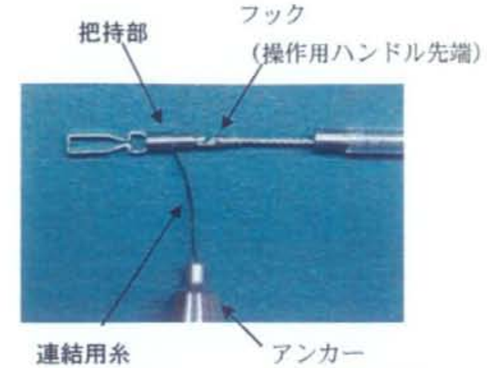

図２　試作磁気アンカー、ハンドル取付状態

一方、破断時にハンドルを持つ操作者の指が痛くなることもわかった。

さらに、把持部とアンカーを連結する連結用糸が接続部の破断に伴って破断してしまう現象も起きた。

２．非磁性内視鏡

チタンを用いて試作した湾曲駒を複数個連結した状態を図３に示す。

図３　試作湾曲駒

次に、上記試作品を円筒状のファントムの外周に取り付けた状態でオープンＭＲＩを用いてＭＲ画像を撮影した。

試作品をファントムに取り付けた状態を図４に示す。

図４　ファントム取り付け状態

実際に取り込んだ画像を図５及び図６に示す。画像の取り込みには、０．３Ｔのオープン MR 装置を用いた。

また、参考として昨年度に撮影した現行ステンレス製湾曲駒と合成樹脂製湾曲駒のＭＲ画像を図７に提示する

図５　ＭＲ画像１（スピンエコー画像）

図６　ＭＲ画像２
（グラディエントエコー画像）

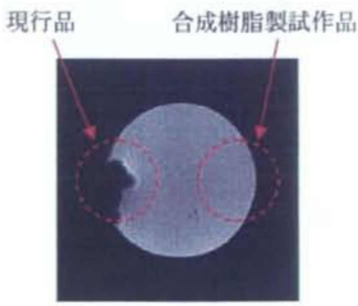

図７　参考：ＭＲ画像（昨年度の報告書から）

図５から図７の画像から現行のステンレス製湾曲駒に比べて画像の欠損がかなり低減さ

れていることが確認できた。

また、グラディエントエコー画像の方により顕著にまだ画像の欠損が残っており、合成樹脂製程度までは至っていないことも確認できた。

3．ステンレス加工部品のアニール検討

本研究にて実施したアニールの方法は以下の通りである。また、実施にあたり、株式会社玉川製作所のご協力を仰いだ。

条件：電気炉内を１０$^{-4}$torr 台の真空にし、鉄のキュリー温度（約７７０℃）＋３０℃の８００℃まで２時間かけて上昇させた。その後、３時間かけて室温まで温度を下げた。

アニールの前後に、振動試料型磁力計を用いて磁化特性を測定した。

今回、内視鏡挿入部構成部品のうち、いずれもステンレス製で、曲げ加工を伴う部品として薄い平板を螺旋状に巻いた螺旋管、湾曲部を湾曲させるために使用されるステンレス製の細線を撚り合わせた牽引ワイヤ、前記牽引ワイヤを案内するための密巻コイルからなる案内コイルの３種類に関して実施した。

螺旋管に関して、アニール前後の磁化特性を測定した結果を図８に示す。

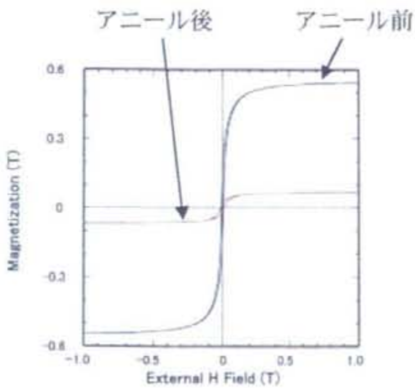

図８　螺旋管の磁化特性測定結果

牽引ワイヤに関して、アニール前後の磁化特性を測定した結果を図９に示す。

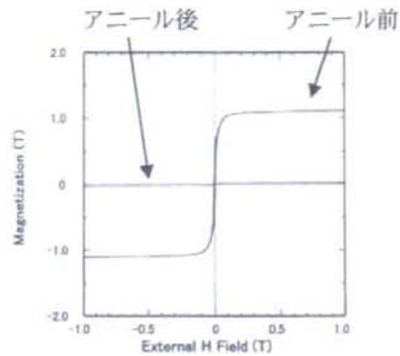

図９　湾曲牽引ワイヤの磁化特性測定結果

案内コイルに関して、アニール前後の磁化特性を測定した結果を図１０に示す。

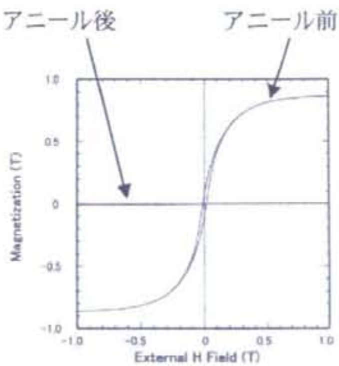

図１０　牽引ワイヤ案内コイルの磁化特性測定結果

前記３種類の部品のうち、螺旋管でやや多めに磁化が残っているが、全体としてアニールすることによって、材料表面の磁化がかなり減少することが確認できた。

一方、アニールにより、表面の酸化に伴う変色が見られた。

D．考察

1．磁気アンカー

試作した接続部は動物実験においても所定の位置で破断し、操作用ハンドルと共に回収可

能であったので、2分割した構造は有効であったと考えられる。

一方、接続部を破断するときに操作者の指が痛くなる現象が生じたことに関しては、実際に内視鏡の鉗子チャンネルに挿入した操作用ハンドルが、机上実験のように真っ直ぐな状態ではなく、湾曲した部分が生じたことにより、摩擦抵抗が大きくなり、指にかかる力量も机上実験以上になったと推察される。また、ハンドルの指かけ部分の面取りが小さく角張っていることも影響があったと思われる。

今後の改良点として、湾曲状態でも摩擦抵抗が少なくなるように、ワイヤの表面をコーティングすることや、ハンドルの指当て部の角部をより大きな丸みを持たせた形状として、指に対する当たりを柔らかくすることなどが考えられる。

2．非磁性内視鏡

今年度は、非鉄金属としてチタンを検討したが、現行のステンレスに比べてＭＲ画像への影響がかなり低減されることがわかった。

しかしながら、合成樹脂のように影響がなくなるまでは至っていないため、内視鏡挿入部に用いる場合には、使用量を少なくして、例えば湾曲駒の連結部分など、合成樹脂の部分的な補強として使用することが望ましいと思われる。

3．ステンレス加工部品のアニール検討

内視鏡挿入部構成部品のうち、曲げ加工が多い螺旋管、湾曲部牽引ワイヤ及び前記牽引ワイヤの案内コイルの3種類に関して、アニールを実施した結果、磁化がかなり低減できることが確認できた。このことにより、現行ステンレス部品を用いた磁気アンカーのはり付き対策としてアニールは有効であると考えられる。

一方、アニールすることで部品の機械的な特性も変化すると考えられるため、この点も今後の確認課題と考えられる。

さらに、今回は部分的に切断した試験片を用いたが、実際の部品の長さを考慮するとアニールするために大きな電気炉が必要になると考えられる。また、表面の酸化を伴ったことから不活性ガスを用いることなどの検討も必要と思われ、今後アニールを実施していくうえでは、こうした設備の点も検討する必要があると思われる。

Ｅ．結論

磁気アンカーの製品化を目指して、磁気アンカーと操作用ハンドルの接続部に関して、前年度の不具合点に対して更なる改良を行い、試作品を作製してその性能を確認した。

その結果、アンカー取り付け時に、爪部を受け環内まで引き込むような過度の引っ張り力がかかることなく、常に所定の位置で破断会うることが確認できた。

一方、動物実験により、破断時に操作用ハンドルにかけた指が痛くなる程度の力が必要になることや、アンカーの把持部とアンカーを連結する連結用糸が接続部と一緒に破断してしまう現象も発生したため、今後、製品化を目指す上では、操作用ハンドルの形状の見直しや接続部を爪部へ取り付ける方法の見直しなどさらなる改良が必要である。

内視鏡の非磁性化に関しては、チタンに関して検討を行った。

今回、チタン製の湾曲駒を試作して、円筒状のファントムに試作品を取り付けてＭＲ画像への影響を比較した結果、現行品に比べて欠損がかなり小さくなることを確認した。

一方、合成樹脂のように欠損がなくなるまでは至っていなかったので、内視鏡挿入部に用いる場合には部分的な使用などを検討する必要がある。

さらに、本年度ではステンレス材が曲げ加工

等に伴って表面が磁化する現象の対策として、アニールを検討した。

今回、内視鏡挿入部に用いられている螺旋管、湾曲牽引ワイヤ、前記牽引ワイヤの案内コイルの3種類に関してアニールを実施した結果、磁化がかなり低減できることがわかった。

これにより、磁気アンカーのはり付き対策としてアニールが有効であると考えられる。

今後、アニールを製品適用するには、アニールに伴う機械的強度の変化の確認、試験サンプル表面に酸化に伴う変色が見られたことから不活性ガスの検討、実際に使用する長さの部品がアニールできる設備の検討などが必要である。

F．研究発表

なし

G．知的財産権の出願・登録状況

1．特許取得

登録特許：1件

・登録番号 4147315（国立がんセンター、株式会社玉川製作所との共同出願）

出願中の特許：４件

・出願番号 2008-168126（国立がんセンターとの共同出願）
・出願番号 2008-173382（国立がんセンターとの共同出願）
・出願番号 2008-177264（国立がんセンターとの共同出願）
・出願番号 2009-012456（国立がんセンター、株式会社玉川製作所との共同出願）

以上

厚生労働省科学研究費補助金　第３次対がん総合戦略研究事業

分担研究報告書

早期胃がん内視鏡切除用磁気アンカー機器装置の臨床標準化装置の開発に関する研究

分担研究者　玉川　克紀　株式会社玉川製作所代表取締役

研究要旨

早期胃がんの内視鏡的切除を補助する磁気アンカー機器装置において、磁気アンカーを牽引、誘導する磁気アンカー駆動装置の開発を行った。今年度は磁界発生部及び電源、冷却機構、検査台について開発、試作を行い、装置の標準化を推進した。

A．研究目的

早期胃がんの内視鏡的切除を補助する磁気アンカー機器装置は、各種実験及び臨床試験によってその有効性が確認された。今年度は、磁気アンカー駆動装置を構成する、磁界発生部及び支持機構、電源、冷却機構、検査台の各要素について新規に開発及び試作を行い、現況の医療施設の設備面に適応させ標準化を推進することを目的とした。

B．研究方法

磁界発生部については、磁気アンカーの安定した牽引、誘導を実現するため、広い範囲で吸引力の変動が少ないものを新規に開発する。また、利便性の向上のため、昨年度は省略した磁界発生部の上下機構を復活させる。

また、駆動装置に必要な入力電力の容量の上限を一般的な１００Ｖコンセントから供給できる１５００ＶＡとして、駆動装置としての効力を犠牲とすることなく低容量化を図ることが可能な電源装置を開発する。

また、従来の水道水使用のみによる冷却から、水道が使用できないことを想定しての、ラジエターと空冷ファンによる循環式の冷却機構を開発し、どちらか選択できる構成とする。そしてこれら要素の開発、試作により完成した装置を用いて動物実験を行い、効果を確認する。

検査台については基本的な性能は臨床試験で使用した検査台と同等としながら軽量化を図り、駆動装置本体と合わせて例えば内視鏡室に設置が十分可能な重量とする。

（倫理面への配慮）

動物実験を実施するに当たっては、動物愛護の観点から使用数は最小にとどめるなど配慮をする。

C．研究結果

装置の有効性を左右する磁界発生部については、消費電力や重量の制限に配慮しつつ、臨床試験モデルに比較して、磁界発生部に近いところでは吸引力を低下させ磁気アンカーを過度に牽引するのを防止し、逆に離れたところでは同等程度の吸引力を発生して確実な挙上と安定した操作を可能とする特性の磁界発生部を設計、開発した。磁気アンカー（約５.８ｇ）１個を牽引した場合の臨床試験モデルとの牽引力（吸引力ー自重）の比較を図１に示す。

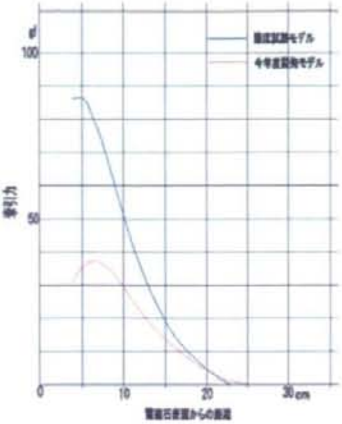

図１　牽引力の比較

また、昨年度省略した磁界発生部の上下機構を再度追加し、検査台の上下機構と併せて高さ設定の自由度を増したことにより、利便性が向上した（図２参照）。

図２　駆動装置外観

現状の一般的な内視鏡室等の電気的設備では､室内には１００Ｖ１５Ａのコンセントのみが敷設されている。従来の磁気アンカー駆動装置は、有効性の確認と共に安全性の確保のため、磁界発生部の性能に余裕を持たせる目的で入力は２００Ｖとし容量はコンセントの容量を超えていたが、標準化を考えた場合は制限事項となる可能性が高いため、一般的な１００Ｖ１５Ａのコンセントからの入力で駆動可能な電源の開発を行った。これまでの試作機のデータや臨床試験での知見から、病変部に把持、固定された磁気アンカーを挙上する場合と、切除のため挙上を維持する場合のそれぞれに必要とされる吸引力に差を設けても影響はないと考え、挙上の維持に対し必要最大の吸引力を発生するための消費電力を基準として、そのときの入力電力が１５００ＶＡを越えないこととし、より吸引力が必要な、把持、固定の後挙上を行う場合は、入力電力の不足分をバッテリーから供給することによって補い、必要な吸引力を得る方式を開発し、試作をした（図３参照）。

図３　電源部

また、磁界発生部は構造上冷却が必要であり、従来は水道水を蛇口から磁界発生部に供給、冷却経路を通過後排水していたが、設備によっては蛇口を占有できないことも考えられるため、磁界発生部内に液体を循環させ、発熱により温度が高くなった液体を放熱板及び電動ファンで冷却するラジエ

ター方式を開発し、従来の水道水冷却方式と選択が可能な構造とした（図４参照）。

図４　ラジエター

これら試作した駆動装置類によって、ブタを用いた動物実験が行われ、従来の駆動装置と比較して、少ない消費電力で安定した牽引を行うことができることを確認した。

次に、施設の床の耐荷重を考慮し、装置全体の重量を軽減させる一端として、検査台についても軽量化を図った。磁気アンカーの牽引方向を検査台の天板の体軸方向及び体側方向へのスライドで調整する方式のため、基本的なスライド量は維持するものとして、安定性を損なわない範囲での軽量化を検討し、臨床試験で使用した検査台の重量が２６０kg であったのに対し、新モデルは約１７０kgと９０kgの軽量化を実現した（図５参照）。

図５　検査台

D．考察

今年度開発の磁気アンカー駆動装置は、有効性を犠牲とすることなく軽量化、低消費電力化を図る事ができた。動物実験では、ほとんど検査台を動かすことなく効果的に磁気アンカーを牽引することができたが、これは磁界発生部の特性が効果的に影響したためだと思われる。

軽量化においては、臨床試験モデルでは駆動装置本体と検査台をあわせた重量が１トンを超えていたのに対し、今年度のモデルは約７００kg強となり、一般的な構造の床であれば耐荷重の問題も無いと考えられる。

低消費電力化においては、磁界発生部の改良の効果と相まって、通電量が定格の半分程度でも挙上及び牽引の維持が可能であったことから、１００Ｖ１５Ａのコンセントを動力源として装置を運用することが十分可能であることが示唆された。

冷却機構については、ラジエター方式を採用した場合、液体の循環ポンプや電動ファンの発生する音が大きく、施設内を設置場所と想定すれば対策が必要である。

E．結論

今年度試作した磁気アンカー駆動装置は、開発当初からの懸案であった軽量化、低消費電力化についてそれぞれ一定の成果を得

ることができ、臨床標準化装置実現の可能性がさらに高まったと考えられる。

F．研究発表

1．論文発表

該当なし。

2．学会発表

該当なし。

G．知的財産権の出願・登録状況

（予定を含む）

1．特許取得（出願）

特願２００９−０１２４５６

「磁気アンカー誘導用磁力発生装置、及び、磁気アンカー遠隔誘導システム」

（国立がんセンター、ＨＯＹＡ株式会社との共同出願）

2．実用新案登録

該当なし。

3．その他

該当なし。

研究成果の刊行に関する一覧表

雑誌

発表者氏名	論文タイトル名	発表誌名	巻号	ページ	出版年
Gotoda T, Kobayashi T, et al	Prospective clinical trial of magnetic-anchor-guided endoscopic submucosal dissection for large early gastric cancer (with videos).	Gastrointest Endosc	69	10-15	2009
Ishiyama K, Yokota C	Cantilevered actuator using magnetostrictive thin film	Journal of Magnetism and Magnetic Materials	Volume 320, Issue 20	2481-2484	2008

ORIGINAL ARTICLE: Clinical Endoscopy

Prospective clinical trial of magnetic-anchor–guided endoscopic submucosal dissection for large early gastric cancer (with videos)

Takuji Gotoda, MD, Ichiro Oda, MD, Katsunori Tamakawa, PhD, Hirohisa Ueda, PhD, Toshiaki Kobayashi, MD, PhD, Tadao Kakizoe, MD, PhD

Tokyo, Japan

Background: The treatment of early gastric cancer (EGC) by endoscopic submucosal dissection (ESD) has been rapidly gaining popularity in Japan. However, the procedure needs a high quality of skill. To facilitate complicated ESD by using a single working-channel gastroscope ("one-hand surgery method"), the magnetic-anchor-guided ESD (MAG-ESD) controlled by an extracorporeal electromagnet was reported to be successful in a porcine model.

Objectives: The purpose of this prospective clinical trial was to evaluate the feasibility of MAG-ESD for large EGC located on the gastric body in human beings.

Design: Prospective clinical trial at a single center.

Setting: National Cancer Center Hospital, Tokyo, Japan.

Subjects: From January 2005 to May 2006, 25 patients with EGC >20 mm in diameter, located in the gastric body, and intestinal-type histology were enrolled. Patients with a cardiac pacemaker, advanced malignancy in other organs, severe cardiac and/or pulmonary diseases, and uncontrolled hypertension and/or diabetes mellitus were excluded from this study.

Interventions: Similar to a standard ESD, the MAG-ESD procedure was performed with the patient under conscious sedation by intravenous injection of midazolam (3–5 mg) and pentazocine (15 mg).

Main Outcome Measurements: Unfavorable events and other intraoperative complications caused by the magnetic anchor or the magnetic force were recorded and evaluated. Two GI endoscopists (T.G., I.O.) assessed whether the magnetic anchor facilitated gastric ESD according to 2 criteria: "supportive" and "not supportive." The en bloc resection rate, complications, total operation time, bleeding, perforation, and recurrence rate were also evaluated. The total operation time was measured from insertion to withdrawal of the endoscope, including the retrieving of the magnetic anchor or anchors.

Results: All tumors were resected en bloc, without any perforations or severe uncontrollable bleeding. All magnetic anchors were safely retrieved. Two endoscopists assessed that the MAG system was supportive in 23 patients. None of the patients experienced physiologic and mental abnormalities as a result of long-term magnetic-field exposure. During a median follow-up of 20 months (15–32 months), neither delayed adverse effects nor allergies caused by the stainless steel of the magnetic anchor were observed.

Conclusions: MAG-ESD is a feasible and safe method that allowed an excellent visualization by suitable tissue tension and facilitated gastric ESD in patients with EGC. The system should be miniaturized to make it applicable in daily clinical practice. (Gastrointest Endosc 2009;69:10-5.)

Abbreviations: EGC, early gastric cancer; ESD, endoscopic submucosal dissection; IT-knife, insulation-tipped diathermic knife; MAG-ESD, magnetic-anchor-guided endoscopic submucosal dissection.

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It has been reported that endoscopic submucosal dissection (ESD) of early gastric cancer (EGC) improves the rate of successful en bloc resection.[1,2] An ESD by using an insulation-tipped diathermic knife (IT-knife), developed at the National Cancer Center Hospital, was the first of such techniques.[3,4] Other endoscopic devices for ESD have been developed.[5-7] ESD has been rapidly gaining popularity in Japan, primarily because of its ability to remove larger EGC en bloc, thus reducing a local recurrence caused by a piecemeal resection.[8] However, it is still an investigational technique and requires a high level of skill from the endoscopists.[9-11]

Endoscopic resection should be safe, effective, and applicable to a wide variety of clinical situations. In particular, when EGC is located in the gastric body, an ESD is more complicated, and the rate of a complete resection is lower than in the gastric antrum.[12] The more difficult extension of the wall and the collection of fluid, including blood and/or gastric juice, hinder the performance of the ESD procedure. Optimal extension of the wall and visualization of the lesion is mandatory for a safe and feasible ESD.

To facilitate a complicated standard ESD procedure performed by using a single working-channel gastroscope (one-hand surgery), the magnetic-anchor–guided ESD (MAG-ESD) controlled by an extracorporeal electromagnet, was developed.[13] We reported that MAG-ESD facilitated the ESD procedure in the porcine model. The purpose of this prospective clinical trial was to evaluate the feasibility of MAG-ESD for large EGC in human beings.

Capsule Summary

What is already known on this topic

- Endoscopic submucosal dissection (ESD) is useful in the en bloc removal of large gastric lesions, thus reducing the risk of a local recurrence caused by piecemeal resection.
- Magnetic-anchor–guided ESD (MAG-ESD), controlled by an extracorporeal electromagnet, facilitates the standard ESD procedure performed by using a single working-channel gastroscope.

What this study adds to our knowledge

- In 25 patients with gastric cancer lesions >20 mm in diameter who underwent magnetic-anchor–guided ESD, all tumors were resected en bloc, without any perforations or severe uncontrollable bleeding, and all magnetic anchors were safely retrieved.
- No patient experienced physiologic or mental abnormalities as a result of long-term magnetic field exposure.

PATIENTS AND METHODS

Patients

The purpose of this prospective clinical trial was to evaluate the feasibility of MAG-ESD. Twenty-five patients with EGC >20 mm diameter, located in the gastric body, were enrolled. The patients were first seen on an outpatient basis, and the tumor was assessed by a gastroscopy. From January 2005 to May 2006, all patients with EGC >20 mm in diameter, located in the gastric body, and with intestinal-type histology underwent an ESD on an inpatient basis at the National Cancer Center Hospital, Tokyo, Japan. The ethics committee approved the study, and a detailed written informed consent was obtained from each patient. The presented study was conducted according to the Declaration of Helsinki.

The patients with a cardiac pacemaker, advanced malignancy in other organs, severe cardiac and/or pulmonary diseases, uncontrolled hypertension, and/or diabetes mellitus were excluded from this study. Pregnant or lactating women, and those who wished to become pregnant during the study were also excluded. Patients with tumors with recurrent disease, fibrosis, deeper invasion, or diffuse-type histology were excluded.

Standard ESD

The standard ESD procedure was initially started by using a standard gastroscope with a single working channel (GIF Q260 or Q240; Olympus Optical Co, Ltd, Tokyo, Japan).[14] Marking dots were placed approximately 5 mm outside the margin of the lesions by using a needle-knife (KD-1L-1; Olympus) and forced coagulation current 20 W (IC C200; ERBE, Tübingen, Germany). First, injection of diluted epinephrine (1:100,000) was performed to raise the submucosal layer and to insert the tip of the IT-knife into the submucosal layer. Then, a small initial incision was made by a standard needle-knife by using 80 W, effect 3 Endocut (ICC200; ERBE). Mucosal cutting at the periphery of the marking dots was circumferentially performed with an IT-knife (KD-610L; Olympus) with 80 W Endocut. After additional submucosal injection of diluted epinephrine, the submucosal layer below the lesion was directly dissected by using the same IT-knife. The final aim was to achieve en bloc resection.

All patients were sedated by intravenous injection of midazolam (3–5 mg) and pentazocine (15 mg), and, if necessary, conscious sedation was maintained with an additional injection of midazolam.

Magnetic anchor and extracorporeal electromagnetic control system

The magnetic anchor (Pentax Co, Tokyo, Japan) consists of 3 parts: a hand-made magnetic weight, made of magnetic stainless steel (SYS420F), microforceps, and a connecting thread. A 1.0 × 1.0 × 1.5-cm weight was designed to facilitate gastric ESD by use of an extracorporeal hands-free electromagnet, whereby magnetic forces allow a suitable counter-traction for submucosal dissection (Fig. 1). The anchor weight used for this procedure was approximately 6 g.

The magnetic control system (Fig. 2) consists of an electromagnet with up-and-down motion; a movable examination table was made by Tamakawa Co (Sendai, Japan) for use in a standard endoscopic room. The magnetic control system consisted of a 0.68 kOe/100A extracorporeal

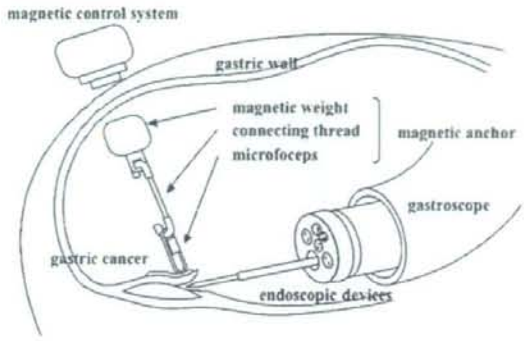

Figure 1. Concept of the MAG-ESD.

Figure 2. Extracorporeal electromagnetic control system.

electromagnet, 350 mm in diameter, positioned at 10 cm from the center of the magnetic yoke. In this manner, the position of the electromagnet was adjusted according to the patient's physique. The examination table was able to move freely to be able to control the magnetic weight so as to achieve ideal mucosal lifting to allow the gastric submucosal dissection.

MAG-ESD

According to the standard ESD, after circumferential mucosal cutting by using an IT-knife, the procedure was switched to an MAG-ESD, controlled by a high-power electromagnet placed outside the body of the patient (Fig. 3). First, an overtube (Sumitomo Bakelite, Tokyo, Japan) was inserted into the esophagus. Second, a tube catheter was passed through the working channel of the gastroscope. A magnetic anchor, with a magnetic weight, a microforceps, and a connecting thread, was attached to the tip of the catheter. The gastroscope that carries the magnetic anchor was reinserted. Inside the stomach, the magnetic weight was pushed out from the catheter. According to the direction of gravity, the microforceps connected to the magnetic weight was placed at the mucosal edge (Video 1, available online at www.giejournal.org). The submucosal dissection by using an IT-knife was performed by suitable tissue tension with hands-free stabilization and visualization (Video 2, available online at www.giejournal.org).

If experienced endoscopists, who have performed more than 100 gastric ESDs, requested additional magnetic anchors to maneuver the traction direction of the exfoliated gastric tissue, then any numbers of magnetic anchors were attached. To maintain suitable tissue tension, either the patients were rotated or the direction of the magnetic anchor was repositioned by using the movable examination table. After endoscopic resection, both the resected tissue and the magnetic anchor or anchors were retrieved into the overtube by using a grasping forceps and were removed from the stomach.

Assessments

The demographic and clinical features of each patient were recorded in a case report form. Unfavorable events and other intraoperative complications caused by the magnetic anchor or the magnetic force were recorded and evaluated. We defined serious adverse events as those that lead to death, threat to life, notable disability, prolonged hospital stay, or hospitalization. Patients were followed-up until adverse events either dissipated or returned to pretreatment levels. Two GI endoscopists (T.G., I.O.) assessed, according to the 2 criteria, whether the magnetic anchor facilitated a gastric ESD. Once the dedicated endoscopists evaluated that the MAG-traction–facilitated gastric ESD compared with the standard gastric ESD technique, it was defined as "supportive." When the ESD procedure was not effectively influenced by using the MAG system, it was defined as "not supportive." The en bloc resection rate, complications, total operation time, bleeding, perforation, and recurrence rate were also evaluated. The total operation time was measured from gastroscope insertion to withdrawal, including retrieving the magnetic anchor or anchors.

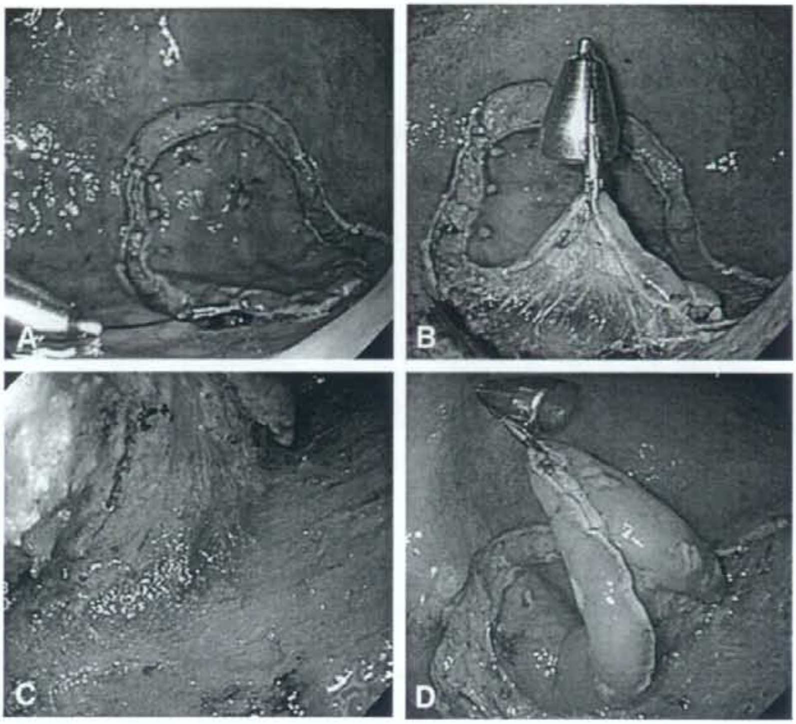

Figure 3. Magnetic-anchor–assisted ESD for large EGC. **A,** Fitting the magnetic anchor onto the tip of the gastric mucosa before applying the magnetic force. **B,** Lifting of the gastric tissue and stretched submucosal layer under strong counter-traction by the magnetic anchor. **C,** Good visualization of vessel in submucosal layer under counter-traction by magnetic force. **D,** Controllable traction by the magnetic anchor with a magnetic field.

RESULTS

The MAG-ESD technique was performed in 25 patients (M/F, 17/8; median age 70 years, range 48-85 years; median tumor size, 30 mm, range 20-70 mm).

The results of the MAG-ESDs are shown in Table 1. All tumors were resected en bloc, without any perforations or severe uncontrollable bleeding. The median size of resected specimen was 55 mm (33-125 mm). The median procedure time was 80 minutes (50-240 minutes). One resection was histologically confirmed as being noncurative because of deep submucosal invasion with positive vertical margins and lymphatic-vessel involvement. This patient underwent additional radical surgery.

One magnetic anchor was required in 21 cases, and 2 magnetic anchors were used in 4 cases. All magnetic anchors were safely retrieved. Two endoscopists assessed that the MAG system was supportive in 23 patients. In particular, the MAG system effectively facilitated an ESD for all 9 tumors located on the greater curvature of the gastric body. However, the magnetic anchor was not helpful in 2 patients. In one case, it was difficult to inflate the gastric lumen because of air leakage through the hiatus hernia. In another case, it was impossible to pull the gastric tissue toward the proper direction, even after changing the patient's position.

TABLE 1. Results of 25 patients treated by MAG-ESD

En bloc resection rate	25/25 (100%)
Median resection size (mm)	55 (range 33-125)
Complications	0/25 (0%)
Median time consumption (min)	80 (range 50-240)
Exposure time for magnetic field (min)	30 (range 10-110)
Endoscopist's assessment	
Supportive	23
Not supportive	2

None of the patients experienced physiologic and mental abnormalities as a result of long-term magnetic-field exposure, neither before nor after the procedure. After a mean of 30 minutes (range 10–110 minutes) of exposure to the magnetic field, no adverse effects of standard ESD procedure were observed regarding pulmonary and cardiac function. During a median follow-up of 20 months (range 15–32 months), neither delayed adverse effects nor allergies were observed because of the stainless steel of the magnetic anchor.

Eight weeks after an MAG-ESD, all artificial defects caused by ESD were completely cured. Neither recurrent cancer nor distant metastases were observed in any of the patients during follow-up.

DISCUSSION

The present study is, to our knowledge, the first clinical trial by using MAG-ESD for EGC in human beings. The feasibility of the technique for gastric cancer treatment was already evaluated in an animal study. The MAG-ESD technique permits excellent visualization of the submucosal layer, because it is possible to achieve suitable tissue tension. This simplifies a gastric ESD, even for large lesions located in the gastric body. The long-term exposure to the magnetic field did not cause any unwanted physiologic or mental effects. Furthermore, no delayed complications or allergies related to the stainless steel of the magnetic anchor were observed. All the tumors were resected en bloc, without any perforation or severe uncontrollable bleeding.

Endoscopic resection is comparable in many respects to conventional surgery, with the advantages of being less invasive and more cost efficient.[15,16] Endoscopic removal of cancer was initially attempted by using colorectal polypectomy with a high-frequency electric surgical cautery.[17] The use of endoscopic polypectomy to treat pedunculated or semipedunculated EGC was first described in 1974 in Japan. In 1984, the technique of EMR, the so-called strip biopsy, was devised for endoscopic snare polypectomy.[18] Today, EMR is established and widely accepted as a minimally invasive treatment for EGC.[19] Although several techniques have been reported to make EMR procedures easier and safer,[20,21] these cannot be used to remove, en bloc, lesions larger than 2 cm in diameter.[22,23] Piecemeal resection may cause the pathologist to inadequately stage the specimen. Furthermore, there is a high risk of a recurrence after a piecemeal resection.[24,25]

An ESD is superior to a standard EMR and provides en bloc specimens with a standard single-channel gastroscope. After an endoscopic resection, pathologic assessment of depth of cancer invasion, degree of cancer differentiation, and lymphatic or blood-vessel involvement allows an accurate prediction of the risk of lymph-node metastasis.[26] The risk of developing lymph-node or distant metastasis is then weighed against the risk of surgery.[27-29]

Endoscopic resection should be safe, effective, and applicable to a wide variety of clinical situations. However, an ESD still requires an experienced endoscopist with a high level of skill, especially when using a single working-channel gastroscope. Recently, the technique of percutaneous traction-assisted EMR by using a laparoscopic port to create a strong counter-traction was reported.[30-32] However, all previous trials showed that the technique was complicated, invasive, and did not make ESD easier.

Magnets and magnetic fields were used to direct the catheter tip during catheter procedures.[33] A magnetic anchoring system was used to achieve laparoscopic surgery by using a single trocar.[34] Very recently, the feasibility of using magnetically anchored instruments was reported as a promising technique to facilitate natural orifice transluminal endoscopic surgery in a porcine model.[35] These magnets may also provide a way to alter tissue contours without any direct contact. A direct-current–generated magnetic field, as used in magnetic resonance imaging, is regarded as the least invasive or even the most appropriate noninvasive procedure that can be medically applied.

In 21 of our patients, only one magnetic anchor was needed to achieve the desired result, either by rotating the patient or by moving the examination table. In 4 cases, 2 magnetic anchors were required. In 2 cases, a second magnetic anchor was helpful. With the other 2 cases, however, the second anchor did not help, because the MAG system did not provide adequate visualization for submucosal dissection or allow suitable maneuvering of the endoscopic devices. This was caused by underinflation of the gastric cavity. Therefore, to obtain better visualization during an MAG-ESD, the prevention of air leakage because of a hiatus hernia should be achieved.

Another limitation of this procedure was that the extracorporeal electromagnetic control system is too large and cumbersome. Although it was possible to achieve hands-free fixation of the mucosa by using the magnetic anchor tractioned with the extracorporeal electromagnet, the system should be miniaturized to allow wider clinical application.

In conclusion, this prospective clinical trial proved that MAG-ESD can feasibly be used in human beings. The MAG-ESD technique was able to obtain excellent visualization by suitable tissue tension and to facilitate the procedures. Further innovations are warranted to apply the MAG procedure in daily clinical practice.

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Cantilevered actuator using magnetostrictive thin film

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Abstract

This paper describes a cantilevered magnetic actuator driven by magnetostriction in a low magnetic field. The dimensions of the two layers actuator were 1 × 5 mm and amorphous FeSiB was used as the magnetostrictive material. Since the FeSiB has excellent soft magnetic characteristics, the actuator with FeSiB was able to work in magnetic field strength of less than 10 kA/m. The theoretical formulas for the amount of the displacement and the force of the actuator were obtained. The theoretical results agreed with the experimental one. According to the theoretical formula, the displacement was calculated with the parameter of the mechanical properties of the substrate. To obtain the large displacement, the actuator with Co substrate was designed based on the theoretical formula. The displacement of 153 μm was obtained using Cu substrate of 1.1 μm thickness in the magnetic field of 10 kA/m. © 2008 Elsevier B.V. All rights reserved

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Keywords: Cantilever; FeSiB; Magnetostriction; Magnetic thin film; Low magnetic field

1. Introduction

Cantilevered actuators were studied using principles of piezoelectric effect [1], thermal expansion [2], and magnetostriction [3]. Using the piezoelectric effect and thermal expansion, the large displacement can be obtained. However, the structures are complicated because they require insulation layers and signal cables. In this study, we proposed a cantilevered actuator driven by magnetostriction. The actuator can drive wirelessly, and the structure is simple. Therefore, the actuator is suitable for miniaturization. In previous works, amorphous TbFe and SmFe thin films were studied for the magnetostrictive materials for the actuator, because they had large magnetostriction constant [3]. However, a large magnetic field of about 80–800 kA/m was required to drive, and it was not suitable for the application in microsystems.

In this work we fabricated the cantilevered actuator using amorphous FeSiB as magnetostrictive material. This material has smaller magnetostriction constant of about 30×10^{-6} compared with rare earth iron alloys, but has large permeability. Therefore this material is suitable for magnetostrictive cantilever in low magnetic field less than 10 kA/m. The theoretical formulas about the amount of the displacement and the force of the actuator were obtained. According to the theoretical formula, the displacement was calculated with the parameter of the mechanical properties of the substrate. The actuator was designed for Young's modulus and the thickness of the substrate, to obtain the largest displacement.

2. Cantilevered magnetic actuator

2.1. Driving principle

The shape of the magnetostrictive material expands or contracts by the rotation of the magnetic moment in the material. The amorphous FeSiB and a non-magnetic material were made up of the two-layer cantilever actuator. Not to receive the influence of a magnetic torque, the magnetic field was applied to the width direction of the actuator. Because the amorphous FeSiB has a positive magnetostriction constant, the FeSiB film contracts to

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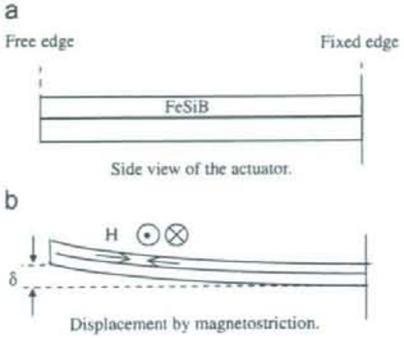

Fig. 1. Configuration and displacement of the magnetic actuator. (a) Side view of the actuator. (b) Displacement by magnetostriction.

transverse direction of the applied magnetic field. Therefore the cantilever bends toward the FeSiB side. The side view of the actuator is shown in Fig. 1(a). By applying an external magnetic field as shown in Fig. 1(b) the actuator bends. The displacement δ and the force F were observed at the free edge of the actuator.

2.2. Fabrication and measurement of the actuator

The amorphous FeSiB thin films were fabricated by the RF sputtering method. The sputtering target was Fe_{72} $Si_{14}B_{14}$ alloy. RF input power was 200 W, and Ar gas pressure was controlled to obtain the best residual stress. During the sputtering, the substrate was cooled by water. The thickness of the FeSiB was 0.7 μm. After deposition, the magnetic film was cut out to 1 × 5 mm with the substrate. We defined it as the cantilevered actuator. To control the magnetic anisotropy, the actuator was heat treated in the magnetic field of 240 kA/m to the longitudinal direction of the cantilever and the temperature of 350 °C in 1 h. The magnetic characteristics were measured using VSM. The amount of the displacement of the actuator in magnetic field 10 kA/m was measured by microscope, and the force was measured by microscope with loads at the free edge of the cantilever. The weights of the loads were measured with the weight meter, with accuracy of μg order beforehand.

3. Derivation of the theoretical formulas

3.1. Displacement

The various theoretical formulas about the amount of the displacement of cantilevered actuator by the magnetostriction have been studied [4,5]. However, the theoretical formulas are suitable only for that the magnetic film is thin enough compared to the substrate. Therefore, it is necessary to obtain a new theoretical formula for this research, because we have to apply very thin substrate for large displacement [6].

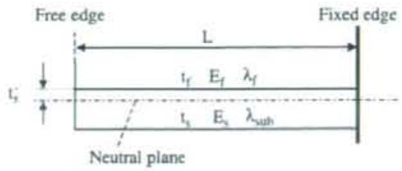

Fig. 2. Structure of the cantilevered actuator and neutral plane.

A neutral plane was defined as shown in Fig. 2. This was the plane in the actuator whose length was not changed when the actuator bents. The distance between the neutral plane and contact plane of the layers was defined as t_s'. The theoretical formula was obtained by using t_s' and the following two assumptions. The bending moment diagram was the same at the total length of the actuator, and the bending angle of the actuator was small enough compared with the actuator length [7]. The obtained theoretical formulas were shownas follows:

$$t_s' = \frac{E_s t_s^2 - E_f t_f^2}{2(E_s t_s + E_f t_f)} \tag{1}$$

$$\delta = \frac{3L^2\{E_s \lambda_{sub} t_s(-t_s + 2t_s') + E_f \lambda_f t_f(t_f + 2t_s')\}}{4\{E_s t_s(t_s^2 - 3t_s t_s' + 3t_a'^2) + E_f t_f(t_f^2 + 3t_f t_s' + 3t_s'^2)\}} \tag{2}$$

where δ is the amount of the displacement in the free edge of the actuator, L is the actuator length, and t_f, E_f, and λ_f are the thickness, Young's modulus, and the magnetostriction of the magnetic thin film, respectively. t_s, E_s, and λ_{sub} are the thickness, Young's modulus, and the magnetostriction of the substrate material, respectively, t_s' is the distance between the neutral plane and contact plane of the layer. In this study, the length L was constant as 5 mm, Young's modulus of the magnetic thin film E_f was 210 Gpa.

When the magnetostriction value λ in the theoretical formulas was used, the following two points were considered. The first point was the influences of the relation between the direction of the applied magnetic field and the observation. The magnetic field was applied to the width direction of the actuator in this experiment; the magnetostriction value λ' was converted into $-1/2$ of the magnetostriction constants. The other point is that the magnetic moment was not saturated at the field of 10 kA/m. Under an assumption that the magnetization changed in rotation in FeSiB because it was exited to its hard direction, we used a ratio between saturation magnetization and the magnetization at 10 kA/m. This ratio was multiplied with the magnetization constant to compare with the experimental value in 10 kA/m.

3.2. Force

We examined the force generated at the free edge of the actuator when the magnetic field was applied to the actuator. The force was equal to the concentrated load on the free edge. Under the same assumption as the

Table 1
Calculated and experimental values for the displacement and force of the cantilevered magnetic actuator ($H = 10\,kA/m$)

Thickness of magnetic thin film, t_f (μm)		0.35	0.70	1.05
Displacement (μm)	Calculated	6.9	7.9	8.3
	Experiment	7.1	8.0	8.4
Force (μN)	Calculated	3.0	4.2	5.0
	Experiment	3.1	4.3	4.9

theoretical formula (2), the theoretical formula about the force of the actuator was obtained as follows.

$$F = \frac{3w\{E_s\lambda_{sub}t_s(-t_s + 2t_s') + E_f\lambda_f t_f(t_f + 2t_s')\}}{4L} \quad (3)$$

where F is the amount of the force in the free edge point of the actuator and, w is the width of the actuator. In this study, the width was constant as 1 mm. Other parameters were the same as those used in theoretical formula (2).

3.3. Experiment and comparison with theory

As shown in Table 1, the calculated values of the displacement and the force agreed well with the experimental results using a polyimide film as the non-magnetic substrate. The mechanical properties were used as the following values: t_s: 30 μm, E_s: 3.5 Gpa. The magnetostriction of the film, λ_f, was -15×10^{-6}, because the field was applied to the width direction of the cantilever while the length was changed by the magnetostriction. From the results shown in Table 1, it is found that the formulas are suitable to design the actuator.

4. Design of a cantilever actuator

4.1. Theory analysis of the displacement

Based on the theoretical formula, the amount of the displacement of the actuator was analyzed with the kinds of the substrates. The dimensions of the actuator were 1 × 5 mm, and the thickness of the FeSiB was 0.7 μm. The parameters for the analysis were the mechanical properties of the non-magnetic substrate as Young's modulus and the thickness. The analytical results are shown in Fig. 3. The horizontal axis shows the Young's modulus of the substrate, and the vertical axis shows thickness of the substrate, and the numerical value which each lines show is the calculated amount of the displacement of the actuator. The substrate material can be decided according to the relation between Young's modulus and the thickness of the substrate.

It is found that the higher the Young modulus of the substrate obtained, the large the displacement, while there was the optimum value for the thickness, as shown in Fig. 3. If the substrate material had a high Young's modulus, the substrate material strongly disturbed the contraction of the FeSiB magnetostrictive material. On the other hand, a soft and thin substrate would contract with magnetostrictive layer. Therefore, the contraction would not be converted to the large displacement in these conditions. Therefore the best substrate thickness and Young's modulus exist to obtain the large displacement. When the material of Young's modulus 130 GPa was applied for the substrate to obtain the amount of the displacement of about 150 μm, the thickness of the substrate must be 1.1 μm. Cu was selected as a substrate material with this Young's modulus, and the calculated displacement value was 155 μm under the actuator length of 5 mm.

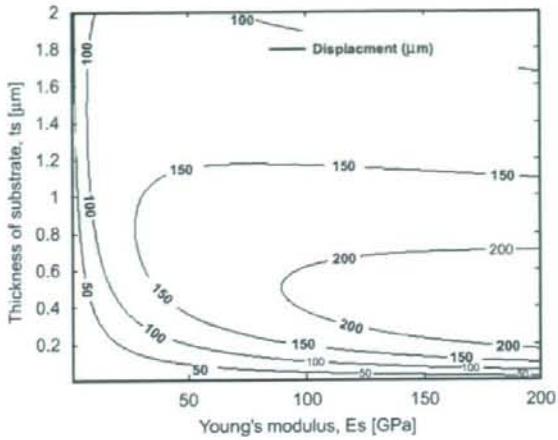

Fig. 3. Figure of the amount of the displacement designed by Young's modulus and the thickness of the substrate.

4.2. Experiment and comparison

Based on the foregoing paragraph, the actuator with the Cu substrate was fabricated. Cu and FeSiB thin films were fabricated by the RF sputtering method. RF input power was 100 W, and Ar gas pressure was 4 mTorr for Cu and 16 mTorr for FeSiB. The annealing temperature was 200 °C in consideration of the difference of the coefficient of thermal expansion.

The displacement was measured as shown in Fig. 4. The experimental result shows the displacement of 153 μm with the magnetic field strength of 10 kA/m. The obtained experimental result was agreed well with the calculated value.

In addition, the produced force of this actuator was 0.30 μN while the calculated value was 0.29 μN. This result confirms the design was suitable for the cantilever actuator.

It is clarified that we could obtain the cantilevered actuator as we designed and the amount of displacement more than 100 μm was obtained. Moreover, the graph showed that the amount of the displacement is almost saturated with magnetic field strength of 10 kA/m, and the influence of hysteresis was hardly seen. These results show

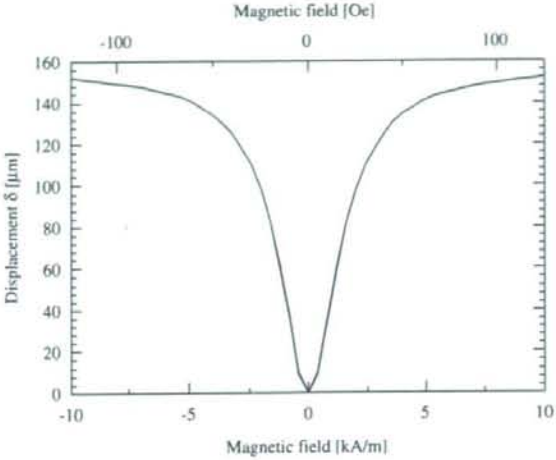

Fig. 4. Experimental result between the magnetic field and the displacement δ caused by the magnetostriction.

that this actuator has the large possibility for the application of the microsystems such as μTAS.

5. Summary

The cantilevered actuator driven by the magnetostriction was examined. The two-layer actuator was made using amorphous FeSiB thin film, so the actuator could be driven in the low magnetic field less than 10 kA/m. The theoretical formulas for the amount of the displacement and for the force of the actuator were obtained. The calculated values agreed well with the experimental results using a polyimide film as the non-magnetic substrate. To obtain the actuator with large amount of the displacement, Cu film was applied for the substrate, based on the design of the theoretical formula. As the results, the actuator with large displacement was fabricated as designed based on the theoretical formula.

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