Abstract (300 words max): 227

Objectives:

The objective was to quantify external skeletal fixator (ESF) associated complications in cats and to identify potential risk factors.

Methods:

A retrospective review of medical records and radiographs following ESF placement was performed.

Results:

Case records of 140 cats were reviewed; fixator associated complications (FAC), occurred in 19% of cats. The region of ESF placement was significantly associated with complication development. Complications developed most frequently in the femur (50%), tarsus (35%) and radius/ulna (33%). Superficial pin tract infection (SPTI) and implant failure accounted for 45% and 41% of all FACs, respectively. SPTI occurred more frequently in the femur, humerus and tibia, with implant failure more frequent in the tarsus. No association between breed, age, sex, weight, fracture type (open vs closed), ESF classification, number of pins per bone segment, degree of fracture load sharing and the incidence or type of FAC was identified. No association between region of placement, breed, age, sex, weight, fracture type (open vs closed), ESF classification, number of pins per bone segment, fracture load sharing and the time to complication development was identified.

Conclusions and relevance:

Complication development is not uncommon in cats following ESF placement. The higher complication rate in the femur, tarsus and radius/ulna should be considered when reviewing options for fracture management; however cats appear to have a lower rate of pin tract infections than that reported in dogs.

Introduction

External skeletal fixators (ESF) are used for numerous orthopaedic conditions including fracture stabilisation, joint immobilisation, angular limb deformity and shear injury management. ESFs may be either a sole fixation device, or used as adjunctive stabilisation and are available in a variety of configurations including linear, circular, hinged, free form and hybrid forms.[1-4] Whilst ESFs remain a versatile and useful tool in orthopaedics, reservations regarding their use are based on high reported fixator associated complication (FAC) rates, particularly implant failure and pin tract infection (PTI).[5-8]

PTIs occur most commonly when there has been significant penetration and disruption to the adjacent soft tissues. This allows bacterial contamination of the skin to pin interface, leading to superficial pin tract infection (SPTI), which can progress to deep pin tract infection (DPTI), with associated bone lysis and osteomyelitis.[9-11] Implant failures include pin loosening, breakage or bending; clamp loosening and connecting bar breakage leading to construct failure. Development of FACs in dogs has previously been reported up to 100% in some reports,[8, 12] although more recent studies in cats have shown lower complication rates, ranging from 26% to 65%.[4, 5, 13, 14]

Whilst individual studies have evaluated specific ESF types, at specific anatomic locations, in defined groups of animals, it remains difficult to compare overall ESF complication rates. To the authors' knowledge, there has been no comprehensive overview of complications arising from all ESFs placed for feline orthopaedic conditions. The aim of this study was to review postoperative complications attributable to the ESF in cats and to identify factors associated with complication development in a large number of clinical cases.

Materials and methods

Medical records of cats with an ESF placed between January 2007 and March 2014 were reviewed. To be included in the study, clinical records needed to be present to the point of frame removal and/or fracture union. The following information was gathered for each patient where possible: signalment, ESF configuration, anatomic region, fracture type (open or closed), the number of pins placed per bone segment (appendicular skeleton only), and FACs. ESF configuration was determined from clinical records and radiographs and categorised into four groups: linear, free-form, hybrid and circular. Long bone fracture load sharing was assessed and separated into load-sharing, partial load-sharing and non-load-sharing as previously described.[15] Specific ESF features were also assessed, see Table 1. Each ESF was assigned to one of ten anatomical regions (Figure 1).

FACs were divided into four categories: **1)** SPTI, including cases with associated pin loosening, **2)** DPTI, including any cases with associated pin loosening, **3)** fractures and **4)** implant failure; defined as any complication associated with the frame without concurrent infection, including loosening, breaking/bending of pins, breakage of connecting bars or clamp failure, and implant migration.

SPTI was diagnosed by presence of one or more of: **(a)** purulent discharge (with or without positive bacterial culture); **(b)** a positive culture result, or; **(c)** at least one sign of infection (pain or tenderness, localised swelling, redness or heat), or a positive response to antimicrobial therapy.[16] DPTIs were diagnosed when the previously mentioned criteria were met and evidence of osteomyelitis or bone sequestrum was seen radiographically.

Statistical analysis

Statistical analyses were performed using IBM SPSS Statistics for Windows, Version 23.0; SPSS Inc. Data were assessed for normality using the Shapiro-Wilk Test. Categorical variables were analysed using Chi-squared or Fisher's exact test as appropriate. For analysis of regional association with complication development and type, regions with less than six cases were excluded from analysis. Analysis of associations between age, weight and development of complications; fracture type (open

vs closed) and time of FAC were assessed using the Mann-Whitney U test. The Kruskal-Wallis test was used to identify associations between patient age, weight and type of complications, and associations between sex, ESF configuration, pin number, load sharing, fracture type (open vs closed) and region of placement with the time to FAC development. Relationships between age, weight and time of complication were assessed by Spearman's rank correlation. A $P<0.05$ was considered significant.

Results

A total of 140 cats managed with an ESF met the inclusion criteria. Age on presentation ranged from three months to 12 years (median two years). Body weight ranged from 1.2kg to 8.6kg (median 4.2kg). Fifty cats were female (41 neutered), and 90 were male (80 neutered). Seventeen breeds of cat were represented, the most common being Domestic Short Hair (n=101), followed by Domestic Long Hair (n = 10), then Siamese (n=7). Of the 140 cats, 74% (n=104) had closed fractures and 26% (n=36) had open fractures. Overall the most common region of placement was the tibia (24%, n=34) as shown in Figure 1.

It was possible to identify specific ESF configuration in 109 of 140 cats. The majority of ESFs were linear in 88% (n=96) of cats, of which 67% (n=54) were type I, 31% (n=32) type II and 2% (n=2) were type III. The remaining fixators were free form in 9% (n=10), and hybrid in 3% (n=3) of cats. The majority of constructs used clamps (86%, n=94) with the remaining 14% (n=15) using epoxy putty. The number of bi-cortical transfixing pins placed was identified in 94 cats, the total number of pins placed ranged from 2 to 9 (mean 6). In the proximal segment this ranged from 1 to 4 (mean 3) and 1 to 6 (mean 3) in the distal segment. Additional ESF configuration results are summarised in Table 2.

FACs occurred in 19% (n= 27), of cats. Two cats had two separate FACs over time, which were treated as separate complications, giving 29 distinct FACs. The time to diagnosis of complications ranged from 10 to 154 days postoperatively (median 43 days). Figure 2 shows the overall frequency and type of FACs that developed; the most common being SPTI accounting for 45% of all complications seen, followed by implant failure (41%).

Complications occurred in eight of the ten anatomical regions, summarised in Table 3. Region of placement was significantly associated with FAC development (P=0.001). The highest complication rate was seen in the femur (50%) followed by the tarsus (35%), and radius/ulna (33%). The lowest complication rates were in the tibia (3%), pes (5%) and stifle (0%). Region was not significantly associated with complication type however (P=0.505). Regional distribution of complication types is shown in Figure 3, with SPTI the most frequent FAC in the femur and humerus (Appendix 1). Implant failure was the most common complication seen in the tarsus (Figure 3).

5

Of the 13 cats that developed a SPTI, four were managed successfully with antimicrobial treatment alone, three required pin-tract care alone until planned ESF removal, and four required pin removal (Appendix 2). Two cats with SPTI required limb amputation; one due to non-union caused by pin loosening attributed to SPTI, and the other due to unrelated wound complications. Of the 12 cats with implant failure, 50% suffered from broken pins, of which 5 were in the distal bone segment and all of these cats had a transarticular tarsal ESFs. The sixth had a fixator placed on the pes. Loose pins accounted for 33% (n=4), of implant failures, one cat traumatically displaced a pin from the femur and one cat bent a pin in the manus. One traumatic clamp and no epoxy putty failures were reported (Appendix 2).

Load-sharing of long bone fractures was assessed from the radiographs of 57 cats. Load-sharing occurred in 12 (21%), partial load-sharing in 10 (18%) and non-load-sharing in 35 (61%) cats. No significant association between the degree of load sharing and FAC development (P=0.161) was identified. No significant associated between breed, age, sex, weight, fracture type (open vs closed), fixators pins per bone segment and the incidence or type of FAC was identified. Similarly there was no association between ESF type and the incidence (P=0.634) or type (P=0.696) of FAC. Time to FAC diagnosis was not significantly associated with any variable tested including age, sex, weight, region of placement, fracture type (open vs closed), ESF classification, pin number, load sharing and complication type.

The only frame feature significantly associated with FAC develop was the use of an intramedullary (IM) pin (Table 2). IM pins were placed in 36 cats, and 44% of cats that had an IM pin placed developed a FAC. No specific complication type was significantly associated with IM pin usage. When assessed by region 53% (n=19) of IM pins were placed in the femur and 25% (n=9), in the humerus.

Discussion

This is the largest review of ESF usage in cats to date. The most common type of ESF used was the linear ESF, of which the type I and II arrangements predominated. Unsurprisingly, male cats were over-represented, and the median age was young, at two years. Tibial fractures were the most common fracture location for ESF placement. The predominance of the tibia probably relates to the ease of placement with the medial tibial providing safe corridors for pin placement. Despite being the location with the highest level of fixator usage, it had one of the lowest complication rates.

The overall FAC rate for cats having an ESF placed was 19%. Region of ESF placement was significantly associated with the development but not the type of FAC developed. The most common locations for FACS were the femur (50%), followed by the tarsus (35%) and radius/ulna (33%). Complication type however, could not be significantly attributed to a location. This may relate to the group sizes when complications were subdivided by type, preventing a significant result from being statistically shown (type II error). To reduce statistical errors, groups with fewer than six cats were excluded from statistical analysis. The majority of complications were SPTI and implant failure, both with a 9% overall complication rate respectively; accounting for 45% and 41% of all FACs, respectively. SPTI is a well-documented complication following ESF placement and was seen in 9% of cats having an ESF placed. This is lower than previously reported SPTI rates in dogs which range from 28% to 57%.[17, 18] It therefore appears that cats are less likely to develop PTIs than dogs, and this is something the authors have noted anecdotally. As a complication type, SPTIs accounted for 45% of all FACs, similar to a previous study investigating feline tibial fixation with 41%.[6] While results of our study showed no significant regional association with FAC type, the low levels of tibial SPTIs and high levels of femoral SPTIs, are suggestive of a true or surrogate influence of anatomic region (Appendix 1). Studies of the canine femur and humerus have shown an absence of clear, safe corridors for transfixation of these bones due to the complex regional anatomy, and only limited safe corridors in the radius.[19, 20] Interference with tendons and musculature in these regions may lead to discomfort, joint stiffness and decrease use of the limb, all of which may predispose patients to increased FACs due to tissue morbidity and patient interference. PTIs and pin loosening are associated with increased tissue penetration and disruption and hence bone segments with prominent adjacent muscle groups,

such as the femur are at risk.[8, 11] The reduced rate of PTIs in cats compared with dogs may be due to the fact that cats appear to have a relatively smaller soft-tissue envelope, typically with significantly smaller proximal limb muscle mass and a more marginal subcutaneous fat layer. This could result in a reduced tissue volume associated with a pin tract and potentially less soft tissue morbidity and a lower risk of pin loosening or PTIs.[11] It is known from animal studies that the technique of pin placement can affect the development of PTIs. Minimising the distortion of soft-tissues is important,[2, 21] and penetrative stab incisions through the soft-tissues of 2-3mm are recommended.[2] Sufficient incision size can reduce the rubbing between the pin and the soft-tissues that contributes to localised tissue reaction. Unfortunately, no such data was present on the sizes and methods used for establishing the soft-tissue releasing incision, however it is commonplace at this institution to make stab incisions of up to 6mm in size and to use a small haemostat to open a tunnel through overlying musculature. In people, PTIs remain a significant issue and numerous postoperative strategies of pin site care have been proposed.[22] However, a recent meta-analysis on pin site care showed insufficient evidence to identify a strategy of pin site care that minimises infection rates.[22] Adequately powered randomised trials are required to examine the effects of different pin care regimens prior to making further recommendations.[22] Other risk factors for small animal surgical site infection included gender, increased bodyweight and duration of anaesthesia.[23, 24] In this study however, when assessing PTIs, no association with age, body weight, or gender was found, although anaesthesia duration data was not available. A further consideration beyond the scope of this study is the varied skin microflora seen in cats and dogs, which may also influence infection development.[25] Despite the frequency of PTIs, which is notably lower in cats than in the dog, PTIs are usually manageable, as ESF implants can be readily removed and minor short term morbidity associated with SPTIs often resolves following antimicrobial administration and adequate pin care or implant removal.[7, 9, 26] Of the 13 cats with PTIs, only 5/13 required specific pin removal, with the remainder managed without surgical intervention until frame removal.

The femur was the region with highest level of fixator associated complications, at 50%. Other studies have reported lower rates of up to 23%.[13] In another study of 35 cats, femoral fracture stabilisation with an ESF resulted in excellent healing in all cats with low morbidity. They concluded that there remains a place for their use in the femur when correctly applied and plate fixation may not be an

optimal choice for all fractures given that application can be expensive.[27] This conclusion is supported by a population of dogs and cats undergoing femoral fracture stabilisation with modified acrylic ESFs in which 100% of the dogs and none of the cats developed an FAC.[28]

Implant failure had an overall incidence of 9%, representing 41% (n=12) of all complications. It was the most common FAC in the tarsus (63% of tarsal FACs). Overloaded implants, either due to patient factors or inappropriate implant choice, are vulnerable to fatigue and failure.[5, 9, 29] In this series, the pin was the weakest part of the ESF construct, with pin breakage in six cats, two of which broke multiple pins. Interestingly, five of these six cats had a tarsal ESF and therefore the inclusion of transarticular tarsal ESFs in this study has given this complication a greater prominence. Other studies have also shown the tarsus as a common region for the development of FACs.[2, 12, 18] Tarsal ESFs are mechanically vulnerable being subject to significant transarticular bending forces as they cross the flexed tarsocrural joint. Relatively small pins may also have to be placed in the metatarsal bones, further increasing the vulnerability to mechanical failure. Interestingly there was a low rate of tarsal PTI, (13% of tarsal FACs), possibly relating to the limited soft-tissue envelop.

Load sharing between the bone and the fixator will undoubtedly alter the loading on the pins. Previous guidelines have advised that surgeons should aim to maximise load sharing between fixator and bone column.[21] A canine tibia study corroborated that pins holding unstable fractures had increased pin loosening.[30] In our study, the degree of load sharing was not associated with the development of complications, however specific fracture configuration is likely to have influenced the surgeon's choice of stabilisation and ESF configuration to account for this. The majority of cats in this study had non-load sharing constructs and that is likely to have been a consideration at the outset when planning the fixation method. Activity will also have a role on implant loading and complication development, however it was not possible to determine activity levels of each individual cat following discharge and this could have had an influence on complication development. All animals were discharged with similar instructions on restricted cage rest and exercise for the first 6-8 weeks, however exercise programmes thereafter may vary. Notably, ESFs placed at the pes, manus and combined mandible/maxilla frequently suffered from implant failure. Mandibular fractures can be stabilised using free form ESFs in cats which have the added advantages of providing low weight versatile

stabilisation.[28, 31, 32] Owen *et al* (2004) reported that in mandibular fractures stabilised with pins and either epoxy putty or acrylic, pin loosening was commonly observed at the time of ESF removal.[32] Due to the low overall numbers of fixators placed at these regions, the groups sizes are too small to infer substantial conclusions. Notably, the IMEX SK clamp system was used over the study period, and only one connecting bar coupling failure was identified, supporting both of their ongoing and versatile use in cats. However, it is acknowledged that mechanical degradation with clamp re-use is reported,[33] and we cannot comment on the exact number of re-uses of the clamps from this retrospective.

This study showed that pin loosening without infection was a rare complication occurring in only four cats. There are several important factors to consider when placing fixators pins to reduce pin loosening. The first factor is pin size, as the surgeon must balance the need to use a pin that is large enough to provide sufficient stiffness, but small enough to avoid leaving a critical size defect following pin removal.[21, 34] The conventional pin size recommendation is between 20 - 30% of bone diameter which should be accurately measured on preoperative radiographs.[21,11, 34] Even small pins of only 20% of bone diameter can cause a 38% reduction in bone strength. [35] Unfortunately, the surgeon must balance a safer, narrower pin diameter, against decreased construct stiffness and thus the potential for greater fracture instability, higher gap strain and impaired fracture healing.[21, 34] A further important factor is the number of pins placed. The most common number of pins in our study was six, with three pins placed in each fracture segment. Few fractures had the minimum of two pins placed per bone segment, and most were within guidelines of placing three to four pins per segment.[21, 34, 36] Increasing the number of pins increases the stiffness of the construct and hence reduces the loading placed on individual pin-bone interfaces. Pin number per segment was not shown to be significantly associated with the development of complications, however only two cats had one pin per segment and one of these developed a SPTI. With such small numbers, no firm conclusions can be made. We also acknowledge that method of pin insertion can also affect development of PTI, as it impacts on the pin-bone interface, critical for overall stability of the fixator. Inappropriate technique can lead to excessive heat generation resulting in thermal osteonecrosis and premature pin loosening.[21, 37] Animal studies have shown that bone undergoes significant resorption when heated to 50°C for 60 seconds or longer,[38] and pin insertion with a high speed drilling results in significantly higher bone

temperatures. It is therefore recommended that pins are placed at a slow speed (150rpm or less), as high speed placement reduces long term pin extraction forces when compared with low speed placement.[2, 21, 36, 37] A further technique factor is the forward drilling force, which can affect maximal cortical bone temperatures when drilling.[39] Again, this type of information was not available in a retrospective study. Pre-drilling a pilot hole prior to pin placement is also standard practice at this institution and has been shown to increase pull out strength by 13.5% when compared to direct pin placement.[40] Pre-drilling also reduces bone micro fracture damage to the entry and exit sites of both the near and far cortices.[40] The ideal sized pilot hole should approximate but not exceed the inner diameter of a positive profile pin. In veterinary medicine it is commonly recommended to use a drill bit 10% smaller than the pin diameter in combination with a drill sleeve to prevent soft tissue trauma.[2] The financial constrains in veterinary practice may influence the maintenance of good quality sharp drills, which may cause increased thermal damage when blunt.[41] An investigation into three commonly used drill bit reprocessing methods for 2.5mm drill bits compared reprocessed with new drill bits found cortical drill time was significantly greater in the reprocessed group compared to the new group.[41] It is therefore important that the surgeons should ensure the equipment is maintained.[21, 42] Irrigation has also been shown to be an important factor in keeping bone temperatures below critical, particularly with larger drill bits.[42] Another approach to maximise the pin-bone interface is to use threaded pins as they have increased pin-bone contact area and hence increased resistance to pull-out when compared with smooth pins.[21, 36]

Iatrogenic bone fracture was uncommon in this study, occurring in only 1% of cats. This serious complication usually has contributing factors such as multiple injuries, the presence of empty drill holes and inappropriate postoperative exercise restriction.[34]

A key feature of the ESF is its flexibility in design, and there are numerous frame configurations, implant types, sizes and materials available which can affect construct strength and stability.[43] The use of an IM pin was show to be associated with complication development, however the vast majority of IM pins used were in the femur and the humerus, which had a higher risk of FAC development. IM pins are commonly used at these sites to help fracture alignment and to improve resistance to bending.[27, 44] Their location of use will also be influence by the regional anatomy, as

some bones lend themselves to adjunctive IM pin fixation, such as the femur, humerus and tibia, however fracture configuration such as comminution will also be a consideration. It is important to note therefore that their risk association may be a surrogate marker for their usage in higher risk zones, or higher risk fracture configurations.

No other ESF feature including frame type, use of epoxy putty or clamps was associated with FAC development. Complications have previously been shown to be more common when more complex ESF frames are used.[5, 6] However in this study, no significant difference was seen between type I, II and III linear ESFs. Type I ESFs only utilise half pins in their frame configuration, compared to types II and III which contain full pins. As discussed, PTIs are more likely to develop when there has been significant soft tissue penetration and the use of half pins may minimises disruption.[11, 45] An effect of full vs half pin was not shown here, whereas the effect of region was. Notably the two most effected regions do not readily lend themselves to full pin usage, and this may have affected the impact of frame configuration type. The role of full vs half pins ideally needs to be compared in single anatomical regions, with sufficient case numbers, in a prospective manner. A caveat when comparing frame configuration data from this study to other situations is the manufacturer of the ESF components; as differing systems have variable bar radius, and clamp stability, leading to differences in frame stiffness, and bending resistance. Furthermore, the retrospective nature of this study means that surgeons were intentionally selecting a particular frame configuration for a particular fracture, and therefore the association of frame configuration with complications has to be viewed carefully.

This study was retrospective in nature, and multiple surgeons contributed cases over the study period, creating variation in case management and case selection. Detailed evaluation of the initial injury was outside the scope of this study and is likely to greatly influence choice of stabilisation and potentially FAC development. Likewise, intra-operative technical aspects of pin placement were not available for evaluation. The type and size of pins placed was also not consistently available for analysis and due to the referral nature of the caseload, under reporting of minor complications could have occurred.

Conclusions

This is the largest study to date, reviewing ESF placement and fixator complications in cats. The overall total complication rate in cats is moderate at 19%; however lower than in dogs. The cat therefore may be a better choice for ESF placement than dogs. Region of placement was significantly associated with complication development, with the femur being the most common site of FACs, and the complications seen there were dominated by PTIs. The next most common site of FACs was the tarsus where implant failures predominated. This difference is attributed to the differing conditions seen in these regions with a bigger soft-tissue mass and lack of safe corridors on the lateral femur, whereas transarticular frames in the tarsus are subject to high biomechanical bending forces and a smaller soft-tissue envelope. Special care should be taken with transarticular frames to ensure sufficient numbers and sizes of pins are used, and that type II frames may be preferable, but no firm conclusions from such as small group can be made. Frame configuration, pins per segment, open vs closed and degree of load-sharing did not appear to affect FACs, however it appears 'the rules' of external skeletal fixation were generally or assumed to have been abided by here. Being a retrospective study, confounding influences and factors such as pin placement technique were not available and may need consideration. However, it is entirely conceivable however that even when all the 'rules' are followed correctly, there will be a finite level of complications, mostly pin tract infections which relate to the nature of a transcutaneous implant. A prospective evaluation of pin designs used for similar fracture configurations from the same anatomical location is needed, and feasibly other strategies such as silver or hydroxyapatite coated pins may be required to reduce these complications further. On balance, ESFs can be successfully used to manage a range of complex injuries in a wide variety of anatomical locations and their use in cats appears to be better tolerated than in dogs. Further consideration should be given when considering placement in certain locations such as the femur and tarsus.

Legend

- **Table 1.** Additional ESF features

- **Table 2.** Additional ESF configuration association with fixator associated complications

- **Table 3.** Fixator associated complication development at each anatomical region

- **Figure 1.** Overall anatomic distribution of fixator placement

- **Figure 2.** Distribution of fixator associated complications

- **Figure 3.** Regional distribution of fixator associated complication types as a percentage of the

  overall fixator associated complications

- **Appendix 1.** Type of fixator associated complications by anatomical region

- **Appendix 2.** Fixator associated complication case details

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