, but calf's size did not allow that. A special goniometer was necessary to be developed. Second, the massive periosteal reaction of calves was not expected and the implant tended to get involved in it. In addition, this capability made measurements on X-rays extremely difficult. Third, independently of the rotation achieved by 3 months, the implant was removed in all cases. There was some degree of rotational potential left in the implant configuration. Therefore, the full rotation capacity was never achieved. Fourth, the timing of intervention was precautious in this sample of 2-month-old calves. In cattle, long bone growth in length persists until their 2nd year of age and its growth in width continues few months after physeal closure. In order to evaluate the rebound phenomena, the calves were followed up for 2 years after implant removal.

The rotation obtained was very obvious both clinically and radiologically in every case by the 2nd month after implant insertion. One individual, which grew a full 2.5 cm, only achieved 7° of rotation. That could be attributed to the implant wire being settled either loose or in a curved trajectory, resulting in a late and weak rotational stimulus.

In contrast to the histological findings reported by Arami *et al.*, 2013,^[4] no swirling of the cell columns in the proliferative zone was found; only a significant angio-hyperplasia and increased ossification were seen at the level of the metaphysis.

Further research is required to accurately plan the timing of intervention and the degree of screws crossing the angle of the PPD configuration before testing this method in humans. In case of applying this technique in a human being, and taking into account that, for every 1 cm of physeal

growth, 10° of rotation could be corrected, the surgical planning should involve: (a) measurement of the amount of correction needed, (b) estimation of the remaining growth in the physis to be guided with multiplier method for example, and (c) schedule the patient for surgery as close as possible to the time of physal closure, in order to avoid the rebound phenomena.

In conclusion, percutaneous-guided growth is an appealing surgical option for correction of rotational deformities in skeletally immature patients such as internal/external femoral torsion, internal/external tibial torsion seen in miserable malalignment syndrome, and neurological and congenital diseases. Something to remark is that no physal arrest, secondary deformities, or relevant growth inhibition was found in any case. This study successfully demonstrated that rotational-guided growth can be achieved safely using the PPD implant with mini-invasive surgery in a large animal model.

Study limitations

There are anatomical, physiological, and biomechanics differences between humans and cattle. This study used growing calves' metacarpal bone for technical demonstration of the PPD. The generalization of the technique in humans requires careful interpretation.

Conclusion



Rotational corrections can be gradually generated in immature growing long bones by means of minimally invasive surgery.

Gradually generated rotational corrections over healthy physis do not generate discrepancies.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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