Evaluation of elasticity and barrier function of synthetic resorbable membrane for Guided Bone Regeneration

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1 INTRODUCTION

Membrane is a key material for the GBR approach. We have developed a synthetic poly (L-lactide-ε-caprolactone) bilayer membrane (PBM, Cytrans® ElaShield) with elasticity and extensibility, and launched it in Japan in August 2020. PBM is composed of two-layer structure, one is a solid layer , the other is a porous layer. A solid layer possesses a dense structure which shows a barrier function. The porous layer allows the deposition of extracellular matrix and promotes osteoblast proliferation and angiogenesis. Furthermore, the porous layer possesses a sparse structure that exhibits the elasticity and extensibility of the membrane.
The barrier function of PBM has been evaluated, but the barrier function in the extended state has not been evaluated. Therefore, the aim of this study was to evaluate the barrier function of PBM in the extended state. In addition, we evaluated the elasticity of various membranes including PBM.

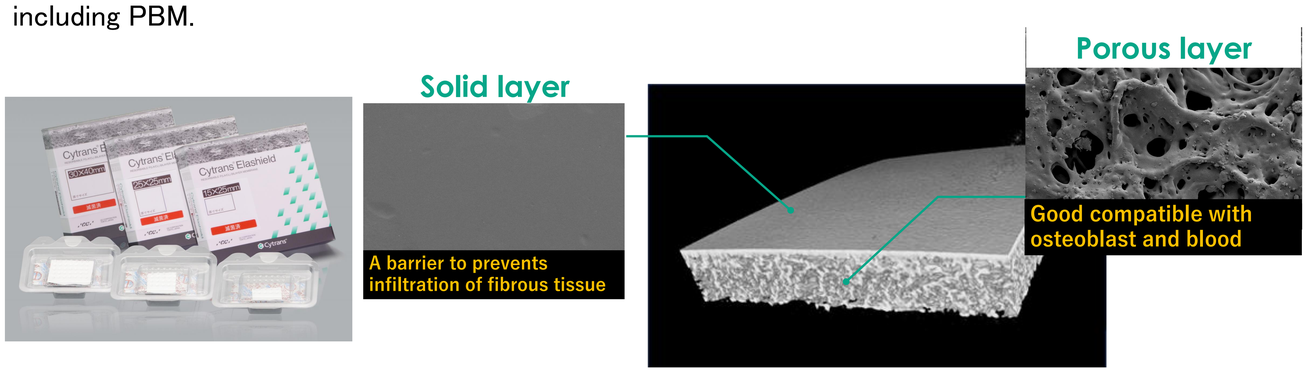


Fig.1. Cytrans® Elashield and its structure

2 MATERIALS & METHODS

Materials

Test sample:
Cytrans Elashield (PBM)

Control sample:
PLGA membrane (PM), Collagen membrane (CM)

Methods

【Tensile strength test】

Tensile strength was measured by using universal testing machine (CR-500DX, SUN SCIENTIFIC CO.,LTD) . Test specimen (2 mm × 15 mm) was fixed with jig, tensile strength was measured at cross head speed of 20 mm/min until the specimen was broken.

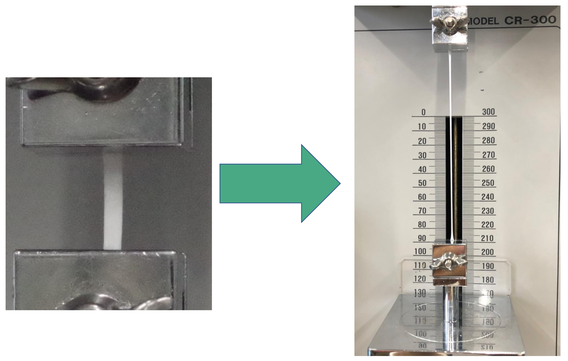


Fig.2. Tensile strength test

【Micro-crack evaluation】

The barrier function was evaluated by observing micro-cracks in the surface structure with scanning electron microscope (SEM) when PBM was stretched.
The stretched length is 2 to 5 times the original length.

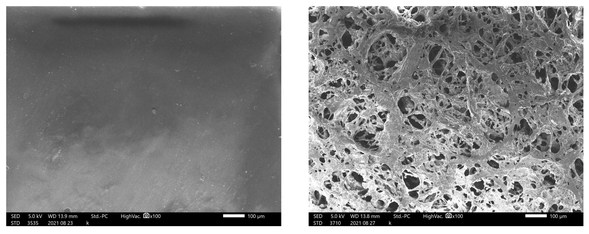


Fig.3. SEM image of membrane surface structure
(Left : Solid layer, Right : Porous layer)

3 RESULTS

【Tensile strength test】

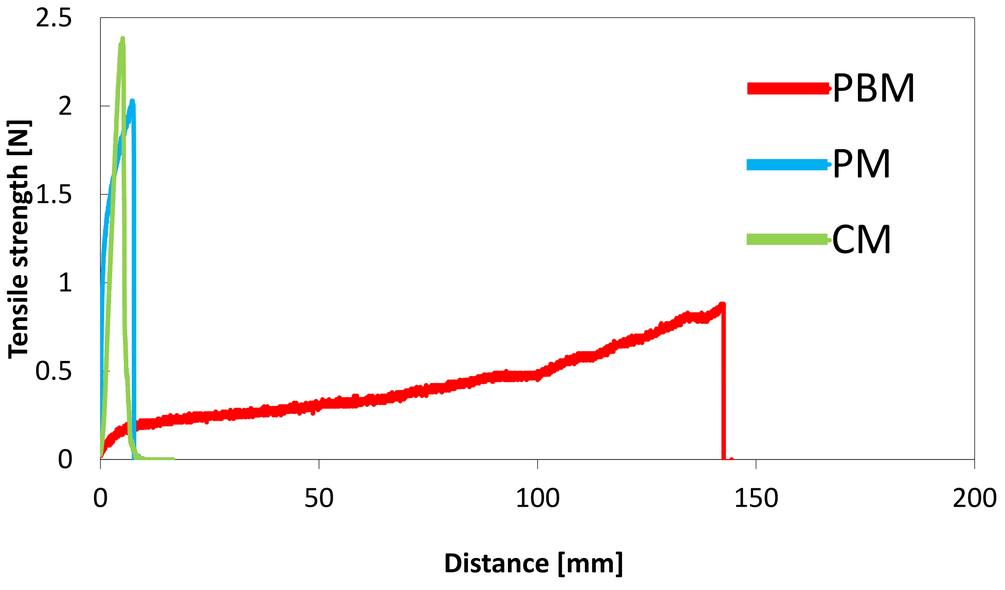
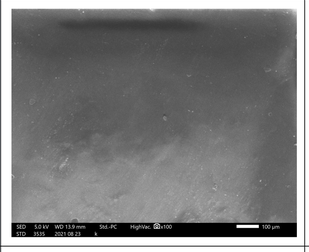
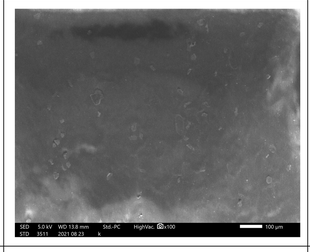
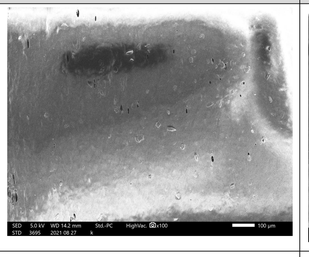
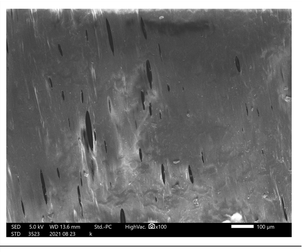
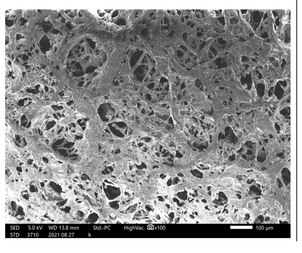
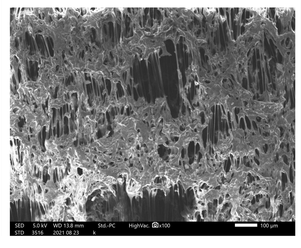
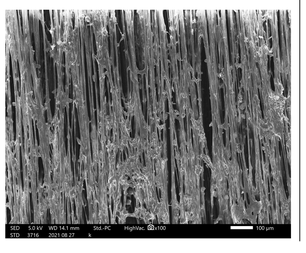
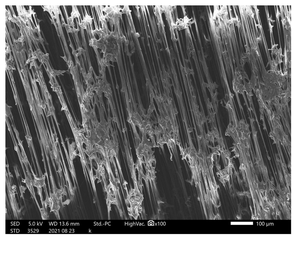


Fig.4. Tensile strength graph

PBM showed elastic characteristic and was broken at longer distance. On the other hand, PM and CM was broken at short distance before they were stretched twice, not showed elastic characteristic.

【Micro-crack evaluation】

Table. 1. PBM surface structure and tensile magnification

Tensile magnification	×1	×2	×3	×5
Solid layer				
Porous layer				

No micro-cracks were observed in solid layer even if PBM was stretched up to twice, suggesting that the barrier function works. However, solid layer had cracks when it was stretched up to 3 times. In addition, when stretched up to 5 times, large cracks were formed in solid layer. From this result, when PBM is stretched more than 3 times, micro-cracks occur in solid layer and barrier function to prevent infiltration of fibrous tissue may not work sufficiently.

4 DISCUSSION

From the result of tensile strength test, it was considered that PBM can be used without broken even if it is stretched according to the defect form. PM and CM may be broken when stretched according to the defect form, and it is required for how to apply force when using.

From the observation of SEM images, no micro-cracks were observed when PBM was stretched up to 2 times. It was thought that cells do not pass through PBM and PBM works as a barrier. Clinically, it is usual unlikely that PBM will be used by stretching it more than 3 times. Even if it is stretched, it will be up to twice, and it can be said that the barrier function of solid layer works sufficiently. However, since the barrier function such as cell invasion has not been evaluated, it is required to evaluate the practical barrier function in the future.

5 CONCLUSION

PBM has more elasticity than other resorbable membranes. It shows that PBM is hard to broke at clinically use. In addition, it was demonstrated that PBM can exert sufficient barrier function even if it is stretched to clinically use.