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

Brian Le, Kevin McVary, Kevin McKenna, and Alberto Colombo

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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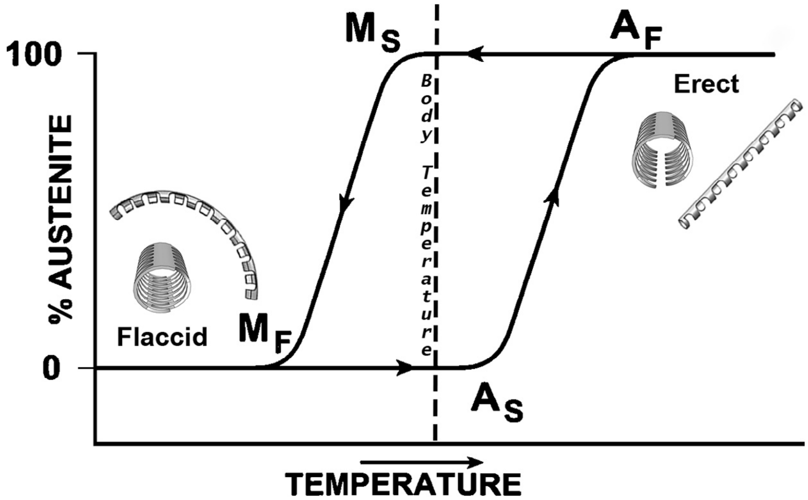


Figure 1. A shape memory alloy characteristic hysteresis curve demonstrates how the device changes configuration with temperature. The direction of the hysteresis curve means that a deactivated device will remain flaccid even at body temperature, and an activated device will remain rigid at body temperature.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

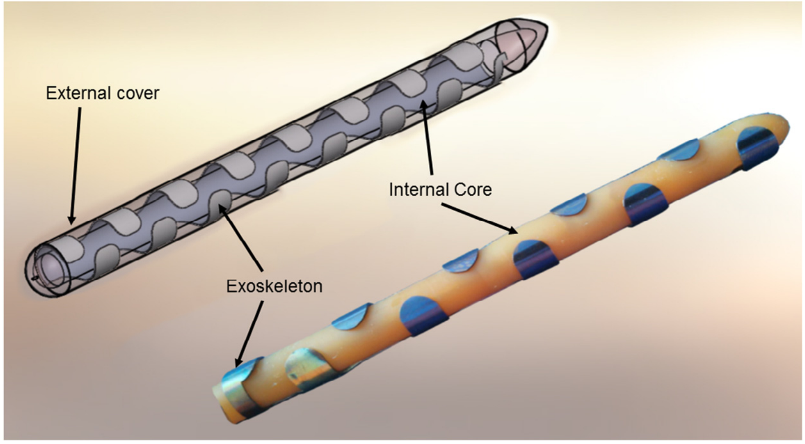


Figure 2. Configuration of the components used in the design of the penile prosthesis: a nickel-titanium exoskeleton surrounds a pliable inner core.

theses. We also evaluated the mechanical parameters of the commercially available prosthetics to guide the development of our Ni-Ti-based penile prosthesis.

Mechanical Testing

We used the AMS 700 CX, AMS 600, and the AMS Spectra as positive controls to serve as benchmarks with which to target our Ni-Ti device's mechanical properties. We subjected all devices to mechanical testing using a machine that gradually delivers an incrementally higher load and measures the distance changed over the course of that load, similar to what occurs during intromission.[14] We can then apply this load in multiple directions relative to the axis of the device. When the distance traveled is disproportionately higher than the incremental load, we say the device has "buckled." This buckling test model is used by penile prostheses manufacturers to test prosthetic devices (source: American Medical Systems, now Boston Scientific). We measured the resistance to bending by applying a force perpendicular to the prosthesis and recording the resistance force. The prosthesis was deformed up to obtain a 30-mm vertical deviation from the axis corresponding approximately to a 30° deviation. Furthermore, we tested the IPP and SMA prosthesis elastic recovery from an angle of 30°.

We used two devices to carry out the test model: an Instron Model 5500 (Instron Corp. Norwood, MA, USA) universal materials testing machine for buckling and bending. For the buckling test, each penile prosthetic was compressed and fixed between two points with a total length of 10 cm between fixed points. The measuring devices were loaded in increments of 0.2 kgf/min until the point of buckling. Buckling in this instance was defined as the inflection point where additional load led to vertical movement of greater than 20% per second due to bending off the axis.

We activated all penile prosthetics to their erect configuration: thus we induced thermal shape-memory activation for the Ni-Ti prosthesis, maximal inflation for the IPP and straightening of the two malleable penile prosthetics. We then subjected all devices to the mechanical buckling protocol. The purpose was to determine if the devices performed similarly when in their erect state under simulated conditions.

To test the how the prosthetics buckled in the deactivated or "flaccid" state, we deflated the AMS 700 CX and lowered the Ni-Ti device temperature past its critical M_f temperature. We did not test the two malleable devices because they do not deactivate.

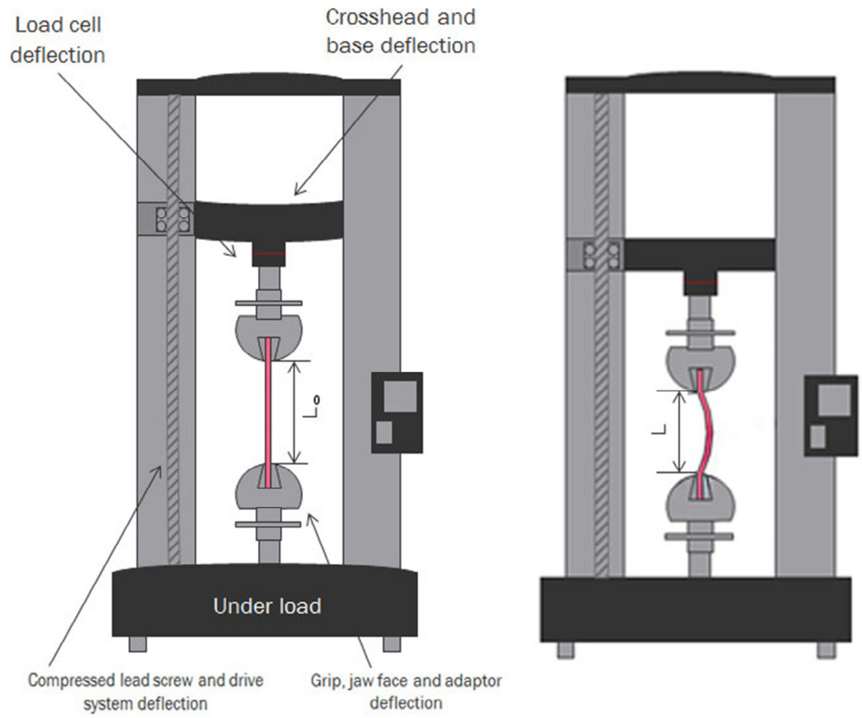
RESULTS

The two malleable prostheses (AMS 600 and the AMS Spectra) buckled at a mean load of 6.45 ± 0.76 kgf and 6.65 kgf ± 0.54, respectively, whereas the AMS 700 CX (an IPP) buckled at 1.42 kgf ± 0.0065 in its activated state. Our Ni-Ti penile prosthesis model buckled in its activated state at a mean load of 2.62 kgf ± 0.045, thus slightly more rigid than the IPP when loaded axially, but less rigid than either malleable prosthesis. This type of rigidity is important for intromission.

When loaded with a force perpendicular to the main axis, the Ni-Ti prosthesis required a mean load force of 0.30 ± 0.0035 kgf to reach a 30° angle, whereas the IPP (AMS 700 CX) required 0.22 ± 0.56 kgf and the malleables required 0.18 ± 0.0068 kgf (AMS Spectra) and 0.24 ± 0.0127 kgf (AMS 600), demonstrating that the prosthetics bend under similar forces in this fashion (Fig. 3). The Ni-Ti prosthesis, like the AMS 700 CX, additionally has a certain amount of elasticity that allows it to return to the on-axis position when the force is removed.

When deflated, the IPP buckled readily with only 0.30 ± 0.34 kgf required. The Ni-Ti prosthesis required slightly more force at 0.45 ± 0.13 kgf and was notably less rigid compared with its state when the 2.62 kgf was applied, demonstrating its change from an erect to flaccid state (shown in Fig. 4).

When transitioning from the flaccid state to the erect state, as occurs during inflation of an IPP, the prosthesis must generate sufficient restorative force to overcome gravity



	Axial Force required for Buckling	Lateral Force	Lateral Force Generated in expansion
AMS Spectra (MPP)	6.45 kgf	0.18 kgf	N/A
AMS 600 (MPP)	6.65 kgf	0.24 kgf	N/A
AMS 700 CX (IPP)	1.42 kgf	0.22 kgf	0.16 kg
SMA	2.62 kgf	0.30 kgf	0.30 kgf

Figure 3. Mechanical testing setup for buckling testing with comparison of mechanical properties demonstrated below. (Color version available online.)

and the weight of the penile tissue. Utilizing the Dillon GL (Dillon Corporation Fairmont, MN, USA) handheld to measure this force, we found the AMS 700 CX generated a force of 0.21 kgf and our Ni-TI prosthesis produced a force of 0.76 kgf. Using the IPP as a positive control, the force generated by our Ni-Ti prosthesis is more than adequate for transition.

DISCUSSION

All penile prostheses aim to mimic the natural physiological erection. Studies looking at the biomechanics of erections demonstrate what the requisite mechanical parameters are to achieve a rigid erection.[15] Current market-available penile prosthetic technology uses the movement of fluid between device components to generate an artificial erection. Although effective, this technology does not take advantage of the developments made over the last 40 years in commercially available materials. Herein, we describe the use of SMA technology to produce a simulated erection through the use of an Ni-Ti alloy. Our study demonstrates that SMAs may be effective materials to develop prosthetics for the treatment of erectile dysfunction. The use of our Ni-Ti-based penile prosthesis allowed successful and repeated transition between the more flexible and flaccid martensitic state to the more rigid and superelastic, austenitic erect state. Furthermore, the mechanical operating characteristics were comparable with that of existing market-available inflatable and malleable penile prosthetics, and our Ni-Ti prosthesis conducted these transitions without the use of a reservoir or pump.

Historically, a force of 1.5 kgF was found to allow successful penetration in 100% of healthy female volunteers.[16] This is the target force that the inflatable prosthesis seems to approach and the malleable exceeds. We found that the malleable prosthesis buckled under a much greater force, but when lateral forces were applied it bent just as readily. However, unlike an IPP, the MPP is not elastic and does not recoil. This could explain some of the "stability" issues that MPP users describe. In real-world applications, the combination of buckling and lateral failure provides a clearer picture of the overall mechanical characteristics of penile prostheses. The SMA prosthesis demonstrated comparable operating characteristics that were between a malleable and an IPP.

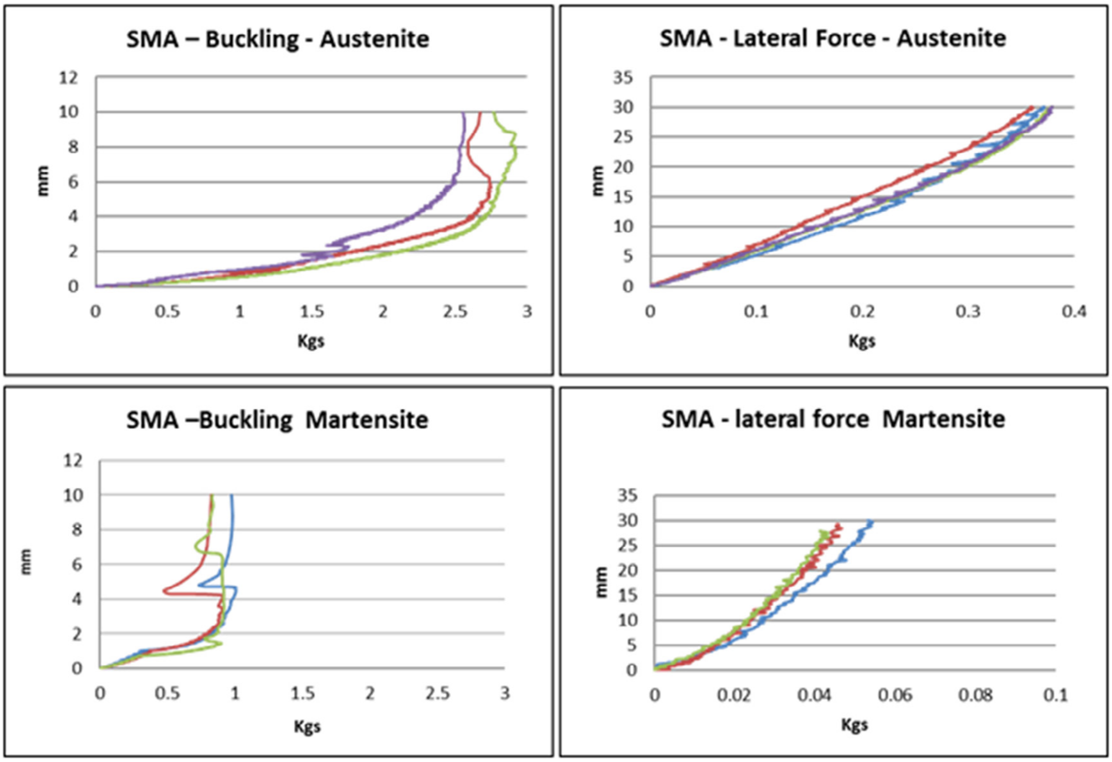


Figure 4. Parameters of mechanical loading in tests of buckling and bending of the shape memory alloy (SMA) prosthesis when activated versus deactivated. (Color version available online.)

The potential advantages of such an approach are severalfold. First, the Ni-Ti prosthesis can have a smaller footprint in the body as there is no need for a pump or reservoir. Moreover, several studies have described the complications associated with the challenging placement of reservoir and pump placement, and given our Ni-Ti prosthesis design model this risk is eliminated.[2,3,6] Second, the transition between the more flexible or flaccid state and rigid or erect state resembles what we see with an IPP, which provides a more physiological erection than a malleable device. Third, girth expansion, although not directly examined in this study, is intrinsic to the design of our Ni-Ti prosthesis and is determined by the cross-sectional diameter of the "remembered" shape. To simplify these initial mechanical studies, we purposely did not test this feature as changes in cross-sectional area affect buckling. However, cross-sectional expansion is a built-in feature of SMA devices. Fourth, without fluid puncture, leakage and valve malfunction no longer become a concern. Fifth, by maintaining a surgical profile familiar to surgeons, placement of intracavernosal cylinders will be able to benefit from the decades of technique refinement used in malleable placement.[17] Sixth, the simplification of the surgery may make the procedure more accessible to low volume implanters. Currently, the majority of penile implants performed in the United States are concentrated in a small number of surgeons.[18] Lastly, the lack of pump and reservoir can have improved cosmesis.

There are certain limitations to this technology that need to be tested. First, the activation and deactivation of the device requires application of a small amount of heat, a few degrees to induce the change. Although our device is calibrated to be within physiological range and to not be uncomfortable at both temperature extremes, heat transfer studies still need to be conducted.[19] One potential approach is employing inductive technology from an external source that allows heat transfer across short distances in a reliable fashion. Another approach is direct application of a heating pad. In both cases, after the heat source is removed, resting body temperature and hysteresis allow the device to stay in its activated state. Additional steps must be taken to deactivate the device by subsequently cooling below its martensitic set point with a cool washcloth to reset the device. Preliminary test work done in our laboratory suggests this is a viable and promising approach. Additionally, the use of an external device for activation and deactivation will have to be market-tested to determine if such an option is preferable from a patient standpoint.

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, and offers distinct advantages over existing prostheses. Further ongoing developments needed to fully realize this concept include material refinement and animal and human testing.

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