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Review Article

The use of polyurethane materials in the surgery of the spine: a review

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Abstract

BACKGROUND CONTEXT: The spine contains intervertebral discs and the interspinous and longitudinal ligaments. These structures are elastomeric or viscoelastic in their mechanical properties and serve to allow and control the movement of the bony elements of the spine. The use of metallic or hard polymeric devices to replace the intervertebral discs and the creation of fusion masses to replace discs and/or vertebral bodies changes the load transfer characteristics of the spine and the range of motion of segments of the spine.

PURPOSE: The purpose of the study was to survey the literature, regulatory information available on the Web, and industry-reported device development found on the Web to ascertain the usage and outcomes of the use of polyurethane polymers in the design and clinical use of devices for spine surgery.

STUDY DESIGN/SETTING: A systematic review of the available information from all sources concerning the subject materials' usage in spinal devices was conducted.

METHODS: A search of the peer-reviewed literature combining spinal surgery with polyurethane or specific types and trade names of medical polyurethanes was performed. Additionally, information available on the Food and Drug Administration Web site and for corporate Web sites was reviewed in an attempt to identify pertinent information.

RESULTS: The review captured devices that are in testing or have entered clinical practice that use elastomeric polyurethane polymers as disc replacements, dynamic stabilization of spinal movement, or motion limitation to relieve nerve root compression and pain and as complete a listing as possible of such devices that have been designed or tested but appear to no longer be pursued. This review summarizes the available information about the uses to which polyurethanes have been tested or are being used in spinal surgery.

CONCLUSIONS: The use of polyurethanes in medicine has expanded as modifications to the stability of the polymers in the physiological environment have been improved. The potential for the use of elastomeric materials to more closely match the mechanical properties of the structures being replaced and to maintain motion between spinal segments appears to hold promise. The published results from the use of the devices that are discussed show early success with these applications of elastomeric materials.

Keywords: Spinal surgery; Disc replacement; Motion sparing; Dynamic stabilization; Polyurethane; Review

Introduction

Surgery to repair the function of the connective tissue portions of the spinal column plays a vital part in the relief of pain and return to function of patients with injuries or degenerative back conditions. Among the materials used as adjuncts to the surgery being performed are autograft and allograft tissues, metals, ceramics, and polymers. Polymers used include ultra–high molecular weight polyethylene (UHMWPE), poly(ether ether ketone) (PEEK), and polyurethanes. Polyurethanes, as a family of polymers, have been introduced for medical

FDA device/drug status: Approved (Dynesys, Bryan Cervical Disc, Transition, NFlex, NFix II, NGarde); Investigational (TOPS, PercuDyn (PDS System), M6-L, M6-C, Theken eDisc, LP-ESP, Freedom Lumbar Disc, Freedom Cervical Disc, Newcleus).

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use because of their elastomeric properties, which may be tailored by varying the composition of the monomer units and the size of the blocks of the dissimilar monomers within the polymer chain. The table lists a selection of the properties of UHMWPE, PEEK, and a subset of some of the polyurethanes that are currently used in spinal surgery. As can be seen, the modulus of polyurethanes reflects the elastomeric properties compared with UHMWPE and PEEK, whereas there are similarities in tensile strength, elongation to failure, and hardness between the polyurethanes and UHMWPE but not with PEEK.

The use of polyurethane polymers in medicine

Historically, polyurethanes have been used in medical applications in which the elastomeric properties of the family of materials have the potential to enhance the success or longevity of the medical device in which they are being used. Among the earliest applications were uses in cardiovascular applications in which flexibility (for pumping), the ability to expand and contract in response to pressure changes without fatigue failure (such as vascular grafts) or to flex without fracture (such as insulators for electrode leads), was important to long-term success [1,2]. Although these uses achieved success as early as 1967, by the middle to late 1980s, it was clear that the poly(ether urethane) (PEU) being used might have previously unappreciated failure mechanisms that required further study [1–4]. Some research suggested that residual stress induced in the polymers because of manufacturing and implantation procedures played a part in failures and that PEUs might be sustainable if residual and applied stress during use could be minimized or eliminated [4]. Polyester urethanes had also been used in medical applications and found to be susceptible to degradation in vivo [2,5]. At least one article suggested that poly(ether urethane urea) (PEUU) would have better biostability and the potential for improved performance [6]. Another study investigating the failure of PEUU heart valves demonstrated that calcification and abrasion because of calcification play a part in failure [7]. Research continued into improvements to make polyurethanes more biostable under the conditions of use and polycarbonate urethanes (PCUs) began to show promise [5,8–10]. In studies comparing PEU and PEUU to PCU under the same conditions, the PCU was found to have superior resistance to degradation under biological conditions [11–20]. In 1991, Szycher et al. [15] reported on the development of a new polyurethane (a PCU) that eliminated ether linkages in the polymer chain and was found in his testing to be resistant to microcracking in biological environments. In comparing PEU with PCU, Tanzi et al. [16,17] similarly found that the PCU was more stable when tested in vitro under alkaline conditions, but PEU was more stable under acidic conditions, concluding that, overall, PCU should be more stable in medical applications. At Case Western University, testing was conducted using a variety of techniques and over a number of years, refining the results seen in comparative testing. Mathur et al. [14] compared several different polymer formulations in a cage implant system, finding that PEUU showed the highest degradation because of oxidation and PCU the least degradation. Wiggins et al. [18] conducted in vitro dynamic testing using a hydrogen peroxide and cobalt chloride solution, initially showing that PEUU exhibited more cracking at higher strain rates and further testing showed that PCU fared much better under similar testing conditions [19]. Christenson et al. [11,12] continued this work, finding similar in vitro results and then returning to the cage implant system, showing that degradation of PCU was occurring because of exposure to adherent cells in vivo and that oxidative degradation appeared to be responsible and recommending further study of PCU for its biostability. Finally, Labow et al. [13] warn that the hard segment chemistry of a PCU polymer may have an effect on the long-term stability in the biological environment.

Polycarbonate urethane elastomer has been experimentally applied to the usage as a joint-bearing surface in at least one device [21–24]. Clinical trials of the device are ongoing with some results being reported [25]. The results of analysis of a retrieved device from the early stages of the clinical trials have suggested that the material is maintaining its integrity as a bearing surface [26]. Studies to compare the biological response to particulate material (wear products) of UHMWPE and the PCU used in this device showed that the response was much milder to the PCU than to the UHMWPE [27,28]. Oxidation testing showed the PCU is also more resistant to oxidation under gamma irradiation than UHMWPE [29].

Table
A comparison of the typical properties of selected polymeric materials used in spinal devices

Materials	Flexural modulus (MPa)	Tensile strength (MPa)	Hardness scale	Hardness	Elongation to break (%)
UHMWPE	500 (tensile)	50	Shore D	65D	450
PEEK	4,000	75	Rockwell R	126 HR_R	25–30
PCU (80A)	28	45	Shore A	80A	525
PCU (90A)	42	55	Shore A	90A	400
PCU (55D)	48	60	Shore D	55D	360

PCU, polycarbonate urethane; PEEK, poly(ether ether ketone); UHMWPE, ultra–high molecular weight polyethylene.

Spinal devices containing polyurethanes being tested or used clinically

Posterior dynamic stabilization devices

The name ‘‘dynamic stabilization’’ seems to imply that the spine is being stabilized, while motion at the segment is being preserved. Many of these devices use elastomeric