

AHT application for clinical research and ethical approval

Please read the accompanying notes before completing this form



1. Overview		Date:	15/11/2015
a) Title of project:	Outcome of caudal auricular axial pattern flaps used to close skin defects involving the head in cats and dogs		
b) Lead investigator:	Proot Joachim		
c) CSAS HOU Approval Name:	E-signature(s):		
d) Collaborator(s):	Felipe de Vicente		
e) Is it a Resident Project? (required for diploma exam credentials)?	Yes If 'yes', when does report/publication have to be completed by? 2018		
f) Grant funded by:	Not Applicable		

2. Details of the project

<p>a) Introduction</p>	<p>Introduction:</p> <p>The caudal auricular axial pattern flap is based on the sterno-cleidomastoideus branches of the caudal auricular artery and vein. This flap is described in dogs and cats and has been used for neck, facial area, dorsal head, and ear reconstruction^{1,2}. The flap is used to reconstruct wounds on the head and complications include seroma formation, severe edema, distal flap necrosis, and alterations in local hair color and direction of hair growth³. Flap survival has been reported as high as 85% in dogs but varies with length² and keeping the flap as short as possible may reduce this complication. Anecdotal evidence would suggest that the true survival rate is significantly lower and a larger case series is currently lacking in the literature.</p> <p style="text-align: center;">References</p> <ol style="list-style-type: none"> 1. Stiles J, Townsend W, Willis M, et al: Use of a caudal auricular axial pattern flap in three cats and one dog following orbital exenteration. <i>Vet Ophthalmol</i> 6:121-126, 2003. 2. Smith MM, Payne JT, Moon ML, et al: Axial pattern flap based on the caudal auricular artery in dogs. <i>Am J Vet Res</i> 52:922-925, 1991. 3. Spodnick GJ, Hudson LC, Clark GN, et al: Use of a caudal auricular axial pattern flap in cats. <i>J Am Vet Med Assoc</i> 208:1679-1682, 1996. <p>Aims/objectives: To describe the outcome of caudal auricular axial pattern flaps used to close skin defects involving the head and neck in cats and dogs and to identify factors associated with outcome.</p> <p>Hypothesis: The outcome of caudal auricular axial pattern flap is lower then previously described in the literature and cats have a more successful outcome then dogs.</p>
<p>b) Description of project</p>	<p>Study design: multi-center, retrospective case series</p> <p>Materials and Methods:</p> <p>Multi-center, retrospective case series.</p> <p>Medical records of specialist referral centers will be searched to identify cats and dogs that had a caudal auricular axial pattern flap for treatment of skin defects involving the head. Animals will be included in the study if the medical records are complete with sufficient descriptions of flap appearance for a minimum period of 2 weeks after surgery to allow outcome to be reliably assessed; animals will be excluded if partial graft take is recorded but no quantitative descriptions of percentage necrosis is available.</p> <p>The following information will be collected from the medical records: patient signalment, location of the skin defect, cause of the skin defect, time between injury</p>

	<p>and skin reconstruction, surgery and anesthesia times, peri-operative and postoperative antimicrobial administration, length and width of the flap, minor and major complications and final outcome of the flap. Flap outcome will be assessed by interpreting descriptions of flap appearance recorded in the medical records, such as percentage of viable tissue and similar descriptions relating to areas of viability or necrosis. For the purpose of the present study, flap outcome will be classified as successful if there was flap viability over $\geq 75\%$ of the original graft area 1 to 2 weeks after surgery and as unsuccessful otherwise.</p> <p>Major complications are defined as requiring revision surgery whereas minor complications do not require further surgical intervention.</p>		
c) Starting date:	January 2005	Likely duration:	July 2016
d) Proposed data analysis:	<p>Depends on the number of cases collected. If case numbers are low then no meaningful statistical analysis can be performed. If case numbers are sufficient, then binary logistic regression analysis can be performed to create a statistical model to predict the binary outcome measure (flap outcome) with species, age, sex, cause, time from injury to reconstruction as predictor variables in the equation. This model will enable the simultaneous examination of all the potential predictors of the outcome measure in a single analysis and allows for multiple testing without further adjustment of the significance threshold. Values of $P=0.05$ will be considered significant.</p>		
e) Proposed outcomes: (papers, talks, grants etc.)	<p>Results will be presented at AVSTS meeting or equivalent surgery meeting (ECVS, ACVS, BSAVA, VSSO, etc...) and will be submitted to peer reviewed journal thereafter.</p>		

3. Ethical considerations

a) Does the project involve any procedures which are not part of the animal's normal investigation or treatment?	No
c) If the answer to (a) is 'yes', detail these procedures below and explain the justification for including them.	
d) Is the project and/or procedures covered by the AHT Client Consent form?	Not Applicable
e) If not, and/or the samples are non-AHT Clinic collected, will you need a separate consent form for this work? If 'yes', please attach the consent form.	Not Applicable
h) Consent form and/or owner information sheet attached for approval.	Not Applicable
f) Does the project require any blood or tissue samples to be taken?	No
g) If 'yes', what are these samples and how will they be acquired?	
h) Are unlicensed drugs to be used in this project?	No

i) Have you applied or do you plan to apply for an Animal Test Certificate-S from the veterinary medicines directorate?	No
j) Independent person to contact if clients/owners are unhappy with the conduct of the study	
Ian Nicholson, AVSTS research Cooperative Coordinator.	

4. Project costs (CSAS applicants only)

a) Please itemise all costs for the project beyond normal clinical charges made to clients	£350 for statistical analysis. The authors will use an independent statistician (Mr. Paul Bassett for all statistical analysis).
b) Amount of funding requested from AHT	£0
c) Source and amount of other funding:	AVSTS

5. For internal use:

Clinical Research approval received?	N/A		
Comments:			
Suitability for external grant funding:	<input type="checkbox"/> Yes	<input type="checkbox"/> No	Sent to RMO: <input type="checkbox"/> Yes <input type="checkbox"/> No
Suggested funding body:			
Timeline:			
Signed by Clinical Research Coordinator:			
Ethics approval received?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		
Comments:	Approved 18 th December 2015		
Signed by the AHT Clinical Research Ethics Committee chairman:			