Journal of Zhejiang University SCIENCE B
ISSN 1673-1581 (Print); ISSN 1862-1783 (Online)
www.zju.edu.cn/jzus; www.springerlink.com
E-mail: jzus@zju.edu.cn

Modeling of human colonic blood flow for a novel artificial anal sphincter system*

Peng ZAN†, Guo-zheng YAN, Hua LIU

(*School of Electronics, Information and Electrical Engineering, Shanghai Jiao Tong University, Shanghai 200240, China*)

†E-mail: zanpeng@sjtu.edu.cn

Received Mar. 28, 2008; revision accepted June 21, 2008

Abstract: A novel artificial anal sphincter system has been developed to simulate the normal physiology of the human anorectum. With the goal of engineering a safe and reliable device, the model of human colonic blood flow has been built and the relationship between the colonic blood flow rate and the operating occlusion pressure of the anorectum is achieved. The tissue ischemia is analyzed based on constitutive relations for human anorectum. The results suggest that at the planned operating occlusion pressure of less than 4 kPa the artificial anal sphincter should not risk the vascularity of the human colon.

Key words: Incontinence, Artificial anal sphincter, Colonic blood flow, Tissue ischemia
doi:10.1631/jzus.B0820099 **Document code:** A **CLC number:** R57; TN99

INTRODUCTION

Attempts have been made to develop an artificial anal sphincter as a solution for faecal incontinence, but to date these devices have been associated with many complications, such as infection, obstructed defecation and skin erosion, and have not gained acceptance (O'Brien and Skinner, 2000; Rothbarth *et al*., 2001; Ortiz *et al*., 2002; Bisset, 2004). There are two limitations for the artificial anal sphincter nowadays. One is that patients cannot apperceive when to defecate, so they must be trained to establish the habit to defecate after the device being implanted; the other is that the patients have to pinch the pump by hand for defecation. Therefore, a novel artificial anal sphincter system is needed to simulate the normal physiology of the human anorectum based on transcutaneous power delivery.

This paper describes part of our ongoing effort to realize an artificial anal sphincter that is a novel hydraulic-electric muscle to treat fecal incontinence. Our efforts lie in the realm of a high integration of all functional components and no wire linking to the outer device, which can make the surgical implantation easy and low risky. Erosion is recognized as one of the most serious complications of alloplastic implants placed around the bowel. This may be the result of ischemia after the use of artificial anal sphincter, because the heterogeneous application of pressure by the above device has the potential to create localized high-pressure zones which may damage the bowel if it is embedded into these areas (Sofia *et al*., 1988; Satava and King, 1989). Use of circumferential occlusive devices has been limited predominantly by the development of intestinal ischemia and ulceration in animal models and in humans. When the artificial anal sphincter is used in animals for prolonged periods without pressure control, unacceptable complications occur (Satava and King, 1989; Shoshany and Pena, 1994). A primary concern is to find the critical stress, or trauma threshold, beyond which irreparable (and therefore unacceptable) tissue damage occurs.

The goal of this work is to develop a colonic blood flow analytical model that can be used to pre-

* Project (No. 20070248094) supported by the Ph.D Program Foundation for New Researchers of Ministry of Education of China

dict the onset of ischemia. Such an analytical model will provide us with a method to design a device that can overcome the risk of ischemic complications. After reviewing the design and function of the artificial anal sphincter prototype in Section 2, Section 3 presents a human colonic blood flow model, and then Section 4 gives the experimental results of the model.

SYSTEM OVERVIEW

As shown in Fig.1, this system mainly comprises three modules including a sensor-execution unit, a transcutaneous energy transmission module and a control-communication module.

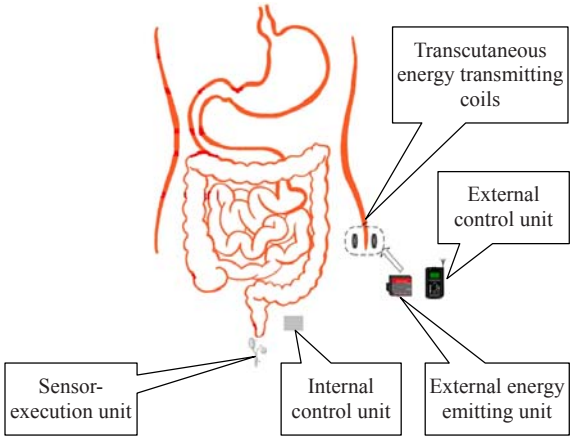

Fig.1 Artificial anal sphincter system architecture

The sensor-execution unit is composed of a reservoir, a front cuff, a sensor cuff and a micropump with motor gear, as shown in Fig.2. There are two sensors in the two cuffs. One can measure the pressure in the front cuff clamping the anorectum, and the other in the sensor cuff can measure the pressure of the anorectum. The front cuff and the reservoir are connected with a bidirectional micropump. By shifting the fluid between the reservoir and the front cuff, the sphincter can be compressed or relaxed and thus the state of continence can be controlled by micro control unit (MCU). For defecation of the bowel and occlusion of the bowel into the front cuff, the fluid has to be pumped into the reservoir.

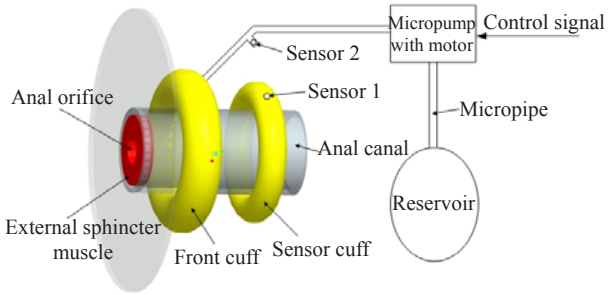

Fig.2 The structure of sensor-execution unit

MCU processes the information of the two sensors and compares the pressure with a threshold. As soon as the pressure closes to the threshold, an alarm signal is sent out. The patients can know whether they should start or stop defecating through the alarm apparatus outside. They can give the start signal to defecate after they are ready and can also give the stop signal to stop defecating. The implanted part is all powered by transcutaneous energy transmission (Yan *et al*., 2007; Tang *et al*., 2007). The energy receiver gets the energy from the coupling between the transmit coil and the secondary coil. The implanted part has no wire linking with the outer device. Prototype of the artificial anal sphincter system is shown as Fig.3.

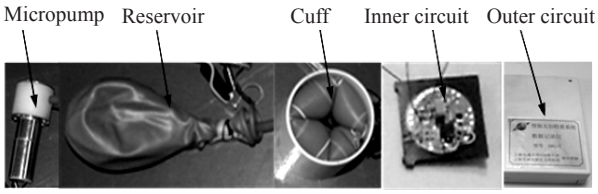

Fig.3 Prototype of the artificial anal sphincter system

COLONIC BLOOD FLOW MODEL

Blood is supplied to the anorectum through the mesentery (Patrício *et al*., 1988). As the mesenteric arteries enter the wall, they branch out into arterioles. When the cuff expands radially to press against the anorectum, the pressure on the tissue increases and eventually becomes larger than the pressure in the tissue arteries. Under these conditions, the compliant arteries may partially or fully collapse. This state of ischemia can damage tissue due to blood and oxygen deprivation (Kloner, 1988). This section develops a relationship between blood flow rate in the anorectum vessels and the operating occlusion pressure applied on to the anorectum wall by the sphincter. With this model, the sphincter could potentially be designed to prevent ischemia. Therefore, this model can also be used as the prediction of ischemia.

Blood supplied to the anorectum

To develop the analytical model, we make some assumptions as follows: the blood vessel tissue and anorectum tissue are incompressible; the embedded anorectum arteries are tubes orthogonal to the longitudinal axis of the anorectum; the operating occlusion pressure is gradually increased. A simplified model of human colonic blood flow of the system is shown in Fig.4, which shows a single artery embedded in anorectum tissue.

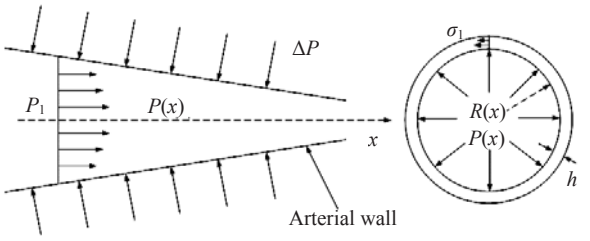

Fig.4 Model of human colonic blood flow

As shown in Fig.4, P is the internal pressure of the anorectum, P_1 is the mesentery artery pressure, σ_1 is the normal stress along a meridian, h is the thickness of the artery, and ΔP is the operating occlusion pressure considered to be uniform.

$$\Delta P=P'-P, \tag{1}$$

here P' is the external pressure of the anorectum.

Because the mechanical behavior of arterial and rectum tissues is similar, an artery will deform with its surrounding tissues; the arterial axial strain is the same as meridional strain. Axial variation in cross sectional area is so gradual that the fluid velocity can be approximated as parallel to the x-axis everywhere in the flow field, and the blood vessels' curvature can be ignored. We assume that blood is a Newtonian fluid. For such flow, the blood flow rate Q is governed by:

$$Q=\frac{1}{8\mu\pi}S^2\frac{\mathrm{d}P}{\mathrm{d}x}, \tag{2}$$

where μ is the fluid viscosity, S is the tube's cross sectional area, and $\mathrm{d}P/\mathrm{d}x$ is the differential pressure gradient.

Arterial stress and strain

While the arterial constitutive relations are nonlinear, we will assume that the constitutive relations can be described by Hooke's law. For thin-walled tubes where the wall-thickness is less than 10% of the diameter, the radial stress can be neglected in comparison with the hoop stress. Thus, the arterial hoop strain (ξ) is given by:

$$\xi=-\sigma_1/E, \tag{3}$$

where E is Young's modulus of elasticity. According to the arterial cross section in Fig.4, a simplified expression for the tube radius at an arbitrary axial location $R(x)$ is:

$$R(x)=h\sigma_1/(P(x)-\Delta P). \tag{4}$$

The arterial hoop strain is equal to the change in tube radius divided by the reference radius. Since the mechanical behavior of arterial and intestinal tissues is similar, an artery embedded in the intestinal wall will expand with its surrounding tissues.

Governing flow equation

Combining the experimentally determined constitutive relations with Eq.(4), we obtain an expression for the tube radius that can be substituted into the governing flow Eq.(2) with boundary conditions:

$$\Delta P=P_1+\frac{8\mu}{\pi}Q\int_0^l\frac{\mathrm{d}x}{R^4(x)}. \tag{5}$$

Using Eq.(4) and Eq.(5), the relationship between the colonic blood flow rate and the operating occlusion pressure of the anorectum is achieved:

$$Q=\frac{\pi h^4\xi^4E^4(\Delta P-P_1)}{8\mu\int_0^l[P(x)-\Delta P]^4\mathrm{d}x}. \tag{6}$$

RESULTS

The derived constitutive relations for human anorectum are shown in Fig.5, which shows that the rectum tissue exhibits nonlinear and anisotropic characteristics, with the circumferential direction being stiffer.

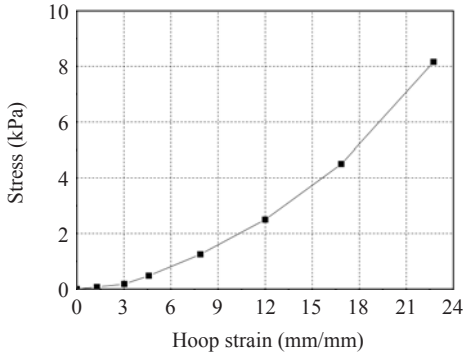

Fig.5 Derived constitutive relations for human anorectum

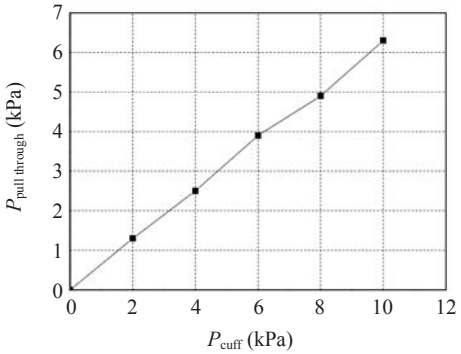

Fig.7 Correlation of operating occlusion pressure ($P_{\text{pull through}}$) versus cuff pressure (P_{cuff})

The curve in Fig.6 shows how the human colonic blood flow rate decreases as the applied cuff pressure increases. As the pressure is increased from 0 kPa to the experimentally measured cut-off pressure of 4 kPa (Hajivassiliou *et al*., 1997a; 1997b; Uozaki *et al*., 2001), the flow rate is cut by 65%, and it drops to 41% as the applied pressure reaches the mesentery driving pressure.

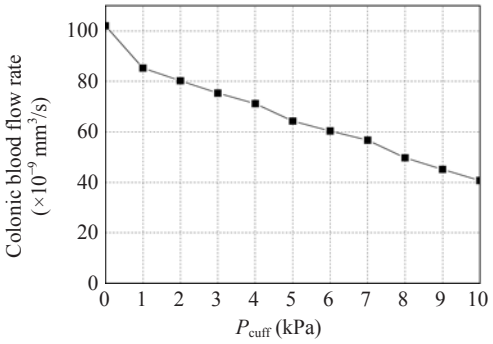

Fig.6 Prediction of blood flow rate with increasing cuff pressure (P_{cuff})

The cuff pressures applied on to the bowel wall by the sphincter ($P_{\text{pull through}}$) were approximately 0, 2, 4, 6, 8 and 10 kPa respectively as the transmission factor was approximately 0.62 kPa occlusion pressure per kPa cuff pressure, as shown in Fig.7. This produced a progressive reduction of blood flow to about 80%, 65%, 60%, 55% and 40% of baseline levels respectively, taking into account biological zero value.

CONCLUSION

The development of a successful artificial anal sphincter would represent a major advance in the treatment of faecal incontinence. The basic function of the prototype has been tested well. To reduce the likelihood of erosion resulting from ischemic effects on the bowel, the paper presents an important colonic blood flow model that must be considered in the design of a novel artificial anal sphincter. Using the model, the design of our prototype can be improved so that it operates within safe limits. In an attempt to overcome ischemic complications, the artificial anal sphincter was designed, which operates at occlusion pressures of only 4 kPa. The results of the present study suggest that at the planned operating occlusion pressure of less than 4 kPa, the artificial anal sphincter should not risk the vascularity of the human colon.

References

Bisset, A.F., 2004. Artificial anal sphincter for faecal incontinence. *Steer*, **4**(3):7.

Hajivassiliou, C.A., Carter, K.B., Finlay, I.G., 1997a. Biomechanical evaluation of an artificial anal sphincter prothesis. *Journal of Medical Engineering & Technology*, **21**(3-4):89-95.

Hajivassiliou, C.A., Carter, K.B., Finlay, I.G., 1997b. Assessment of a novel implantable artificial anal sphincter. *Diseases of the Colon & Rectum*, **40**(6):711-717. [doi:10.1007/BF02140902]

Kloner, R.A., 1988. Introduction to the role of oxygen radicals in myocardial ischemia and infarction. *Free Radical Biology and Medicine*, **4**(1):5-7. [doi:10.1016/0891-5849(88)90004-4]

O'Brien, P., Skinner, S., 2000. Restoring control: the acticon neosphincter artificial bowel sphincter in the treatment of anal incontinence. *Diseases of the Colon & Rectum*, **43**(9):1213-1216. [doi:10.1007/BF02237423]

Ortiz, H., Armendariz, P., DeMiguel, M., Ruiz, M.D., Alós, R., Roig, J.V., 2002. Complications and functional outcome following artificial anal sphincter implantation. *British Journal of Surgery*, **89**(7):877-881. [doi:10.1046/j.1365-

2168.2002.02137.x]

Patrício, J., Bernades, A., Nuno, D., Falcâo, F., Silveira, L., 1988. Surgical anatomy of the arterial blood-supply of the human rectum. *Surgical and Radiologic Anatomy*, **10**(1): 71-75. [doi:10.1007/BF02094074]

Rothbarth, J., Bemelman, W.A., Meijerink, W.J.H.J., Stiggelbout, A.M., Zwinderman, A.H., Buyze-Westerweel, M.E., Delemarre, J.B.V.M., 2001. What is the impact of fecal incontinence on quality of life. *Diseases of the Colon & Rectum*, **44**(1):67-71. [doi:10.1007/BF02234823]

Satava, R.M., King, G.E., 1989. An artificial anal sphincter. Phase 2: implantable sphincter with a perineal colostomy. *Journal of Surgical Research*, **46**(3):207-211. [doi:10.1016/0022-4804(89)90057-7]

Shoshany, G., Pena, A., 1994. Evaluation of a silastic anorectal sphincter placed by the posterior sagittal approach in pigs. *International Journal of Pediatric Surgical Science*, **8**:67-69.

Sofia, C.A., Rush, B.F., Koziol, J., Rocko, J.M., Seebode, J.J., 1988. Experiences with an artificial sphincter to establish continence in dogs. *The American Surgeon*, **54**:390-394.

Tang, K., Huang, Z.J., Jin, T., Bao, R., Chen, G.B., 2007. Influence of input acoustic power on regenerator's performance. *Journal of Zhejiang University SCIENCE A*, **8**(9):1452-1456. [doi:10.1631/jzus.2007.A1452]

Uozaki, Y., Dihmis, W.C., Yamauchi, H., Moczar, M., Miyama, M., Pasteau, F., Tixier, D., Bambang, S.L., Loisance, D.Y., 2001. Intestinal tissue oxygenation and tumor necrosis factor-α release during systemic blood flow changes in pigs with left ventricular assist devices. *Artificial Organs.*, **25**(1):53-57. [doi:10.1046/j.1525-1594.2001.025001053.x]

Yan, G.Z., Zan, P., Ye, D.D., Liu, H., 2007. Design of Transcutaneous Energy Transmission System for Artificial Anal Sphincter. The 2007 IEEE International Conference on Mechatronics and Automation. Harbin, China, August 5-9, p.1434-1438.