Available online at www.sciencedirect.com
ScienceDirect
Journal of Cleaner Production 16 (2008) 1764–1776
Journal of Cleaner Production
www.elsevier.com/locate/jclepro

Development and environmental improvements of plastics for hydrophilic catheters in medical care: an environmental evaluation

Håkan Stripple [a,*], Robert Westman [b], Daniel Holm [b]

[a] IVL Swedish Environmental Research Institute, Aschebergsgatan 44, P.O. Box 5302, SE-40014 Gothenburg, Sweden
[b] Astra Tech AB, P.O. Box 14, SE-43121 Mölndal, Sweden

Received 28 June 2007; received in revised form 22 November 2007; accepted 3 December 2007
Available online 28 January 2008

Abstract

Single-use medical devices have been under close scrutiny for several years, especially the choice of plastic materials. Many different requirements such as medical safety, treatment functionality and efficiency, environmental performance, etc. have to be fulfilled. Today, the most commonly used materials for hydrophilic urinary catheters are polyvinylchloride (PVC) and thermoplastic polyurethane (TPU). In this research study, these two materials' environmental performance was evaluated. In light of the knowledge gained in that study a new plastic material for use in urinary catheters was developed. The aim of the development of this new material was to design a high performance material with superior environmental performance. The newly developed plastic material is a polyolefin-based elastomer. The ecological environmental performance of the new material was evaluated and compared to the existing plastic materials. The study focused exclusively on the choice of plastic materials and their ecological environmental performance.

The analysis has been performed using a system perspective and a life cycle assessment (LCA) methodology. The functional unit has been set to the treatment of one patient during one year. The results from the LCA models have been presented both in terms of direct inventory data, such as energy use and formed emissions, and in terms of the results from four different impact assessment methods. Analysis of the results based on direct inventory data, i.e. common inventory results such as energy resource uses and emissions of CO_2, NO_x and SO_2 show an overall better environmental performance for the new polyolefin-based elastomer compared to the existing PVC and TPU plastic materials. The normalization and weighting steps in the analyzes have indicated the importance of energy resource uses and global warming as indicator for the environmental performance even if other impact categories also can play a role. In the environmental impact assessment, the polyolefin-based elastomer showed a clearly better environmental performance than the TPU material. Compared to PVC plastic material the new polyolefin-based elastomer showed an almost equivalent environmental performance. This can be mainly explained by the different materials' energy use. The new material has thus also shown to be an environmentally good alternative to PVC if a PVC-free material is requested. Basing the plastic formula, on simple bulk plastics with low energy use in the production of single-use medical devices, has been shown to be a successful method of producing high quality products with superior environmental performance.

Keywords: Environment; Disposable articles; Medical care; Medical device; Plastics; Hydrophilic urinary catheter; Single-use catheter; Astra Tech; Lofric; Intermittent catheterisation; PVC; TPU; Polyolefin; LCA

1. Introduction

The endeavour towards a more sustainable society with low environmental impact affects most of industrial production processes and products. Single-use disposable products have been under close scrutiny for their environmental impact and different studies investigating the possibilities to replace single-use products have been initiated. However, single-use products have many advantages compared to other products, especially for medical devices. They are often easy to handle and offer an easy solution to a common problem.

For medical devices, single-use disposable devices offer additional and essential advantages. Risk of infection and

* Corresponding author. Tel.: +46 31 725 62 00; fax: +46 31 725 62 90.
E-mail address: hakan.stripple@IVL.se (H. Stripple).

0959-6526/$ - see front matter © 2007 Elsevier Ltd. All rights reserved.
doi:10.1016/j.jclepro.2007.12.006

sterilization requirements often make the use of recycled products in medical care impossible. Disposable products are therefore used very frequently in medical care and offer safe medical treatment. However, medical materials are also subject to environmental requirements and ambitions to improve their environmental impact. Medical devices have many different requirements to fulfill, such as medical treatment performance and technical functionality, handling and operational performance, medical/patient safety, environmental impact and cost efficiency. All of these aspects have to be weighed against each other and optimized.

Astra Tech is a large producer of medical devices with a world-wide market. The environmental aspect is of major concern for Astra Tech and an important factor in the development of new products. The aim of the present research work was to establish a base for the internal choice of material in the production and to show the environmental performance for the different alternatives. However, ecological aspects are complex and require advanced handling methods. In order to be able to analyze the present product situation and to design new products with high environmental performance, it is important to establish a method for evaluating the environmental impact. For this purpose, IVL Swedish Environmental Research Institute carried out the present study.

In this study, we analyzed the environmental performance of three different plastic materials for urinary catheters. These three plastic materials represent a bulk plastic material (polyvinylchloride, PVC), a high quality performance plastic (thermoplastic polyurethane, TPU) and a newly developed plastic material based on the experiences from the present environmental evaluations (a polyolefin-based elastomer). In this article we show how the material selection for a product and the development of a new, environmentally improved, material can be based on LCA results.

2. Description of the product group

A urinary catheter is used as a standardized treatment method for intermittent emptying of the bladder, e.g. for patients suffering from urine retention. The surface structure of the catheter is of special importance and designed to avoid damage to the urethra. Historically, uncoated catheter tubes in combination with low friction gels have been used. Later, catheters with a hydrophilic coating were developed. However, these hydrophilic catheters carry with them a significant risk of osmotic dehydration of the surface coating. To counteract dehydration of the surface coating and thus secure low friction throughout the entire procedure, a hydrophilic surface coating with salt was developed. This was first achieved with LoFric™ catheters equipped with Urotonic™ Surface Technology. The surface structure and coating varies for different materials in the catheter tube. A modern coating process, however, reduces friction between the urethra and the catheter by 90–95%. This considerably reduces the discomfort for the patient and minimizes the risk of trauma and complications.

The physical and chemical properties of the plastic material used in the catheter tube are other important design aspects. Some essential properties for plastic materials used in hydrophilic catheters are listed below:

1. The catheter must be flexible but without a tendency to kink when bent.
2. The material must not break, i.e. have acceptable mechanical strength.
3. The material must tolerate the sterilization process.
4. The material must be compatible with the chemical coating process.

These constraints considerably limit the choice of materials. The choice of plastic material is thus of great importance for the product's functionality and overall behaviour.

The product in this study is a single-use hydrophilic catheter used in hospital medical care and for home treatment of patients. The main function of the product, besides the medical treatment, is to offer patients a comfortable therapy, efficient treatment and a safe product. The urinary catheter consists of a catheter tube and a connector that can be connected to a urine collection bag. The tube and the connector are welded together. Fig. 1 shows a picture of a typical urinary catheter.

The physical geometry of the product and the surface structure are of great importance for the product's functionality. The catheters are produced with different diameters (charrière 06-24) and different lengths (15, 20, 30 and 40 cm) to fit varying patient requirements. The charrière number is three times the outer diameter of the catheter tube, measured in millimetres. The two most common catheter tips are Nelaton and Tiemann.

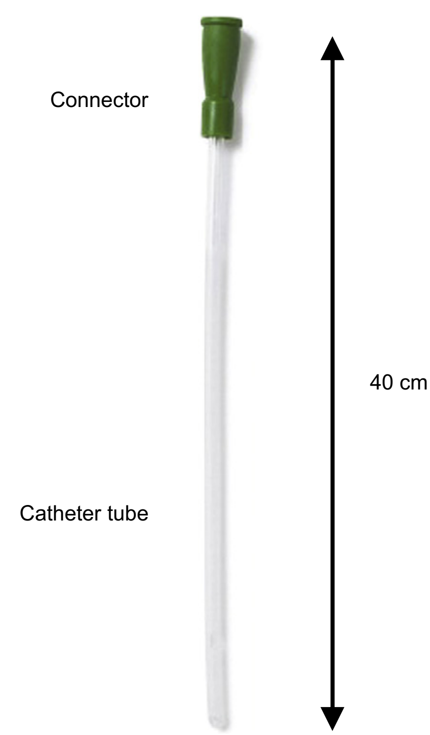

Fig. 1. The picture shows a typical design for a urinary catheter.