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SPIROTOME as an alternative to vacuum-assisted mammotome biopsy systems

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Summary

Increasing interest in precise pre-treatment diagnostics of solid tumors by immunohistochemical and molecular techniques requires from the clinicians to search for the methods of large core biopsy allowing to obtain specimens with intact morphological structure. Minimum tissue damage, low cost of the technique and optimal adjustment to the patient's needs are the primary concerns. Spirotome is a large core biopsy system with (single-use) and without (reusable) vacuum assistance, designed for obtaining soft tissue biotates. Its good performance under clinical conditions, causing no damage to the breast tissue nor artifacts of the collected specimen has been proven. The first prospective analysis of the group of patients who were proposed to undergo biopsy performed with Spirotome or automatic version of the device (Coramate) has been reported. The biopsies were performed in 31 cases, and in 30 of them the examination goals were achieved. The system is a safe diagnostic device with excellent characteristics. Spirotome/Coramate covers a broad spectrum of large core biopsy from Gauge 14 to 8. The system guarantees high specimen quality, the patients' safety and the clinicians' satisfaction.

Key words: breast cancer • large core needle biopsy • mammotome biopsy

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Tumor biopsies performed in order to obtain material for histopathological investigations belong to the everyday practice in oncology. Clinicians increasingly rely on the information coming from biopsy. The objective of this examination is not only to establish unequivocal diagnosis of the tumor, but also to determine the grade of malignancy, histological type, hormonal receptors, or other biological markers (e.g. Her2-neu). Good clinical practice comes to include immunohistochemical or molecular analysis of fresh tumor tissue, preceding neoadjuvant (preoperative) chemo- and/or radiotherapy. Additionally, tumors impalpable on physical examination may become accessible for biopsy under the guidance of imaging techniques (USG, MMG, MRI).

The ideal system should allow to obtain large tumor tissue specimens with intact structure (tissue architectonics preserved), be easy to operate, inexpensive and applicable in multicenter studies. Such biopsy method should be minimally burdensome for the patient. The particular stages of the procedure should be visualized so that the view of the

biopsy needle reaching the lesion would correspond with the pathology visible in diagnostic images.

The new low-invasive and precise breast biopsy method has been developed since the 1990's. The essential part of the biopsy system is a needle (4 mm in diameter) containing a rotational mechanism. In contrast to conventional fine and large core needle biopsies, this method requires only one insertion of the needle, because, owing to its rotation, it can collect the tissue from any site around the biopsy needle. The collected tissue specimens are introduced into the needle, and then, with a rotating internal element, propelled outside.

Other biopsy systems, based on vacuum aspiration, are not widely used, primarily because of high costs and limited applicability in multicenter clinical studies.

The system called *Spirotome*, tested already on various solid tumors, mainly breast cancers, is an alternative solution to expensive and complicated vacuum-assisted biopsy systems.

Large core needle biopsy is a promising alternative to open surgical biopsy because of high sensitivity (97%) and consistency (94%) of histopathological re-classification. It is, however, necessary to determine the limitation of this technique and to develop the optimal criteria for qualification of patients. Without precise knowledge in this area, diagnoses of benign lesions established on the basis of large core needle biopsy in countries with high incidence of breast cancer should be treated with considerable caution [1].

The possibility of accurate determination of breast tumor malignancy is an important feature of mammotome biopsy. Nevertheless, in 24% who underwent such biopsies, the tumors were classified as more advanced after surgical resection [2]. The underestimation rates for high risk tumors and DCIS for 11G vacuum-assisted biopsy were 16% and 11%, respectively, and were lower than those obtained for 14G automatic biopsy – 40% and 15%. Vacuum-assisted biopsy, in comparison with 14G automatic biopsy, may reduce underestimation of for high risk tumors and DCIS. A question remains, whether the benefits from use of vacuum-assisted biopsy outweigh the extra costs incurred by the technique [3].

According to the Center for Health Care Quality Monitoring, an ideal biopsy system is „a sensitive and specific diagnostic method of impalpable breast lesions, characterized by very high accuracy and safety“.

Other characteristics of so-called ideal biopsy system include: 1) unequivocal tumor diagnosis by determination of malignancy, histological type, hormonal receptors, biological markers (immunohistochemical and molecular analysis of fresh tumor tissue); 2) precision – impalpable tumors should be accessible for USG, MMG, MRI-guided biopsy; 3) low invasiveness; 4) low inconvenience for the patient; 5) easy operation of the biopsy system; 6) low cost and 7) easy applicability in multicenter studies. Additionally, an ideal biopsy system should make it possible to collect tissue specimens: 8) by single needle insertion; 9) from any location in the breast (another organ); 10) with intact structure; 11) with large volumes – representative for the whole tumor.

One of the systems meeting all the above requirements is *Spirotome* (Figure 1).



Figure 1. Four main parts of the *Spirotome* system.

The *Spirotome* biopsy system has many advantages, including the possibility of:

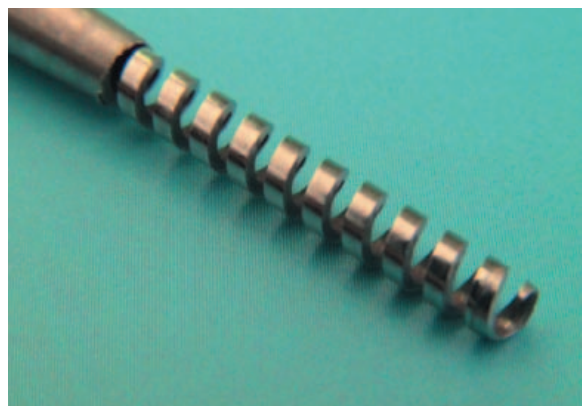
- use for each type of soft tissue, for superficial or deep tumors, in the vicinity of the pleural cavity, ribs, bones, skin, in breasts of all sizes,
- intraoperative biopsy of interstitial organs, including very soft, e.g. hepatic tissue,
- obtaining bioptates of Ø 2–3 mm with max. Ø 4 mm needle,
- multiple biopsies with single needle insertion,
- sterilization and multiple use as well as single use.

Biopsy with *Spirotome* is characterized by:

- no necessity to be performed in the operation room, with the help of assistants and expensive accessory equipment,
- sufficiency of local anesthesia for the procedure,
- lower costs than those of other macro-biopsy systems,
- no “firing” sound distressing for the patient, no cell dispersion through shooting,
- availability of different needle gauges, the largest ones (Ø 4 mm) can be used for resection of small lesions,
- excision of the tissue with a sharp edge without damage caused by aspiration inside the needle, as it is the case of the other vacuum-assisted systems,
- visibility under USG how *Spirotome* progresses and penetrates the tumor, which ensures the biopsy of the appropriate tissue direct frontal approach.

The technique of *Spirotome* biopsy, allowing direct frontal access to the suspicious lesions (Figure 2) is notable. Additionally, the bioptate to needle size ratio of 0,75 – bioptate 3 mm (8 – 10 Gauge), needle thickness 4 mm, is very favorable.

The first results of clinical studies testing the new biopsy system *Spirotome* have already been published [4]. The aim



of these studies was to develop a system allowing to obtain large tissue specimens and large numbers of specimens (up to 1000) from one procedure. The following criteria were adopted:

- the biopstate should be of good quality, with no damage due to collection procedure,
- the specimen dimensions should be consistent with the requirements of immunohistochemical and molecular investigations,
- the system should ensure equally easy collection of normal and malignant tissues, „in situ” lesions,
- the system should be relatively inexpensive and easy to use in multicenter studies,
- the method should be „patient-friendly”,
- it should be possible to record (control) the particular stages of the biopsy procedure to be sure that the collected specimen comes from the lesion observed in diagnostic imaging studies.

The study included 30 patients from different centers in Belgium and France. The **rotational excision** technique was assessed. The following results were obtained:

• Tissue specimen

- diameter 2.6 mm; length 20 mm
- 10 Gauge tissue cylinder

• Cost per biopsy

- the materials were generally re-used (one to eight times) after thorough cleaning and sterilization
- cost of 1 device – € 250, the cost of materials with cleaning and sterilization is slightly higher

- The procedure was found not to be associated with “firing/shot” sound unpleasant for the patients. No distant complications of the procedure were noted. In 5 (16%) patients subcutaneous hematomas developed. There was one case of intra- and post-operative hemorrhage, but pressure applied onto the needle insertion site stopped the bleeding within 10 min. One patient experienced painful symptoms for technical reasons; the procedure was discontinued too early and the amount of collected tissue was too small.

- All biopsies can be performed within 20 minutes, and 80% within 10 minutes

- Biopsies were performed in 31 cases and in 30 they were successful – the diagnostic efficacy amounted to 97%. In these cases, reliable histopathological and immunohistochemical assessment of specimens obtained by biopsy was possible (Figure 3).

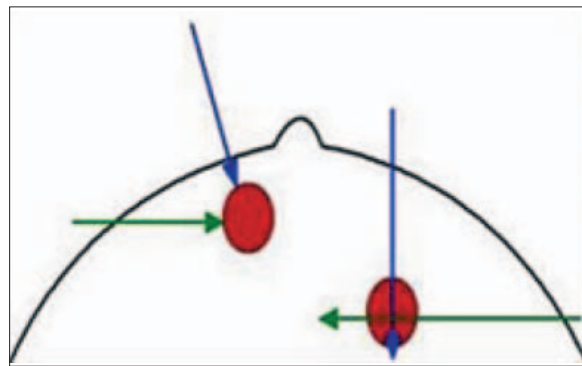


Figure 2. With *Spirotome*, direct frontal access to the suspicious tissue is possible.

Clinical assessment of the new biopsy system was the subject of report published by German authors from the academic center in Erlangen [5]. The aim of the study was to assess the diagnostic value of a new mechanical system for breast biopsy. Between 01/2004 and 03/2004, patients with BIRADS 5 underwent USG-guided *Spirotome* (8–10 G) biopsy. The patients' age ranged from 23 to 66 lat. From each tumor, 5 tissue cylinders were collected and subjected to morphological, histological and molecular investigations. The malignancy of 48 out of 50 focal lesions (96%) was confirmed and in 2 (4%) cases a benign character was determined both in biopsy and in intraoperative specimens. In conclusion, the authors state that the new mechanical breast biopsy system (*Spirotome*) is a technically advanced and ready-to-use method, especially because of the installed steel screw designed for optimal retrieval of the collected biopsy material. The system is also advantageous from the economical point of view, because *Spirotome* is a multiple-use device (after sterilization).

At the beginning of the design process concerning the biopsy system based on rotational excision technique with spiral harvesting needle (*Spirotome*) it was expected to solve the following problems associated with soft tissue biopsy systems: provide high diagnostic efficacy, without crushing-related artifacts, reliability, high biopstate/needle diameter ratio, low cost, low incidence of complications and a possibility to reach the areas previously inaccessible for the classic biopsy system. At least two systems of large core needle biopsy are currently available on the market – *Vacuflash* and *Mammotome*, both based on the same vacuum assistance technology. *Spirotome* is a spiral system without vacuum assistance with diagnostic efficacy so high that there is no difference between such type of biopsy and open surgical biopsies.

With biopstate/needle diameter ratio of 0.75, *Spirotome* makes it possible to collect large tissue specimens with relatively thin needles (in comparison with *Mammotome* – 0.42 or *Vacuflash* – 0.70). This property, in combination with no „shot” sound distressing for the patient, explains the low rate of complications and side effects, making it possible to use the technique also in more delicate tissues such as the brain, liver or kidney. In hands of a good operator, the patient gets no unpleasant impressions associated with the procedure, because the trephines are small and the sound minimal. The examination is well tolerated and

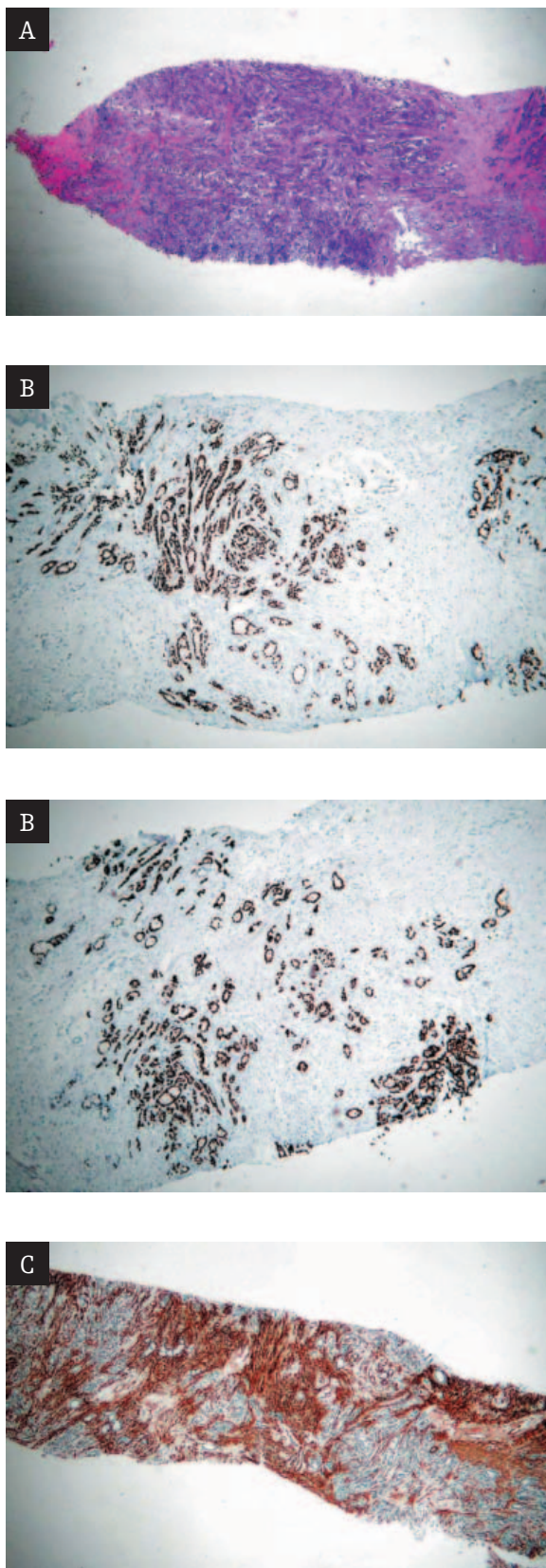


Figure 3. Histopathology of biopsates obtained with *Spirotome*. A – H&E staining: a breast biopsate without artifacts due to structural distortion or crushing. Immunohistochemical staining: B – ER/PGR and C – HER2.

safe for the patient, it can be performed in life-threatening situations and for so-called difficult locations, such as the vicinity of large blood vessels, bones or peripheral nerves. Because of its safety and unlimited potential of needle size increase, the *Spirotome* system with larger needle diameter could be used for resection of smaller tumors.

To localize the biopsy site, a clip or dye marker can be left in it. As *Spirotome* „seizes” the tissue prior to excision and protects it during the excision, the histological preparation undergoes no damage. The absence of artifacts increases the reliability of the method and minimizes the interlaboratory differences.

Spirotome is relatively inexpensive – approximately 250 Euro. It can be used to equip almost all centers (especially those treating high numbers of breast cancer cases). The cutting instrument can be used many times – after cleaning and sterilization, and its efficiency remains unaffected. *Spirotome* is the only system, in which one biopsy set can be used many times (up to 8 times with the same efficacy). No need of hospitalization reduces the costs increasing the applicability of this method.

Spirotome can be inserted under mammography, USG, CT or MRI control. Such technique is generally recommended because it allows to diagnose the disease at preclinical stage.

Most radiologists prefer the automatic version of the system. In the manual version of USG-guided biopsy collecting system, the operator needs both hands and assistance of a technician or nurse, which is not always possible. An automatic version of the biopsy system based on rotational excision technique – *Coramate* (Figure 4) is also available. Automation makes material collection even more reliable and repeatable. However, the costs are higher and adjustment to other radiological equipment is not so easy. Although *Coramate* was designed to facilitate clinicians’ work, the introduction of automatic system function improved neither the sample quality, nor the patients’ comfort.

Another concern is the risk of implantation of tumor cells along the biopsy canal. This is possible not only with biopsy systems based on rotational excision technique, but also with all biopsy methods, including vacuum-assisted systems or aspiration fine needle biopsy. Keeping in mind the possibility of false overestimation of tumor stage and consequent “overtreatment”, care should be taken to reduce the risk of tumor cell implantation [6]. The biopsy system based on rotational excision technique, collecting tumor tissue with intact structure and preserved architectonics, addresses these expectations.



Figure 4. Automatic version of the biopsy system based on rotational excision technique – *Coramate*.

The unique feature of this system are spiral needles. Tissues in the vicinity of bones or large blood vessels can be biopsied at the distance of up to 1 mm away from these structures. It may not be so important in case of breast biopsy, but in case of soft tissue sarcomas located close to skeletal structures this feature is of utmost importance. The same concerns subcutaneous or intracutaneous lesions. In vacuum-assisted systems, all the biopsied area should be located below the skin. Biopsy performed with *Spirotome* can be commenced on the skin surface. It is very important when the breast is squeezed on the stereotaxic table. In postmenopausal women, the breast can be compressed up to 3 cm, which is a distance difficult to reach with vacuum-assisted needles. Similar problems can be encountered in the regions below the areola of the nipple.

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Conclusions

- The biopsy system based on rotational excision technique (*Spirotome/Coramate*) is a safe diagnostic tool with excellent parameters.
- *Spirotome/Coramate* covers a wide range of large core needle biopsy, from 14 to 8 Gauge.
- The system ensures high biopate quality and clinicians' satisfaction.
- The reusable system is very advantageous from the economical point of view, because of the possibility of multiple use of the materials.
- This biopsy system can take biopsies in every site in the breast, also out of lesions where the other vacuum assisted systems have problems or cannot take biopsies.