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Design of an Improved Surgical Instrument for the

Removal of Bladder Tumours

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Abstract

The aim of this work was to design an add-on instrument that could potentially decrease the recurrence of non-muscle invasive bladder cancer. The current surgical approach permits spilled tumour cells to disseminate within the bladder, re-implant and cause tumour recurrence. An add-on instrument has been designed in the form of an opening cone intended to provide space for surgery and yet reduce tumour cell spillage and dissemination. A prototype was manufactured using the shape memory metal Nitinol which was activated using an electrical current to facilitate opening, and supplemented with latex to provide a sealed environment. The prototype was tested in comparable surgical conditions utilising *porcine* bladder wall and blue dye to simulate tumour cells. It was demonstrated that the vast majority of dye was retained within the device, supporting the proposed aim.

Keywords

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1. Introduction

In the UK there are approximately 10,200 new cases of bladder cancer per year[1]. In the USA and EU these figures have been estimated at 72,570 and 123,135[2], respectively. At diagnosis, over 75-85 % of tumours are non-muscle-invasive bladder cancer (NMIBC) [3–5]. NMIBC is typified by a high rate of recurrence (15-61 % at one year, depending upon risk category[6]) and so long-term, even lifelong, surveillance with outpatient flexible cystoscopy is the mainstay of subsequent management[3,7]. Progression to muscle-invasive disease (MIBC) is also a concern for high-risk NMIBC patients, occurring in up to 17 % of patients at one year. Progression to, or presentation with, muscle-invasive disease (stages T2-4) represents the critical step in the disease course, necessitating more radical therapies and carrying a 5-year survival rate of only 27-50 %[8,9].

Transurethral Resection of Bladder Tumour (TURBT) is the mainstay of treatment for NMIBC and was first described as suitable surgery by Maximillian Stern and Joseph McCarthy in 1930[10]. It is still considered to be the gold standard today[11]. The equipment required for TURBT comprises of: a stainless steel outer and inner sheath, an irrigation system, a light source provided via a fibre optic guide from a filament lamp, a rod lens cystoscope attached to a video camera head and a trigger-operated spring-loaded electrically-active wire cutting loop or diathermy loop (figure 1). The combination of the cutting loop, the cystoscope and the camera head are termed a 'resectoscope'. There are many resectoscopes on the market made

by companies including: Olympus (Tokyo, Japan), Stryker (Kalamazoo, USA), Storz (Tuttlingen, Germany) and Richard Wolf (Knittlingen, Germany).

[Insert Figure 1]

Figure 1 – Side view of Olympus OES Pro resectoscope

Briefly, the method for TURBT procedures is as follows: following a thorough cystoscopy and bimanual examination, the surgeon inserts the resectoscope into the bladder via the urethra. Once inside the bladder, the surgeon will examine the bladder and locate the tumour(s) utilising the high quality video camera attached to the cystoscope. The TURBT will then commence utilising the diathermy cutting loop. The diathermy loop is used to cut into the tumour to remove it in slices or 'chips'. Irrigation into and out of the bladder via the sheath is used throughout the procedure to distend the bladder (which smooths its mucosal surface which is otherwise folded when the bladder is empty) and to wash away blood and smaller pieces of tumour debris (to maintain good vision). The larger pieces of tumour or 'chips' are either drained out of the bladder by simply removing the resectoscope from the outer sheath, or washed out by the use of an Ellick bladder evacuator or similar. The surgeon will repeat this process until all of the tumour has been visually removed. The diathermy cutting loop, or alternatively a diathermy 'roly-ball', will then be used to cauterise bleeding vessels and healthy-looking bladder mucosa immediately surrounding the base of the tumour to achieve a 'negative margin' (a margin of normal healthy tissue around the base of the tumour to improve confidence in complete tumour removal and to reduce the risk of tumour recurrence).

The tumour is thus removed piecemeal (contrary to basic principles of surgical oncology whereby tumours should be removed *en bloc*[11,12]) and a negative lateral or deep margin cannot be guaranteed. Moreover, resecting the tumour whilst irrigating the bladder creates a solution of potentially viable tumour cells within the bladder, and these cells can subsequently re-implant at the tumour site or elsewhere within the entirety of the bladder[13,14]. The mechanisms of recurrence of NMIBC were thus described by Kondas *et al*[14] as: (i) incomplete resection of the primary urothelial cancer; (ii) tumour cell re-implantation; (iii) growth of microscopic tumours present at the time of the previous resection and (iv) new tumour formation. Utilising alternative optical technologies (such as narrow band imaging and photodynamic diagnosis[15]) may reduce the positive margin rate (incomplete resection) and may also identify small tumours otherwise missed by conventional white light cystoscopy, but these approaches have not been universally-adopted and do not change the fundamentals of the procedure. Thus, surgical failure is considered to be an important contributor to the high recurrence rates observed in patients with NMIBC[13]; these rates are considered to be unacceptably high[6,11], and result in repeated TURBTs which are both burdensome to patients and expensive for healthcare providers[16,17].

Although much research is underway to investigate how to remove tumours *en bloc* and whether novel imaging techniques are sufficient to find smaller tumours[18], little has been done to reduce the scattering effect of the procedure[11]. This paper describes the design, development and *in vitro* testing of a novel enhancement to the current surgical instruments

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used for TURBT that aims to reduce the occurrence of tumour cell dissemination and re-implantation.

2. Design Requirements

The design requirements were formulated in accordance to BS EN ISO 16061:2009[19] and BS ISO 8600-1:2013[20]. The instrument enhancement should:

- Be able to remove an entire tumour from the bladder.

- Limit tumour cells from re-implanting elsewhere on the bladder wall.

- Not increase surgery time which generally takes 51 minutes[21].

- Be able to withstand the force of the urethral tissue.

- Not cause harm to the patient.

- Not cause an immune response from the body and hence be manufactured from biocompatible materials.

- Be able to enter and exit the bladder via the urethra.

- Not impede the surgeon's view of the tumour.

- Be single use. Therefore sterilisation will only be performed by the manufacturer.

- Be able to work with existing surgical instruments for TURBT, such as various sheaths, cystoscopes, light source and diathermy loop.

- Be able to work in an isotonic or hypotonic aqueous environment at 37 °C for times of up to one hour[21].

- Be no more than 350 mm long (with all parts connected), more than 8.5 mm bore and no more than 11 mm in outside diameter.

The main design consideration was that the add-on device should be able to limit the movement of tumour cells after the main tumour has been cut into. The authors believe that this can be achieved by limiting fluid transfer to within the device only and not to the remainder of the bladder by fluid irrigation.

3. Design Development

After careful consideration of the design requirements a concept of an add-on cone to current resectoscope sheaths was selected as the solution for development. The closed cone would have to be inserted into the bladder along with the sheath through the urethra and then be able to open once inside the bladder (figure 2). The cone once opened would then be positioned against the wall of the bladder covering the tumour, creating a flat surface against which the surgeon could operate. The creation of this flat surface may be aided by a negative pressure within the cone induced by the irrigation system currently used in the resectoscope.

The tumour would then be resected as normal and once finished the cone would close and be taken out of the bladder.

[Insert Figure 2]

Figure 2 – Opening of cone within bladder

The greatest challenge associated with this design was the method of opening the cone. Due to the limited diameter of the urethra and that of the existing instruments, conventional actuators would not be applicable. Current resectoscopes have an outer diameter of around 8.5 mm and any add on device would aim to not to have a diameter greater than 11 mm. The shape memory alloy Nitinol (NiTi) was selected to create the opening of the cone since it enables a device to conform to different shapes (i.e. one shape for access to the bladder, and another when inside the bladder). For example, it has previously been used to mimic the movement of a jellyfish[22]. Furthermore Nitinol has already been used within the body in different applications such as stents, heart valve frames, orthodontic implants and bone plates[23,24].

4. Final Design

[Insert Figure 3]

Figure 3 – Final design render

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The final design for the add-on cone had three main parts: eight Nitinol wire actuators, the housing for the base of the Nitinol wires and the flexible polymer 'leaves' (which created the sealed environment within which surgery could take place). The cone was opened using resistance heating - passing a current through the wire caused it to heat due to the relatively high resistance of Nitinol. The connections for the Nitinol wiring can be seen in figure 4.

[Insert Figure 4]

Figure 4 – Render of prototype including Nitinol wires (dark grey), connective wiring (gold) and wire housing (white). The blue and red wires show the input and output of the electrical connection, respectively.

5. Prototype Manufacture

5.1. Shape Memory Theory

A prototype of the design was manufactured to test the ability of the Nitinol to actuate the cone. A shape memory alloy (SMA) such as Nitinol, has the ability to 'remember' a pre-set shape and because of this can be trained to return to a particular shape when heated. This is due to the two solid phases that shape memory alloys have: martensite and austenite. When the SMA is at a lower temperature than its transition temperature it is in the martensite phase and has a specific crystal structure, then when it is heated past its transition temperature the crystal structure of the SMA changes to austenite. This crystal structure change is also called a

phase change and provides the means for the material to return to a set high temperature shape. This high temperature shape is trained into the material by fixing it in a desired position and heating it to a very high temperature. Then when the alloy is below the transition temperature it can be deformed to any shape and when heated past the transition temperature it will return to the trained high temperature shape[25].

5.2. Actuator Wire

Nitinol wire (50% nickel and 50% titanium) of diameter 0.5 mm was acquired from Dynalloy Inc (Tustin, California, USA). Eight sections of Nitinol wire were then cut into 90 mm sections and heated to 550 °C for 15 minutes in a Carbolite LMF1 furnace (Carbolite, Derbyshire, UK). This heat treatment made the wire ductile and able to form shapes; when the Nitinol was received from the supplier the metal exhibited superelastic behaviour which made it difficult to work with. Superelasticity can be defined as a material that will recover from an induced strain by just releasing the load applied to it. This is due to the material's Austenite finish (A_f) temperature being below the temperature at which it is being tested[25].

The ductile sections of wire were then fixed to a jig (figure 5). With the use of bolts, nuts and washers the sections of the wire were bent to an angle of 40°. This jig was then inserted into the same furnace as before and heated to 550 °C for 15 minutes. The jig was then quenched in water until cool (less than 20 seconds) and the wires were removed from the jig.

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These parameters were found using trial and error after considering the methods suggested by Morgan and Broadley[26].

[Insert Figure 5]

Figure 5 – High temperature training jig.

The heat treatment described, 'trained' a high temperature shape into the Nitinol. The Nitinol could then be deformed into any shape and once heated past its activation temperature (55 °C for this specific alloy) it will return to the 40° bend shape. For the instrument the desired actuation is from a straight (closed) wire to a 30° bend (open) wire. The loss of 10° accounted for the stiffness of the polymer leaves in between the Nitinol wires. This would result in a cone maximum diameter of 5.5 cm, large enough to treat the majority of bladder tumours in the UK which are less than 3 cm in diameter [27].

The Nitinol was heated using resistance heating by passing a current through the Nitinol which created the heat to enable the wire to actuate. A supply of 2.3 A and 30 V, from a model LT 30/2 Farnell Instruments power pack (Wetherby, UK), was used to bring the Nitinol to and past its activation temperature. When measured using a steel 1 mm diameter k-type touch thermocouple (RS Components, Corby, UK), connected to a Comark model 6600 digital thermometer (Norwich, UK), the Nitinol wire reached an average temperature of 58.2 °C (with a standard deviation of 1.9 °C) when it had finished actuating.

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The Nitinol circuit diagram can be seen in figure 6. A series configuration was used as opposed to a parallel one as a high current was required rather than a split in the current.

[Insert Figure 6]

Figure 6 – Prototype circuit diagram.

The Nitinol wires were connected around the wire housing using a tin based solder (Fisher Scientific, UK) and connective wiring made up of 3 strands of 0.2 mm diameter tin coated copper wiring. Great difficulty was experienced when soldering to nickel titanium due to the oxide layer that had built up around the wire, therefore, flux (Toolstation, Bridgwater, UK) was used with good results.

5.3. Wire Housing

Once the wires had been trained, the 'bases' of the wire were inserted into a 3D printed cylindrical housing (figure 7). The housing was manufactured using an Eden 250 additive manufacturing machine (Objet, Billerica, USA) and made out of an acrylic monomer based resin (brand name Fullcure 720). The outside diameter and bore of the wire housing were 11 mm and 9 mm, respectively. There were also 16, 0.75 mm diameter holes through the wall of the housing all at a 10 mm pitch circle diameter. This housing provided a stable structure against which the wires could actuate.

5.4. Polymer Leaves

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Latex was selected as a preferable polymer material as it exhibits low stiffness and has a comparatively high yield limit. Liquid latex (MB Fibreglass, Newtonabbey, UK) was painted onto an aluminium cone along with the Nitinol wiring and connective wiring (figure 7), in three layers. The aluminium cone mimicked the shape of the device when open. In preliminary tests three layers of latex showed good strength, flexibility and the ability to provide a sealed environment. When the third layer of latex was dry, washing up liquid was rubbed onto the surface to ensure the latex did not stick to itself when being removed from the mould. The latex was then removed from the mould.

[Insert Figure 7]

Figure 7 – Finished cone prototype (left) and aluminium cone onto which the latex was painted (right).

6. Testing

6.1. Prototype Actuation

The ability of the prototype to actuate was tested using a 2.3 A 30 V supply as previously described in section 5.2. The opening actuation time for the prototype device was around 12 seconds; this can be seen in figure 8 going from the closed (top) to open (bottom) state. The opening time could be reduced by increasing the current as this increases the heating of the Nitinol wires. However, a higher current is more likely to melt the latex and the solder.

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[Insert Figure 8]

Figure 8 – Closed (top) and open (bottom) prototype.

6.2. Fluid Testing Methods

The ability of the prototype to open and seal in a liquid environment was tested in two experiments. The cone prototype was inserted into a Perspex cylinder (figure 9) in hypotonic and isotonic aqueous environments at 37 °C. These parameters corresponded to different operating conditions of TURBT. Crocodile clips were attached to the electrical connections of the device which was then actuated using the same 2.3 A 30 V supply.

The ability of the prototype to seal and potentially hold tumour cells within the device was tested by pressing the open device against a stretched *porcine* bladder wall sample at the bottom of the Perspex testing device and adding blue dye (Coomassie Brilliant Blue 250R, Sigma Aldrich, Gillingham, UK). The *porcine* bladder sample was obtained from Fresh Tissue Supplies (East Sussex, UK), the dome and trigone regions of the bladder were removed and another cut was made adjacent to the first two incisions to create a roughly rectangular sample of bladder. The bladder sample was then stretched, inner bladder wall facing up (so as to make contact with the device), by hand and four holes were made into the rectangular sample so that it could fit over the bolts securing the Perspex testing device. All incisions and cuts were made using surgical scissors (Fisher Scientific, UK). Plastic tubing (Fisher Scientific, UK) was then inserted through the middle of the device into the cone so that the blue dye

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could be injected. The ability of the latex to keep the dye within the cone was tested with the dye that was less dense (958 kg/m^3) than the surrounding fluid (hypotonic 1000 kg/m^3 and isotonic 1005 kg/m^3). Conversely the bladder wall cone interface seal was tested using a dye denser (supplemented with salt, 1185 kg/m^3) than the surrounding fluid. The device was then observed over 5 minutes to see whether the dyes remained within the cone. The tests were recorded using a Google Nexus 4 video recording device (San Francisco, USA).

6.3. Fluid Testing Results

Figure 9 shows the closed and open states of the prototype device in a hypotonic solution.

[Insert Figure 9]

Figure 9 – Closed and open state of the prototype device in fluid.

The time taken to open the device was 20 seconds. This was found to be repeatable and very similar results were found when testing in an isotonic solution. The time taken to open was longer than the 12 second actuation in air and was attributed to the increased heat transfer in fluid. The subsequent dye test results can be seen in the figure 10.

[Insert Figure 10]

Figure 10 – Instrument dye tests. Less dense blue dye a – d. Denser blue dye e – h. Where: a) & e) are the inserted devices pressed against a sample of *porcine* bladder wall, b) & f) are the

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dyes being inserted into the device which is where the timing of the test started, c) & g) are the device with blue dyes inside once the tubing has been removed and d) & h) are the blue dyes escaping once the device is taken out after the 5 minute test has been completed.

The vast majority of the dye remains within the device during the 5 minute tests (Figure 10b-c & 10f-g). A small amount of dye can be seen leaving the cone in the test with the less dense dye (Figure 10c). This may be due to small holes in the latex or gaps in the connection of the latex to the wire housing. In the test with the denser dye (Figure 10e-h) only a few segments of dye leave the device, this may be due to a fold in the latex which is in contact with the bladder wall. For each test the effect of buoyancy due to the different densities of the respective dyes can be seen after the device was removed, where the dye rises when less dense (Figure 10d) and sinks when denser than the surrounding fluid (Figure 10h).

7. Discussion

This paper has described a novel enhancement to current surgical instruments used for TURBT. It is hoped that this design will, if implemented, decrease the recurrence of NMIBC by restricting the area in which tumour cells are allowed to travel[13,14]. This paper has also described the manufacture of a working prototype which would be able to open and close once inside a bladder environment and *in vitro* testing to determine the ability of the add-on device to contain substitute tumour cells hence demonstrating potential feasibility during TURBT.

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Observations following *in vitro* testing demonstrate that the device is able to actuate in both hypotonic and isotonic irrigation fluids, which are commonly utilised during TURBT, and can be used with both mono and bi-polar energy sources. Also the device was able to restrict the majority of the blue dye, both denser and less dense than the surrounding fluid, within the cone part of the device. The different densities allowed for testing of the seal at the bladder wall cone interface (denser dye) and the effectiveness of the latex in keeping the dye within the cone (less dense dye). Some leaking of the dye was seen and this has been attributed to insufficient contact with the bladder wall and/or small unseen tears in the latex cone. Once the device is deployed, it may also be feasible to induce a pressure differential between the fluid in the cone and the fluid in the rest of the bladder. By controlling the irrigation a positive pressure in the remainder of the bladder would gently push the device against the bladder wall. Furthermore, the irrigation system, when used within the device, may be more effective in drawing the tumour cells back through the scope as there would be less volume of fluid within the cone, as opposed to irrigating the entire bladder.

Extensive work was carried out on attempting to use the two-way shape memory effect to open and then close the device; however, the low force and slow return speed in the absence of enhanced cooling made this unworkable. Instead the device would be able to open using the one-way shape memory effect and then, when the current to the device is turned off and the Nitinol wiring becomes ductile, the device will close whilst being removed through the urethra. The Nitinol and connective wiring is surrounded by the latex used to create the cone;

this will prevent any damage to the bladder neck, urethra and surrounding structures when it is removed.

The next stages in the development of this device could make use of different materials and techniques. The wire housing could be made from a stiffer material such as stainless steel which is commonly used in current resectoscopes; this would allow for a thinner wall thickness and hence a smaller device, although the channels for the Nitinol wire and other connections would have to be insulated so as not to short circuit the device. Furthermore, the wire housing length would be increased to be compatible with and connect to current resectoscopes. Different moulding techniques could also be explored to better incorporate the diameter of the Nitinol when the latex cone is being added. A different grade of latex could also be sought to increase the ultimate strength and to decrease the Young's modulus so that the folding, that can be seen when the device is closed (figure 8 & figure 9), does not occur. Also potential additives to the latex to prevent it from sticking to itself once being removed from the mould would be explored providing it did not adversely affect the mechanical properties of the latex or its biocompatibility. Other polymers would also be investigated so that the device could be used for patients with latex allergies.

Improved techniques for the electrical connections of the device could also be beneficial. Soldering to Nitinol was difficult and other techniques such as using copper tape and connections by contact were trialled but were unsuccessful. If soldering is continued different techniques and potentially different materials could be sought to decrease the

amount of solder being used and remove the need for flux. Methods to prevent accumulation of the oxide layer on the Nitinol wiring could also be advantageous, as this would decrease the likelihood of any electrical connections failing. Sandpaper was used to try and remove this layer before forming the connections but did not have much of an effect.

After manufacture of a next stage prototype, testing with a resectoscope in a model bladder environment such as a whole *porcine* bladder or a surgical trainer could also be completed. The instrument would be added to a current resectoscope so that the opening of the device and ability of the resectoscope to work in the cone part of the instrument could be seen. This would ensure that the diminished volume of the working environment did not adversely affect the optics and the electrically active wire loop. With further development of the device more comprehensive testing will be necessary. The dye test used here could be improved with the use of microscopy to assess whether any dye has escaped the cone device and 'stuck' to the *porcine* bladder wall. Testing of insertion and removal of the instrument would also be completed. Incorporating a comparable tumour material into this testing would further gauge the effectiveness of the design.

After this initial testing, *in vivo* animal testing could also be completed leading on to early-phase randomised clinical trials gauging the effectiveness of the cone add-on against TURBT with resectoscope and postoperative courses of chemotherapy and immunotherapy.

8. Conclusion

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This paper has presented the current problems associated with the surgical treatment of non-muscle invasive bladder cancer and the development of a novel instrument in which the concept of actuation with shape memory alloys using current actuation has been proven. Also it has been shown that the prototype described is able to limit fluid transfer within an opening cone environment. The author's believe that the concept design and method of actuation has potential for clinical use.

9. Acknowledgements

10. Competing Interests

RTB has contributed to an advisory board for Olympus Medical Systems with regard to narrow band imaging cystoscopy. All other authors declare that they have no competing interests.

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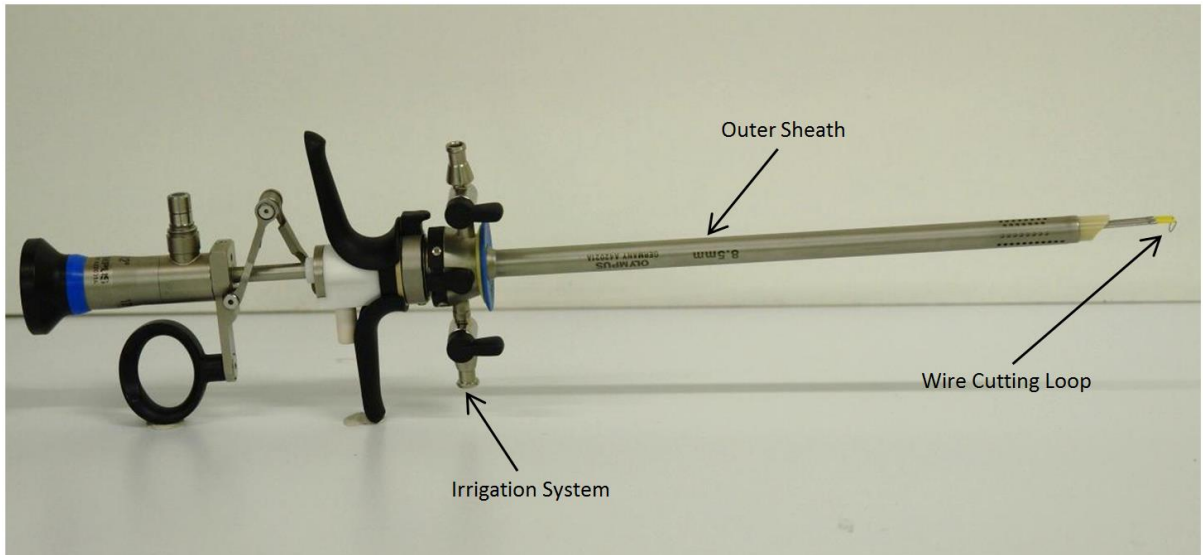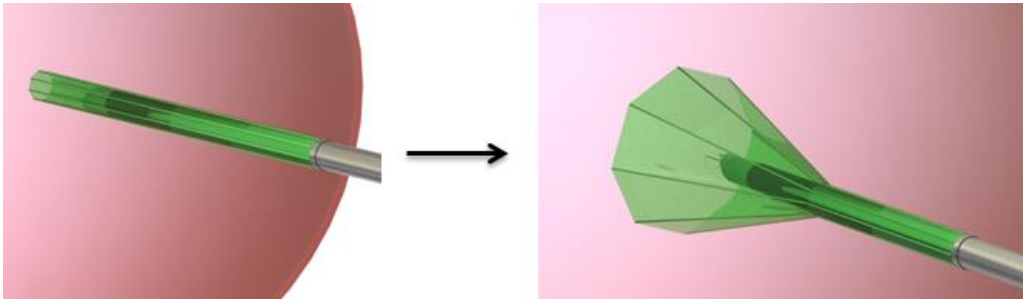
Figure 1

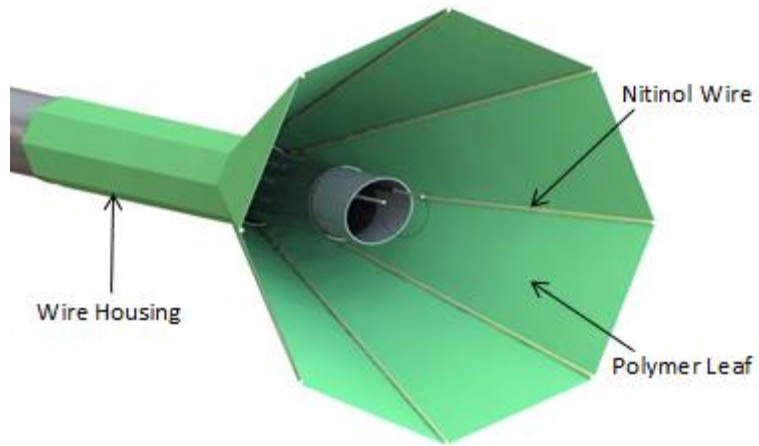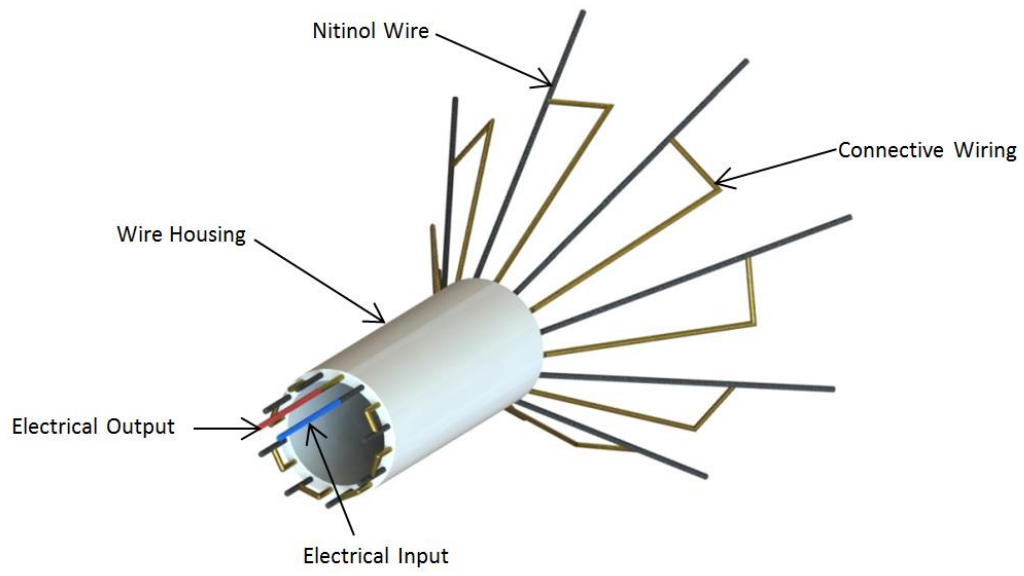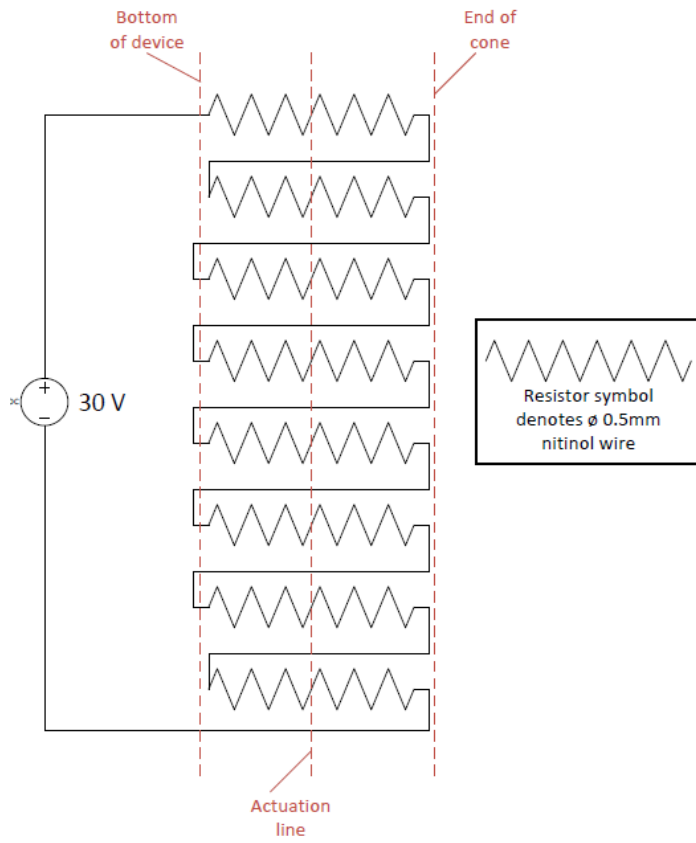Figure 2

Figure 3

Nitinol Wire
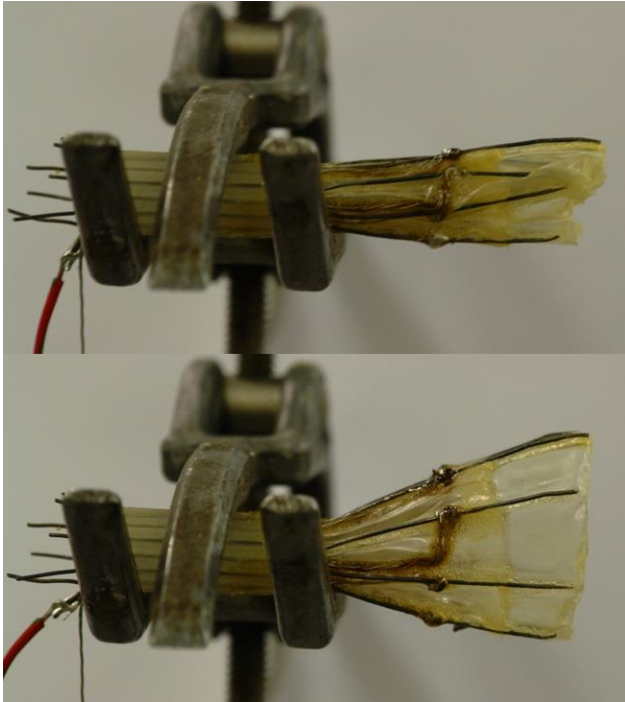
Wire Housing
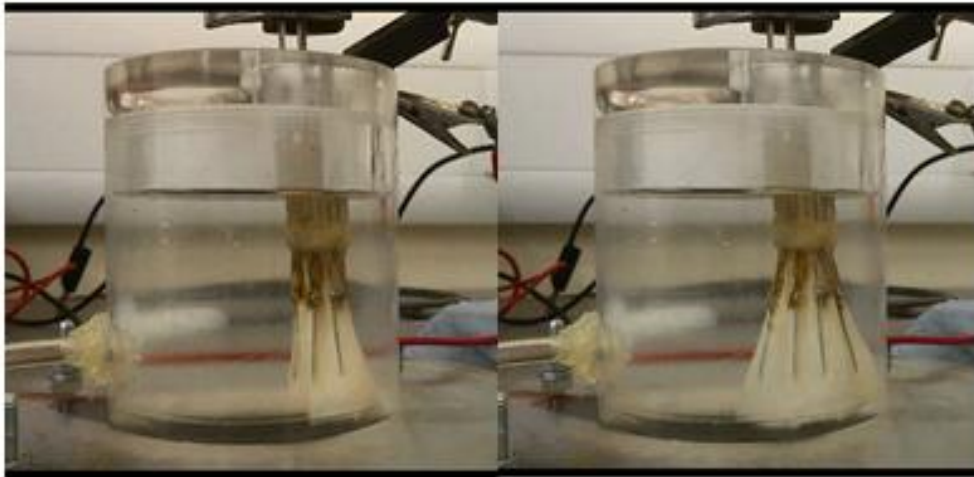
Polymer Leaf

Figure 4

Figure 5

Figure 6

Figure 7

Figure 8

Figure 9

Figure 10