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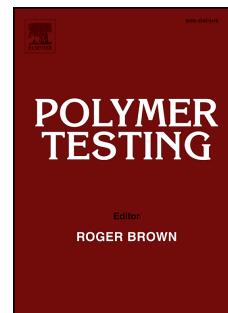
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Product Performance

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ABSTRACT

It is estimated that 15.000 to 20.000 breast augmentations are performed annually in Germany and several million worldwide. To obtain better knowledge of the reason for and the time of a possible failure of the implant shell, it is important to acquire information regarding the stability and durability of the material used and the associated failure criteria. The mechanical properties of silicone elastomers have, therefore, been investigated with regard to breast implants. Sample strips of the elastomer of various thicknesses were prepared and exposed to a cyclic bending load for a number of load cycles. Tensile specimens were punched out according to a defined pattern from the preloaded sample strips and tested with regard to their tensile properties, particularly the influence of cyclic loading on the stress at break. However, as quality of a silicone implant depends, not only on the strength of the material, but also on the spatial variation in the mechanical properties the quality of the silicone samples was also assessed in terms of the characteristic stress at break and the Weibull modulus, applying Weibull statistics to the tensile test results. The study revealed that the characteristic stress at break remained constant with increasing number of load cycles, but that the Weibull modulus decreased exponentially during the first 10.000 cycles to a critical level.

Keywords: Silicone breast implants; failure; mechanical properties; mapping

INTRODUCTION

Silicone-gel-filled implants are nowadays commonly used for breast augmentation or reconstruction following mastectomy. The implants are made of polydimethylsiloxane (PDMS) and consist of a highly crosslinked silicone shell and a lesser crosslinked silicone gel inside. Improvements have been made in both device design and manufacturing technology over the years. Nevertheless, long-term reliability is still doubted and neither the causes nor the incidence of prosthesis failure are yet clearly defined. It is estimated that worldwide more than 15 million women are carrying breast implants. In recent studies rupture and leakage in up to 63.5 % of breast prosthesis have been reported after an implantation time varying from 1 to 25 years.¹ In general, the longer the implantation time, the greater the risk of rupture.²

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