

差圧特性の機能性評価による 医療用正流・逆流バルブの技術開発

Development of Medical Valve Technology Based on Functionality Evaluation of Differential Pressure

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The object of this study was to develop technology for a valve to be mounted in a disposable medical device and obtain highly robust technical information before the product planning stage. The valve had two opposing functions: to limit the amount of blood flowing backward into a needle when the needle is inserted into a blood vessel; and when medicine is administered, to allow the prescribed amount to flow forward without resistance into the subject's body. The basic function of the valve was defined in terms of input and output, the input being fluid pressure (blood pressure or medicine pressure), the output being the differential pressure on the two sides of the valve. Experiments were performed after assignment of noise factors. To increase the efficiency and reduce the cost of the experiments, they were carried out on a scaled-up version of the contemplated product. The two opposing functions were optimized simultaneously by finding their mutual S/N ratio. The valve was thereby developed in one-fourth the time spent on previous valves, and at one-fourth the cost.

Key words: technical development, medical valve, functionality evaluation, differential pressure, Taguchi methods, quality engineering, parameter design, S/N ratio, test piece, robust engineering information, process task visualization chart

1. 研究の目的と概要

医療機関において,医療の質を向上させ安全性を 担保することは重要な課題であり,医療従事者の安 全管理や医療事故の未然防止に対する関心は高い。 使い捨て医療機器に求められる医療従事者のニーズ は、代表的なインシデントである針刺し損傷や血液 暴露による職業感染を予防することである。

本研究の目的は、使い捨て医療器に搭載するバルブの要素技術開発を先行して行い、商品企画前にロバスト性の高い技術情報を獲得することである。

研究対象バルブは、血管に針を刺した時に流出 (逆流) する血液量を抑制し、かつ投薬時は指示し た量の薬液を抵抗なく体内に投与(正流) する2つ

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