

The new approach for surgery using magnetic marker system and magnetic probe for localization of non-palpable lesions of breast in Japan

Abstract

•With advances in neoadjuvant chemotherapy for breast cancer and diagnostic imaging for screening, cases of non-palpable lesions requiring surgical intervention are being reported in ever greater numbers. It is of vital importance to reliably resect these lesions.

•We conducted a study probing the feasibility of using a guiding-marker system® and handheld magnetic probe originally developed for sentinel lymph node identifications in breast cancer patients, for surgical operation on non-palpable breast cancer lesions.

•We performed the operation on 25 cases and succeeded in achieving adequate resection in all patients.

•The procedure uses a simple and useful method.

Introduction

•Clinically-occult breast cancer lesions are increasing due to the spread of screening programs and development of neoadjuvant chemotherapy. A correct approach to non-palpable breast lesions requires an accurate intraoperative localization to achieve a complete surgical resection.

•We conducted a clinical study which aimed to demonstrate non-inferiority of sentinel lymph node (SLN) detection rates by using a superparamagnetic iron oxide (SPIO)/magnetic probe system (fig1) on a conventional radioisotope (RI) technique in patients with breast cancer. This study was supported by AMED (Japan Agency for Medical Research and Development) research funds. The novel magnetic probe is equipped with a permanent magnet and a magnetic sensor (Sci Rep 8, 1195, 2018).

•Through these clinical trials, we believe that the application to non-palpable lesion via the magnetic probe was possible. We can use a magnetic marker (guiding-marker system®) where the tip is stainless steel along with nylon sutures in Japan. We seed this marker in the non-palpable lesion and search for it using this probe; therefore, it is possible to more accurately search for the lesion during surgery.

Fig1. Magnetic handheld probe



•Detection of the magnetic marker using a handheld magnetic probe developed by the School of Engineering, The University of Tokyo (Sci Rep 8, 1195, 2018).
•This probe is compact, cordless and lightweight (108 g), that is, high usability.
•The probe head consists of a permanent magnet for the generation of DC magnetic fields that magnetizes the magnetic marker, and a Hall-effect sensor for the detection of magnetic fields that are generated by the magnetized magnetic marker.

Objectives

• In addition to the usual mapping, we underwent the non-palpable lesion using the guiding-marker system® and magnetic probe.

•To confirm that we can resect the lesion by radiography of the specimen and magnetic probe.

•To confirm that it is possible to safely and reliably resect the non-palpable breast lesion by marking the non-palpable breast lesion with the aid of the guiding-marker system® and localizing the lesion through a magnetic probe.

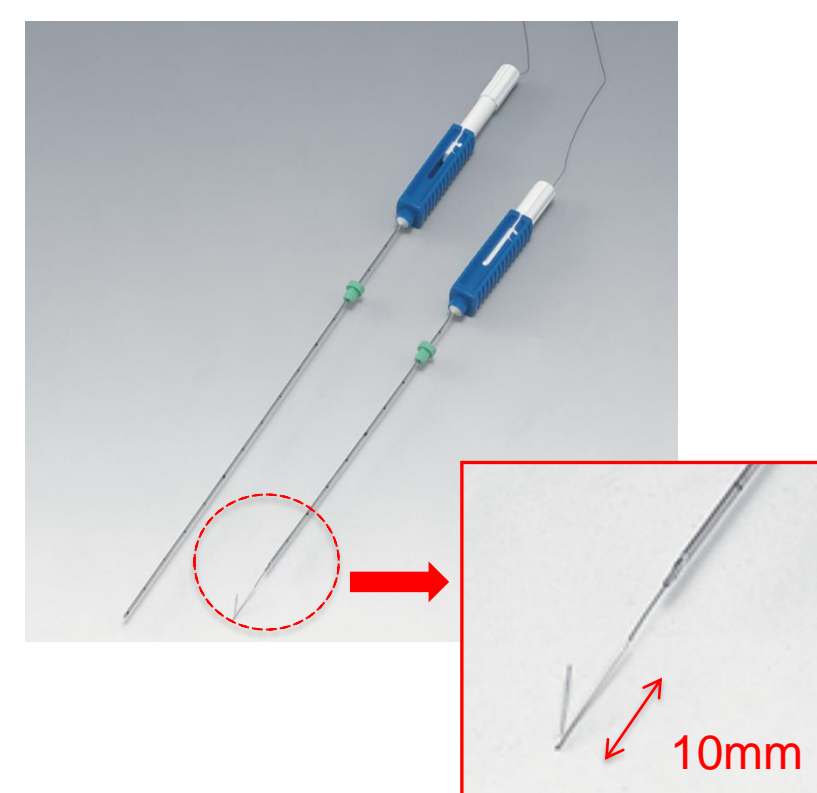
Primary outcome measures: that the guiding-marker system used in the marking is included in the incisional biopsy.

Secondary outcome measures: Pathological assessment, reoperation rate.

Methods

- Our institute saw an intake of 25 cases from September to December 2018.
- From a time period ranging from two weeks prior to the operation to immediately pre-operation, we implanted the guiding-marker system (fig2) through stereotactic or ultrasonic guidance (fig3)
- After insertion, we confirmed that the guiding-marker system was embedded in the removed sample through specimen imaging.
- We confirmed with a magnetic probe that the guiding-marker system was embedded in the removed sample (fig4).

Fig2. guiding-marker system®



Magnetic marker

- Guiding-marker system
 - Originally developed for lung cancer patients
 - Made by HAKKO CO.,LTD., Japan
- Specification**
- Stainless-steel: SUS304 (approved for medical use)
 - Marker size: $\phi 0.28 \times 10$ mm with a hook (~7 mm)
 - 300 mm of nylon thread
 - Needle: 21G (Inner/outer diameter; 0.51/0.81 mm)

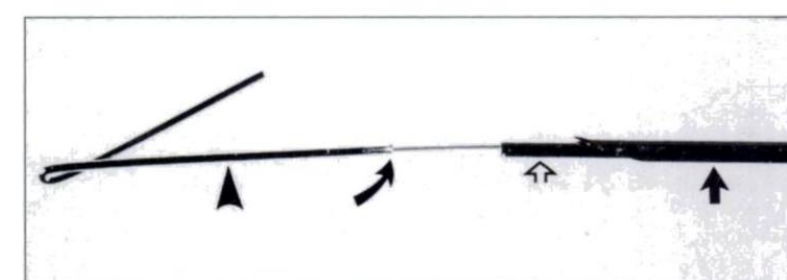
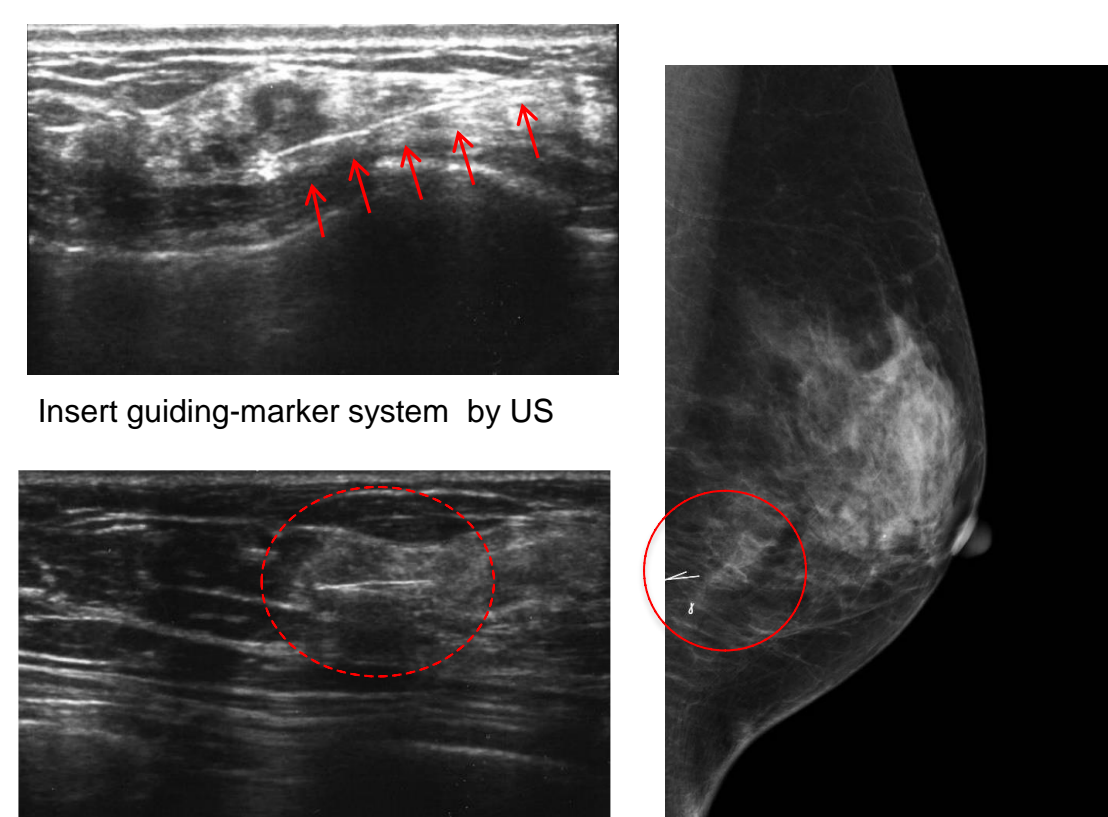


Fig 1.—Magnified photograph of hookless (arrowhead), hollow (upper arrow), and curvilinear (lower arrow) areas. Monitoring system (Fig 2) is fully attached to sensor (closed) proximal end of hookless (lower arrow) (d).

Fig3. Procedure



implanted the guiding-marker system

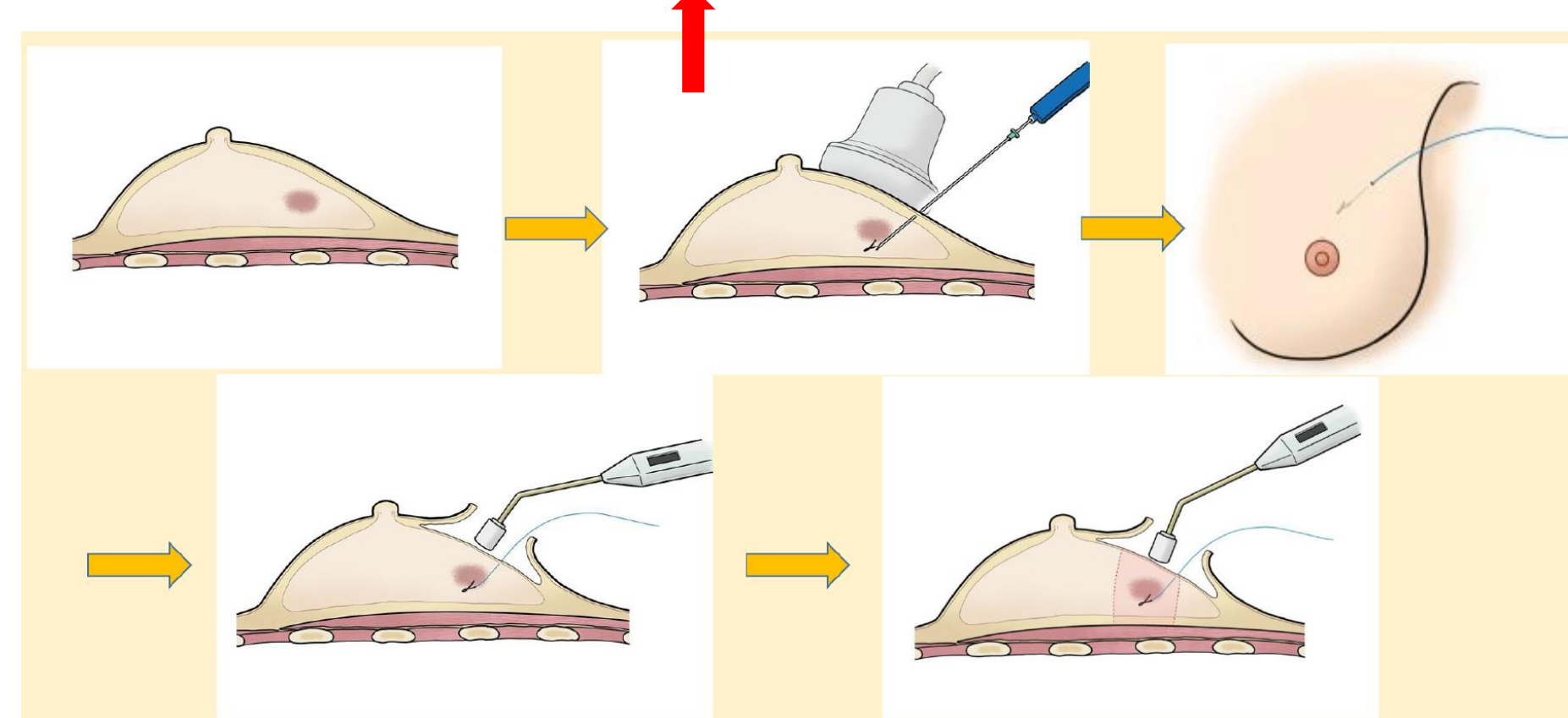
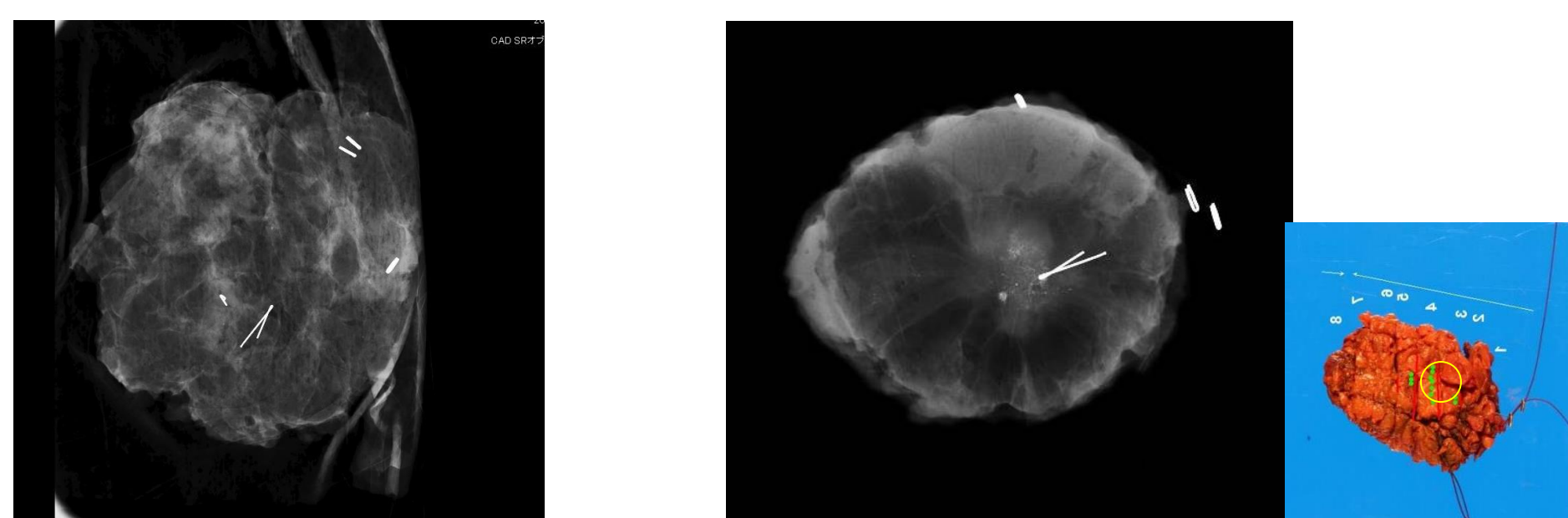


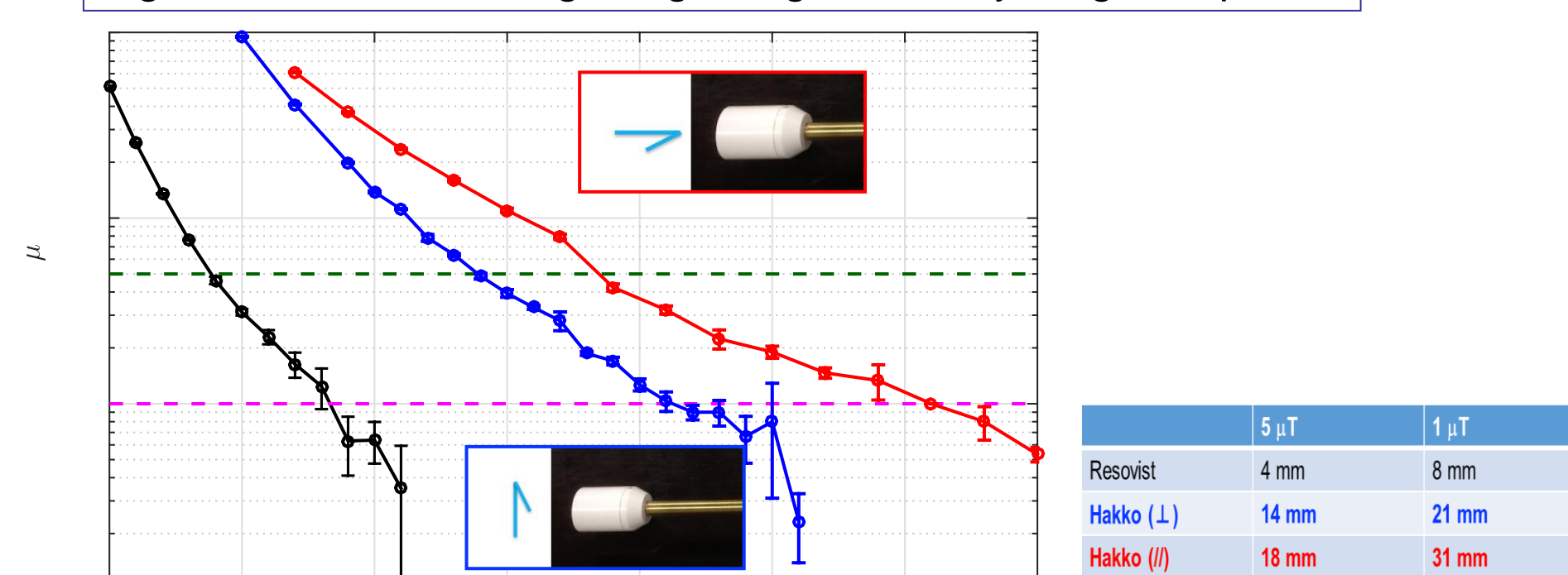
Fig4. specimen imaging and pathology



Case1. Patient who underwent neo-adjuvant chemotherapy. She underwent marking on-magnetic marker on the middle of chemotherapy because of near cCR. We seed guiding marker system near marker, and remove both of them. Pathological finding is just fibrosis. Chemotherapeutic effect is Grade3.

Case2. Lesion is calcification and low echoic area. Pathological margin is negative. We can find guiding marker system in yellow circle area.

Fig5. measurement range of guiding marker by magnetic probe



•The measurement range of the magnetic probe is as follows: the guidance marker system in a breast measures 5 μ T at a distance of 14-18 mm, and 1 μ T at a distance of 21-31 mm.
•These are sufficiently detectable distances in a breast.

Results

•Localization of this method was performed on 25 patients with non-palpable lesion of breast, from September to December 2018 at Showa University, Japan.

•We confirmed placement of magnetic marker by specimen radiography and magnetic probe in all cases (25/25 cases, 100%).(Table1)

•There were 6 cases after neoadjuvant chemotherapy. In most of the cases, it was difficult to detect the lesions prior to surgery. But this method makes it easier to resect the lesion. (Table1)

•In a postoperative pathology evaluation, the margins were negative in all cases. (Table2)

•There was no adverse event.

Table1

Patients and study characteristics	n (%)
Patients	25
Age (median, range)	51y.o (22-72)
Neo-adjuvant chemotherapy	6 (24)
Operation	
Excisional biopsy	3 (12)
Partial mastectomy	22 (88)
Clinical tumor size	
0-0.5cm	2 (8)
0.5-1cm	8 (32)
1-1.5	3 (12)
1.5-2cm	4 (16)
<2cm	2 (8)
unclear	6 (24)
Marker placement	
Mammography guidance	1 (4)
Ultrasound guidance	24 (96)
Marker placement on the day of surgery (under anesthesia)	24 (96)
Mean marker replacement before excision: days (range)	0.16 (0-4days)

Table2

Results	n (%)
Markers successfully removed	25 (100)
Detection of marker	
Specimen radiography	25 (100)
Magnetic probe	25 (100)
Magnetic probe range of specimen	80 μT (7.0-99.9 μT)
Pathology	
DCIS	2 (8)
IDC	16 (64)
ILC	1 (4)
Fibrosis (after neoadjuvant chemotherapy)	5 (20)
Benign lesion	1 (4)
After neoadjuvant chemotherapy	6
Grade 3	5
Grade 2b	1
Pathological tumor size	
0-0.5cm	8 (32)
0.5-1cm	6 (24)
1-1.5cm	4 (16)
1.5-2.0cm	1(4)
2.0cm<	6 (24)
pathological margin	
>5mm	20 (80)
<5mm	5 (20)
positive	0
additional surgery	0

Discussion & Conclusions

This combined technique using a magnetic marker and magnetic handheld probe for non-palpable lesions is an accurate and safe way to achieve a complete surgical resection. Larger studies are needed to confirm these findings.