1 **Postoperative Complications Associated with External Skeletal Fixators in Dogs**

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3 **L. Beever1; K. Giles1; R. L Meeson1.**

4 1Queen Mother Hospital for Animals, Department of Clinical Sciences and Services, Royal Veterinary College,

5 Hawkshead

6 Lane, North Mymms, Hertfordshire, UK

7

8 **Authors**

9 Lee Beever BVetMed (Hons), MRCVS

10 Kirsty Giles BVetMed, MRCVS

11 Richard Meeson MA VetMB, MVetMed, DipECVS, PGCertVetEd, FHEA, MRCVS

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16 **Running head**

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22 **Correspondence to:**

23 Richard Meeson MA VetMB, MVetMed, DipECVS, FHEA, MRCVS

24 The Royal Veterinary College

25 Queen Mother Hospital for Animals

26 Hawkshead Lane, North Mymms

27 Hatfield, Hertfordshire AL9 7TA

28 United Kingdom

29 Phone: +44 707 666 366

30 E-mail: rmeeson@rvc.ac.uk

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1   **Summary**

2   **Objectives:** To quantify and evaluate risks of complications attributable to external skeletal fixator (ESF) usage

3   in dogs.

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5   **Methods:** A retrospective review of medical records following ESF placement.

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7   **Results:** Case records of 97 dogs were reviewed; fixator associated complications occurred in 79/97 dogs.

8   Region of ESF placement was significantly associated with complication development (p=0.005), not

9   complication type (p=0.086). Complications developed most frequently in the tarsus (9/10), manus (8/9) and

10   humerus (8/9). Superficial pin-tract infection and implant failure occurred in 38/97 and 17/97 dogs, respectively.

11   Superficial pin-tract infection occurred frequently in the femur, humerus, radius and ulna and the pes, with implant

12   failure frequent in the tarsus and deep pin-tract infection in the manus and tibia. Transarticular frames were

13   significantly more likely to develop a complication (p=0.028). Age was significantly associated with complication

14   development (p= 0.029). No associations between breed, sex, weight, fracture type (open or closed), ESF

15   classification and the incidence or type of complications were identified. No associations between, breed, age,

16   sex, weight, fracture type (open or closed), ESF classification and the time to complication development were

17   identified.

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19   **Clinical significance:** Fixator associated complications are common in dogs, with the majority of complications

20   related to implant infection. Region and placement of transarticular frames should be carefully considered when

21   selecting stabilisation method.

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1   **<u>Introduction</u>**

2   External skeletal fixators (ESF) are commonly used for fracture stabilisation in veterinary orthopaedics and are

3   available in a variety of configurations. They can be used as either sole fixation or adjunct stabilisation for a wide

4   variety of conditions. Numerous reported advantages of ESF include, ease of placement, accessibility for open

5   wound management, ease of implant removal and reduced cost of placement with minimal requirement for

6   specialised orthopaedic equipment[1-4]. While improvements with surgical technique and equipment have led to a

7   decreasing frequency of complications over the last three decades, fixator associated complication rates remain

8   high[5], particularly implant failure and pin-tract infection[3, 6-11]. Development of fixator associated complications in

9   dogs has previously been up to 100% in some studies[9, 12].

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11   Although numerous published studies of specific ESF configurations at defined anatomical locations have been

12   reported, to the authors' knowledge, a comprehensive multiregional review of fixator complications has not been

13   undertaken. The aim of this study was to review postoperative complications directly attributable to the ESF

14   apparatus in dogs, specifically implant infection, implant failure and bone fracture, and to identify factors

15   associated with their development.

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Materials and methods

Medical records of dogs with an ESF placed between January 2007 and March 2014 at the Queen Mother Hospital for Animals were reviewed. The information in the records was reviewed in full for the entire period until the fixator was removed. The following information was gathered for each patient: signalment, ESF configuration, anatomical region, fixator associated complications and fracture type (open or closed). Patients were omitted if complete records were not available. Fixator configuration was determined from clinical records and radiographs, and categorised into four groups: linear, free-form, hybrid and circular. Specific ESF features also assessed included presence of a tied-in intramedullary pin, transarticular frame, A-frame configuration and the use of epoxy putty or clamp. Each ESF was assigned to one of nine anatomical regions (Table 1). If the fixator involved more than one region, they were classified according to the region of injury requiring stabilisation. Fixator associated complications recorded by the case clinician were identified from the medical records and were divided into four categories: **1)** Superficial pin-tract infection , including cases with associated pin loosening, **2)** Deep pin-tract infection, 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, breakage or bending of pins, breakage of connecting bars or clamp failure, and implant migration. Superficial pin-tract infection was diagnosed by presence of one or more of the following: **(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, localized swelling, redness or heat), or a positive response to antimicrobial therapy[13]. Deep pin-tract infections were diagnosed when the previously mentioned criteria were met and radiographic evidence of osteomyelitis or bone sequestrum was seen.

Commercially available statistical software was used to perform all statistical analyses [a]. Data were assessed for normality using the Shapiro-Wilk Test. Categorical variables were analysed using Chi-square 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 or closed) and time of fixator associated complication 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, with fixator associated complication development and the time of fixator complication. Relationships between age, weight and time of complication were assessed by Spearman's rank correlation. A $p < 0.05$ was considered significant.

Results

Review of the medical records from the specified period identified 119 consecutive dogs in which an ESF had been applied. From these cases, 22 were excluded due to incomplete medical records. Therefore, a total of 97 dog met the inclusion criteria. Age on presentation ranged from two months to 13 years (median two years). Body weight ranged from 2.1kg to 50.8kg (median 18.5 kg). Forty-five dogs were female (23 neutered) and 52 were male (23 neutered). Forty-one breeds of dog were represented, the most common being mongrels (n=20) followed by Labrador (n = 11) then Greyhound, (n=6). Of the 97 dogs, 67 had closed fractures and 30 open fractures. Overall the most common region of placement was the radius and ulna (20/97), as shown in Table 1. The majority of ESF were linear in 79/97 of dogs, of which 36 were type I, 42 type II and 1 was type III. The remaining fixators were free form in 12, circular in 4, and hybrid in 2 dogs. The majority of constructs used the IMEX SK clamp system[b] (81/97) with the remaining 16 using epoxy putty. Detailed ESF configuration results are summarised in Table 2. Of the 36 transarticular frames, two involved the radius and ulna, eight the manus and 13 the pes. All fixators involving the tarsus and stifle were transarticular. All transarticular fixators were non-articulating fixed angle.

Fixator associated complications occurred in 67/97 of dogs which had an ESF placed. Three dogs had two distinct complications over time; these were treated as separate complications giving 70 distinct complications. The time to diagnosis of complications ranged from 1 to 28 weeks postoperatively (median 5 weeks). Figure 1 shows the frequency of complications that developed; the most common being superficial pin-tract infection occurring in 38/97 dogs, followed by implant failure (17/97). Of these 38 dogs, 30 were radiographed to rule out deep pin-tract infection. Complications occurred in all nine anatomical regions, summarised in Table 1. Excluding regions with less than six dogs, region of placement was significantly associated with fixator associated complication development (p=0.005). The highest complication rates were recorded in the tarsus, humerus, manus, and pes as summarised in Table 1. However, region was not significantly associated with the type of complication that developed (p=0.086). Regional distribution of complication types is shown in Figure 2 with superficial pin-tract infection the most common complication in four regions, including the femur (2/2), humerus (6/9), radius and ulna (11/20), and the pes (9/17). Implant failure was the most common complication in the tarsus (5/10). Deep pin-tract infection was the most frequent complication in the tibia (3/17), manus (4/9) and stifle (1/3). Bone fracture occurred in only 1 dog with a fixator applied to the manus. This transarticular circular fixator had wires placed in the distal 1/3 of the radius leading to a fracture in the distal radius at the proximal wire tract when the dog jumped from a height. The wire occupied 28% of the bone diameter.

Age was significantly associated with the incidence (p=0.029) not the type (p=0.805) of complication that developed. The median age of dogs that developed a complication was 3 years (range four months to 11 years)

99   and those without a complication was 1 year (range three months to 13 years). No significant association

100 between breed, sex, weight, fracture type (open or closed) and the incidence or type of fixator associated

101 complication was identified. Similarly, there was no association between ESF type and the incidence (p=0.121) or

102 type (p=0.108) of complication.

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104 Of the frame features outlined in Table 2, only transarticular ESF design was associated with an increased

105 incidence of fixator complications however not the type of complication. The remaining features shown in the

106 table were not significantly associated with the incidence or type of complication that developed. Thirty-six

107 fixators were transarticular of which 29 suffered a complication in comparison to 38/61 frames with no

108 transarticular component. Anatomical region was the only factor significantly associated with time of complication

109 diagnosis (p=0.01). The shortest median time to diagnosis was in the femur at two weeks, followed closely by the

110 pes with a median of two and a half weeks and longest was the crus at 10 weeks. The three dogs that suffered

111 two separate complications had transarticular frames two at the pes crossing the tarso-metatarsal and intertarsal

112 joints and one at the tarsus crossing the tarsocrural joint. All three had both a superficial pin-tract infection and an

113 implant failure that occurred separately.

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Discussion

The most common type of ESF used was the linear ESF, of which the type I and II arrangements predominated. Radial and ulnar fractures were the most common location for ESF placement, which is unsurprising as the radius and ulna are reported to be the most commonly affected region of fracture in the dog[14]. The predominance of fixator use at this location also relates to the frequency of open fractures, the relative paucity of soft tissue and the ability to construct bilateral or biplaner frames[4, 5, 8, 11, 15].

The overall fixator associated complication rate in this study was high at 69% (67/97 dogs). Previously reported complication rates in canine populations are highly variable ranging from 5% to 100%[1, 8, 11, 12, 16, 17]. The vast majority of complications were superficial pin-tract infection followed by implant failure. While the complication rate in this study is comparable to previously reported canine complication rates, it is higher than those reported in cats ranging from 26%-50%[6, 18]. It therefore appears that dogs may be more likely to develop complications than cats, and this is something the authors have noted anecdotally. Region of ESF placement was significantly associated with complication development, however not the type of complication that developed (Figure 2).

Pin-tract infection remains one of the most significant complications of external fixation, compromising otherwise successful treatment. Infection can lead to increased patient morbidity, increased treatment costs and client frustration[13]. Superficial pin-tract infection was recorded in 38/97 dogs, this is similar to previously reported superficial pin-tract infection rates in dogs ranging from 13% to 58%[9, 15, 19]. Pin-tract infections are thought to occur when soft tissue penetration allows bacterial contamination of the skin to pin interface, leading to superficial pin-tract infection, which can progress to deep pin-tract infection, with associated bone lysis, pin loosening and osteomyelitis[10, 20, 21]. Additionally, implant surfaces enable biofilm formation allowing bacteria to evade the host immune response and antimicrobial therapy[22, 23]. Studies of the canine humerus and femur have shown an absence of clear, safe corridors for pin placement due to the complex regional anatomy with only limited safe corridors in the radius[24, 25]. This concurs with the results of this study showing superficial pin-tract infection as the most common complication in these regions. Interference with tendons and musculature may lead to additional discomfort, joint stiffness and decrease limb use, all of which may predispose patients to increased complications due to tissue morbidity and patient interference. While the overall complication and superficial pin-tract infection levels remain similar to other canine studies, direct comparison is fraught due to differences in study population, case definitions and study power leading to discrepancies when comparing studies[13]. Pin-tract infection and their prevention remains a difficult research area due to the multifactorial nature of surgical site infection. Various strategies of pin site care have been proposed in humans, however a recent Cochrane review suggested there was insufficient evidence to identify a strategy of pin site care that minimises infection rates[26]. Other reported risk

167 factors for small animal surgical site infection included gender, concurrent endocrinopathies, increased

168 bodyweight, duration of anaesthesia and surgical hypotension[27-29]. Importantly, it has been shown that the risk of

169 developing a surgical site infection in dogs following implant placement was 5.6 times that of dogs with no

170 surgical implants[29]. In this study however, when assessing complications, no association with body weight, or

171 gender was found, although anaesthesia duration data was not available. Despite the high frequency of

172 infections, ESF implants are readily removed and minor short term morbidity associated with superficial pin-tract

173 infection often resolves following antimicrobial administration and adequate pin care or removal[7, 17, 20].

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175 In our population complications were less likely in younger patients. A rat model of bone healing showed that, six

176 week old rats regained normal bone biomechanics at four weeks after fracture compared with one year old rats

177 requiring more than six months[30]. The speed of fracture healing will doubtless impact on both the duration of

178 fixator placement and the degree of load sharing, which affects load and duration of loading upon the implants.

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180 The manus and pes suffered from high complication rates with deep and superficial pin-tract infections

181 predominating respectively. It has been reported that pin-tracts of fixators used to stabilise the small bones of the

182 metacarpus and metatarsus are particularly problematic with two out of three dogs in one study developing

183 osteomyelitis[31, 32]. Similarly, the present study found that deep pin-tract infections were the most common

184 complication to occur in the manus. Deep pin-tract infections were also common in the tibia; the limited soft tissue

185 coverage over the medial aspect of the canine and feline tibiae make them particularly prone to complications

186 with fracture healing due to the poor extraosseous blood supply and reduced intramedullary blood supply in the

187 early stages following fracture[33, 34]. Interestingly, in an experimental model of canine pin-tract infection, the

188 infective agent in 88% of medullary canal cultures was also cultured from the skin[35]. Given the limited soft tissue

189 envelope in these regions and reduced vascularity it would seem logical that superficial infection could readily

190 progress to involve bone due to the close proximity of the bone to surface of the skin-pin interface.

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192 Implant failure occurred in 17/97 dogs and was common in the tarsus (Figure 2). The tarsus has previously been

193 shown as a common region for fixator complication development[9, 31], however reported tarsal fixator complication

194 rates vary between 15% and 74%[9, 36]. In our definition, tarsal ESF were transarticular, spanning the tarsocrural

195 joint, and indeed transarticular configurations are an independent risk for complication development. Clearly,

196 overloaded implants, either due to patient factors or inappropriate implant choice are mechanically vulnerable,

197 being subject to significant transarticular bending forces as they cross the flexed tarsocrural joint[11, 19, 20].

198 Additionally relatively small pins placed in the metatarsals, further increase mechanical vulnerability.

199 Reassuringly iatrogenic bone fracture was uncommon, occurring in only one dog. A case series of 11 dogs and

200 cats found that this complication usually had contributing factors including multiple injuries, the presence of empty

201 drill holes and inappropriate postoperative exercise restriction[37].

202

203 A key ESF feature is its design flexibility, with numerous frame configurations, implant types, sizes and materials

204 from which to choose[38, 39]. The only ESF feature associated with increased complications was the presence of a

205 transarticular frame, which may inevitably relate to the biomechanical requirements of a transarticular frame.

206 Complications have previously been shown to be more common when more complex ESF frames are used[6, 11],

207 however in this study no significant difference was found between type I, II and III linear ESF. This was surprising

208 as there was an expectation that increased frame complexity would be associated with increased complications,

209 due to greater soft tissue disturbance from increase pin penetration[3, 10].

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211 Several factors not evaluated in our study must be taken into consideration when discussing fixator

212 complications. The first is the method of pin insertion which influences the critical pin-bone interface. It is well

213 documented that inappropriate insertion technique can lead to excessive heat generation resulting in thermal

214 osteonecrosis and premature pin loosening[40, 41], particularly when bone is heated above 50°C for 60 seconds[42].

215 Canine models have shown that high speed pin insertion produces significantly higher bone temperatures and

216 therefore slow speed insertion is recommended (150rpm or less)[3, 40, 41, 43]. Insufficient axial force when drilling

217 bone can also significantly increase cortical bone temperatures[44]. Pre-drilling a pilot hole has been shown to

218 increase pin pull out strength by 13.5% and reduce cortical microstructural damage leading to bone resorption

219 and premature loosening [45]. The common recommendation in veterinary medicine is a drill bit 10% smaller than

220 the pin diameter[43]. Unfortunately, this information was not available to this retrospective study, however these

221 principles are typically adhered to in this centre. Another approach to maximise the pin-bone interface is to use

222 threaded pins[3, 40]. Threaded pins have increased pin-bone contact area and increase resistance to pull-out which

223 may significantly affect pin loosening and complication development. Finally, pin size and number influence the

224 pin-bone interface. A minimum of two pins should be placed per bone segment with the majority of authors

225 recommending three to four per segment[3, 37, 40].The conventional pin size recommendation is 20% to 30% of

226 bone diameter[40,10, 37]. Pin size is a balance between a pin that is large enough to provide sufficient stiffness but

227 small enough avoid leaving a critical size defect following removal[37, 40]. We should note here that even when all

228 guidelines are followed a degree of complications are expected due to the nature of a transcutaneous implants.

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230 This study has some limitations, particularly being retrospective in nature, with multiple surgeons contributing

231 cases, creating variation in case management and selection. Detailed evaluation of the initial injury, exact

232 surgical technique and the pin type used wasn't possible and must be considered when discussing complications.

233   We intentionally focussed on complications associated with the fixator *per se*, and further those that could be

234   confidently evaluated to provide robust information. The small sample size is some regions such as the stifle and

235   femur must also be taken into consideration when interpreting regional results and may lead to overestimation of

236   regional complication rates. Due to the referral nature of the caseload and lack of specific long term follow up

237   under-reporting of minor complications may also have occurred. Overall it is also important to acknowledge that

238   complication are multifactorial and a single causative factor is not always clear with multiple independent factor

239   interacting to result in complications. The only way to evaluate all factors fully would be to perform a large

240   prospective comparative study. Nonetheless, this represents a large overview of complications relating to

241   external fixators and is informative to the surgeon.

242

243   **Conclusions**

244   On balance, ESF complications are very common in the dog, however particular consideration should be given

245   prior to their usage in certain locations, including the radius and ulna, humerus and femur, which are prone to pin-

246   tract infections. Mechanical failure was not common except when used for transarticular tarsal stabilisation and

247   bone fracture was extremely rare. This study could not show an effect of fracture configuration, open or closed

248   nature, or frame design on the development of complications.

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Footnotes

- **a**- IBM Corp. Released 2012. IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp

- **b**- IMEX SK Linear External Skeletal Fixation System: IMEX Veterinary Inc., Longview, TX, USA

Table 1 Fixator associated complication development at each anatomical region.

Region	Number of dogs that developed a complication	Total number of fixators in region
Radius & Ulna	14	20
Tibia	7	17
Femur	2	2
Tarsus	9	10
Humerus	8	9
Mandible & Maxilla	4	10
Manus	8	9
Pes	14	17
Stifle	1	3

Table 2 Additional external skeletal fixator configuration details and association with complication development

Frame Feature	Total number	FAC developed	Incidence of FAC	Type of FAC
Tied-in IM Pin	9	7	P=0.574	P=0.088
Trans-articular ESF	36	29	*P=0.028	P=0.163
A-frame ESF	6	4	P=0.585	P=0.108
Epoxy putty	16	11	P=0.560	P=0.519

FAC-Fixator associated complication, IM- Intramedullary pin, ESF-external skeletal fixator, * values of P<0.05 are significant.
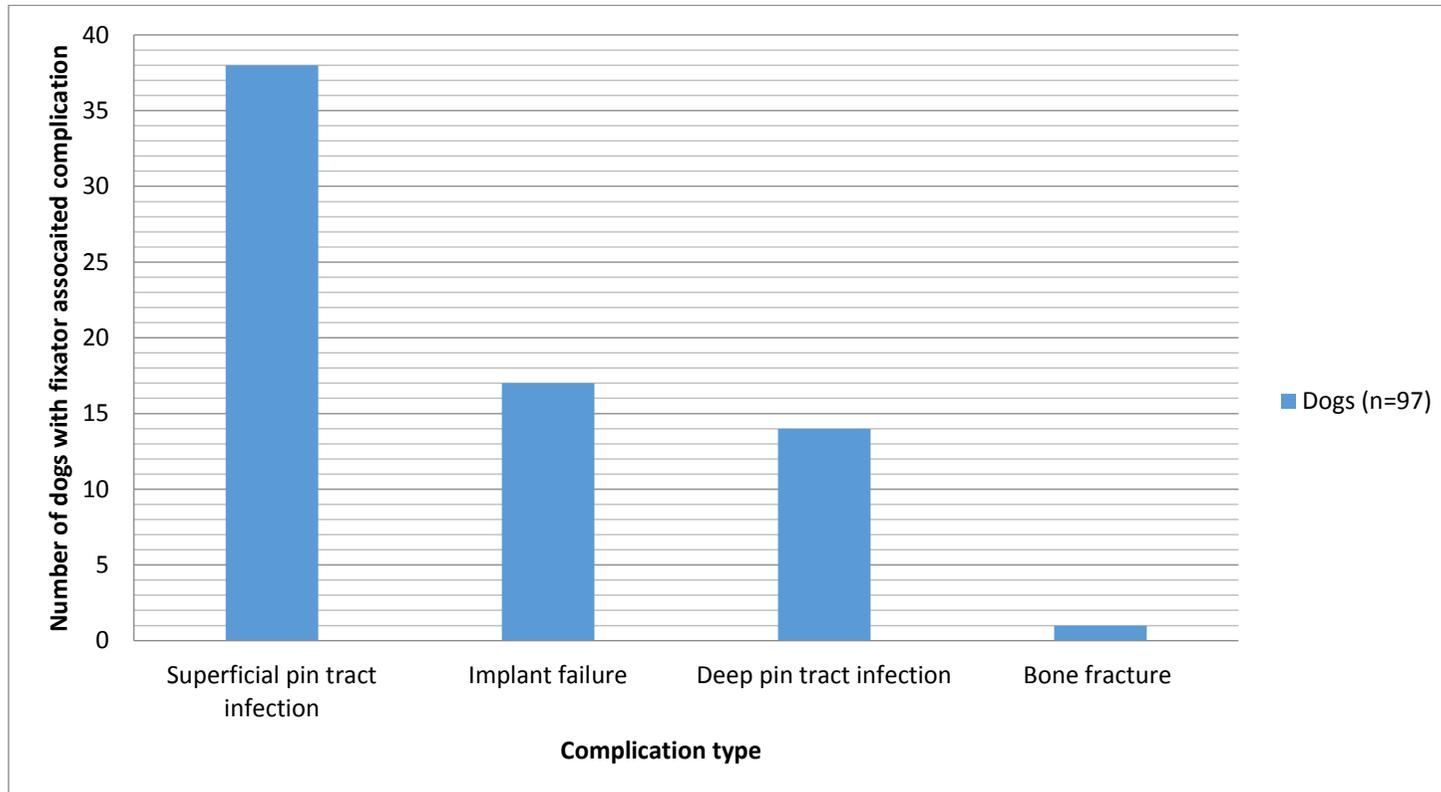
Figure 1 Distribution of fixator associated complications.
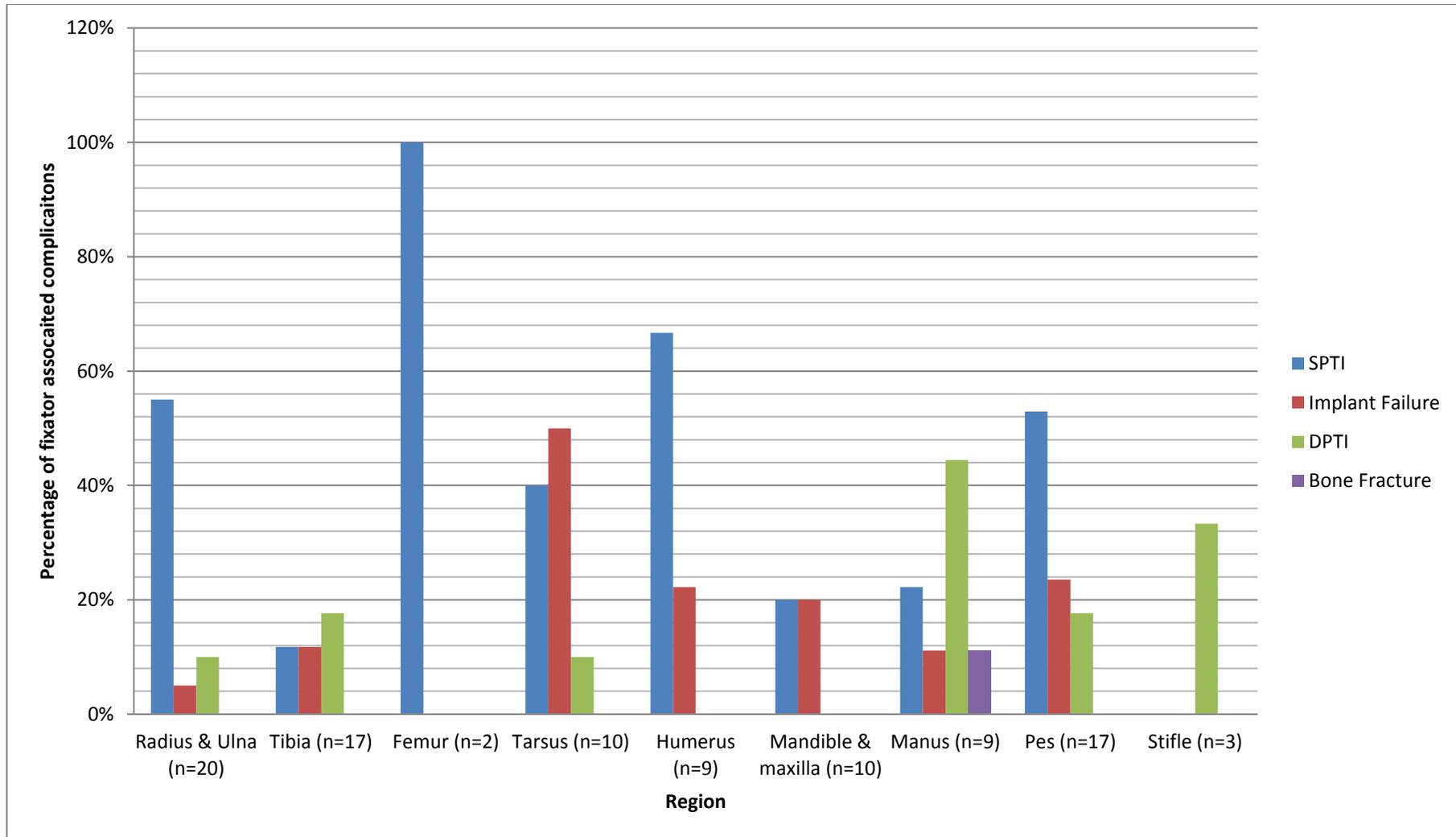
Figure 2 Regional distribution of fixator associated complication types as a percentage of the total number of fixators at each site.

SPTI- Superficial pin tract infection, DPTI- Deep pin tract infection