

## SUMMARY

The goal of the present study was to evaluate the efficacy of a 4-layer porcine small intestinal submucosa (Vetrix® BioSIS Multi-Layer ocular discs) used as single scaffold for the surgical treatment of deep corneal defects in cats and dogs. Lesions and after surgery outcome were rated with a clinical score.

## INTRODUCTION

We can define deep corneal defects as lesion with severe loss of tissue up to perforations. They are mostly caused by traumas, infections or may be subsequent to deep lamellar keratectomies. In the infectious and inflammatory forms the tissue loss is frequently exacerbated by the occurrence of collagenolysis which results in stromal malacia, or "melting". Surgical treatment of these lesions aims to replace lost tissue, providing a scaffold for corneal recovery and temporary giving mechanical resistance until healing. Extra-cellular matrices (ECMs) such as porcine small intestinal submucosa (SIS) have been widely used and described as bioscaffolds for the treatment of corneal lesions. Single layer SIS have been mostly used, with the disadvantage to provide often a deficient tectonic support and the need of additional conjunctival graft or third eyelid flap. The aim of this study is to describe the use of recently marketed 4-layer SIS as single scaffold for the treatment of deep corneal lesions.

## MATERIALS AND METHODS

Six dogs and two cats affected by deep corneal lesions have been included in the study. On all the patients a complete ophthalmologic examination has been performed including slit-lamp biomicroscopy. Clinical signs have been recorded, such as corneal transparency, neovascularization, depth and melting with a clinical score ranging from 0 to 3

SCORE	TRANSPARENCY	NEOVASCULARIZATION	DEPTH	MELTING
0	lost	Absent	less than 1/3	absent
1	greatly reduced	Scarce	1/3	scarce
2	mildly reduced	Moderate	2/3	moderate
3	slightly reduced	Intense	more than 2/3	severe

Table 1. Clinical score for evaluation of the lesions.

#	SPECIES	BREED	AGE	SEX	LESION	TRANSPARENCY	NEOVASCULARIZ.	DEPTH	MELTING
1	DOG	Deutscher Boxer	3y	FN	perforation	0	3	3	2
2	DOG	American Bulldog	3y	F	descemetocoele	1	2	3	2
3	CAT	European Shorthair	7y	FN	epibulbar melanocytoma	3	0	3	0
4	DOG	Bouledogue Fr.	1y	M	corneal ulcer	0	2	3	3
5	CAT	European Shorthair	12y	MN	corneal ulcer with perforation	0	1	3	2
6	DOG	Am. Pitbull Terrier	4m	F	perforation	1	0	3	1
7	DOG	Mongrel	2y	M	epibulbar melanocytoma	2	0	3	0
8	DOG	Bouledogue Fr.	3y	F	corneal ulcer	1	3	3	2

Table 2. Signalment and lesion scoring at pre-surgery examination.

All the procedures have been performed with the help of an operating microscope. In the eyes with ulcers and melting a keratectomy has been performed to remove the malacic tissue. In the patients with epibulbar melanomas, the masses have been excised by lamellar keratectomy. BioSIS plus has been rehydrated in sterile saline solution for some minutes and then cut 1 mm wider than the corneal defect. The graft has been sutured to the cornea with 4 simple interrupted sutures of at cardinal and then with a continuous suture in the remaining areas with 9-0 poliglactyne 910.

The post-operative therapies included topical tobramycin and ofloxacin three time a day for 5-7 weeks and systemic doxycycline ( 10 mg/Kg/ 24 hrs) for 20 days.

The patients have been rechecked after surgery at 7,14,21,28 days and further when possible. At each follow-up a complete ophthalmologic evaluation has been performed with the same clinical scores. In addition the entity of graft integration and the occurrence of complications have been recorded.

## RESULTS

The treated lesions in dogs were two deep corneal ulcers, one descemetocoele, two perforations and one limbal melanocytoma. In cats were one deep corneal ulcer and one limbal melanocytoma. In all the cases the BioSIS was applied successfully. Complications: in one case of perforation, partial collagenolysis occurred 7 days after surgery, but resolved with medical therapy. All the eyes were visual at the final examination with a good recovery of corneal transparency and only mild corneal fibrosis.

Tables 3 and 4. Clinical findings at follow-ups

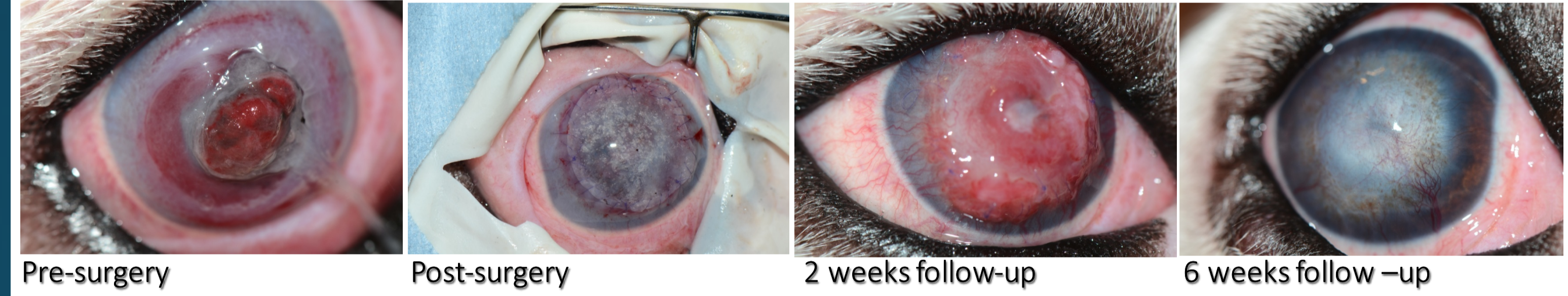
CASE	FOLLOW UP AT 7 DAYS				FOLLOW UP AT 14 DAYS				FOLLOW UP AT 21 DAYS			
	TRANSPARENCY	NEOVASC.	INTEGRATION %	COMPLICATIONS	TRANSPARENCY	NEOVASC.	INTEGRATION %	COMPLICATIONS	TRANSPARENCY	NEOVASC.	INTEGRATION %	COMPLICATIONS
1	0	2	50	Partial collagenolysis	0	3	100	no	0	3	100	no
2	0	2	70	no	0	3	100	no	1	2	100	no
3	2	2	70	no	2	2	100	no	2	3	100	no
4	0	2	50	no	0	2	70	no	0	3	90	no
5	0	2	50	no	0	2	70	no	0	3	90	no
6	1	2	50	no	1	3	100	no	1	2	100	no
7	2	1	50	no	1	2	70	no	0	3	100	no
8	1	2	50	no	1	3	100	no	1	3	100	no

CASE	FOLLOW UP AT 28 DAYS				FINAL FOLLOW UP			
	TRANSPARENCY	NEOVASC.	INTEGRATION %	COMPLICATIONS	TRANSPARENCY	NEOVASC.	INTEGRATION %	COMPLICATIONS
1	1	2	100	no	2	1	100	no
2	1	2	100	no	1	1	100	no
3	2	2	100	no	3	1	100	no
4	1	2	100	no	3	1	100	no
5	1	2	100	no	2	1	100	no
6	1	2	100	no	3	2	100	no
7	2	2	100	no	2	1	100	no
8	1	3	100	no	2	2	100	no

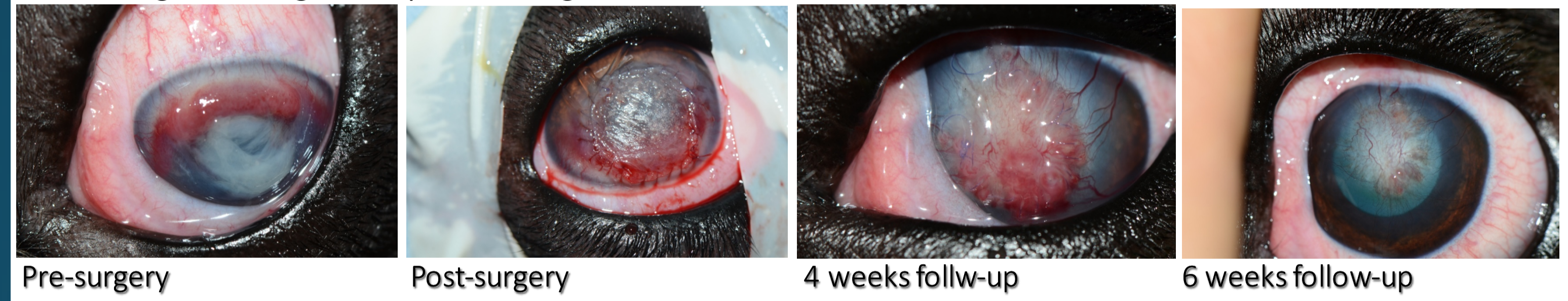
On average we can observe that BioSIS+ showed a complete corneal integration about 2-3 weeks after surgery with some differences from case to case depending on initial neovascularization of the cornea.

No other complications except those listed above occurred and no case of graft rejection was recorded. All the patients were visual at the last follow-up, with complete healing of the corneal defect. Corneal transparency improved significantly, with good regression of the scars and of the neoformed vessels.

Case1: dog, Boxer, 3y, FN. Traumatic perforation.



Case 4: dog, Bouledogue fr, 1y, M. Melting ulcer.



Case 5: cat, European Shorthair, 12y, MN. Perforated melting ulcer.



## DISCUSSION

In the examined cases BioSIS+ used as single scaffold showed a good versatility for the treatment of different kind of deep and huge corneal lesions.

In general the tectonic support was satisfactory with good maintenance of the anterior chamber conformation and no case of suture dehiscence. Also the integration of the graft and the regression of the exuberant neoformed tissue appeared to proceed quite likewise in all cases in terms of times and clinical presentation.

While the use of BioSIS+ in the cases reported showed to be effective, the results of this study support the further development and evaluation of this grafts in dogs and cats with deep corneal defects.

## CONCLUSION

These preliminary data suggest that the use BioSIS+ as single scaffold is a good alternative to the conventional conjunctival flap and single layer SIS for the treatment of deep corneal lesions. Further studies should focus in acquiring a larger number of cases with longer follow up.