A Novel Thermal-activated Shape Memory Penile Prosthesis: Comparative Mechanical Testing

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OBJECTIVE To compare a novel nickel-titanium (Ni-Ti) shape memory alloy (SMA) penile prosthesis of our own design with commercially available prostheses using a format similar to mechanical testing done at major penile prosthesis manufacturers. We evaluated the mechanical parameters of commercially available penile prostheses and used this information to guide the development of the Ni-Ti-based physiological penile prosthesis that expands and becomes erect with a small amount of heat applied.

METHODS A penile prosthesis consisting of an exoskeleton of temperature-tuned Nitinol was designed and prototyped. Mechanical testing was performed in a model of penile buckling, penile lateral deviation, and original penile shape recovery commonly used by penile prosthesis manufacturers for testing.

RESULTS Our SMA penile prosthesis demonstrated useful mechanical characteristics, including rigidity to buckling when activated similar to an inflatable penile prosthesis (2.62 kgf SMA vs 1.42 kgf inflatable penile prosthesis vs 6.45 kgf for a malleable prosthesis). The Ni-Ti also became more pliable when deactivated within acceptable mechanical ranges of existing devices. It could be repeatedly cycled and generate a restorative force to become erect.

CONCLUSION An SMA-based penile prosthesis represents a promising new technology in the treatment of erectile dysfunction. We demonstrated that an Ni-Ti-based prosthesis can produce the mechanical forces necessary for producing a simulated erection without the need for a pump or reservoir, comparable with existing prostheses. UROLOGY 99: 136–141, 2017.

In the United States, the two types of penile prosthetics most commonly used are the inflatable penile prosthesis (IPP) and the malleable penile prosthesis (MPP). Since the original design of the IPP in 1973 by Dr. Scott in 1973,[1] few substantive changes have been made in the mechanical functioning of inflatable penile prostheses. Even less has changed in the mechanical design of the MPP which straightens to allow penetration.

With an IPP, the transfer of fluid from one compartment of the device to another is how the prosthesis mimics the penis from the flaccid and erect state. As time-tested as this method is, it has certain drawbacks. The surgical implantation of the inflatable prosthetic device is complex because of the multiple components to insert. An adequate control mechanism must be positioned precisely to allow for easy end-user manipulation. Moreover, the IPP device components themselves carry an inherent risk of mechanical failure or leakage.[2-5] At 10 years, only 67%-88% of inflatable penile prostheses are fully functional.[6,7]

The MPP, however, is much less involved than an IPP and balances being sufficiently rigid for penetration yet flexible enough to allow downward positioning when not in use. The advantages of using an MPP are its reliability, a small surgical dissection, minimal device components, and little user dexterity needed for operational use,[8] and is used more prevalently in developing countries than in the United States.[9] Its disadvantages are that it makes the penis appear erect constantly, does not mimic a physiological erection, and may have stability issues during usage.[10] The MPP also exerts more force on the surrounding tissues, increasing the risk for erosion.

In broad terms, penile prosthetics are used to restore function and make the body "whole" again. As such, the ideal penile prosthetic device to treat erectile dysfunction would mimic a native physiological erection as closely as possible, both in function and appearance. It should perform

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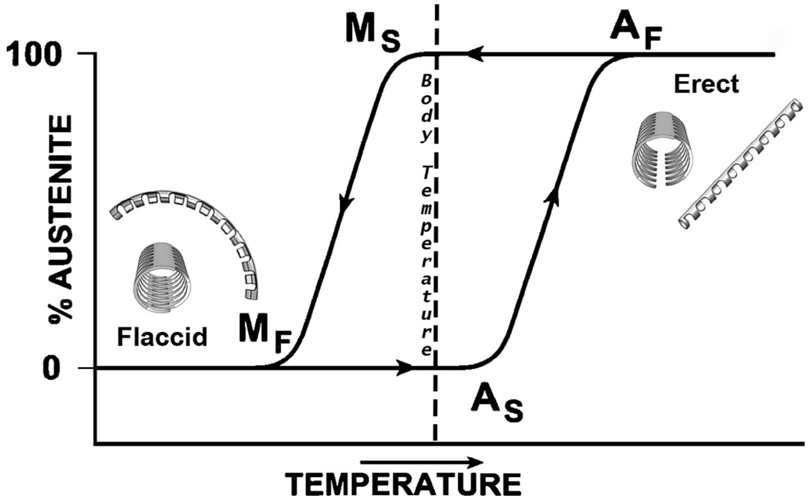

Figure 1. A shape memory alloy characteristic hysteresis curve demonstrates how the device changes configuration with temperature. The direction of the hysteresis curve means that a deactivated device will remain flaccid even at body temperature, and an activated device will remain rigid at body temperature. This property is utilized in our prosthesis design.

the mechanical duties necessary for successful intercourse when erect and be durable enough to match usage during the lifespan of the patient. When not in use, the ideal prosthetic would mimic the flaccid state of the penis and be discreet. The ideal device would also not interfere with urination and other activities of daily living. As a component of the sexual experience, the prosthetic too should essentially maintain or improve the quality of the experience for the patient (eg, sensation, spontaneity.) With regard to surgical implantation, the ideal prosthesis could be implanted via a simple surgical dissection with minimal recovery time.

With the many improvements in materials and alloys since the introduction of the IPP device, we developed a novel shape memory alloy (SMA) implantable penile prosthesis. SMAs such as nickel-titanium (Ni-Ti or "Nitinol") have the ability to "remember" a determined shape. A deformed Nitinol object can return to its original shape any time the temperature is increased above a critical temperature, known as the austenitic temperature (A_f). Conversely, as the temperature drops below a critical temperature, the martensitic temperature (M_f), it returns to its more flexible and deformed state. Between these temperature points (A_f and M_f), the two phases of rigidity and flaccidity can coexist, with percentages of austenite or rigidity increasing or decreasing depending on which temperature point it approaches. This hysteresis property allows for an activated device to remain in its remembered shape as its temperature returns to body temperature, and equally important a deactivated device to remain flaccid as it returns to body temperature (Fig. 1). Thus, the material acts as a molecular ratchet.

Using this technology, we developed a novel Ni-Ti penile prosthesis (Fig. 1), and a United States Patent was granted for this concept.[11,12] We compared our novel Ni-Ti alloy prosthesis with commercially available prostheses using a standard format, similar to mechanical testing done at major penile prosthesis manufacturers. We evaluated the mechanical parameters of commercially available penile prostheses and used this information to guide the development of the Ni-Ti-based physiological penile prosthesis that expands and becomes erect with a small amount of heat applied.

METHODS

Prototyping

The Ni-Ti penile prosthesis consists of an exoskeleton of temperature-tuned Nitinol tubing from a commercial provider surrounding a pliable core of latex rubber buttressed on both ends by silastic caps. The prosthesis was designed and developed at Northwestern University and Southern Illinois University, using SOLIDWORKS (Dassault Systèmes SolidWorks Corporation Waltham, MA, USA) to create three-dimensional models.[13] Based off these models, the Nitinol tubes were laser-cut to specifications. The Ni-Ti device measures 19 cm in length, 1.10 cm in its outer diameter, and 0.96 cm in its inner diameter, and is intended to be implanted intracavernosally.

Thermal treatment of the Nitinol was carried out using a salt pot to raise the final A_f temperature from 0°C to 42°C. We chose an A_f of 42°C because it is above the normal resting human body temperature and lower than the temperature at which heat pain nociceptors activate. The structure's overall rib and spine design are so that a change from the Nitinol's martensitic to austenitic phase will increase the diameter of the prosthesis, simulating normal penile girth enlargement (Fig. 2).

We compared the Ni-Ti alloy prosthesis with three penile prosthetics: the AMS 700 CX, AMS 600, and the AMS Spectra (American Medical Systems, Minneapolis, MN). We selected these devices to represent current state-of the-art, market-available inflatable and malleable penile pros-