

BIOCOMPATIBILITY AND PERFORMANCE OF AN INTERBODY RESORBABLE FUSION CAGE IMPLANTED IN FUNCTIONAL SITE IN SHEEP

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INTRODUCTION : The aim of the study was to evaluate by histology the performance, the biocompatibility and the degradation kinetic of a resorbable PLA 98 spinal cage following lumbar implantation in sheep.

METHODS : One resorbable PLA 98 spinal cage (Phusiline®, Phusis, France) was implanted per animal between L1 and S1 according to table 1. Undecalcified sections were performed for each implant. Qualitative and semi quantitative histological evaluations were performed.

Table 1: Study design -16 adult sheep

Time	3m	6m	9m	12m	24m	36m
Animal	3	3	2	3	3	2
Implant	3	3	2	3	3	2

RESULTS : After 3 months, early signs of degradation of the cages (fragmentation) were detected. In addition, adaptative changes to the local biomechanical conditions were detected. No signs of osseointegration of the implant were detected at this time period. No signs of resorption were found. Early signs of bone ingrowth in the cage were observed.

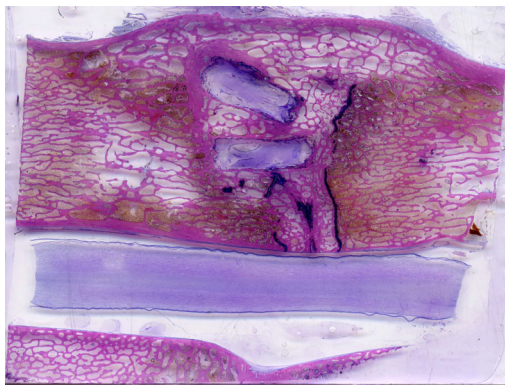


Fig. 1: 24 months: interbody osseous fusion within and outside of the resorbable cage. Major degradation of the implant material with modification of the pH (basophilic affinity to the bluish Giemsa dye) and hollow structures formation (white areas.). Macroscopic picture. Paragon staining.

After 6 months, osteogenesis and bone remodelling around the implant progressed. At this time period

signs of biodegradation and bioresorption were both visible. In some cases, the first microscopic signs of bone fusion were found, mostly around the cages.

Nine months after implantation, fragmentation and erosion of the implants progressed.

Osseointegration was found in several areas of the implant. In 50 % of the cases, microscopic spinal fusion was visible, outside of the cages.

After 1 year, 30 % of the initial implant volume resorbed and was replaced by a trabecular bone. With regard to the implant degradation, cell penetration within the implant was observed. Actual signs of interbody arthrodesis were observed both within (30 %) and outside (100 %) of the cages.

At 2 years, the implant resorption progressed and the implant fragmentation was almost total (Fig.1). Almost 70% of the cases showed osseous fusion within and outside the cage whereas in all cases, bone fusion was observed externally to the device.

Three years post-implantation, the remaining implant was totally resorbed and replaced by bone marrow or connective tissue showing a few bridges of trabecular bone tissue. A complete intervertebral arthrodesis was observed at this stage for all of the cases.

DISCUSSION & CONCLUSIONS : For all time periods considered, no local signs of intolerance was observed around the implant. The tested device allowed early fusion in the selected preclinical model. When actual fusion occurred within the implants, it was demonstrated that approximately 30 % of the implant volume degraded and resorbed. In spite of the low osteointegration of the device observed at early times, total implant material resorption and complete arthrodesis were obtained after 3 years of functional implantation in sheep. These results confirmed the capability of the implant to degrade without impairment of the device performance. Use of this resorbable spinal cage may be a valuable alternative to metals and non-degradable materials¹.

REFERENCES

¹D.S. Brodtkle et al (2002) J Spinal Disord Tech 2002 **15**:206-212.