INSTITUTE OF PHYSICS PUBLISHING JOURNAL OF MICROMECHANICS AND MICROENGINEERING

J. Micromech. Microeng. **15** (2005) 2045–2055 doi:10.1088/0960-1317/15/11/008

Shape memory alloy clamping devices of a capsule for monitoring tasks in the gastrointestinal tract

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Received 8 June 2005, in final form 24 August 2005
Published 20 September 2005
Online at stacks.iop.org/JMM/15/2045

Abstract

This paper describes the development of an active clamping mechanism to be integrated into a swallowable pill for the diagnosis of the gastrointestinal (GI) tract. The clamping system allows us to stop the pill at desired sites of the GI tract for long monitoring purposes. After discussing the major technical constraints, the design of the core component, i.e. the gripper, based on FEA (finite element analysis), is illustrated as well as its fabrication process. Symmetric and asymmetric gripper designs are described. The actuation is provided by shape memory alloys (SMA), and it is driven by a dedicated electrical interface. Then the working prototypes have been tested *in vitro*: for both kinds of grippers a pull-back force up to 0.6 N has been measured. A preliminary theoretical model for the gripper has been derived and compared to the experimental results.

1. Introduction

In recent years, the interest in the development of endoscopic capsules has grown at a tremendous pace, since they promise both to perform diagnosis in a less invasive way in those areas accessible by traditional exams, such as gastroscopy and colonoscopy, and to access new areas of the GI (gastrointestinal) tract, above all the small bowel.

Conceiving a teleoperated microcapsule able to make on-board diagnosis, therapy and biopsy is a challenging goal, whose achievement depends on the technological development in many engineering fields, such as micromachining, microactuation, sensorization, localization and teleoperation.

First examples of wireless monitoring systems and capsules date back to 1957: endoradiosondes, also called radio-pills, were developed by Jacobsen *et al* and used in many medical and biological studies [1]. Few years later, Nagumo *et al* [2] developed a passive echo capsule for temperature and pH monitoring.

Lately, several biomedical companies and research centers have aimed at realizing swallowable capsules. In this framework, Given Imaging Ltd has been the pioneer, being the first company in the world to sell a wireless pill for monitoring the GI tract [3, 4]. The device is essentially a tiny camera, without any active locomotion and stop systems. Once ingested, the capsule is carried inside the GI tract by peristalsis, and the lack of stop mechanisms does not allow us to conduct, at desired locations, tasks such as biopsy, drug release, long-time pH monitoring and accurate visualization. More recently, Given Imaging has launched another pill, this time devoted to the monitoring of the esophagus.

In 2004 some alternatives to Given Imaging came from Norika [5], Olympus [6] and Smart Pill Corporation [7]: in all cases they work on devices without any stop mechanisms. Norika is developing a battery-free pill with semiautonomous locomotion that is able to steer thanks to an external electromagnetic field. The same principle is exploited by the Olympus capsule which is suitable for esophagus, stomach and intestine at the same time. Finally, Smart Pill Corporation sells a battery-powered pill able to measure the pH, the pressure level and the elapsed time in the whole GI tract.

In order to outperform the devices so far realized, an endoscopic capsule should possess an active locomotion mechanism to proceed independently of the peristalsis motion.

Moreover, the pill should integrate a reliable and safe clamping mechanism, able to counteract the peristalsis force, and to stop the system every time it is required. Concerning the first issue, the authors have conceived a legged locomotion solution [8, 9]. The second issue is the object of this paper, which is organized as follows. Section 2 presents an analysis of the clamping problems by considering the constraints derived from the integration into a swallowable and wireless device; section 3 illustrates a possible solution of a clamping capsule which integrates three frontal and reversible clamping systems with two independent degrees of freedom actuated by nickel–titanium shape memory alloy (SMA). Two different solutions of clamping systems are illustrated in sections 4 and 5, including their modeling, fabrication and testing.

2. General design issues

The need for a device that has to interact with the GI tract and must be integrated in an ingestible capsule should be evaluated carefully, by taking into account several aspects both from the engineering and the medical viewpoint [10]:

- The capsule (whose specifications can be found in [11]) is a hollow cylinder 26 mm in length, with an external diameter of 12 mm and an internal diameter of 8 mm. In the cavity, a video acquisition unit is lodged, while the overall length also includes a battery to supply the video unit, the clamping system and the other monitoring sensors. The maximum power needed for the clamping mechanism has been estimated as 800 mW. Obviously the grasping system must be small to save as much room as possible. On the other hand, the clamping system cannot be too tiny because it has to counteract large forces which can arise in the GI tract.
- Both reversible and non-reversible clamping systems can be conceived. In the first case an actuator allows the capsule to clamp the gut wall and to detach from it, generally in a controlled and teleoperated manner. In the second case the clamping system is a one-shot mechanism: it is able only to grasp the tissue, but not to detach in a controlled manner. Only a physiological degradation of the tissue can generate the detachment action. Undoubtedly the first concept has the advantage of making possible a thorough analysis in many areas of the organism, whereas the second solution is limited to one-site analysis. Obviously a capsule with a reversible clamping system is more versatile and safer, but also more challenging, since a reliable actuator must be developed.
- Since travel inside the GI tract can last several hours and also the monitoring phase can be quite long, power consumption is a critical issue. The ideal solution consists in designing a normally closed mechanism, whose power consumption is negligible both during grasping and resting. Power should be necessary just to change configuration (from closed position to open position and vice versa). In the case of a reversible system, this effect can be obtained, for instance, by exploiting flexure joints.
- The way the clamping system approaches the gut wall for grasping is an issue to be considered: the clamping can be lateral, i.e. along the lateral surface of the capsule, or frontal. The advantage of a frontal mechanism is basically related to the possibility of having a visual feedback before and during the clamping procedure. A drawback of this solution is the low effectiveness of the gripper, since the gut tissue is normally collapsed on the lateral surface of the capsule and not in front of it. Therefore, a lateral clamping system would surely 'snap' the tissue, while a frontal one can encounter some difficulties since the shape of the video unit is spherical and can reduce the contact area between the graspers and the gut.
- Given the compliant, nonlinear and viscoelastic nature of the tissue, it is important to consider also its biomechanical properties. The tissue is typically covered by a thick (up to 2 mm) layer of lubricant mucus [12], with a friction coefficient as low as 10^{-3} [13].

3. The clamping capsule

A clamping system was formerly developed by Dario *et al* [14, 15], by combining the tissue's collapse by suction with mechanical grasping of the same tissue. Although this device proved to be effective and safe, it is not possible to scale it down to the size of a capsule which has a volume of about 2 cm^3, including also the video unit. This consideration has suggested following a different approach: instead of forcing the tissue into the adhesion/clamping area, the mechanical clamping system can be pushed against the tissue.

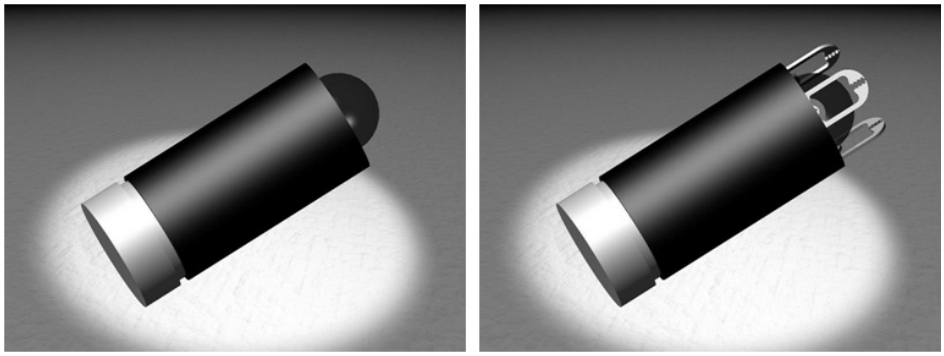
By considering the importance of performing diagnosis in multiple areas of the GI tract, a reversible solution has been conceived, thus involving also the development of an actuation system for the clamping mechanisms. The authors have selected the frontal clamping architecture in order to provide the operator with a visual feedback of the grasping procedure. The system consists of three clamping systems, each including a gripper and a support to lodge the gripper. These subsystems are lodged in the body of the capsule and are able to move forward and backward up to 6 mm, thanks to a couple of actuators. A third actuator makes the opening of the gripper independent of the sliding movement of the support, and hence the gripper. A basic concept of this solution is shown in figure 1.

3.1. Gripper design criteria

Today, with the advent of microtechnologies, the number of applications requiring to handle microcomponents is increasing quickly. Carrozza *et al* [16] developed a microgripper, fabricated by LIGA, suitable for manipulating biomedical devices. An SU-8 gripper, actuated by SMA, was conceived by Roch *et al* [17] for handling microelectronics components.

In this paper the core component of the clamping system is a gripper, which has to satisfy the following requirements:

- It must be normally closed, thus avoiding power consumption at rest and during long monitoring. The system will be activated just when opening is required.
- Wide spanning is desired in order to 'embrace' as much tissue as possible. In this regard, the gripper profile must be shaped carefully since it is important that the GI wall is grasped gently, thus avoiding bleeding or trauma.



(*a*) (*b*)

Figure 1. Basic concept of a clamping capsule before (*a*) and after gripper protrusion (*b*).

- The force should be maximized in order to reach its maximum value after grasping the tissue, thus ensuring stable clamping.

By taking into account all these aspects, the following subsection deals with the actuator selection.

3.2. Actuator selection

Building a reversible clamping solution requires a dedicated actuator, which has to be expressly developed, because there are no suitable actuators for this small size. This is noteworthy because some technologies work well in the macroscale, but they lose effectiveness when scaling down. Moreover, both biocompatibility and reliability are critical, given the medical application of the capsule, which has to embed no toxic materials and perform many clamping cycles without any risk of malfunctioning. Finally a large stroke, spanning from some millimeters up to 1 cm, is required.

From a preliminary analysis, piezoelectric and SMA actuators looked the most promising for the targeted application. In the case of piezoelectric actuators, displacement amplification mechanisms are required in order to reach the desired stroke.

Besides satisfying all the above requirements, SMA show a silent and smooth movement which can be very adequate for operating in the human body. Based on the above considerations, thermally activated nickel–titanium SMA wires have been exploited to actuate the gripper. Since the cooling process plays an important role in the bandwidth of a SMA actuator, it is mandatory to consider all the effects of heat transfer. In [18] it is found that irradiation is negligible since the activation temperature, called 'Austenite Start' (A_S), is around 90 °C, while convection is limited to the fluids inside the organism. Therefore only conduction is considered and can be computed by (1)

$$P_t = h \cdot S \cdot \Delta T \tag{1}$$

where P_t is the thermal power (W), h is the heat transfer coefficient (W m^{-2} K^{-1}), S is the surface exposed to the cooling medium (m^2) and ΔT is the temperature difference between system and environment (K).

When considering SMA, ΔT is related to the transformation temperatures that depend on the ratio between nickel and titanium in the alloy. The other important parameter

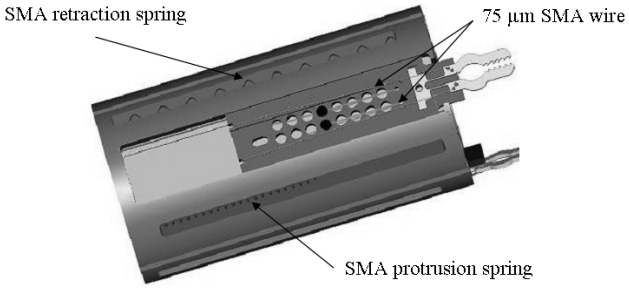


Figure 2. Clamping capsule.

which affects the conduction is the surface exposed to the cooling medium. By maximizing the surface–volume ratio, the performance of SMA wires can improve: reducing the wire diameter shortens the activation and the cooling time. Moreover less current is required since smaller wires have larger resistance and thus they require less current. The heating of the SMA wire can be performed either by the Joule effect or by means of an electron or photon beam [19]. In this work the Joule effect has been adopted.

The main drawback of SMA is the nonlinear relationship between current—hence heating—and movement which affects the controllability of the final clamping mechanism. When cooling down, SMA wires are not able to recover the initial configuration, that is the extended one. This is due to a phenomenon called 'twinning' of the atomic crystal. Therefore SMA need an external device, acting as bias mechanism, to recover the original shape. This process is known as 'detwinning' of the lattice [20]. A flexure joint has been selected as the bias mechanism and its modeling is discussed in the following section.

An advanced concept of the capsule with the clamping systems and actuators is shown in figure 2.

As reported in figure 2, nickel–titanium SMA has been chosen as the actuation means both for the opening of the gripper and for the protrusion/retraction of the clamping system. In particular a 75 μm diameter SMA wire of Flexinol® [21] has been selected to open the gripper, as illustrated in the following section. The SMA wire is wound around a sliding support, as depicted in figure 2.

In the same figure two SMA springs are also shown. They provide protrusion and retraction of the clamping system. They have been obtained by a 100 μm diameter wire [22]

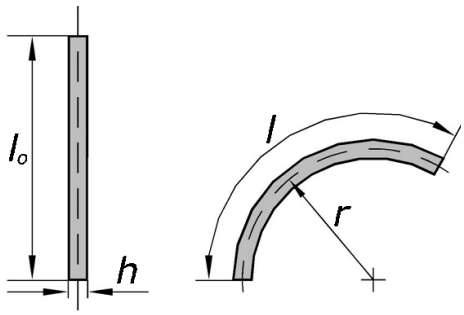


Figure 3. Bending of a beam.

and have a length of 12 mm at rest and an external diameter of 0.6 mm. Moreover they can generate a pulling force of 0.07 N.

The whole actuation system makes the opening of the gripper independent of the protrusion/retraction of the clamping system.

4. Symmetric gripper

4.1. Flexure joint modeling

In SMA the solid state transformation from martensite to austenite occurs when there is a change of temperature. However, if properly treated, they show a different effect, so-called superelasticity, instead of the thermal one. It means that the phase change is due to an applied stress [20]. Once the stress is removed, the device automatically recovers the initial shape. The basic idea for the clamping mechanism design has been to combine superelastic joints and SMA actuators in order to obtain a reversible and low consumption gripper. In addition, superelastic SMA has been preferred over other metals for the flexure joints, because it shows larger displacement than the conventional metals. Moreover, given its metallic nature, superelastic SMA is stronger than polymers. In this way it is possible to build a gripper which is able to generate, when closed, a larger force than in the case of a polymeric flexure joint.

In order to model the flexure joint effectively it is necessary to evaluate the behavior of the material during bending. In this way the joint can be considered a beam, as depicted in figure 3.

Referring to this figure l_0 is the length at rest, while h is the width. According to the continuum mechanics theory the external fibers undergo a stretching, whereas the internal fibers undergo a shortening. Conversely, the fibers in the middle do not experience any length variation because they belong to the neutral axis. During the rotation of an angle θ with a bending radius r, we obtain

$$l_0 = r\vartheta \qquad l = \left(r + \frac{h}{2}\right)\vartheta. \tag{2}$$

The strain can be expressed by

$$\varepsilon = \frac{\Delta l}{l_0} = \frac{l - l_0}{l_0} = \frac{h}{2r}. \tag{3}$$

The previous relations have been exploited to preliminarily model the flexure joint. Then it has been extensively modeled by finite element analysis (FEA) [23].

Flexure hinges must act as effective bias mechanisms for the SMA actuators, but they must not be too stiff, because the force produced by the SMA actuators is limited. In order to ensure a wide opening, a bending angle of 60° has been selected. For a length at rest $l_0 = 1$ mm, equation (2) yields a bending radius of 0.94 mm. By imposing a maximum strain of 8% for the fibers, from equation (3) h is 0.15 mm. Therefore a simulation in ANSYS has been carried out, for a flexure joint 150 μm large and 1 mm long. This yields a spanning angle of the gripper of 128° (64° for each side), when a vertical displacement of 0.8 mm is produced by the contraction of the SMA wires. The results of the simulation are reported in figure 4.

Although SMA wires are able to contract up to 8%, it is better to limit this value to 4% in order to ensure a large number of cycles. Wires with a length of 20 mm are adequate for producing a displacement of 0.8 mm. Based on the FEA, the necessary force to generate this spanning angle is 1.27 N. The selected wire has a diameter of 75 μm that ensures a maximum recovery force of 2.4 N, by considering a stress of 600 MPa.

The gripper has been fabricated by using a 250 μm thick ribbon of superelastic SMA of Memory-Metalle GmbH [22]. First, three holes have been fabricated by Sarix Micro Sink EDM (Electrical Discharge Machine); then the profile has been produced by Sodick AP 200L WEDM (Wire Electrical Discharge Machine). The prototype and the dimensions are reported in figure 5. In the same figure a complete prototype of the clamping system is shown too.

The Flexinol® wire has been fixed into the gripper holes and then wound around a support. The features of the clamping mechanism, as a result of experimental tests, are as follows:

- typical spanning angle of the gripper: 60° (experimentally measured);
- typical required current for opening: 150 mA;
- typical opening time: 0.2 s;
- typical closing time after stopping the current: less than 1 s.

The integration of the clamping system into the body of the capsule is shown in figure 6.

Both the support and the body of the capsule are made of PEEK (Polyether-ether-ketone) and have been manufactured through Kern Hspc Micro CNC. As illustrated in figure 2, the clamping system is connected to a couple of SMA springs assuring the protrusion and retraction of the gripper.

4.2. Driving and control

The clamping system is controlled by means of a microprocessor which defines the logic sequence of the actuation. Since there are three different SMA actuation devices (two springs for the protrusion and return of the clamping systems and one wire for the opening of the gripper) three drivers are required. The actuation sequence consists of three stages and is shown in figure 7. The automatic sequence can be described as follows:

- *Protrusion*: a PWM (pulse width modulation) technique has been selected since it ensures a more uniform heating of the SMA spring. The pulse takes 0.125 s with a current

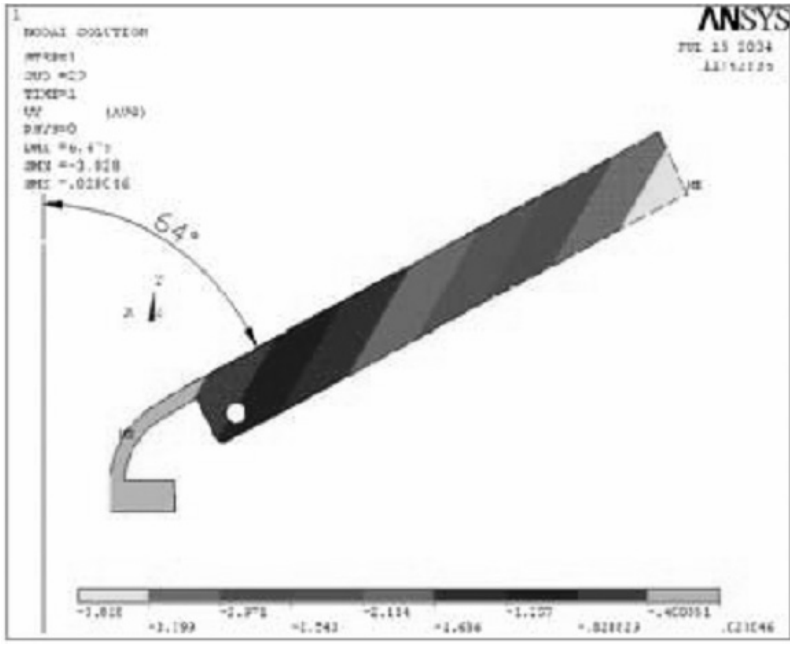


Figure 4. Clamping system FEA (finite element analysis) of the gripper.

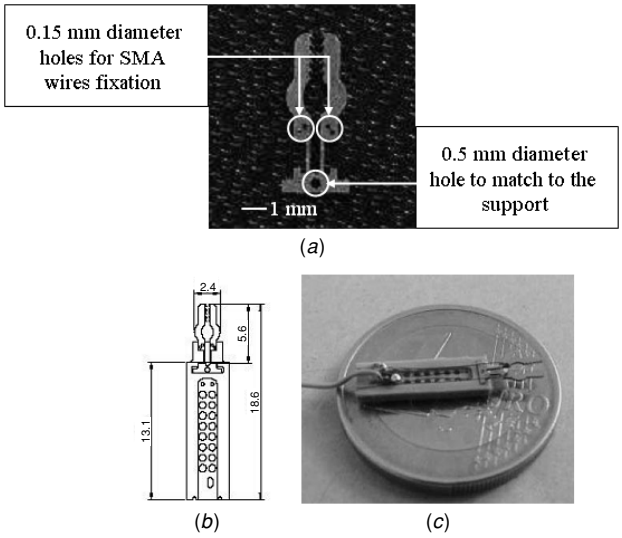


Figure 5. Symmetric gripper: prototype (*a*), dimensions (in mm) (*b*) and integration with the support (*c*).

peak of 350 mA. Then, for 0.125 s the pulse is set off. A second pulse is sent to the spring and then the signal is set off for 0.625 s. The overall sequence is repeated a second time, making this phase take 2 s.

- *Opening*: after 1 s for the gripper protrusion, a 140 mA current is provided to the 75 μm SMA wire for 1 s. In this phase the clamping system opens.
- Automatic gripper closing by removing current.
- Retraction: PWM, as during protrusion stage with the same operative sequence.

4.3. Retraction tests

A preliminary set of *in vitro* tests has been performed in order to evaluate how much the gripper is able to drag a sample of tissue, once having grasped it. A load cell [24] (Sensotec, Model 11/1127-02, measurement range 0–1000 g, sensitivity 2.2 mV/V) has been selected in order to measuring the resulting force.

This test is devoted to measuring the retraction force produced by the spring mechanism during grasping. During the tests the sample has been fixed at one end, while the other end has been connected to the load cell through an elastic wire, as shown in figure 8.

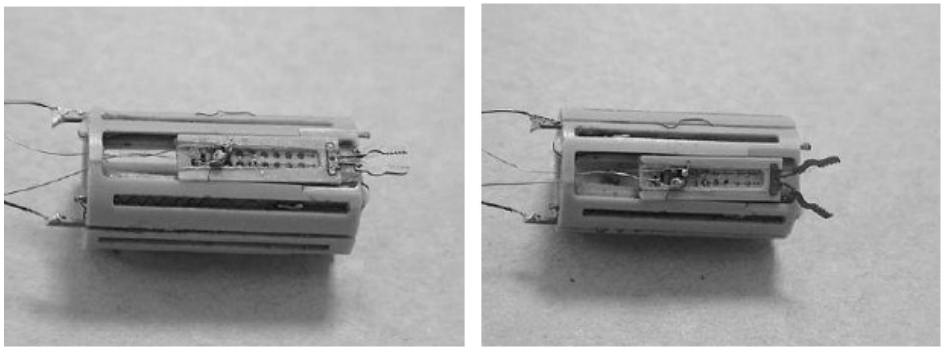
The operative sequence is as follows:

- The protrusion spring is activated to move the clamping system forward and then electrical power is switched off.
- Power is supplied to the SMA wire to open the gripper; during this stage the tissue sample is manually inserted into the gripper and then power is turned off, thus causing the gripper to close automatically.
- At this point data acquisition begins and the retraction spring is activated to pull back the clamping system.
- During data acquisition the force increases linearly up to a saturation limit, when the clamping system is completely retracted into the lodgment.

By exploiting the described experimental setup, a set of retraction tests has been carried out using porcine tissue. Some measurements are reported in figure 9.

The overall force is produced by two components: a preload (offset), depending on the initial length of the elastic wire, and an increasing component, corresponding to the extension of the wire during the retraction of the clamping system. By moving the capsule horizontally, it has been possible to perform tests with different preloads, as indicated by the four measurements reported in figure 9.

During all tests, the retraction produces an additional force of about 0.05 N. The set of measurements shows that the maximum pull-back force is approximately 0.4 N (the line



(*a*) (*b*)

Figure 6. Clamping capsule prototype with protruded gripper: closed gripper (*a*) and open gripper (*b*).

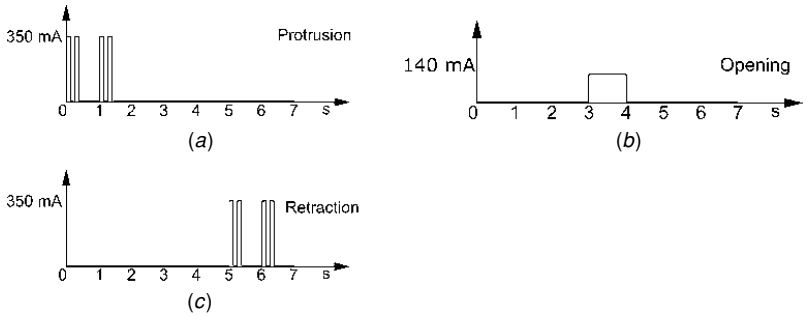


Figure 7. Actuation phases: protrusion (*a*), opening (*b*) and retraction (*c*).

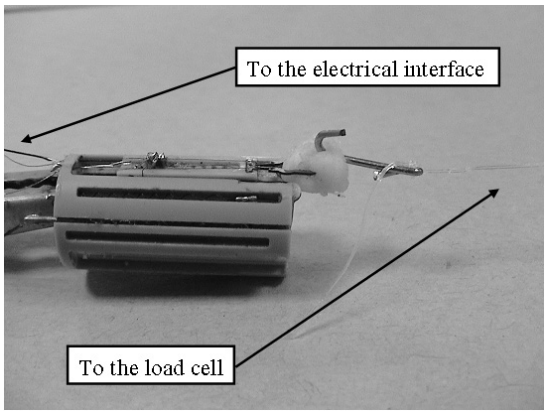


Figure 8. Experimental setup.

at the top of figure 9). Above this value, grasping becomes unstable and the sample slips off the gripper. By considering that the working capsule weight should not exceed 0.05 N, we can conclude that the system is able to generate a force eight times larger than its weight; therefore it has good possibilities to overcome the peristalsis forces during its travel.

During tests, it has been observed that the protrusion/retraction mechanism and the grasping mechanism have operated more than 100 cycles without failure. On the other hand, for the selected shape of the gripper, some room remained between the tips after closure. This means that small tissue samples could slip out of the gripper, thus making it very difficult to perform repeatable measurements. Moreover, the higher the number of cycles, the greater the space between the tips. This inconvenience is due to some degree of hysteresis, typical of the superelastic SMA.

4.4. Test model

A model of the phenomena occurring during grasping has been developed in order to better understand the test results. The goal of the model is to find the necessary force to tighten a sample of tissue. In particular two different analyses have been performed in order to compare the analytical and experimental results. In the first case, the gripper tightens on the tissue and the support is at rest, meaning that no retraction occurs. In the second analysis retraction is considered and consequently there is also a traction force, as reported in figure 10.

The relation between force and strain, without traction, is given by equation (4):

$$N = \sigma \cdot A = E \cdot \varepsilon \cdot A \tag{4}$$

where N is the grasping force; E is the Young modulus (0.7 MPa [25]); ε is the deformation of the tissue, which is 45% (experimentally measured); A is the contact area between the gripper and tissue.

With a contact area of 0.18 mm^2, a value of 0.057 N has been estimated for the normal force N.

When the traction occurs the sample of the tissue tends to slip and detach from the gripper: the gripper reacts, exerting the force R in the figure, that is a resistance to avoid any slip of the tissue.

The relationship among the forces is described by equation (5):

$$F = \mu \cdot N + R \tag{5}$$

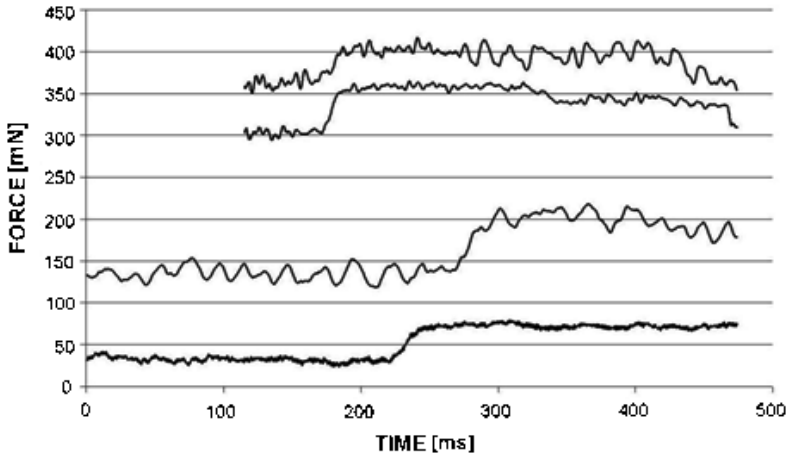


Figure 9. Measurements for the evaluation of the retraction force for the clamping capsule with symmetric gripper.

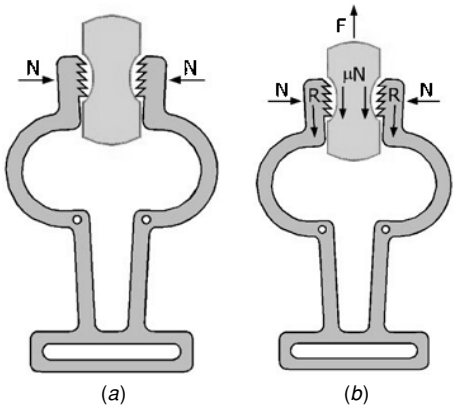


Figure 10. Forces scheme without (*a*) and with traction (*b*) for the symmetric gripper.

where F is the traction force arising when the clamping support starts to retract. It can be assumed as 0.35 N (starting level of the maximum retraction force profile in figure 11); μ is the static friction; N is the grasping force; and R is the resistance force of the gripper.

In (5) N, R and μ are unknown. In the literature [13] data exist on the dynamic friction coefficient between porcine tissue and a metal substrate: this average value is 0.49. Thus, we can simplify equation (5) by introducing μ' (dynamic friction coefficient) which takes into account also the R component deriving from the traction condition. Thus, equation (6) is obtained:

$$N = \frac{F}{\mu'}. \tag{6}$$

Introducing the above values for μ' and F, we obtain $N = 0.7$ N.

5. The asymmetric gripper

As observed in the previous section, the grasping force is limited by the gripper shape which is not able to keep firm hold of the tissue, especially after many working cycles. For this reason, the authors developed a different gripper with an asymmetric shape which exploits an overlapping design of the chelae, thus being more effective at clamping the tissue.

5.1. Modeling, fabrication and integration

In order to obtain a large span during the gripper opening also with longer chelae tips (compare figure 5(*a*)), the gripper must integrate less stiff flexure hinges than in the previous design. This requires changing the parameters in equations (2) and (3). In particular l_0 should be larger, while h should be smaller. In this case $h = 0.1$ mm and $l_0 = 1.6$ mm have been selected.

As for the symmetric gripper, the new model has been made of a 250 μm thick ribbon of superelastic SMA of Memory-Metalle GmbH. Also in this case a couple of holes with a diameter of 0.15 mm have been made by Sarix Micro Sink EDM; then the profile has been obtained by Sodick AP 200L WEDM. The prototype and its dimensions are reported in figure 12.

Figure 12(*b*) shows that the tips of the gripper have 0.6 mm overlap. Concerning the integration of the gripper, the support and the body of the capsule are the same as the symmetric gripper, as reported in figure 13.

5.2. Retraction tests

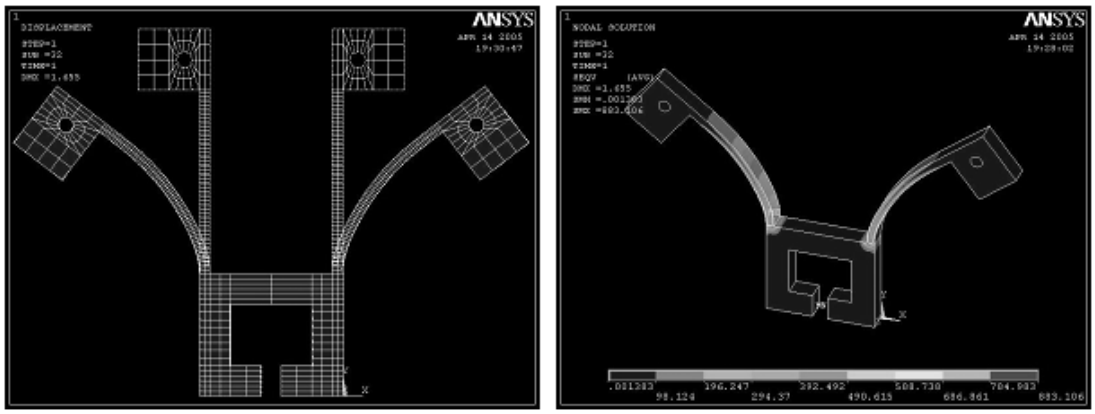
In vitro tests have been performed with the capsule with the asymmetric gripper in order to evaluate the force during retraction and also the ability to grasp a sample of porcine tissue.

The setup for this kind of measurement is the same as in the case of the symmetric gripper. A set of measurements is reported in figure 14 for two different preloads.

Similar to the previous tests, the measurements include an initial steady tract (see also section 4) and an uphill tract, corresponding to the retraction of the support with the gripper. By varying the preload and again with a step of 50 mN during retraction, a pull-back force up to 0.6 N has been achieved (top line in figure 14).

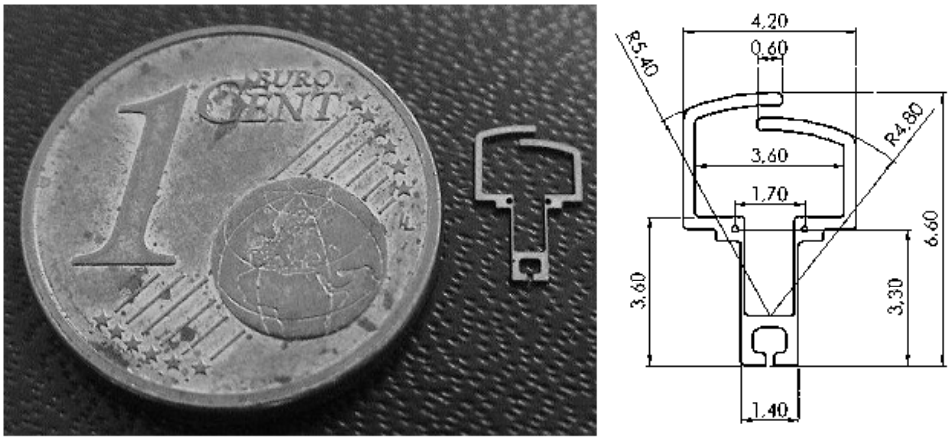
5.3. Grasping tests

The goal of these tests has been to find a relation between the necessary current to open the gripper and the force generated by it. An indirect measurement has been performed according



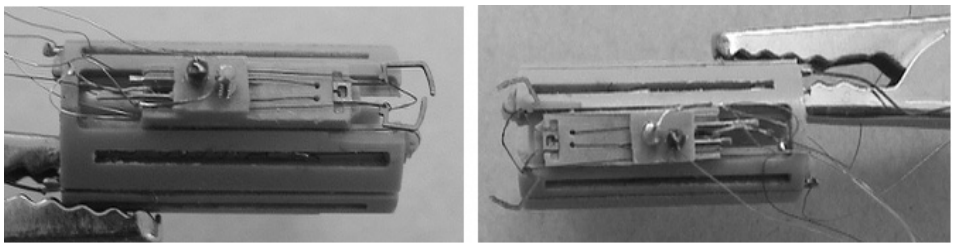
(*a*) (*b*)

Figure 11. Finite element analysis (FEA) of the flexure joints of the asymmetric gripper: deformed and undeformed structure (*a*) and enlarged view (*b*).



(*a*) (*b*)

Figure 12. Prototype of the asymmetric gripper (*a*) and dimensions (in mm) (*b*).



(*a*) (*b*)

Figure 13. Prototype of the clamping capsule with asymmetric gripper: retracted support and closed gripper (*a*) and protruded support with open gripper (*b*).

to the following steps:

- manual shifting of the capsule to open the gripper at different angles (a photograph of the position has been taken);
- simultaneous reading of the generated force by a load cell connected to the gripper chelae;
- the capsule is disconnected from the load cell and electrical power is supplied to the gripper: the opening depends on the level of current (a photograph of the position has been taken).

Some pictures of this measurement process are shown in figure 15.

The comparison of photographs with the same opening angle has provided the relationship between current and force, as reported in figure 16.

The gripper has also been tested under conditions beyond those of this figure. The gripper proved to open up to 90° (considering both tips) with 170 mA of current. Table 1 summarizes the values of the maximum opening angles both for the symmetric and asymmetric grippers.

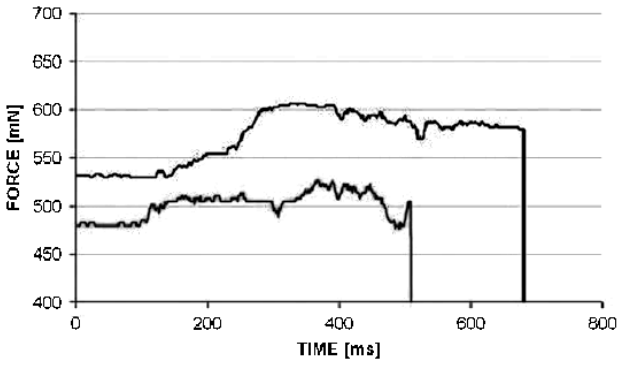


Figure 14. Measurements for the evaluation of the retraction force for the clamping capsule with asymmetric gripper.

Table 1. Theoretical and experimentally measured opening angle for the two different kinds of gripper.

	Theoretical angle	Experimentally measured angle
Symmetric gripper	128°	60°
Asymmetric gripper	180°	90°

Table 2. Parameters of the flexure joints for the symmetric and asymmetric gripper.

	l_0 (mm)	h (mm)
Symmetric gripper	1.0	0.15
Asymmetric gripper	1.6	0.10

In particular the theoretical values have been achieved thanks to the different geometries of the flexure joints. In table 2 the values for l_0, h are reported for both grippers.

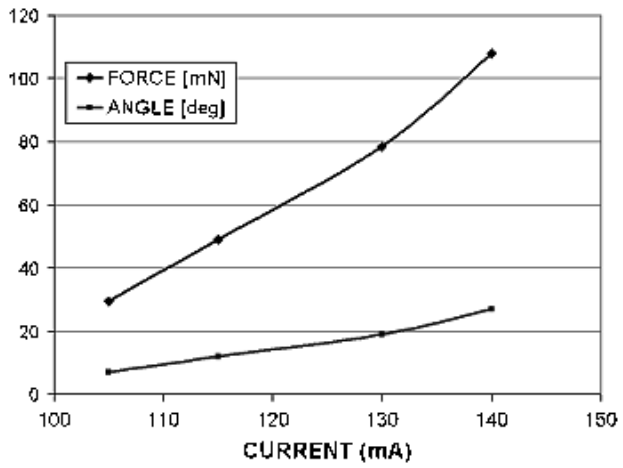


Figure 16. Measurement of the current–force relation.

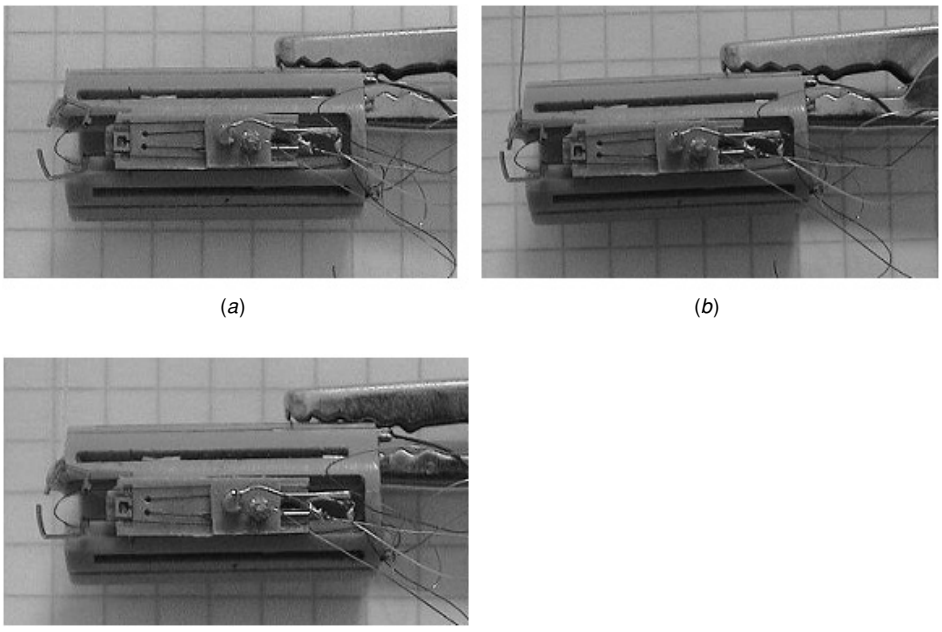
5.4. Test model

The forces scheme for the asymmetric gripper is shown in figure 17.

For this kind of gripper there is also a tangential component, since the tissue compression is not collinear. At rest, i.e. without a traction component, the value of the normal force N is 0.03 N, with a contact area of 0.103 mm^2 (using equation (4)).

Similar to the previous gripper, during traction the tissue tends to slip and detach from the gripper. Also in this case the gripper reacts by exerting a resistance force R to avoid any slip of the tissue.

According to the different geometry, equation (5) can be rewritten in the following way:



(*a*) (*b*)

(*c*)

Figure 15. Operative sequence for the evaluation of the force–current relation: before (*a*) and after (*b*) manual opening of the gripper and during electrically driven opening (*c*).

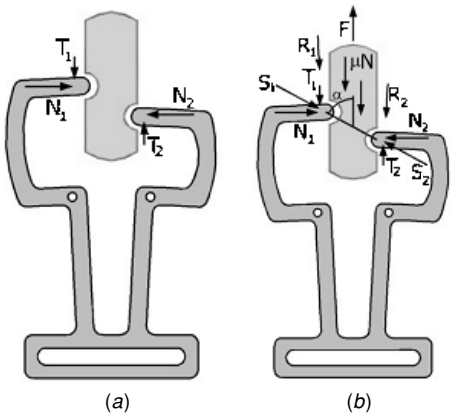


Figure 17. Forces scheme without (*a*) and with traction (*b*) for the asymmetric gripper.

Table 3. Theoretical grasping force for the symmetric and asymmetric grippers without and with an external traction force.

	Grasping force without traction (N)	Grasping force with traction (N)
Symmetric gripper	0.057	0.7
Asymmetric gripper	0.03	1.1

$$F = \mu \cdot N \cdot \cos(\alpha) + R \tag{7}$$

where α is the angle between the traction force F and the resultant clamping force S in figure 17.

Similar to equation (6), a simplified model can be adopted and expressed by equation (8):

$$N = \frac{F}{\mu' \cdot \cos(\alpha)}. \tag{8}$$

By introducing $F = 0.53$ N (starting level of the maximum retraction force profile in figure 14) and $\alpha = 10^\circ$ in (8), we obtain $N = 1.1$ N. In table 3 the values of the grasping forces are reported for the two types of gripper, with and without traction.

The results reported in table 3 demonstrate that the asymmetric gripper design is more adequate for producing large forces in traction conditions. When traction is not present, the grasping force depends basically on the gripper tip size.

6. Conclusions

This paper addresses the innovative concept of an active capsule for diagnosis purposes in the GI tract. The distinguishing feature of the proposed capsule is an on-board mechanical system which enables us to clamp the tissue for long duration monitoring applications. The core components of the device, i.e. the gripper, have to satisfy critical requirements in order to work properly: it must provide enough force to counteract external forces (due to peristalsis), but it should consume little power, because the power source is on-board the capsule and—for this reason—the power is limited.

Therefore a fine modeling of the clamping system has been illustrated. The actuation of the gripper is discussed, showing how the two effects of SMA, i.e. thermal effect and superelastic effect, are considered adequate to realize an effective grasping unit.

In particular, the gripper exploits superelastic flexure joints, which act as bias mechanisms for a 75 μm diameter SMA wire which makes the gripper open. By adopting this solution, power consumption is limited just to the opening of the gripper and the speed of the mechanism is acceptable for the intended application. SMA have been exploited not only to activate the clamping system, but also to implement a protrusion/retraction system and to allow the gripper to shift along the external surface of the capsule, when required. Preliminary *in vitro* tests on porcine tissue have been reported for a first clamping system prototype, thus demonstrating a pull-back force of the grasping system up to 0.4 N, a retraction force of 50 mN, and a maximum span of 60°, taking into account both chelae of the gripper.

Thus, a second prototype has been design and developed by exploiting the same combination—SMA wire, SMA springs, superelastic flexure joints—but with a different chelae design in order to improve the grasping force and stability, which was poor in the first prototype. In fact, the new gripper has proved to have a pull-back force up to 0.6 N, a retraction force of 50 mN and an opening angle of 90°, considering both chelae of the gripper. Theoretical modeling has been conceived for both kinds of grippers in order to compare the results with those of the *in vitro* tests and to produce guidelines for future gripper designs.

Acknowledgments

This work has been supported by the Intelligent Microsystem Center (Seoul, South Korea). The authors would like to thank Mr N Funaro and Mr C Filippeschi for manufacturing the prototypes, Mr M Quirini for his help during FEA and Mr I Izzo for his suggestions on the test model.

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