JMEPEG (2011) 20:663–665
DOI: 10.1007/s11665-011-9869-4

1059-9495/$19.00

Nitinol for Prosthetic and Orthotic Applications

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(Submitted April 21, 2010; in revised form January 27, 2011)

As global populations age, conditions such as stroke and diabetes require individuals to use rehabilitation technology for many years to come due to chronic musculoskeletal, sensory, and other physical impairments. One in four males currently aged 45 will experience a stroke within 40 years and will often require access to prolonged rehabilitation. In addition, worldwide, one individual loses a limb every 30 s due to the complications of diabetes. As a result, innovative ideas are required to devise more effective prosthetic and orthotic devices to enhance quality of life. While Nitinol has already found much favor within the biomedical industry, one area, which has not yet exploited its unique properties, is in the field of physical rehabilitation, ranging from prosthetic and orthotic devices to assistive technology such as wheelchairs. Improved intervention capabilities based on materials such as Nitinol have the potential to vastly improve patients' quality of life and in the case of orthoses, may even reduce the severity of the condition over time. It is hoped that this study will spark discussion and interest for the materials community in a field which has yet to be fully exploited.

Keywords biomaterials, material selection, modeling processes

1. Introduction

Nitinol has been widely utilized within the medical devices industry in a variety of areas, from self expanding stents to orthodontic archwires. The demonstrated biocompatibility of the alloy, combined with its unique properties makes it an obvious choice for many modern biomedical applications. However, the area of prosthetics, orthotics, and rehabilitation has remained largely untouched by the exploitation of this material. A review of the literature has uncovered only a handful of papers, 29 in total that discuss the utilization of a material that has been successfully integrated into so many other biomedical areas. The majority of papers identified discuss the utilization of Nitinol actuators for upper limb, and in particular hand and finger prostheses. Few focus on lower limbs prosthetic and orthotic devices. This study is presented from a multidisciplinary angle, combining experience from both an engineering and prosthetics and orthotics point of view to discuss the further exploitation of Nitinol within the biomedical industry. A proof of concept project currently running at the University of Strathclyde shall be cited as one example of such exploitation.

This article is an invited paper selected from presentations at Shape Memory and Superelastic Technologies 2010, held May 16-20, 2010, in Pacific Grove, California, and has been expanded from the original presentation.

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2. The Field of Prosthetics and Orthotics

Global trends indicate that amputation levels are likely to grow in years to come. This is not set to be matched by an increase in the numbers of professionals trained and equipped to deal with the challenges of prosthetic replacement. Without new technological approaches, prosthetic restoration will remain a custom, largely handcrafted technology that is in relatively short supply. Increases in the numbers of dysvascular amputees in general, the rate of amputation due to complications of diabetes in particular, and even the impact of landmines in parts of the world, all are contributing to a gap between social need for prostheses and our ability to supply.

Prostheses are interventions designed to replace a part of the body that is absent, usually due to amputation or congenital deformity. The focus of this discussion will be on limb prosthesis, for replacement of upper and/or lower limbs, lost due to illness, trauma, or congenital deformity. Orthoses are specialized mechanical devices, designed to support (static) or correct (dynamic) musculoskeletal deformities and/or abnormalities of the human body. The overall aim of orthotic interventions is to restore function to a part of the body that is not able to function properly.

A modern prosthesis is an engineering assembly with components typically fashioned from a variety of materials and, in some cases, with highly sophisticated embedded control systems. Examples include micro-processor controlled stance and swing phase management of prosthetic knee joints, and the control and actuation of prosthetic hands. Prosthetic devices can be separated into interface and structural components. It is understood that the nature of the interface at the prosthetic socket, between the prosthesis and the tissues of the amputee's residual limb, particularly in lower limb prostheses, is also a critical factor for the overall success of the prosthesis.

Historically, prosthetic devices are static structures with limited adaptability to the ever changing environment and dynamic conditions. Current developments are mainly in the field of componentry, for example, prosthetic feet with a high

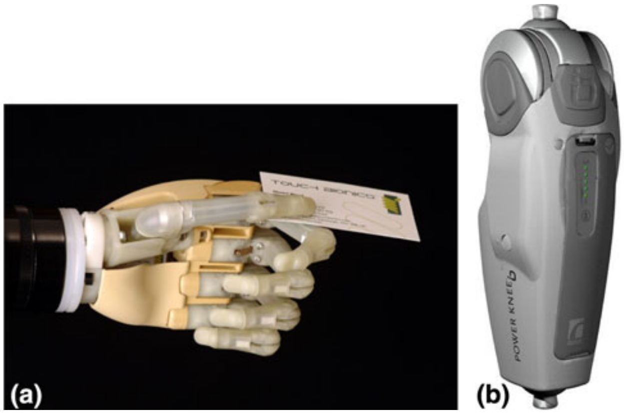

Fig. 1 (a) The i-LIMB prosthetic hand for Touch Bionics and (b) The Powerknee from Össur

energy return during gait and the utilization of carbon composite-based structures. Reasonable progress has been made in relation to actuation of joints. However, a distinction between positional actuation, for example, the angle of an elbow or the ground clearance of a prosthetic foot, and power actuation used to deliver a torque for the purposes of active assistive knee movement to enable sit-to-stand motion or stair ascent are areas which remain underdeveloped. It may be recognized that the requirements for achieving passive movement utilizing Nitinol are less arduous than those for realizing movement in conjunction with a usable force. This is the case for prosthetics and orthotics alike. State of the art, motorized, actuators are predominantly used in prostheses rather than orthotic interventions. Examples for prosthetics include the i-LIMB prosthetic hand from Touch Bionics (Ref 1) and the Powerknee from Össur (Ref 2) (Fig. 1). Although motorized actuators have proven their place within prosthetics they are still seen as rather complex, noisy, and relatively heavy and as such further development is required.

Contextual parallels between the engineering and the historical aspects for prosthetics and orthotics can be drawn. Although, there is a distinct difference between the purposes of the interventions, both are engineering assemblies with components fashioned from a diversity of materials to achieve the desired behavioral characteristics. Additionally, both devices can be separated in to an interface, *where man meets machine*, and a structural component. It is understood that the nature of the interface is a critical factor for the overall success of the interventions; however, we will focus on the structural components. From a historical perspective, strong similarities are identifiable, especially the need for actuation or immobilization (locking) of joints to assist in normal daily activities. The only distinctive differences between orthoses and the prostheses are the exercising and corrective capabilities required in orthoses that are not required for prosthetic devices. We ask the question, can those capabilities be generated by both super elasticity and or shape memory properties of Nitinol?

3. Exploiting Nitinol

Several authors have investigated the use of Nitinol within hand prosthesis and actuator devices, most recently O'Toole et al. (Ref 3) in 2007 who investigate the use of shape memory alloy wire bundles for the actuation of finger joints. The work first quantifies the dynamic performance requirements of the human hand, and goes on to test several bundles of shape memory alloy wires for force and speed of actuation. The article concludes that a bundle of 15, 150 μm diameter wires will produce adequate force required for basic gripping actions. Further study is directed at cooling the wire via an adaptive control strategy and appropriate heat sinking in order to cool the wire at similar rates to the heating, and the mechanical framework for the device.

There have also been a small number of papers that investigate alternative uses of the shape memory and superelastic properties in prosthetics and orthotics. Viscuso et al. (Ref 4) utilize the superelasticity of Nitinol in an upper limb orthosis for stroke patients. The device does not fully constrain movement at the elbow. The wire was heat-treated and then two straight wires of 2 mm diameter were used on each side of the brace to provide a stable corrective force. The application of constant load rather than deformation was made possible by the utilization of Nitinol. In the small, 2 patient studies were reported, very favorable results were found.

Pittaccio et al. (Ref 5) also investigate utilizing Nitinol for stroke patients, concentrating on a shape memory activated exerciser for the ankle in the early stages of poststroke care. This device, when activated, applied dorsiflexion to the ankle using electrical resistance before allowing the material to cool by natural convection. The main challenge identified in this study deals with lengthy cooling times.

Tarkesh and Elahinia (Ref 6) investigate the use of actuators in ankle foot orthoses, focusing on those with drop foot. They specifically discuss the requirements for controlling the complex non-linear relationship between stress, martensite fraction, and transformation temperature to adequately control the design of shape memory alloy actuators, and advise the use of PID/Sliding mode control for active ankle foot orthoses.

Finally, Xu et al. (Ref 7) compare using the superelastic capabilities of Nitinol for bending overload protection in an osseo-integrated trans-femoral prosthetic attachment system, comparing Nitinol and steel components in a short finite element study.

While these articles have explored avenues into the utilization of Nitinol within the rehabilitation field, there are still many areas ripe for exploration.

4. What is the National centre doing?

An ambitious multidisciplinary project is underway at the University of Strathclyde to investigate the utilization of the shape memory material properties of Nitinol to produce an assistive device to complement current commercially available knee joints and aid sit to stand motion and stair ascent for trans-femoral amputees.

The two way shape memory properties of the material are being investigated as a means to provide an additional force to partially overcome the difficulty of the sit to stand motion. The project, currently in its initial stages and funded by the UK Ministry of Defence's Science, Innovation and Technology Department, aims to produce a concept design to help people with trans-femoral amputations, including servicemen injured by landmines or gunshot.

5. Conclusions

This discussion has shown that the prosthetics, orthotics, and rehabilitation industry is ripe for twenty-first century technological advancement. The very nature of prosthetic and orthotic devices suggest that materials such as Nitinol hold much promise to be employed, exploiting both their shape memory and superelastic capabilities within the correct context. Work has started to try and take advantage of these opportunities; however there are still many opportunities to be realized within this field.

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