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Application News

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Material Testing System

Tensile Testing of Cultured Epidermis

Introduction

Various research institutes and businesses have been developing regenerative medical products*1 in the recent years in order to facilitate the spread of regenerative medicine. Since quality control is crucial for regenerative medical products, various material[1][2] has been issued by the Pharmaceuticals and Medical Devices Agency (PMDA) which conducts reviews. Although the issued material calls for dynamic evaluations in addition to biological evaluations, they do not include a description of specific evaluation methods. Dynamic evaluation was conducted upon transplanting iPS cell-derived retinal pigment epithelial cell sheets, but the evaluation method was no more than qualitative, consisting of only checks for damage at the time of graft preparation.[3] However, quantitative evaluations will likely be necessary for cell sheets[5] which require mechanical strength such as cultured skin sheets[4] and myocardial cell sheets. Furthermore, unlike the current regenerative medical products using autologous cells, it is possible that regenerative medical products using allogeneic cells[6], which are expected to become mainstream in the future, will be required to observe specification tests based on quantitative quality standards.

In this research, tensile tests were performed using cultured epidermis, which is a regenerative medical product, and milk membrane imitating cultured epidermis (collected from the surface of hot milk) as an example of a quantitative evaluation of a material's mechanical properties.

*1 Regenerative medical products are items created by processing human or animal cells for reconstructing, repairing, or forming body structures and functions or for treating or preventing diseases.

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Measurement System

Table 1 and Table 2 indicate the system composition and information of the specimens respectively. Fig. 1 shows a cultured epidermis specimen. The tests were performed using milk membrane imitating cultured epidermis (dummy specimen) and two types of research-purpose cultured epidermis (A and B)*2 with differing firmness made by using the same method as that for autologous cultured epidermis JACE®. The thickness of cultured epidermis specimens was less than 100 µm and the structure of the specimens consisted of a few layers of epidermal cells. Specimens were flexible and kept moist by soaking in preservative solution. The specimens therefore had to be mounted and measured quickly during the tensile tests in order to maintain their moistness. Fig. 2 is a picture of the test. Cylindrical sponges are used for the fixture. By wrapping a specimen around these sponges, specimens can be held during the test without damaging them. Table 3 shows the test conditions. The test speed was set to a low speed within the speed range in which specimens remain moist.

*2 Provided by Japan Tissue Engineering Co., Ltd.

Table 1 System Composition

Testing system	EZ-LX
Load cell	10 N
Test fixture	Tensile test fixture for cultured epidermis

Table 2 Specimen Information

Dimensions	50 mm × 100 mm Thickness of less than 100 µm
Types	Milk membrane Cultured epidermis A Cultured epidermis B

Table 3 Test Conditions

Test speed	20 mm/min
Test environment	Room temperature

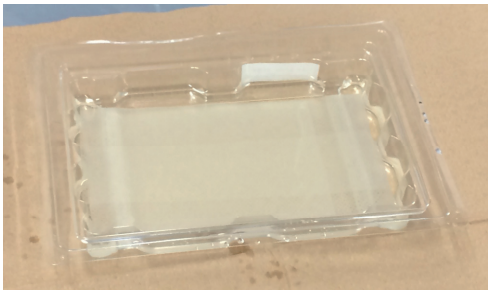

Fig. 1 Cultured Epidermis

Fig. 2 Picture of the Test (Milk Membrane)

Test Results

Fig. 3 shows the load-displacement curves. Table 4 indicates the maximum load applied to each material and the slope of the linear portion of the curves. The maximum load applied to a material indicates the strength of the material and therefore the higher the value, the more robust the material is. The slope of the linear portion of the curve indicates compliance and thus the flexibility of the specimens. A clear difference between cultured epidermis A and B was confirmed regarding the maximum load applied. Although there was some variation among the slopes of the linear portion of the curves on the graph, no significant difference was observed between the cultured epidermis specimens.

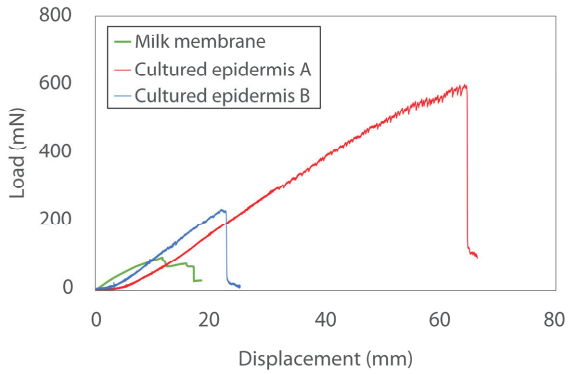

Fig. 3 Load - Displacement Curves

Table 4 Test Results (Average)

Specimen	Maximum load [mN]	Slope of the linear portion [mN/mm]
Milk membrane	95	10.2
Cultured epidermis A	579	13.1
Cultured epidermis B	237	12.6

Conclusion

In this research, tensile tests were performed using cultured epidermis, which is a regenerative medical product, and milk membrane as an example of a quantitative evaluation of a material's mechanical properties. We were able to perform successful tests and to confirm the difference between two types of cultured epidermis specimens by using our newly developed tension test fixture for cultured epidermis.

Our evaluation system enables evaluations of the mechanical properties of regenerative medical products and is suitable for the development and evaluation of regenerative medical products.

References

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