

Osseogenetic collagen complex as an effective graft alternative in experimental posterolateral lumbar spine arthrodesis

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INTRODUCTION: Spinal fusion has been used since the late 19th century. Two frequently applied techniques are anterior interbody fusion and posterolateral intertransverse process fusion. Posterolateral lumbar intertransverse process arthrodesis is the most common procedure performed. Autogenous bone is considered the golden standard for bone graft material used for spinal arthrodesis. Unfortunately, morbidity associated with autograft harvest may occur in as many as 25-30% of patients. Currently, there are several competitive strategies either to augment healing or to replace autogenous bone graft in the spine. These include biologically active bone void fillers with growth factors derived from animal bone.

METHODS: COLLOSS E by OSSACUR AG is a bone void filler extracted from the extra-cellular matrix of cortical diaphyseal equine bone. It is a lyophilisate in collagenous matrix form, consisting of Type I collagen chains with other insoluble proteins present. It is supplied in 20 mg vials. 12 New Zealand immune competent, white rabbits underwent single level, posterolateral intertransverse process arthrodesis bilaterally at L4-L5, using COLLOSS E alone or in combination with either a titanium mesh cage, a PEEK cage, a TCP block or a stent filled with COLLOSS E. The animals were divided in four group and were euthanized 6 weeks after surgery, the lumbar spines were excised, and the fusion assessed by manual palpation, radiographs, and CT.

RESULTS: Manual fusion status: In group A and B fusion success was achieved in 75% (3 out of 4 rabbits). In group C and D only the animal with COLLOSS E combined with a stent developed a spinal fusion, whereas the 2 rabbits with TCP plus stent failed to fuse.

Radiography and CT: Imaging of group A showed a very good bone formation in 75%, except one animal which completely failed to develop a spinal fusion. Using 6 or 12 vials of COLLOSS E did not influence the radiographic fusion mass.

Similar results were observed in group B, where in 50% of fusion sites a very good bone formation was seen. In group C and D, 2 of the 3 animals with stent implants and both rabbits with TCP blocks developed moderate bone masses (2+ and 3+).

DISCUSSION & CONCLUSION: Autograft bone is considered to be the most osteogenic graft material in spine fusion surgery.

These problems have prompted the search for bone graft substitutes to achieve spinal fusion [1]. DBM derived from human allograft is effective as graft

extender and enhancer in the rabbit model of posterolateral lumbar spine fusion with fusion success rates of up to 100% [2,3]. Early studies with recombinant BMPs and purified BMP extracts were successful in a variety of rodent models, yet early clinical trials in humans resulted in disappointing outcomes.

Recombinant BMP-7 has demonstrated variable success in rodents, recombinant BMP-2 has demonstrated consistent success, and an bovine-derived mixture of BMPs has also led to spinal fusion in a rodent and monkey model, as well as in humans in 94% [4]. As promising as their results may be, dose relationships, carrier substrates, possible antibody formations, and unknown long-term outcome may provide continued challenges, and the high manufacturing cost may further preclude routine clinical application.

The data of the current study show favorable results of COLLOSS E in supporting spinal fusion in combination with the titanium mesh and the PEEK cage. The success rate of spinal fusion was 88% (7 of 8 animals) according to the radiological findings and 75% (6 of 8 animals) according to manual fusion criteria. These rates correspond to data when autografts or DBM are used in the rabbit model.

The presented data have to be seen as a pilot study with a relatively small sample size. Further studies may be conducted to investigate the use of COLLOSS E in conjunction with spinal implants.

COLLOSS E is effective in supporting new bone formation and in achieving a spinal fusion with comparable success rates as autografts. These results suggest the feasibility of COLLOSS E to support bone growth without the need for a second site bone graft harvest or internal fixation.

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