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One-bloc percutaneous large biopsy of soft-tissue tumours: feasibility study and possible indications

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AIM: To report the early results of the Intact lesion excision system (LES) regarding feasibility, tolerance and efficiency in obtaining soft-tissue tumour samples under ultrasound guidance.

MATERIALS AND METHODS: The feasibility and tolerance of Intact LES procedures under ultrasound guidance were studied prospectively in 15 patients. The procedure was performed on an outpatient basis under local anaesthesia by a single interventional radiologist with 6 years of experience and lasted around 30 min.

RESULTS: The feasibility of the Intact LES for soft-tissue masses was good except when lesions were hard and calcified. Tolerance was good, with median pain experienced during the procedure evaluated at 4.5/10 (SD 2.2) and median post-procedural pain at day 1 evaluated at 1.8/10 (SD 2.5). No major complications were observed; however, for vascularised lesions, one case of acute wound bleeding and two post-procedural haematomas led to delayed pain.

CONCLUSION: Percutaneous biopsy of suspected soft-tissue sarcoma using the LES device under ultrasound guidance is well tolerated and feasible. After a first non-contributing core biopsy, and especially, in the case of lipomatous lesions, it is a valuable option to consider, as is surgical incision biopsy.

Introduction

Soft-tissue masses comprise a very broad spectrum of benign to highly aggressive lesions.[1] Sarcoma is a rare diagnosis requiring specific curative surgery and multidisciplinary management at expert centres.[2,3] Biopsy is a prerequisite for optimal management.[4,5] The completeness

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of initial surgery (R0) is the strongest favourable prognostic factor. The surgery is often extensive, complying with specific oncology rules in order to avoid recurrence.[6,7] When the diagnosis has not been established, patients may undergo incomplete or margin-positive resections, which subsequently compromise local control.[8] A preoperative biopsy helps to establish the diagnosis and provides key prognostic factors to propose the best therapeutic options while certain neoadjuvant radiotherapeutic strategies are emerging.[2,3,9,10] Due to its accessibility, image-guided percutaneous biopsy has become the consensual standard for soft-tissues masses[2–4,11,12]; however, the pathology of sarcoma is complex, with >70 different types and subtypes with very different prognoses, even in subtypes classes.[13,14] Tumour heterogeneity or necrosis inside the mass can lead to risk of underestimation (incorrect tumour grading or misdiagnosis) due to a limited or fragmented sample of the mass.

The Intact breast Lesion Excision System (LES), Medtronic, Fridley, MN, USA, was introduced for percutaneous removal of small breast tumours.[15–18] It combines a ultrasound-guided targeted biopsy with a large “surgical” sample, which preserves the tumour architecture and facilitates assessment by the pathologist. To the authors’ knowledge, it has not been evaluated outside the breast.

The IDEAL recommendations describe a five-phase roadmap for introducing a new interventional procedure: Idea, Development, Exploration, Assessment, and Long-term study.[19] Following this method, the present study reports the early results of the LES in terms of feasibility, tolerance, and efficiency in obtaining soft-tissue tumour samples under ultrasound guidance. In addition, the potential indications regarding preoperative management strategy are also discussed.

Material and methods

Selection

The present study was approved by the Institutional Review Board. Fifteen patients with uncharacterised soft-tissue tumours were included prospectively within an 18-month period starting in May 2015. All patients were referred following a multidisciplinary board meeting including an interventional radiologist (IR).[20] The patients were informed and written consent was obtained. Non-inclusion criteria were tumour size <2 cm, a lesion not visible at ultrasound, coagulation disorders, and the presence of a pacemaker (radiofrequency [RF] interference).

Material

The Intact LES device is composed of a 7-G needle containing a motorised wire basket using RF to capture the sample. During the capture sequence, RF energy cuts and coagulates tissue, isolating the contiguous sample for removal through a 6 mm incision (see Electronic Supplementary Material, Video S1). The size of the basket is adaptable and provides a one-block sample with a length of 7–30 mm. The system can be operated directly from the handle or by using a foot pedal base.

Supplementary data related to this article can be found at https://doi.org/10.1016/j.crad.2019.05.004.

Procedure

The procedure was performed on an outpatient basis under local anaesthesia and lasted around 30 min. A single IR operator with 6 years of experience performed all of the biopsies. According to current good medical practice, the needle path has to be resected during the final sarcoma surgery.[8] To comply with this, the surgeon marked the skin beforehand so that the IR could perform the percutaneous biopsy from the same pathway as the planned surgery.

The biopsy was performed under real-time ultrasound guidance (Fig 1, Electronic Supplementary Material, Video S1) combined with a computed tomography (CT) examination for deeper intra-abdominal lesions. The ideal target within the tumour was defined as the site most likely to be significant for analysis (solid part for necrotic lesions, heterogenic part for lipoma, or the most hypermetabolic part on positron-emission tomography [PET]). The biopsy path was planned in order to avoid any vascular or neural structures, and the size of the sample was also adapted beforehand according to the tumour presentation.

For all of the patients, anaesthesia with 5 ml xylocaine 20 mg/ml 1% adrenaline was given via a 22-G needle under the skin and around the lesion. For patients 7–15, 20 ml Naropeine (ropivacaine) 2 mg/ml was added and the patients received a nitrogen monoxide–oxygen mixture on demand to improve analgesia.

A 1 cm skin incision was made to introduce the LES under the skin. To improve comfort for the operator, an assistant was present to start the sampling when asked. The patient was informed that he or she might experience moderate pain for 10 seconds and was asked to count during this process in order to create a distraction. The post-procedural haematoma was controlled with a compression bandage maintained for 24 hours after biopsy. Usual practice is to take a photograph after the biopsy to show the surgeon the exact skin entry point.[8]

Pain was evaluated on a numerical scale (0–10) during the procedure. One day afterwards, patients were checked with a phone interview to screen for abnormal pain or haematoma and were re-examined if needed. Three days later, patients were asked about their overall satisfaction regarding the procedure using a Likert scale by phone interview (2, very satisfied; 1, satisfied; 0, unsure; −1, dissatisfied; −2, very dissatisfied) and asked if they would undergo the procedure again if necessary.[21]

Analysis of results

According to the IDEAL recommendations, a critical evaluation was performed in order to report the learning curve, technical feasibility, pain experienced, complications, patient satisfaction, and histological analysis.[19]

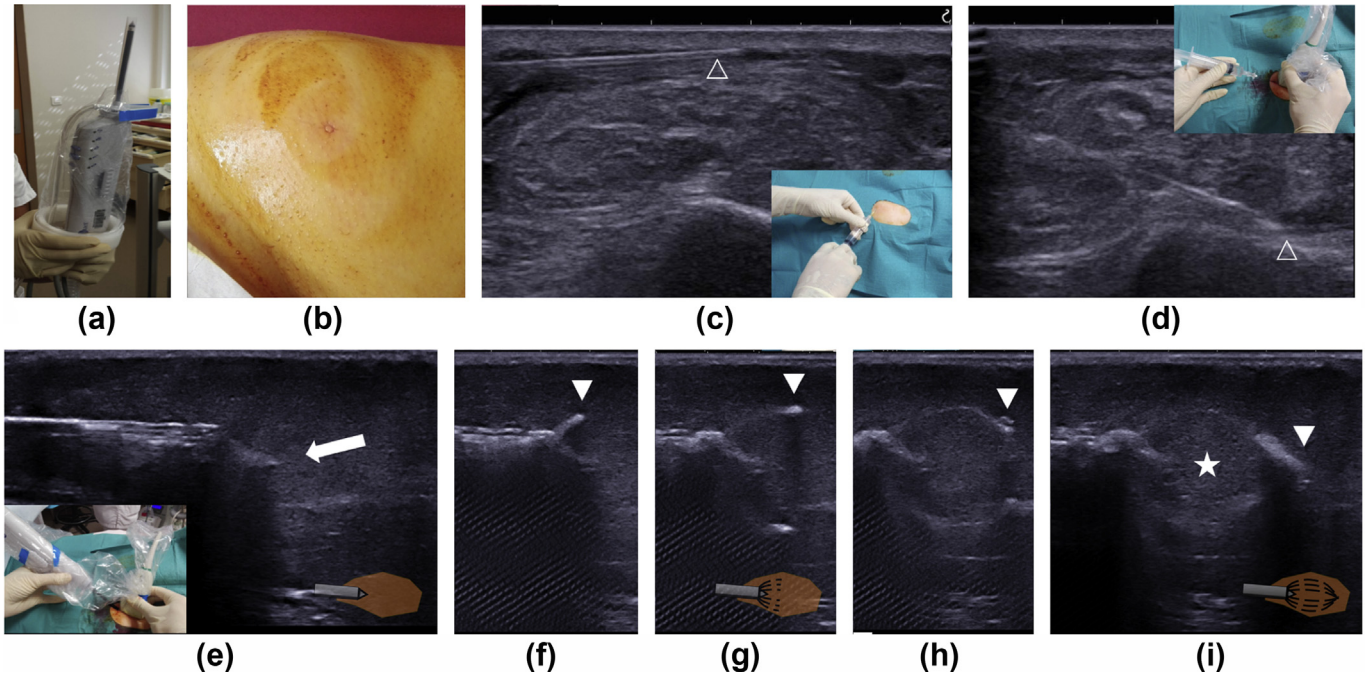

Figure 1 Detailed procedure of the LES sampling. (a) The LES device is a motorised introducer linked to an electro-surgical RF generator and aspiration system used to capture the sample. (b) A prior comprehensive ultrasound evaluation makes it possible to plan the biopsy path and adjust the size of the sample beforehand. The skin entry point is marked and the skin is disinfected. (c,d) Superficial and deep local anaesthesia under ultrasound guidance with a 21-G needle (empty triangle). (e) A 1 cm incision was made to introduce and position the LES in front of the planned sample site before beginning automatic sampling (arrow). (f–h) The 10-second automatic sampling is controlled under real-time ultrasound guidance (assistant needed). The basket is slowly deployed (white arrowhead). (i) The basket contains the sample (star).

Results

Population

The median age of the patient cohort was 40 (19–76) years old. Median lesion length at its longest was 11 cm (5–20 cm). Thirteen lesions were located in limbs and two lesions were intra-abdominal. Twenty-seven percent of patients were referred after having had a previous non-contributing percutaneous core or surgical biopsy. A wide range of imaging presentations were included (Fig 2).

Feasibility

Fourteen of 15 procedures were completed. Only one technical failure was reported due to the hardness of a calcified tumour (patient 5). The motorised basket was not able to open inside the lesion.

Tolerance

The median pain experienced during the procedure was 4.5 (SD 2.2). At day 1, median post-procedural pain was 1.8 (SD 2.5). The first six patients experienced relatively more intense pain compared to the rest of the patients who benefited from the additional Naropeine. Three grade B complications according to the Society of Interventional Radiology (SIR) classification occurred.[22] No inpatient admission was reported. There was one case of immediate wound bleeding (patient 4) and two delayed haematomas measuring <3 cm (patients 2 and 4). More than 50% of patients were very satisfied with the procedure overall, and 80% would undergo the procedure again if needed.

Histopathology

The median sample length provided for analysis was 14.6 (12–20) mm at its longest. Histology analysis was always representative and peripheral thermal damage was not a limitation. A large range of tissues was sampled and most lesions contained fat (Table 1; Fig 2). The LES specimens revealed 4/15 benign lesions (one haemangioma, one chronic haematoma, two lipomas) and 11/14 sarcoma lesions (two chondrosarcomas, one osteosarcoma, eight liposarcomas). When the lesions were excised, no diagnostic discordance was reported between the LES and the final excision.

Discussion

Standard biopsies

Various techniques are available to sample an expansive soft-tissue lesion. Image-guided percutaneous core biopsy, surgical open incision biopsy, and surgical open excision are all possible (Fig 3). According to sarcoma expert recommendations, image-guided multiple core needle biopsies (possibly using ≥14–16 G needles) are the first-line

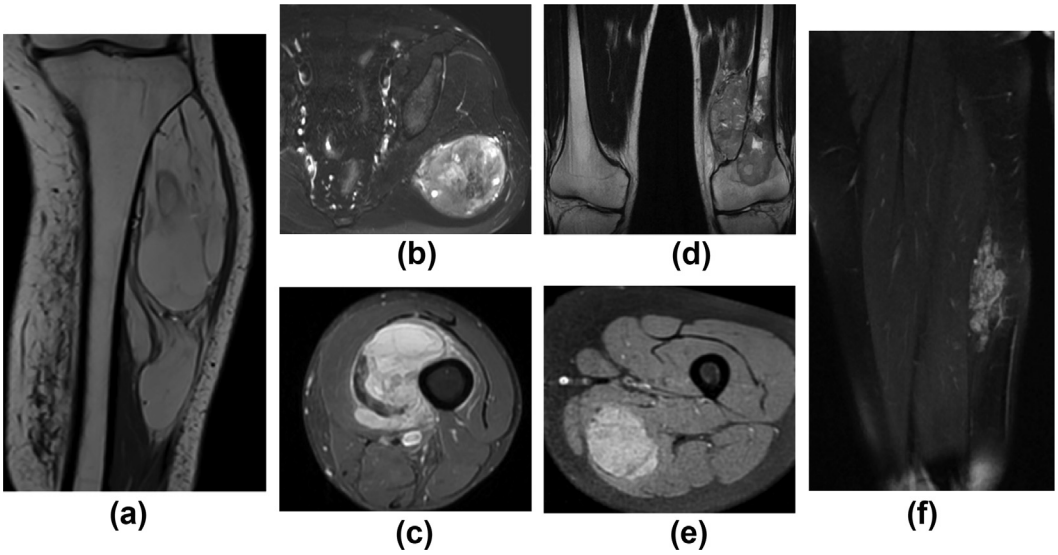

Figure 2 Examples of sampled soft-tissue masses. A wide range of imaging presentations and histology has been included: (a) patient 6, sagittal T1, liposarcoma "lipoma-Like"; (b) patient 5, axial Proton Density (PD) fat-saturated (FS), mesenchymal chondrosarcoma; (c) patient 1, axial T1 gadolinium FS, undifferentiated sarcoma; (d) patient 2, coronal T1, conventional osteosarcoma; (e) patient 3, axial T1 gadolinium FS, cystic chronic haematoma; (f) patient 4, sagittal PD FS, benign haemangioma with equivocal imaging features.

Table 1
Study population and results.

No.	Sex	Age	Situation	Tumour size (cm)	Sample size (mm)	Pain d0/d1	Satisfaction score at d3. Would you have the procedure again?	Previous non-contributory histology	LES histology	Surgical excision discordance
1	M	61	Thigh	7	15	2/1	2/Y	Incisional Biopsy	Undifferentiated sarcoma	None
2	M	19	Thigh	14	20	3/8	-1/N	None	Conventional osteosarcoma	None
3	F	47	Thigh	6	12	10/2	0/N	None	Cystic chronic haematoma	*No surgery*
4	F	20	Thigh	5	12	8/7	-1/N	None	Benign haemangioma	*No surgery*
5	M	35	Buttock	15	15	6/2	2/Y	Incisional Biopsy	*Failure*	Mesenchymal Chondrosarcoma
6	M	70	Leg	20	15	6/3	2/Y	Surgical Excision R1	Liposarcoma "lipoma-like"	None
7	F	76	Shoulder	6	12	3/0	2/Y	None	Lipoma	*No surgery*
8	M	34	Thigh	8	12	4/0	2/Y	None	Myxoid liposarcoma	None
9	F	33	Pelvis	20	20	2/0	2/Y	Core Biopsy (16-gauge)	Lipoma	None
10	F	40	Arm	10	12	4/1	1/Y	None	Liposarcoma "lipoma-like"	None
11	H	24	Thigh	10	20	5/1	1/Y	None	Liposarcoma "lipoma-like"	None
12	F	48	Abdomen	15	15	3/0	0/Y	None	Undifferentiated retroperitoneal liposarcoma	None
13	H	45	Arm	13	15	5/0	1/Y	None	Liposarcoma "lipoma-like"	None
14	F	30	Leg	6	12	4/0	2/Y	None	Myxoid liposarcoma	None
15	F	25	Buttock	8	12	3/2	2/Y	None	Mesenchymal chondrosarcoma	None

Three patients had a surgical sample taken that was non-contributory. For patient 5, histology was obtained on a second incisional biopsy.

procedures due to their low cost and low risk of contamination.[2–4,12,23] Open surgical biopsies (excisional and incisional) should only be proposed in selected cases. First, for practical reasons and small lesions, excisional biopsy may be proposed for a superficial lesion measuring <3 cm.[24] Second, when the result of the percutaneous biopsy is non-diagnostic, a small incisional open biopsy should be performed.[23,25]

Potential complications of all of these techniques include post-puncture haematoma, inaccurate sampling, an improperly placed incision that complicates future surgeries, and healthy tissue contamination that can add morbidity to the definitive surgery. Imaging guidance improves diagnostic accuracy and minimises complications by targeting the non-necrotic part of the lesion and avoiding vascular structures. Open biopsies are associated with an increased risk of tumoural seeding of the biopsy site and local recurrence.[26,27]

The overall accuracy of core biopsy in differentiating soft-tissue sarcomas from benign soft-tissue tumours is high at >95%[5,28–30]; however, grading is more challenging.[11] The tumour subtype and grade are misidentified in approximately 15–20% of soft-tissue sarcomas depending on the studies.[5,28,29] The grades of lipomatous tumours

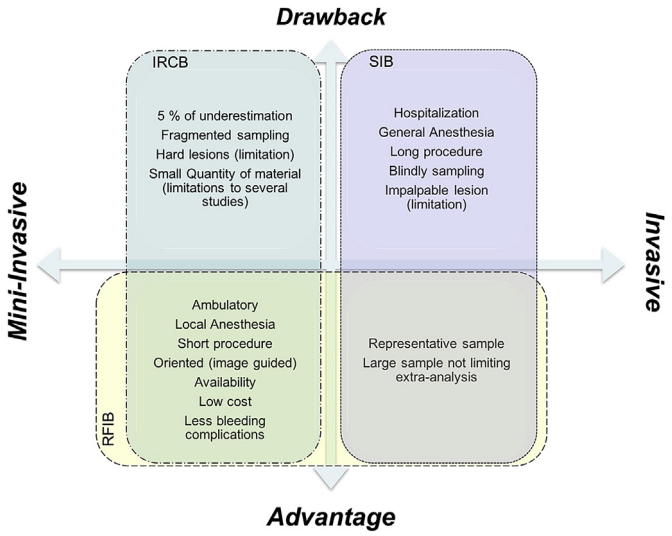

Figure 3 Drawbacks and advantages of the various techniques for histology sampling. IRCB, interventional radiology core biopsy; SIB, surgical incisional biopsy; RFIB, radio-frequency Intact biopsy. LES combines the advantages of IRCB and SIB.

are still frequently misdiagnosed due to the loss of tissue architecture (patient 9; Fig 4).

Routine availability of immunohistochemical and fluorescence *in situ* hybridisation helps characterise certain sarcoma subtype markers, such as MDM2 translocation for well-differentiated liposarcoma tumours.[31] With surgical biopsy, the macroscopic architecture of the lesion is preserved and the sampled material is larger, which decreases the risk of underestimation[32]; however, in the study population, two open biopsies were non-contributory due to a necrotic lesion, underscoring the importance of image guidance for targeting.

Intact® LES biopsy

This is the first study proposing the use of the LES for soft-tissue lesion assessment, although previous articles have been published on the primary utilisation of the device, i.e., in breast tumours.[15–17]

With regard to feasibility, there was only one failure concerning a hard lesion (patient 5). The present authors would not recommend the procedure on hard, "stony"

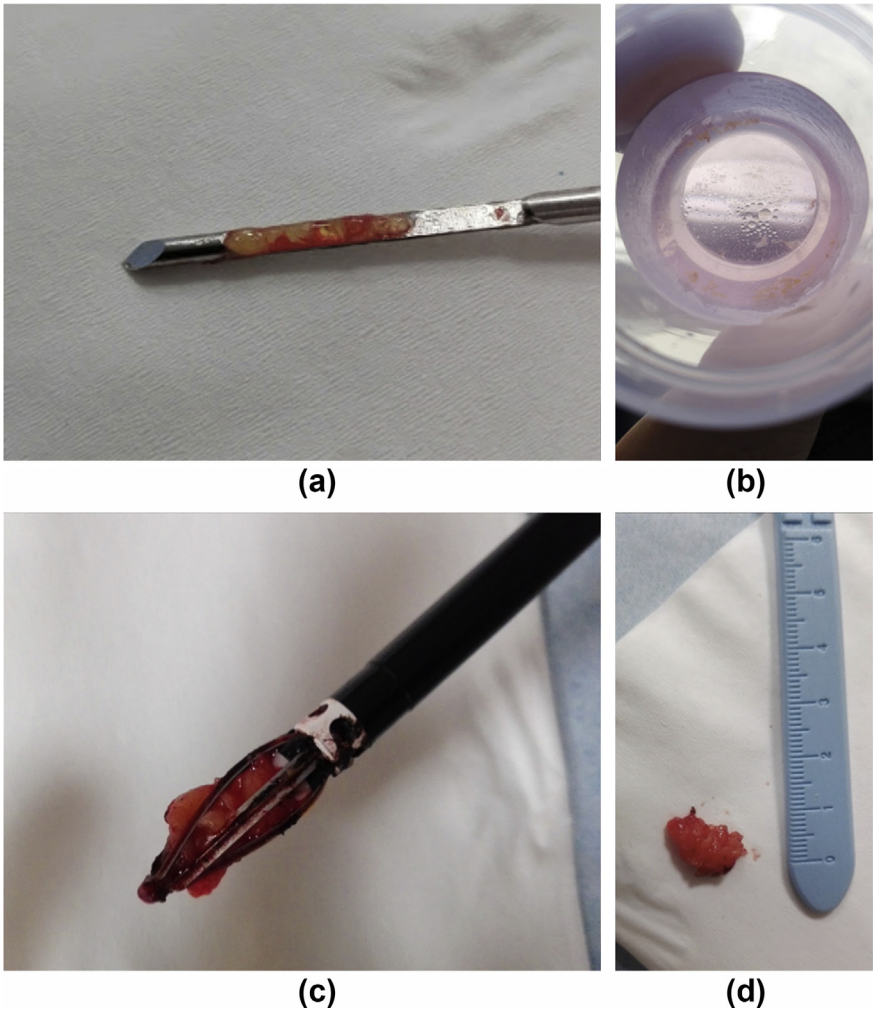

Figure 4 Comparative samples of a Tru-cut and an Intact device biopsy of a lipomatous lesion. (a) Eighteen-gauge Tru-cut core biopsy of a fat-containing lesion. The sample is 1 mm thick. (b) The architecture of the 18-G sample is not preserved. The sample is diluted in formalin and forms floating fat spots. (c) The 7-G LES needle tip contains the sample inside a basket deployed during the sampling process. (d) The intact sample is approximately 1 cm long and its architecture is preserved.

lesions, as the basket is not able to open properly to collect the sample. Conversely, purely cystic lesions are a limitation, because the non-solid architecture is not suitable for an Intact large sample. Targeting a solid or mixed zone is recommended to obtain a well-preserved specimen. Nerves and vessels have to be at least 1 cm from the planned excision zone. Basket size can be adjusted for small lesions (the smallest basket is 7 mm long).

Regarding limitations, the target lesions included were always larger than the basket sample. As a rule, samples were not taken from outside of the lesion in order to prevent dissemination. For this reason, complete lesion excision with a safety margin could not be performed, although theoretically, it would be possible for small lesions. The RF ablation of the sample's margins was not a limitation for the pathology assessment, as this has been reported in some articles on breast excision.[15]

The cost of the device is a limitation to use, as it costs approximately five-times more (USD400) than a core-biopsy device; however, compared to an incisional surgical biopsy with hospitalisation and operating room cost, the procedure is not as expensive.

Regarding tolerance, it is recommended that the procedure be thoroughly explained to the patient beforehand. Pain management is essential, as the maximum pain experienced lasts for 10 seconds during the procedure. For this reason, wide local anaesthesia is necessary around the excision site. The three patients who would not undergo the procedure again, experienced a high level of pain, but they had the procedure done before the improvement in local anaesthesia with the addition of Naporeine on the deep and superficial layers of the sampled zone (Fig 2). A non-invasive analgesia, such as a nitrogen monoxide–oxygen mixture or anxiolytic medication could also help. Overall satisfaction with the procedure was high, even for patients who underwent a previous biopsy. No post-procedural pain was experienced if there were no complications. Two painful delayed haematomas occurred, which were more frequent when the lesion was vascularised. These complications have also been reported with breast biopsy, and in the opinion of the present authors, these should not be considered contraindications.[17]

Regarding the learning curve, the technique is similar to breast macrobiopsy, and by analogy, it was performed with a technical assistant already trained in interventional breast biopsy.[19] With ultrasound, the visualisation of the needle tip is not an issue and the procedure is controlled in real-time.

Finally, concerning the advantages of the technique, the large and non-fragmented sample clearly helped the expert pathologist establish a diagnosis. This is particularly beneficial in lipoma lesions, which do not generally maintain their architecture with micro-biopsy (Fig 4; patients 6 and 9). The subtype and grade assessment concordance for excised lesion was 100%. Some (minimal) uncertainty remains with lesions that were not excised. The surgeon is more comfortable because this step makes it possible to postpone surgical incision biopsy and plan an excision after neoadjuvant radiotherapy based on the results.[10] The outpatient setting of the biopsy is a plus for the patient and increases the availability of the technique.

The LES provides an oriented image and a large sample with preserved architecture, which is valuable in the histopathology analysis of sarcoma. It is an outpatient, minimally invasive technique that is safe and well tolerated. In the authors' experience, for soft-tissues tumours, the LES could be proposed as an alternative to incisional surgical biopsy after a first non-contributory core-biopsy in selected patients. Large heterogeneous lipomatous lesions could benefit most from this technique, so as not to underestimate differentiation.

Conflict of interest

The authors declare no conflict of interest.

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