A Novel Holding Mechanism for Next Generation Active Wireless Capsule Endoscopy

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Abstract—This paper proposes that next generation wireless capsule endoscopy (WCE) technology will feature active mechanical components (i.e. actuated) as opposed to current systems that are predominantly passive (e.g. for imaging purposes). Future systems will integrate microsystems that use micro-actuators to, for example, perform micro-surgery, take tissue samples, deliver medication, etc. In this paper we detail a novel, ultra-compact integrated mechanism for resisting peristalsis and describe how this can be fabricated in Nylon 6 using CNC milling. The holding action is achieved by extending an “anchor” spanning an effective 60.4 mm circumference, for a 11.0 mm diameter WCE. This function is achieved by a mechanism that occupies only 347.0 mm³ volume, including mechanics and actuator. This shows how exploiting conventional manufacturing processes can result in a radical change in the capabilities of WCE systems and empower the next generation of active devices.

I. INTRODUCTION

Wireless capsule endoscopy (WCE) has become a valuable tool for the diagnosis of pathologies of the gastrointestinal (GI) tract [1]. These small pill-sized cameras allow the gastroenterologist the ability to diagnose pathologies such as Crohn’s disease, small intestinal cancer or ulcerative colitis in the small intestinal tract, which is the most difficult section of the alimentary canal to reach. The pill-sized cameras take pictures of the intestinal wall and relay them back to a recorder for evaluation at a later date.

An early example of a swallowable WCE is the M2A developed by Given Imaging Ltd. in 2000 [2], it was renamed PillCam^{TM} SB(R) in September 2004. The PillCam^{TM} was specifically designed to overcome the problem of examining the small intestine. The capsule which is 11.0 mm in diameter and 25.0 mm long comprises a complementary metal oxide semiconductor (CMOS) camera, four illuminating light emitting diodes (LEDs), a radio frequency (RF) module and a power supply. WCE has now become the gold standard for examining the GI tract and there are a number of WCE available commercially for this purpose, a detailed review of commercial WCE systems can be found in [3] [4].

WCE systems are generally restricted to diagnostic use as the availability of onboard space for surgical tools or medication limits the ability to treat pathologies such as ulcerative colitis [5]. This inability to deliver therapy to an area of interest in the GI tract leaves only the curative

options of administering large quantities of drugs or surgical intervention.

This paper presents a novel holding mechanism to assist in targeted drug delivery in next generation WCE. The paper is organised as follows: Section II presents the design and analysis of the holding mechanism, Section III presents a prototype of the holding mechanism and Section V concludes this work.

Fig. 1. Microrobot concept with a volume of 3.0 cm³. It is capable of resisting peristaltic pressure through an integrated holding mechanism and delivering 1 ml of medication to a target site

II. NOVEL MECHANISM FOR RESISTING PERISTALSIS

There is a clinical need to target and treat pathologies of the GI tract such as ulcerative colitis, polyps and Crohn’s disease [6]. These pathologies are currently being treated by using conventional endoscopes in the upper and lower regions of the GI tract but the middle section, the jejunum and ileum, are only reachable through viewing a series of pictures from a WCE. Passive WCE do not meet the clinical need to directly treat these pathologies of the small intestines. In order to examine or treat a specific location or feature within the GI tract a WCE would be required to stop. However it would still require small overall geometry to enable the capsule to pass through the junctions of the GI tract without becoming an obstruction.

A. Microrobot concept

Figure 1 represents a microrobot concept design capable of resisting peristaltic pressure through the deployment of an integrated holding mechanism and delivering a 1 ml dose of medication to a targeted site through the positioning of a

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needle. The needle has the ability to be positioned in a 360 degree envelope while simultaneously maintaining a diametrically opposite relationship with the holding mechanism, this novel feature guarantees needle penetration of the GI tract wall. A detailed evaluation of the targeting mechanism can be found in [7].

Fig. 2. Fully extended holding mechanism and micromotor driving a bevel gear set a), holding mechanism shown in the fully retracted position b)

B. Microrobot technical specification

Conventional WCE have a volume of 2.0 cm^3 however the increased functionality requires a greater volume to house the mechanisms therefore a volume of 3.0 cm^3 has been chosen for the microrobot. The microrobot is still within the boundaries of swallowing [8] and it would also be capable of navigating junctions of the the small intestine such as the ileocolic valve. The detailed specifications for the microrobot's performance is outlined in Table I.

TABLE I
OVERALL MICROBOT TECHNICAL REQUIREMENTS

Requirement	Specification
Microrobot volume	Maximum 3.0 cm^3
Sensing	pH, temp and pressure
Vision	CMOS and optical dome
Illumination	4 white LEDs
Power source	Onboard supply
Tracking	RF and time
Telemetry	Bidirectional
Attaining equilibrium	Expansion
Delivering therapy	Liquid medication
Drug reservoir	1 ml

In order to realise a WCE with added functionality such as the ability to resist natural peristalsis or targeted drug delivery it is important to consider how these mechanisms can be operated.

A single micromotor manufactured by Faulhaber (02/1) has been selected to drive the holding mechanism Fig. 2a). The micromotor's small package size of $\text{Ø}1.9\text{ mm} \times 10.82\text{ mm}$ long allows the motor to be orientated perpendicular to the microrobot. The micromotor's novel configuration coupled with the bevel gear set allows rotation to

be translated through 90 degrees and also a reduction in the micromotor's RPM while maximising the use of space, Fig. 2b). The reduction in RPM will result in a multiplication of the micromotor's torque, this will give the legs the strength required to distend the GI tract wall and hold the microrobot in place [9]. The thin leg sections pose a potential risk of damaging the GI tract wall if external forces become too high. However a larger surface area could easily be integrated into the distal profile of the holding mechanism's legs to eliminate any potential trauma from operating the mechanism.

The bevel gear set comprises a 13 toothed drive gear, connected to the micromotor, and a 48 toothed follower gear, Fig. 3a). The stability of the follower gear is derived from the casing of the microrobot and a cover which holds the micromotor and bevel gear in position. The 48 toothed bevel gear drives an 8 toothed spur gear, Fig. 3b). The 8 toothed spur gear drives a gear train which runs inside a recess in the 48 toothed bevel gear. The last pair of 22 toothed gears drive the holding mechanism in and out via a connection between the gears and two legs.

Fig. 3. Fully extended holding mechanism: a) 0.2 module 13 tooth and 48 tooth bevel gear set, b) the 48 teeth bevel gear drives the central 0.1 module 8 toothed spur gear with the gear train running in a recess set in the bevel gear

C. Gear train parameters

The gear train reduces the 1,538 RPM output from the micromotor to 8.4 RPM this allows the holding mechanism to be fully deployed in approximately 1.8 s. Based on an average transit time through the small intestines of 23 mm/min [10] the capsule would have travelled approximately 0.7 mm before the holding mechanism is fully deployed. The response time of the holding mechanism can be adjusted by reducing or increasing the number of teeth on the driver or follower gears.

The overall geometry of the microrobot and the gear module, which is the ratio of the pitch diameter to the number of teeth on the gear, has a direct influence on the dimensions of the gears. For example, the 48 toothed bevel gear has a module of 0.2 this results in an overall diameter of 10.0 mm which represents the maximum diameter that could fit within the microrobot. A module of 0.1 has been selected for the gear train as this facilitates maximum speed reduction yet minimises the use of space. The design parameters for the complete gear train are specified in Table II.

TABLE II
BEVEL GEAR AND SPUR GEAR DESIGN PARAMETERS

	Number of teeth (z)	Normal module (m_n)	Outside diameter (OD)	Tooth depth (h)	Tooth thickness (t)	Face width (b_t)
Bevel gear 1	13	0.2	3.0	0.48	0.314	0.7
Bevel gear 2	48	0.2	10.0	0.48	0.314	0.7
Drive gear	8	0.1	1.0	0.24	0.157	0.45
Follower gear	34	0.1	3.6	0.24	0.157	0.45
Leg drive gear	22	0.1	2.4	0.24	0.157	0.45

Dimensions in mm

D. Gear tooth loading analysis

The 0.1 module chosen for the gear train results in a micro-metre gear tooth profile, Fig. 4. It is therefore important to determine if the teeth can withstand the bending loads which they will be subjected to when the micromotor is operated at its maximum RPM. The Faulhaber (02/1) micromotor has been selected for the purpose of the gear train analysis. It has a two stage 13:1 reduction gearbox which results in an output of 1,543 RPM and a torque of 0.15 mNm. The following sections analyse the loads which the teeth would be subjected to when the mechanism performs a full cycle.

1) *Gear tooth loading*: For the purposes of analysis the tooth can be modelled as a cantilever beam with an involute gear tooth profile. Figure 4 shows the forces acting at the pitch circle of the involute tooth profile and some additional relationships between features.

Fig. 4. Gear tooth loading modelled as a cantilever beam

The contact angle between mating teeth is known as the pressure angle (Φ) and in this application it is set at an industry standard of 20 degrees for a spur gear.

2) *Bending stress calculations*: The stress figures determined by analysis are an important resource as they can be used to determine the material the gears are to be manufactured from and the manufacturing process.

The bending stress for a spur gear tooth or a straight toothed bevel gear can be obtained by using the Lewis formula which has been modified to take into consideration the contact impact of the gears through the addition of a velocity factor:

$$\sigma = \frac{F_t}{K_v b_t m_n y} \quad (1)$$

Where F_t is the load applied to the tooth, K_v is the velocity factor, b_t is the face width, m_n is the normal module and y is the Lewis form factor.

The assumptions made with the modified Lewis formula are that the full load is applied to a single tooth and the radial component force (F) is ignored, also that the force is distributed evenly over the full face width of the tooth and that the stress concentration effect of the tooth fillet is also ignored.

To calculate the load (F_t) acting at the circular pitch:

$$F_t = \frac{2000T_{f1}}{d_1} \quad (2)$$

Where T_{f1} is the torque on the drive gear and d_1 is the reference diameter of pinion and can be calculated by the number of teeth on the pinion (z) multiplied by the normal module (m_n).

The velocity factor K_v compensates for the dynamic effect of the gears pitch line velocity and the manufacturing method used to produce the teeth profile. For a hobbed or shaped gear the Barth's formula can be used to calculate the velocity factor:

$$K_v = \frac{3.54}{3.54 + \sqrt{V}} \quad (3)$$

Where V is the pitch line velocity and is calculated by:

$$V = \frac{\pi d n}{60} \quad (4)$$

Where d is the pitch diameter and n is the rotating speed of the gear in revolutions per minute.

The Lewis form factor (y) is a function of tooth shape and is independent of tooth size, it also does not take into consideration the stress raiser effect of the tooth fillet. It can be calculated as follows:

$$y = 0.484 - \frac{4.24}{z + 6} \quad (5)$$

Where z is the number of teeth on the gear.

3) *Tooth bending stress*: Applying the modified Lewis formula (Eq. 1) to the bevel gear set, which has a module of 0.2, results in a tooth bending stress of 3.57 Nmm^{-2} for the 13 toothed gear and 2.30 Nmm^{-2} for the 48 toothed gear. The calculated low figures for stress can be used to guide the design of the gears as the results suggest the gear set could be manufactured from a polymer such as PEEK. The benefit of making the 48 toothed gear from a polymer would be a simplified assembly as friction bushes can be eliminated by designing the gear to have bearing surfaces and reduced weight. However applying the formula to the next gear in the train results in significantly higher levels of bending stress.

Applying the Lewis formula to the 8 toothed drive gear, which has a module of 0.1 and is connected to the 48 toothed bevel gear, yields a stress of 176.21 Nmm^{-2} . At this level of stress it would result in a polymer tooth yielding therefore a metallic gear would be required. The Lewis formula does not take into account the stress raising effect of the fillets or the stress distribution when the radial component load (F) is applied, therefore an FEA analysis has been performed to

Fig. 5. Von Mises FEA 2D isoareas analysis of a 0.1 module gear tooth profile with a radial component load of 1.473 N

determine a more accurate level of stress distribution through the tooth, Fig.5.

Figure 5 shows a Von Mises FEA 2D isoareas analysis of a 0.1 module gear tooth profile with an applied radial component load of 1.473 N. The radial load F has been calculated from the applied load F_t and the pressure angle Φ . There is a distinct difference in the result for loading: Fig. 5 A) shows the compressive stress to be 139.42 Nmm^{-2} while Fig. 5 B) shows the tensile stress to be 121.69 Nmm^{-2} . Although the FEA figures are lower than the calculated figures it confirms that the 8 toothed gear must be manufactured from a metal rather than a polymer to ensure the teeth do not yield under load.

The Von Mises FEA analysis assumes a worst case scenario, that is, at any one time only one pair of teeth are in contact with each other and that they take the total load. Generally two pairs of teeth are in contact however this may drop to 1.5 depending on the degree of tooth truncation and inaccuracies in tooth profile due to the manufacturing process. Increasing the value of the face width or increasing the module would reduce the stress in the tooth, however increasing the module would result in an increase in the overall diameter of each gear in the set and hence the overall size of the gear train would increase. Also increasing the tooth thickness will influence the overall length of the microrobot due to the stack-up of dimensions. However increasing the size of the components would make manufacturing generally easier.

III. FABRICATING THE HOLDING MECHANISM

There are a number of process routes which can be used to produce the holding mechanism's gear train, for example hobbing, rapid prototyping or wire EDM are all methods which could be employed to produce the spur gear set which drives the legs in and out. However, feature geometry, material selection and manufacturing cost dictated that CNC milling was chosen. Figure 6 shows a 5:1 scaled model of the complete gear train assembled in the gear box housing.

Fig. 6. 5:1 scale prototype of the holding mechanism's gear train

Prototyping the gears using a CNC milling machine allowed the use of small diameter end mills ($\emptyset 0.5 \text{ mm}$) to generate the tooth profiles and to achieve the tight root radii of the teeth. However the use of Nylon 6, which was selected for its mechanical properties, resulted in the gears having significant burrs owing to the manufacturing process.

A. Gear measurements

Removing the burrs from the 8 tooth spur gears with a very sharp blade, such as a razor blade, allowed for inspection of the gears to confirm dimensional accuracy. Inspection was performed on a profile projector type PJ-300 manufactured by Mitutoyo at 10X magnification and a Mitutoyo 0-25 mm digital micrometer. The measured results have been collated in Table III.

TABLE III
STATISTICAL MEASURED DATA FOR THE 8 TOOTH SPUR GEARS

	Value	Average	Min.	Max.	SD
Outside diameter (OD)	5.0	5.032	5.02	5.04	0.008
Face width (b_t)	2.25	2.291	2.28	2.30	0.009
Tooth thickness (t)	0.785	0.798	0.79	0.81	0.006
Tooth depth (h)	1.2	1.16	1.14	1.18	0.011

Dimensions in mm

Comparing the measured dimensions with the design values shows that the average gear tooth thickness is greater than the nominal value and that the average tooth depth is shallower than nominal. The measured dimensions are well within the expected manufacturing tolerance limit for the given part however the tendency for the teeth to be slightly bigger than required may pose problems with the gears meshing and running smoothly in the assembly.

The average thickness of the teeth (0.798 mm) suggests that the gear train would not run smoothly due to the reduced clearance however on the larger gears the average thickness of the teeth was undersized (0.71 mm). This compensated for

the thicker teeth and resulted in a smooth running gear train, once the burrs had been removed. The slightly larger sized teeth on the smaller gears are an advantage in this instance as they can withstand a greater bending stress during operation.

B. Prototype holding mechanism

The prototype holding mechanism comprises the micro-motor, gear train (bevel gears and spur gears) and two legs connected to the gear train which drive the tie bars and centre support in and out (Fig. 3). The legs, tie bars and centre support are pinned together to allow them to pivot freely. Fig. 7 shows a section view of the fully assembled holding mechanism with some components removed for clarity and Fig. 8 shows the complete microrobot with the holding mechanism fully expanded.

Fig. 7. 5:1 scale prototype of the holding mechanism fully collapsed

Fig. 8. 5:1 scale prototype of the holding mechanism fully expanded

Figure 8 shows a prototype of the holding mechanism which can be manually operated through the rotation of a

driveshaft connected directly to the gear train and which protrudes through the side of the gearbox; it also has a simplified spur gear train. The purpose of the simplified spur gear train was to enable manual functionality testing of the gears and the holding mechanism's legs and as such the number of turns required to operate the holding mechanism was kept to a minimum. However the gear train uses all the gears specified in the concept design (Fig. 3 and Table II).

Manually operating the gearbox resulted in a smooth, free-running mechanism that took three and a half turns to fully expand the holding mechanism and three and a half turns to collapse it. However the calculated number of turns required to operate the mechanism is 2.6 turns. The difference in these two figures can be attributed to the backlash in the gear train which predominantly comprises of the clearance between the gear, required for free running, and also the clearance between the gears' driveshaft and the housing.

IV. CONCLUSION

In this paper we have presented the first holding mechanism of its kind for the purpose of resisting natural peristalsis in the GI tract. Exploitation of micro actuators and conventional manufacturing techniques resulted in a holding mechanism which has been integrated into a WCE, occupying just 9% of the total available volume. The outcome of prototyping spur gears manufactured from Nylon 6 has highlighted the limitations with conventional CNC milling and material selection. This shows how adapting manufacturing methods to meet intended requirements can allow for radical changes in the capabilities of WCE systems in the future.

REFERENCES

- [1] A. Culliford, J. Daly, B. Diamond, M. Rubin and P. Green 2005 *The value of wireless capsule endoscopy in patients with complicated celiac disease* Gastrointestinal Endoscopy, vol. 62, pp. 55-61
- [2] G. D. Meron 2000 *The development of the swallowable video capsule (M2A)* Gastrointestinal Endoscopy, vol. 52, pp. 817-819
- [3] G. Ciuti, A. Menciassi, and P. Dario 2011 *Capsule endoscopy: from current achievements to open challenges* Biomedical Engineering, IEEE Reviews in, vol. 4, pp. 59-72
- [4] M. Sitti, H. Ceylan, W. Hu, J. Giltinan, M. Turan, S. Yim and E. Diller *Biomedical applications of untethered mobile milli/microrobots* Proceedings of the IEEE, vol. 103, no. 2, pp. 205-224
- [5] T. Ang, K. Fock, T. Ng, E. Teo and Y. Tan 2003 *Clinical utility, safety and tolerability of capsule endoscopy in urban southeast asian population* World Journal of Gastroenterology, vol. 9, pp. 2313-2316
- [6] N. Goldfarb, L. Pizzi, J. Fuhr, C. Salvador, V. Sikirica, A. Kornbluth, and B. Lewis 2004 *Diagnosing Crohn's disease: an economic analysis comparing wireless capsule endoscopy with traditional diagnostic procedures* Disease Management, vol. 7, pp. 292-304
- [7] S. P. Woods and T. G. Constandinou 2011 *Towards a micropositioning system for targeted drug delivery in wireless capsule endoscopy* Proc. IEEE International Conference of the Engineering in Medicine and Biology Society, pp. 7372-7375
- [8] A. Connor, P. Evans, J. Doto, C. Ellis and D. Martin 2009 *An oral human drug absorption study to assess the impact of site of delivery on the bioavailability of bevirimat* The Journal of Clinical Pharmacology, vol. 49, pp. 606-612
- [9] S. P. Woods and T. G. Constandinou 2013 *Wireless capsule endoscope for targeted drug delivery: mechanics and design considerations* Biomedical Engineering, IEEE Transactions on, vol. 60, no. 4, pp. 945-953
- [10] Quotient Clinical 2003 *Innovations in early development*