DEVELOPMENT OF A NOVEL MEMBRANE FOR GUIDED TISSUE/BONE REGENERATION

E. Pirhonen, T. Pohjonen and J. Nieuwenhuis
Inion Oy, Lääkärinkatu 2, 33520 Tampere, FINLAND (eija.pirhonen@inion.fi)

Introduction:

The principle of guided tissue regeneration (GTR) using a barrier membrane has been used in treatment of periodontal defects for almost 3 decades [1]. More recently the principle of GTR has also been used in guided bone regeneration in various other indications, for example to treat bony defects in dental implantology and also in other areas in the skeleton [2]. So far several non degradable and degradable membranes have been developed. The design criteria for optimal GTR/GBR membranes is slightly controversial since the membrane has to be malleable so that it can be placed onto the contoured 3D surfaces. But it also needs to provide stiff coverage on top the defect in order to maintain the defect space, so that the blood clot under the membrane is stable, as this allows optimal healing of the defect. Until now the optimal design criteria for GTR/GBR membrane has not been achieved. The aim of this study was to develop a membrane which would be malleable enough to enable easy remoulding of membrane, but at the same time would full fill the criteria of space maintenance.

Materials and Methods:

The polymeric film, composed of polylactide, polyglycolide and trimethylene carbonate was first extruded and further compression moulded into a thickness of 0,2 mm. Thereafter film specimens, with a width of 10 mm, and a length of 50 mm were cut from the compressed film. In order to make the film malleable, the films were plasticized with "dipping" method, which was developed within this study. In this "dipping" method the plastic specimen was first immersed into N-methyl-pyrrolidone solution (NMP) for 25 seconds, thereafter the specimens were allowed to stabilize for approximately 30 minutes.
The tensile testing was performed with Zwick Z020/TH2A universal materials testing machine. Gauge length of 30 mm and tensile speed of 20 mm/min were used. The specimen were either tested in room temperature (initial) or tested in water bath at +37 C after specified immersion time (immersion into phosphate buffer solution at + 37 C).

Results and Discussion:

With the developed "dipping" method stiff polymeric films were transformed rubbery and easily mouldable. As soon as the plasticized film was in contact with watery solution the rubbery films stated to become stiff again, as in a watery solution plasticizer diffuses out from the polymeric film. Stiffening effect is dependent of the immersion time and after 30 minutes the maximum stiffness is reached (See figure 1.).

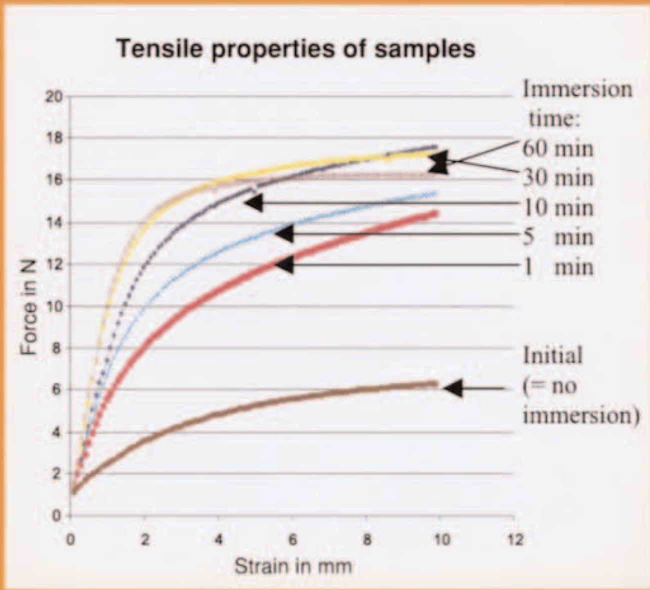

Figure 1. *Tensile properties of plasticized samples after immersion into phosphate buffer solution. The average curves from 4 parallel measurements are shown.*

Guided bone regeneration relies primarily on four principles: exclusion of unwanted tissues and cells, space creation and maintenance, protection of underlying blood clot and wound stabilation [3]. The developed membrane has initially good malleability and the optimal placement to cover the defect area is obtained easily. After being in contact with body fluids the membrane does start to stiffen up and forms a stable coverage over the defect.

Conclusions:

A novel functional barrier membrane was developed. Initially the membrane is malleable and enables optimal placement. When brought in contact with body fluids, the membrane stiffens up forming a good goverage over the defect.

References:

[1] J. Gottlow, S. Nyman, "Barrier membranes in the treatment of periodontal defects" *in Current Opinion in Periodontology 1996, 3:140-148.*
[2] J. Van Reck "Self-Reinforced PGA Membranes in Maxillo-Facial Surgery". In Self-Reinfoced bioabsorbable polymeric composites in surgery, Eds. P.Rokkanen, P. Törmälä. Tampere 1995, pp.435-460.
[3] S. Kay, et. al. "Guided bone regeneration: integration of a resorbable membrane and bone graft material" *in Pract Periodontics Aesthet Dent. 1997 Mar; 9(2): 185-94.*