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## Safety of a novel piezoelectric extracorporeal shockwave device for use in dogs

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### Purposes:

The objectives of this study were:

1. Use the extra-corporeal shockwave therapy (ESWT) device on 5 dogs that have had tibial plateau leveling (TPLO) surgery and assess for any adverse effects associated with use of the device.
2. Determine whether dogs would tolerate use of the device without being sedated or anesthetized.
3. Compare bone healing between these patients and historical controls to determine whether a subsequent study might detect a statistically significant difference between control and treatment groups.

### Hypotheses:

- No adverse events would be suffered from use of the device.
- Some dogs, but probably not all, would tolerate use of the device without sedation or anesthesia.
- Bone healing would be more advanced in dogs treated with ESWT in comparison to the historical controls. However, no statistically significant evidence of efficacy or superior bone healing with use of ESWT would be identified, potentially due to type II statistical error.

### Methods:

Five dogs undergoing arthroscopy and TPLO had the device used immediately following surgery and at 2 weeks following surgery. The protocol for ESWT was to treat four quadrants around the surgical site as follows:

Craniomedial and Caudomedial areas:

Standoff: 10mm

Energy Flux Density (EFD): 0.17mJ/mm<sup>2</sup>

Number of Shock Waves: 1,200 per each area

Caudolateral and Craniolateral areas:

Standoff Focal Depth: 30mm

Energy Flux Density (EFD): 0.22mJ/mm<sup>2</sup>

Number of Shock Waves: 1,200 per each area

The treatment provided on the day of surgery was delivered while the dogs were still anesthetized (time 0). At time = 2 weeks treatment was performed without sedation. Orthogonal radiographs were made at 7 weeks post-operatively to assess osseous healing.

**Outcome measures:**

The following outcome measures were obtained:

1. Subjective recording of any adverse events by the owner in a booklet/diary and returned to the study coordinator at week 7.
2. Recording of the canine brief pain inventory (CBPI) by the owner pre-operatively, at 2 weeks post-operatively, and 7 weeks post-operatively.
3. Radiographs were assessed for osseous union using a 12-point scale, the same methodology previously used in a study assessing bone healing following TPLO.<sup>1</sup> The scores for bone healing for these 5 dogs at 7 weeks were compared to the scores obtained in that prior study (at 7 weeks post op) using an unpaired T-test.

**Results:**

- All 5 dogs successfully completed the study including 2 treatments with the device and with all owners providing recording of adverse events (ie the diaries), CBPIs, and radiographs obtained at 7 weeks as planned.
- Treatment was provided at 2 weeks post-surgery without use of sedation in all 5 dogs.
- There were no adverse events recorded by any owner, at any time point.
- Based upon the CBPI, all dogs improved by 7 weeks post-operatively. Note that higher score indicates more pain or dysfunction, except for the “Overall impression” question, in which a higher score indicates better overall quality of life:

Table 1. Mean CBPI Scores for the categories of “Pain”, “General Activity”, and a singular question on “Overall quality of life”. Means are reported (+/-standard deviation). Lower scores indicate less pain and lower impairment of general activity. A higher “Overall” score indicates a higher quality of life.

	Pre-op	2 weeks	7 weeks
Pain	20.8 (13.5)	11 (5.6)	2 (4.5)
Activity	31.6 (22.1)	16 (9.7)	2 (4.5)
Overall	3.6 (1.1)	3.8 (0.4)	4.8 (0.4)

- All dogs were subjectively meeting or exceeding expectations of the principal investigator at 7 weeks post-operatively in comparison to other dogs treated with TPLO.



- The mean radiographic score for the five dogs at 7 week post-operatively was 8.0 (2.75). The mean score of 60 previously evaluated dogs was 6.52 (2.23). The difference between these two was not statistically significant ( $p = 0.16$ ).
- A power analysis was performed to determine how many dogs would be needed per group for this difference to become statistically significant. With a difference of 1.5, a sample variance of 4.96 (the variance for the 60 dogs in the previous study), a one-tailed test, and alpha of 0.05, over 100 dogs per group would be needed.

#### **Conclusions:**

- The device was found to be safe in this small group of dogs with no adverse events reported.
- The device could be used consistently without sedating the patients.
- All dogs showed improvement over time based upon the CBPI.
- No statistical superiority in terms of bone healing in comparison to a historical control was demonstrated. However, this small study was designed as a safety without the intent to demonstrate efficacy. But, it seems that a study designed to demonstrate improved osseous union would either need a different radiographic scoring scale and/or a large number of dogs included in the study. This is in part because routine TPLOs already heal very well in terms of radiographic bone healing.

#### **Next steps:**

- Based upon these results, I think it is feasible to consider a study that assesses efficacy of ESWT in treating dogs with osteoarthritis, or treating dogs post TPLO. However, if the latter is done, the focus should be on clinical function and outcome, such as with pressure sensitive walkway, rather than radiographic assessment of bone healing.

#### **Literature cited:**

<sup>1</sup>Franklin SP, Burke E, Holmes SP. The effect of platelet-rich plasma on osseous healing in dogs undergoing high tibial osteotomy. PLoS One. 2017; May 16;12(5):e0177597. doi: 10.1371/journal.pone.0177597.