The use of absorbable staples for skin closure following tibial plateau levelling osteotomy (TPLO)

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Abstract

Objectives: To compare the use of stainless steel staples with absorbable staples for closure of skin incisions in dogs undergoing tibial plateau levelling osteotomy (TPLO).

Study Design: Prospective study.

Sample Population: Client-owned dogs (n=80).

Method: With client consent, dogs were randomly assigned a staple type (stainless steel or absorbable) immediately prior to incision closure, following TPLO. In addition to recording incision length, staple type and number, the incision was given an Inflammation-Infection score at the two weeks postoperative recheck.

Results: Inflammation-Infection score was not significantly different between staple groups. Overall, 18.8% of cases developed inflammation or infection. No significant difference was found between incision length, number of staples used or general anaesthetic time between the two staple groups, but time to closure was significantly longer in the absorbable staple group ($p<0.001$). There was a significant negative correlation between time taken to close the incision and the number of occasions that the absorbable staple method was used ($p=0.01$).

Conclusion: This study shows that absorbable skin staples can successfully be used to close skin incisions after orthopaedic surgery in dogs and do not lead to an increased level of inflammation or infection postoperatively.

Clinical Significance: Veterinary patients for whom surgical incision closure methods requiring subsequent removal are impractical may benefit from absorbable staples with no detrimental effect on the inflammation or infection rate of their wound.

Introduction

Tibial plateau levelling osteotomy (TPLO) is a commonly performed procedure for treatment of cranial cruciate ligament disease in dogs[1–4]. Reported complication rates range between 3.40% to 34.00%[5–11]. Wound-related complications such as swelling, irritation, bruising and haematoma formation at the surgical site have been reported and may contribute to significant patient morbidity, manifesting as pain and lameness[5,9–11]. Surgical site infection (SSI) rates following TPLO are higher than expected for clean orthopaedic surgery; reported incidence rates are between 0.00% and 18.80%[2,6,7,9,12–14]. Incisional seroma occurred in 0.80% of cases in one series of 1000 sequential TPLO surgeries between January 2004 and March 2009 with at least 6 month post-operative follow-up[2]. Another large case series found oedema or bruising at the incision site in 6.00% of cases, incisional site inflammation in 1.00% of cases and premature staple removal by the patient in 2.00% of cases, up to 14 days postoperatively[7] .

Tibial Plateau Levelling Osteotomy is performed through a craniomedial skin incision over the stifle[3], which upon completion of the surgery, is routinely closed using absorbable intradermal sutures, non-absorbable skin sutures or metallic skin staples. In human medicine there are conflicting reports of the benefits[15,16] and drawbacks[16] of using staples over suture material for closure of surgical incisions. Veterinary studies also have conflicting findings, reporting that inflammation and/or infection was both increased[17], decreased[14] or had no difference[18] when stainless steel staples were compared to suture material. In human medicine, reduced overall intraoperative closure costs and reduced closure times are often cited as an advantage of staples over sutures for closure of skin incisions[15,19,20], supported by findings in a randomised, controlled trial[21]. However, increased pain on staple removal compared to sutures has been reported in people[21]. Non-absorbable skin sutures and metallic staples have been shown to be of comparable mechanical strength when used to close a skin incision in an animal model[22].

In an effort to reduce surgical incision discomfort, inflammation and infection, absorbable subcuticular staples have been developed (Insorb® Absorbable Stapler, Incisive Surgical Inc., Minnesota, United States). Insorb® staples are made of a poly-lactic acid and poly-glycolic acid co-polymer, which are hydrolysed by bodily fluids and ultimately exhaled as carbon dioxide over a period of months, though 50% is absorbed by 10 weeks[23]. The initial strength of each single staple is 1.8lbf (100%), reducing to 72.22% of maximum strength a week later and 16.67% of maximum strength by 3 weeks postoperatively[23]. An *in vitro* biomechanical evaluation of the Insorb® stapler compared to metallic staples, nylon and polyglyconate suture material was carried out in equine skin[24]. They found that the Insorb® staples underwent significantly greater loading before first failure than the metallic staples, though both the Insorb® and metallic staples had weaker ultimate tensile strength than the nylon and polyglyconate. Failure occurred at loads of more than 30N and the authors concluded that this exceeded plausible tensile forces across a surgical incision in the ventral abdomen of a horse. When compared to metal staples, Insorb® staples have been shown to lead to comparable or improved levels of inflammation and infection at surgical incisions following both orthopaedic and soft tissue surgery in people[23,25,26].

The aim of this study was to compare the use of stainless steel staples with Insorb® staples for closure of skin incisions in dogs undergoing orthopaedic stifle surgery. We hypothesised that there would be no significant difference in incidence of inflammation or infection at the incision site between the two types of staple.

Materials and Methods

Case Selection

All surgeries were performed by a single surgeon between May 2011 and January 2013 at a single orthopaedic referral hospital. Cases were prospectively included if they were to undergo unilateral open stifle arthrotomy and TPLO and attended their two week post-operative recheck at the hospital. Those with evidence of pre-operative skin infections and those suffering significant intra-operative complications were excluded. For dogs who underwent bilateral simultaneous TPLO, one leg was randomly chosen, by flipping a coin, to be followed as part of the study. Included cases were randomly assigned to one of two groups by flipping a coin immediately prior to skin closure. Skin incisions were closed using stainless steel staples (Manipler®, Braun; Hessen, Germany) or Insorb® staples (Figure 1). Informed consent was given by all owners of dogs included. The study was continued until there were 40 cases with complete data sets in each group.

Surgical Procedure

All dogs received acepromazine (0.01-0.03mg/kg [Calmivet®, Vetoquinol, Buckingham, UK]) and methadone (0.2-0.3mg/kg [Physeptone®, Martindale Pharmaceuticals, Brentwood, UK]) premedication intramuscularly (IM) and anaesthesia was induced using propofol (Vetofol®, Norbrook, Corby, UK) followed by endotracheal intubation and maintenance of anaesthesia by isoflurane (Isoflo®, Abbott Laboratories, Abbott Park, Illinois, USA) in oxygen. Morphine sulphate (0.15mg/kg [Martindale Pharmaceuticals; Buckinghamshire, United Kingdom]) and bupivacaine (0.7mg/kg [Marcaine®, AstraZeneca; New South Wales, Australia]) were administered to the epidural space immediately preoperatively. Intravenous cefuroxime (10mg/kg [Zinacef®, GlaxoSmithKline, Brentford, UK]) was administered at least 20 minutes before the first incision and every 90 minutes until the end of skin closure. Following clipping and aseptic skin preparation, a craniomedial skin incision was made over the stifle and an open craniomedial stifle arthrotomy was performed to allow inspection of the cruciate ligaments and menisci. If present, meniscal injuries were treated by removal of the damaged portion and/or meniscal release. The joint capsule was closed with polydioxanone (PDS, Ethicon, Edinburgh, UK) before proceeding to the TPLO procedure which was performed as described in detail by Slocum and Slocum[3]. The surgical site was closed in two layers (pes anserinus, subcutaneous layer) using polydioxanone. The skin was closed with the staple type that the dog had been randomly assigned. Where Insorb® staples were assigned, forceps were used to lift 5mm of tissue at either side of the incision line and presented into the path of the stapler. The nose of the stapler was positioned over the incision directly below the grip of the forceps and the lever was squeezed until a click was heard, thus releasing a staple. A semi-permeable dressing spray (Opsite; Smith & Nephew, Canada) and light adhesive dressing (Primapore; Smith & Nephew, Canada) was used to cover the surgical site. Limbs were not bandaged postoperatively. Post-operative analgesia included administration of methadone (0.2-0.3mg/kg IM q4hr) for 24 hours following surgery and oral robenacoxib (2mg/kg q24hr [Onsior®; Novartis, Camberley, UK]), meloxicam (0.1mg/kg q24hr [Metacam®, Boehringer Ingelheim; Bracknell, UK]) or carprofen (2.2mg/kg q12hr [Rimadyl®, Pfizer; London, UK]) for two to four weeks. Postoperative antibiotics were not prescribed routinely. Patients were discharged with an Elizabethan collar (BUSTER collar; Kruuse, Denmark) and owners were advised to leave it in place until the two week post-operative re-examination.

Study Measurements

Recorded information included patient breed, age, sex and weight, total anaesthetic time (from induction to cessation of inhalation anaesthetic), total length of surgery (from first incision to end of closure) the time taken to staple the surgical site, the number of staples used and the length of the incision. During the postoperative discharge appointment, owners were instructed on how to notice clinical signs detailed in the Inflammation-Infection score and asked to report them, should they occur. At the two week re-examination, dogs were examined by a Veterinary Surgeon and assigned an adapted Inflammation-Infection score[27,28], described in Table 1. A photograph was taken of each closed incision immediately postoperatively and at the two week postoperative re-examination.

Statistical analysis

Data was collected in Microsoft Excel 2010 and exported to IBM SPSS Statistics 20 for analysis. A Kolmogorov-Smirnov test was used to assess the continuous variables for normality. Variables were compared using an Independent Sample T-test, Mann-Whitney U test, One-way ANOVAs and Kruskal-Wallis tests, depending on the normality of the independent variables and number of groups in the dependent variable. A Chi-squared/Fisher's Exact test was used to evaluate the relationship between the staple type and the presence or absence of complications between the two groups. For all analyses, p-values less than 0.05 were considered significant.

Results

Patient Signalment

Eighty dogs were prospectively recruited into the study, 40 in each staple group. Twenty-one breeds were represented; 13 (16.25%) Labradors, 10 (12.50%) Golden Retrievers, 9 (11.25%) Rottweilers, 8 (10.00%) Boxers, 5 (6.25%) Springer Spaniels, 2 (2.50%) of each Newfoundland, German Shepherd Dog, Dogue De Bordeaux, Chow Chow, Bernese Mountain Dog and Akita, 1 (1.25%) of each Staffordshire Bull Terrier, Pointer, German Short-Haired Pointer, Chesapeake Bay Retriever, Bulldog, Bull Mastiff, Border Collie and American Bulldog, and 12 (15.00%) crossbreed dogs. Thirty-eight (47.50%) dogs were male (11 entire, 27 neutered) and 42 (52.50%) dogs were female (9 entire, 33 neutered). Mean age was 64.61 months (SD = 34.44 months) and mean weight was 38.11kg (SD = 12.14kg). No significant difference was found for age or weight between the two groups.

Surgical Incision

Mean anaesthetic time was 207.53 minutes (SD = 46.93 minutes) and mean surgical time was 34.44 minutes (SD = 9.11 minutes). No significant difference was found between the two groups for length of anaesthesia or surgery. Median time taken to staple the skin incision closed was 22.50 seconds (range: 11.00 - 180.00) for stainless steel staples and 56.50 seconds (range 18.00 - 190.00) for Insorb® staples. Time taken to staple the incision closed was significantly greater for Insorb® staples ($p < 0.001$). The median number of staples used was 12.00 (range: 8.00 - 21.00) for stainless steel and 12.00 (range: 8.00 - 19.00) for Insorb® staples. No significant difference was found in the number of staples used between the two groups. Mean incision length was 74.77mm (SD = 13.12mm) and no significant difference was found between the two groups. Examples of incisions closed with stainless steel and Insorb® staples immediately postoperatively can be found in Figure 2. Table 2 gives details of tests carried out and their p-values.

Inflammation-Infection Score

Dogs were examined by a Veterinary Surgeon at a median of 14 days (range: 10-19 days) postoperatively. The two weeks post-operative Inflammation-Infection score for dogs in each group can be seen in Table 3. No significant association was found between staple groups for incidence of Inflammation-Infection (χ^2 (1, n=80) = 0.000, p = 1.00, ϕ = 0.32) or for the attributed Inflammation-Infection score (p = 0.330) using Chi-squared with Yates' continuity correction and Fishers tests, respectively. Overall, 18.80% (15/80) of cases developed some degree of inflammation or infection. The 5 dogs (6.25%) with an Inflammation-Infection score of 2 were all prescribed antibiotics; 2 of those dogs had swab samples taken of the wound discharge and both cultured positive for a bacterial infection; Staphylococcus pseudintermedius in one and Escherichia coli and Enterococcus in the other).

No significant relationship was detected between age, weight, total surgery time, time to close the incision, number of staples used or incision length and the Inflammation-Infection score. The total anaesthetic time was significantly different between Inflammation-Infection scores (p = 0.025) and, following Bonferroni post hoc tests for multiple comparisons, it was found that the total anaesthetic time for dogs with an Inflammation-Infection score of 1 was significantly lower than those scored 0 (p = 0.024), though this was not replicated between scores 0 and 2 or 1 and 2. Table 4 gives details of the univariate tests carried out and their p-values.

Discussion

This study found that there was no difference in inflammation or infection rates at two weeks postoperatively between incisions closed using stainless steel staples and Insorb® staples, and as a result we accept our null hypothesis. Overall inflammation and infection rates were 12.55% and 6.25% respectively, which are within the realms of previously reported rates for canine TPLO[3,6,7,9,10,12,14].

The main finding in this study is in agreement with one human study that found no difference in wound-related complications between stainless steel and absorbable staples when used to close Pfannenstiel caesarean incisions[29]. Additionally, a study using pig models with full-thickness abdominal wounds found comparable inflammation and infection parameters between stainless steel and absorbable staples[30]. Other human studies have reported less early and overall complications in wounds closed with absorbable staples compared to stainless steel staples, in cases of caesarean surgery[31] and total hip arthroplasty[23]. Finally, one study reported exposure of one or more absorbable staples in 5% of patients who underwent anterior abdominal dermatolipectomy, total circular abdominal dermatolipectomy, bilateral breast reduction, or bilateral mastopexy, the only complication type seen, compared to no complications when sutures were used[32]. No human studies have reported using absorbable staples in patients undergoing total knee arthroplasty or compared absorbable staples to stainless steel staples in surgery of the knee. As depicted in Table 3, 10% of dogs in the stainless steel staple group had an Inflammation-Infection score of 2, but only 2.5% of dogs in the absorbable staple group scored a 2. From these results, it seemed likely that a Chi Squared test would reveal a significant association between staple group and Inflammation-Infection score, but this was not the case.

Incision closure took, on average, more than twice as long when using absorbable staples than when using stainless steel staples, as seen in another study[29]. Time taken to close a surgical incision with the absorbable staples was negatively correlated with days spent using the new absorbable staple system (Pearson’s r = -0.38, n = 40, p = 0.01), likely attributable to increasing surgeon experience, as seen in another study comparing Insorb® absorbable staples to stainless steel staples in human patients[29]. No significant correlation was seen for the stainless steel staples (Pearson’s r = -0.21, n = 40, p = 0.203). The additional tissue handling associated with increased closure time may have been expected to increase incidence of inflammation and/or infection postoperatively, but this was not the case. In human medical studies, closure of a surgical incision with stainless steel staples has been found to be significantly quicker than compared to sutures[15,19–21,26] and so, despite a longer closure time with absorbable staples, it is likely that incision closure time is still within acceptable limits.

Total anaesthetic time seemed to affect the Inflammation-Infection score; dogs with an Inflammation-Infection score of 1 had a significantly shorter anaesthetic time than those that scored 0. The authors expect this is a spurious result, as it is not currently supported by the literature. Increased surgical time has been significantly associated with, or a significant risk factor in developing a postoperative infection[33–36], and one paper has found this link with total anaesthesia time too[35].

Limitations

Whilst this study was randomised and controlled, it was not blinded and subsequently, observer bias could have occurred during the re-examination process. The subjective nature of the scoring system used to score postoperative wounds could also have incurred some bias. Unfortunately, these results had low power ($1-\beta = 0.053$) meaning a larger population would be required to make confident conclusions. A follow-up time of 14 days could be insufficient to record all rates of inflammation or infection as there is a possibility that surgical site infections could manifest up to 30 days postoperatively, or up to 1 year for deep incisional infections[37]. Finally, the suspected surgeon learning curve that took place with the absorbable staples could have hidden a true benefit of the absorbable staples compared to stainless steel staples.

Conclusion

This study shows that Insorb® absorbable skin staples can successfully be used to close skin incisions after orthopaedic surgery in dogs and do not lead to an increased level of inflammation or infection for up to 14 days postoperatively. In future it would be beneficial to test this stapler with an experienced or practiced user, on different sites of veterinary surgery and with longer follow-up.

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Disclosure Statement

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Figure Legends

<u>Figure 1:</u> (A) Diagram showing how the Insorb® stapler closes a wound and (B) a picture of a single absorbable staple[1].

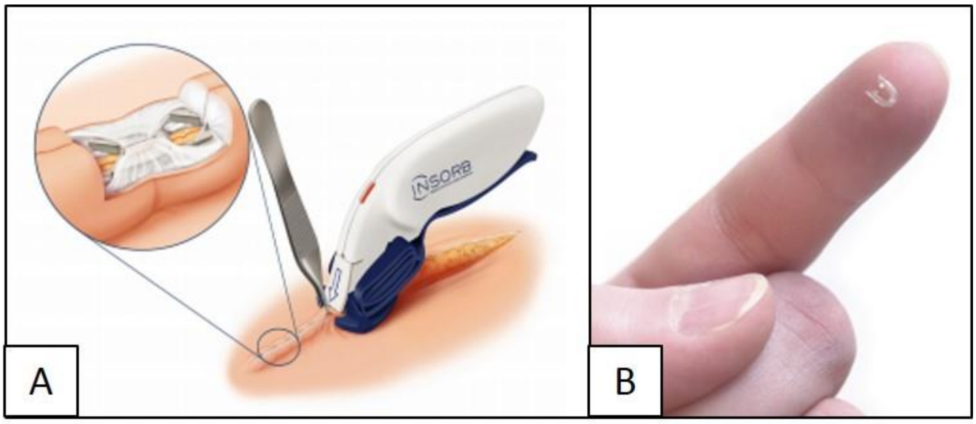

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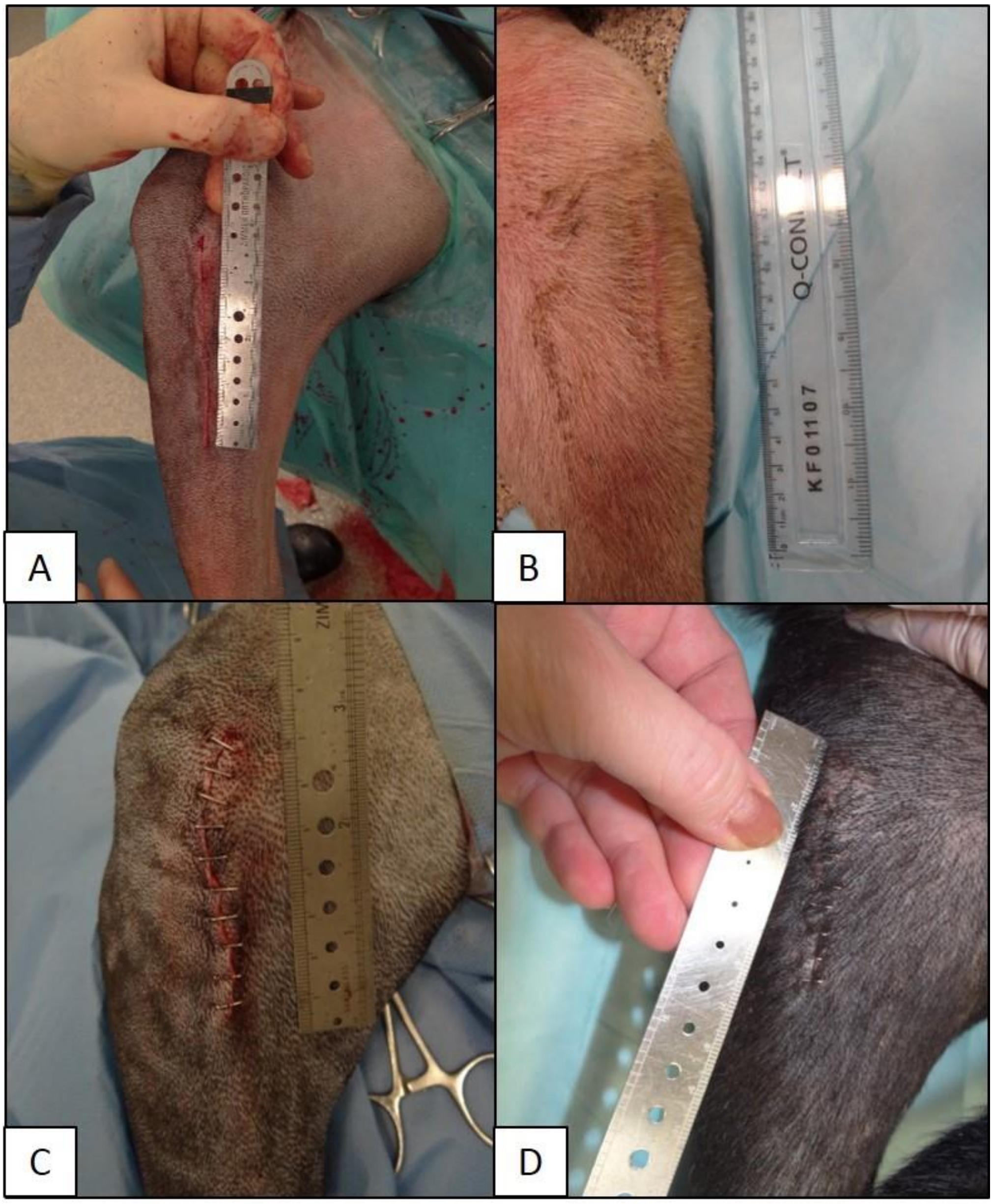
Figure 2: TPLO skin incision closed with Insorb® absorbable subcuticular staples immediately post-operatively (A) and at two week recheck (B) and a TPLO skin incision closed with Stainless steel staples immediately post-operatively (C) and at two week recheck (D). Both incisions received a two week post-operative Inflammation-Infection score of 0.



Tables

Table 1: Inflammation-Infection scoring system for the surgical incisions two weeks post-operatively.

Score	Clinical Signs
0	No signs of infection or inflammation beyond 48h post-operatively
1	Evidence/history of redness, swelling, heat, pain or serous discharge for >48h post-operatively
2	Evidence/history of surgical site breakdown/dehiscence, positive bacterial culture, serosanguinous or purulent discharge present for >48h post-operatively

Table 2: Summary table for all statistical tests to compare the stainless steel staple group and the Insorb® staple group.

	Stainless Steel Staples	**Insorb® Staples**	**Test**	**p-value**
Age (months)	60.58	68.65	Independent Samples T-Test	0.297
Weight (kg)	36.92	39.30	Independent Samples T-Test	0.385
Incision length (mm)	73.88	75.68	Independent Samples T-Test	0.543
Time to staple closed (s)	22.50	56.50	Mann-Whitney Test	>0.001
Number of staples used	12.00	12.00	Mann-Whitney Test	0.938
Total surgical time (min)	34.28	34.60	Independent Samples T-Test	0.874
Total anaesthetic time (min)	216.15	198.93	Independent Samples T-Test	0.101

Table 3: Inflammation-Infection score two weeks post-operatively for dogs in each staple group.

Score	Stainless Steel Staples	Insorb® Absorbable Staples
0	32 (80.00%)	33 (82.50%)
1	4 (10.00%)	6 (15.00%)
2	4 (10.00%)	1 (2.50%)

Table 4: Summary table for all statistical tests comparing Inflammation-Infection Scores.

	Inflammation-Infection Score			Test	*p*	Bonferroni Post Hoc Test		
	0	1	2			0 to 1	0 to 2	1 to 2
Age (months)	66.11	58.30	57.80	ANOVA	0.726	n/a	n/a	n/a
Weight (kg)	38.37	34.98	41.02	ANOVA	0.618	n/a	n/a	n/a
Incision length (mm)	75.12	71.10	77.60	ANOVA	0.594	n/a	n/a	n/a
Time to staple closed (s)	38.00	48.00	22.00	Kruskal-Wallis	0.304	n/a	n/a	n/a
Number of staples used	12.00	12.00	13.00	Kruskal-Wallis	0.722	n/a	n/a	n/a
Total surgical time (min)	35.29	31.50	29.20	ANOVA	0.197	n/a	n/a	n/a
Total anaesthetic time (min)	213.89	172.00	196.00	ANOVA	0.025	0.023	1.000	1.000