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INTERVENTIONAL

Radiofrequency ablation versus magnetic resonance guided focused ultrasound surgery for minimally invasive treatment of osteoid osteoma: a propensity score matching study

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Abstract

Objectives To compare outcomes in pain relief and motor functional recovery in patients with an osteoid osteoma treated by magnetic resonance guided focused ultrasound surgery (MRgFUS) or radiofrequency ablation (RFA) using a propensity score matching study design.

Methods Thirty patients with osteoid osteomas were included in this institutional review board (IRB)-approved study. MRgFUS was performed in 15 subjects. These subjects were matched by propensity analysis with a group of 15 subjects treated by RFA. Pain relief in terms of complete response (CR) and motor functional recovery were measured.

Results A similar proportion of subjects treated by MRgFUS (94 %) or RFA (100 %) experienced CR 12 weeks after treatment, with no significant difference. The improvement in pain control following MRgFUS or RFA paralleled with improved motor functional recovery. The treatment failure rate was 6.6 % in the MRgFUS group and 0 % in the RFA group. No major complications were observed following either ablative treatment.

Conclusions Although this study involved a limited number of patients, MRgFUS favourably improves perceived pain and motor functional recovery, with no major complications. No difference was found in the achievement of primary and secondary outcome measures with respect to RFA.

Key Points

- *To demonstrate the effectiveness of a recent technique for treating osteoid osteoma*
- *MRgFUS results compared with results of the gold standard treatment (RFA)*
- *MRgFUS is effective both from a clinical and functional point of view*
- *No significant side effects compared with RFA*

Keywords Osteoid osteoma · MRgFUS · RFA · HIFU · Thermal ablation

Introduction

In recent years, the use of interventional radiology treatments in daily practice has increased [1, 2], along with various methods for diagnostic guidance and treatment evaluation [3, 4]. Osteoid osteoma, a small (less than 2 cm), benign, painful bone lesion with distinctive clinical and imaging features, occurs most often in men between the first and third decades of life. The main symptom is severe pain, especially at night, which typically subsides with aspirin and other non-steroidal anti-inflammatory drugs (NSAIDs). Apart from medical and surgical therapy, which are limited to special cases, the therapeutic gold standard is thermal radiofrequency ablation (RFA) under computed tomography (CT) guidance [5].

First described in 1989 and published in 1992 [6], RFA is safe and effective and is performed under spinal or general anaesthesia. The treatment duration is approximately 90 min

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and patients are typically hospitalized for 2 days. The main contraindications are pregnancy, sepsis, cellulitis, bleeding disorders and lesions that are close to vital structures such as nerves (<1 cm). The documented success rate is 89–95 % [5], with possible failures due to inaccurate needle placement, inadequate tissue ablation and transient or permanent damage of structures close to the lesion.

At our centre, we routinely treat osteoid osteoma using RFA. We recently identified high-intensity focused ultrasound (HIFU) as an alternative minimally invasive thermal ablation technique. HIFU utilizes a beam of focused ultrasound instead of RF to ablate tissue, and it enables entirely minimally invasive ablation of deep lesions without the need for needle insertion. This technology is performed under the continuous guidance of magnetic resonance imaging (MRI) and is referred to magnetic resonance guided focused ultrasound surgery (MRgFUS) [7–9]. MRgFUS treatment of osteoid osteomas has been documented in the literature [9, 10], although on a small number of patients. The aim of the current study was to confirm the safety and efficacy of MRgFUS on a larger patient cohort and to highlight its potential advantages compared to RFA.

Materials and methods

Patient selection

In this active control trial, patients with radiologically confirmed osteoid osteoma and receiving MRgFUS (group 1) were prospectively recruited from January 2012 to December 2013 and matched by propensity score analysis with an historical pool of patients affected by the same pathology and treated with RFA (group 2) from January 2010 to December 2011. The historical pool was composed of 30 patients. This statistical strategy allowed us to obtain two groups of patients virtually randomized for important clinical characteristics (see "Statistical analysis" section). MRI or computed tomography (CT) was planned within the 4 weeks prior to the procedures in all patients. Eligibility criteria included clinically significant pain, evaluated on a 0–10 visual analogue scale (VAS) over the prior 24 h. A pain score of 6 or more on the VAS was considered clinically significant. This algic threshold was considered an inclusion criterion with or without clinically significant functional limitations.

Functional assessment was graded according to two functional indices: the upper extremity functional index (UEFI) [11] and the lower extremity functional index (LEFI) [12] for the upper and lower extremities, respectively. Specifically, these scales assess the degree of functional impairment due to disease (80 = no functional impairment, 0 = total functional impairment). A score of 32 or less on this scale indicates clinically significant pain. Other inclusion criteria were an osteoid osteoma with an acoustic window that enables access of the ultrasound beam. An appropriate acoustic window is defined as a conical pathway between the transducer, which generates the ultrasound beam, and the target lesion. This pathway must exclude metallic devices, scars or other structures that reflect or refract the ultrasound beam, because they can prevent effective ablation. In fact, the presence, along the acoustic window, of many interfaces between the tissues (soft tissues and bone) can reduce effective penetration and concentration of the ultrasound beam and so can make this type of lesion unsuitable for MRgFUS treatment (see "Discussion" section). Moreover, all lesions located deeper than 1.2 cm from the bone surface (the bone cortex) were also considered unsuitable for MRgFUS treatment (because this distance can impede the effective penetration of the ultrasound beam and thus effective ablation) (Fig. 1). Other exclusion criteria included (i) target lesions positioned within 1 cm of critical structures such as nerves, tendons, ligaments and tendon insertion points; (ii) target lesions previously treated with ablation techniques. The clinical characteristics of the two groups matched by propensity analysis are listed in Table 1. Written informed consent was obtained from research subjects prior to all procedures and the study was approved by the institutional review board (IRB).

MRgFUS ablation

All patients were hospitalized on the day prior to ablation for blood testing and presurgical evaluation. On the day of ablation, all 13 patients treated with MRgFUS received spinal anaesthesia (bupivacaine 20 mg). Patients with the osteoid osteoma localized at the humeral diaphysis received a peripheral nerve block. Each patient was positioned on the MRgFUS table (ExAblate 2000, InSightec, Tirat Carmel, Israel), with the acoustic window centred on the targeted lesion. Treatment began with verification sonications, which involve subtherapeutic ultrasound delivery to check the accuracy of the ultrasound beam and the effect on the targeted tissue.

On average, we performed 2.9 verification sonications per patient (range 2–4) using low energy (150–434 J, mean 290 J) for a short period of time (8–15 s, mean 10 s). After completing the verification sonications, we proceeded with the treatment, using higher levels of energies (mean 815 J) that produced a temperature rise to 65–85 °C and caused coagulative tissue necrosis. The number of therapeutic sonications ranged from 3 to 8 (mean 6.4), depending on the size of the lesion. At the end of the treatment, the patient was administered pain medication via infusion pump for a total of 8–12 h, which included morphine, gastroprotective and anti-emetic drugs. All patients also received cortisone therapy for 2 days following treatment (betamethasone, 4 mg twice daily) and were discharged the day following

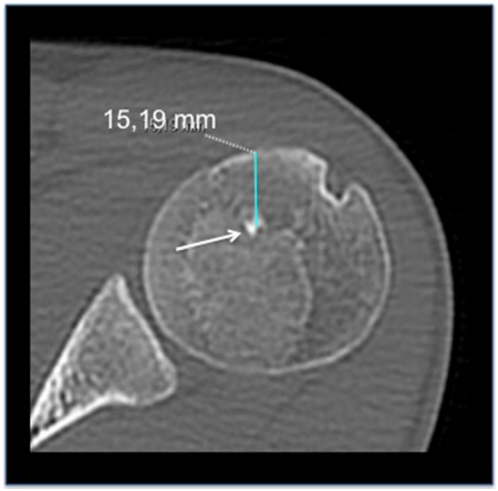


Fig. 1 An osteoid osteoma of humeral head (*arrow*) not suitable for treatment with MRgFUS. The distance between the centre of the lesion and the cortical profile of the humeral head is greater than 1.2 cm and so we cannot be sure to obtain an effective ablation

the procedure (mean hospitalization time 48 h). All procedures were performed by an experienced interventional radiologist and a resident radiologist. No complications were observed in any of the treated patients.

Radiofrequency ablation

RFA was performed under CT guidance (Toshiba Aquilion One, Toshiba Medical Systems Corporation, Japan). Thirteen patients received spinal anaesthesia (bupivacaine 20 mg), whereas two patients who had a lesion at the radius received peripheral nerve block. RF thermal ablation was performed according to standard techniques [1] (using an RF 3000 generator, Boston Scientific Corporation, Natick, MA, USA; and a 17G needle electrode of 1-cm ablation diameter, MedItalia Biomedica, Genova, Italia). In cases where the nidus was surrounded by perilesional sclerosis, the tumour was accessed with the help of a drill (17G-diameter Kirschner wire guide). Before turning on the RF generator and treating the lesion, we evaluated the correct position of the electrode within the nidus using CT.

RFA was performed with impedance control. In all cases, we began with the power at 2 W, increasing the power by 1-W increments every minute until the completion of ablation (average duration 7 min). Before treatment, a topical broad-spectrum antibiotic was applied, and after treatment analgesic therapy, which included morphine, gastroprotective and antiemetic drugs, was administered by infusion pump (for a total of 8–12 h). All patients also received four doses of corticosteroids (betamethasone 4 mg) every 12 h for 2 days (as with MRgFUS). One patient who received RFA presented with a complication of myofasciitis with involvement of the sciatic nerve. The patient was treated with cortisone and discharged 5 days following the procedure. All the procedures were performed by an experienced interventional radiologist and a resident radiologist. The average number of hospitalization days was 2.6 for all other patients.

Patient assessment before and after ablative approaches

A full physical examination was performed and data on direct and indirect changes in pain levels and function were assessed. Patients were evaluated weekly during

Table 1 Clinical characteristics according to propensity score

Characteristics	MRgFUS	RFA	*P* value
Age (years), median (CI 95 %)	23 (19.3–30)	28 (25–31)	0.24
VAS score, median (CI 95 %)	8 (8–8.5)	8.5 (8–9)	0.18
Functional limitation, median (CI 95 %)	7 (6.6–7)	7 (7–7.4)	0.33
Sex, *n* (%)			
Male	10 (66.7)	8 (53.3)	0.71
Female	5 (33.3)	7 (46.7)	
Tumour size			
Longest diameter (cm), median (CI 95 %)	6 (5–6.7)	6 (5–6)	0.44
Radiation exposure (mean, mSv)	–	5.6; 95 % CI 4.35–6.85	–
Median daily dose of acetylsalicylic acid (g)	0.5 (0.39–0.62)	0.5 (0.25–0.75)	0.94
Lesion location, *n* (%)			
Femur	8 (53.3)	7 (46.7)	1.0
Tibia	2 (13.3)	3 (20)	1.0
Talus	2 (13.3)	3 (20)	1.0
Humerus	2 (13.3)	2 (13.3)	1.0
Hip	1 (6.7)	0 (0)	1.0

the first month and every 3 months thereafter. Patients were clinically monitored up to 24 months after the end of treatments.

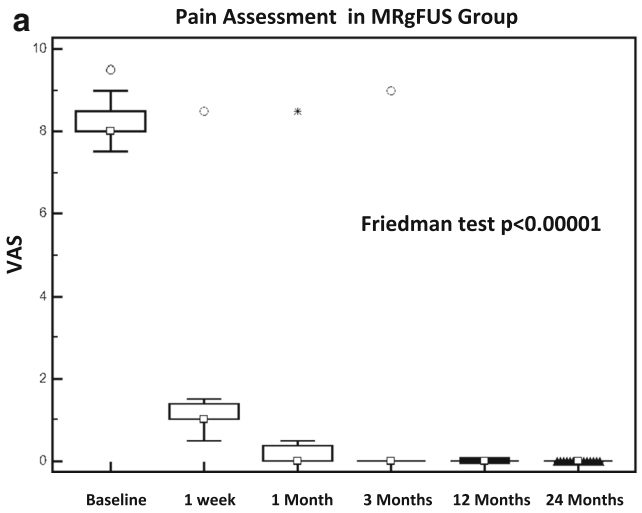
Post-treatment monitoring was also performed by MRI (Signa 1.5 T, GE Healthcare) or CT up to 12–24 months post-treatment. MRI was performed with SE T1, FSE T2 and STIR sequences in the most representative planes for each location.

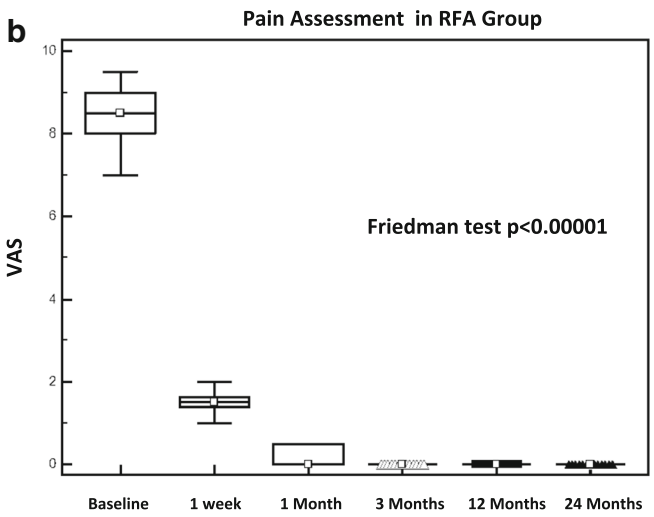
Study endpoints and response criteria

The primary endpoint was to compare the rate of complete response (pain relief) at 12 weeks after treatment. The complete response was defined as the complete disappearance of pain, measured by the VAS. The secondary endpoint was to compare the recovery rate of compromised motor function, measured with UEFI and LEFI.

Statistical analysis

The data analysed in this report were derived from a population-based observational study. In order to reduce treatment selection bias and realistically determine the treatment effects, a case control-matched propensity analysis was performed. Multivariate logistic regression was used to calculate the predicted probability of the dependent variables, as well as the propensity score for all observations in the data set. The dependent variables included in the multivariate analysis were age, anatomic site, lesion depth, VAS score and functional condition assessed by UEFI and LEFI, before procedures. A 1:1 matched analysis was performed wherein 15 cases (subjects treated by HIFU) were matched to 15 controls (subjects treated by RFA). Continuous variables not normally distributed (Shapiro–Wilk test) were presented as medians and 95 % confidence intervals (CI 95 %). The Mann–Whitney *U* test was used to evaluate the difference between two groups and the Kruskal–Wallis or Friedman test was used to evaluate the difference among more than two tests when appropriate. If the Kruskal–Wallis or Friedman test was statistically significant, a pairwise comparison of subgroups was performed according to Conover [13]. Dichotomous variables were summarized by absolute and/or relative frequencies. The chi-squared test or Fisher's exact test was used to evaluate the difference between two groups. For multiple comparisons, the alpha value threshold was adjusted by using Bonferroni correction. All tests were two-sided except where specified and were determined





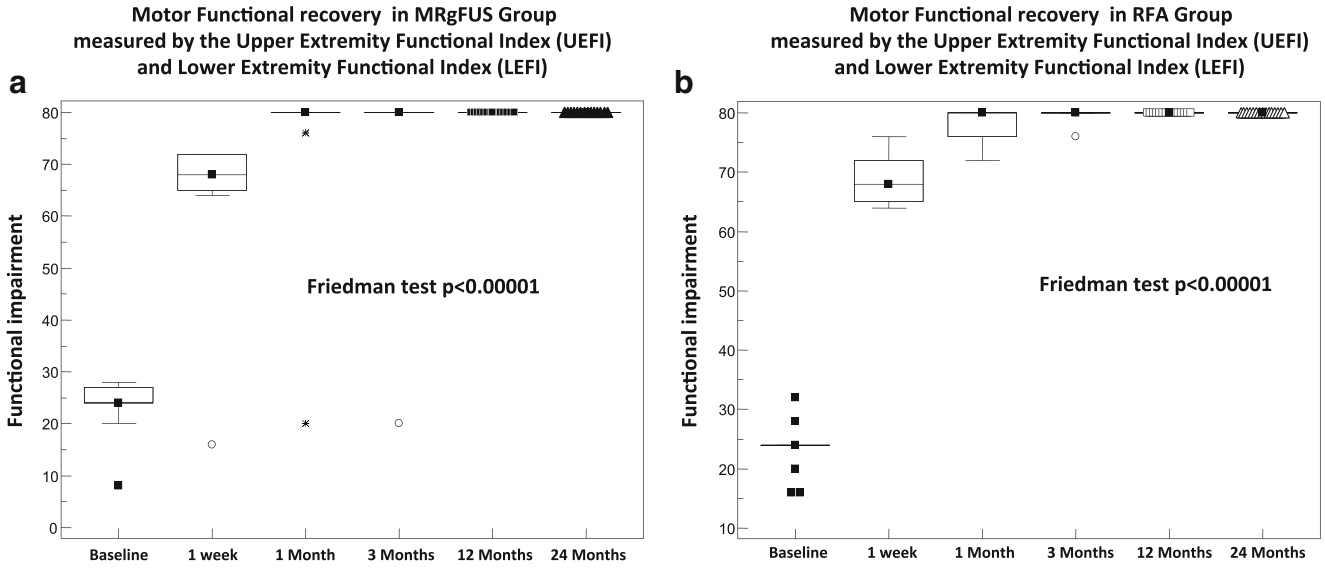
Post-hoc multiple comparison according to Conover

Variables	Mean rank	Different (P<0.05) from variable nr
(1) Baseline	6.0000	(2) (3) (4) (5) (6)
(2) 1 week	5.0000	(1) (3) (4) (5) (6)
(3) 1 month	2.8214	(1) (2) (4) (5) (6)
(4) 3 months	2.3929	(1) (2) (3)
(5) 12 months	2.3929	(1) (2) (3)
(6) 24 months	2.3929	(1) (2) (3

Post-hoc multiple comparison according to Conover

Variables	Mean rank	Different (P<0.05) from variable nr
(1) Baseline	6.0000	(2) (3) (4) (5) (6)
(2) 1 week	5.0000	(1) (3) (4) (5) (6)
(3) 1 month	3.0769	(1) (2) (4) (5) (6)
(4) 3 months	2.3077	(1) (2) (3)
(5) 12 months	2.3077	(1) (2) (3)
(6) 24 months	2.3077	(1) (2) (3)

Fig. 2 Pain assessment after MRgFUS (**a**) or RFA (**b**) during follow-up



Post-hoc multiple comparison according to Conover

Variables	Mean rank	Different (P<0.05) from variable nr
(1) Baseline	1.0000	(2) (3) (4) (5) (6)
(2) 1 week	2.0000	(1) (3) (4) (5) (6)
(3) 1 month	4.3929	(1) (2)
(4) 3 months	4.5357	(1) (2)
(5) 12 months	4.5357	(1) (2)
(6) 24 months	4.5357	(1) (2)

Post-hoc multiple comparison according to Conover

Variables	Mean rank	Different (P<0.05) from variable nr
(1) Baseline	1.0000	(2) (3) (4) (5) (6)
(2) 1 week	2.0000	(1) (3) (4) (5) (6)
(3) 1 month	4.0333	(1) (2) (4) (5) (6)
(4) 3 months	4.5667	(1) (2) (3)
(5) 12 months	4.7000	(1) (2) (3)
(6) 24 months	4.7000	(1) (2) (3)

Fig. 3 Motor functional recovery changes measured by the upper extremity functional index (UEFI) and lower extremity functional index (LEFI) after MRgFUS (**a**) or RFA (**b**) during follow-up

by Monte Carlo significance. An alpha value threshold of 0.05 was used. All statistical analyses were performed using the SPSS® statistical analysis software package, version 10.0 (IBM Corporation, Armonk, New York USA).

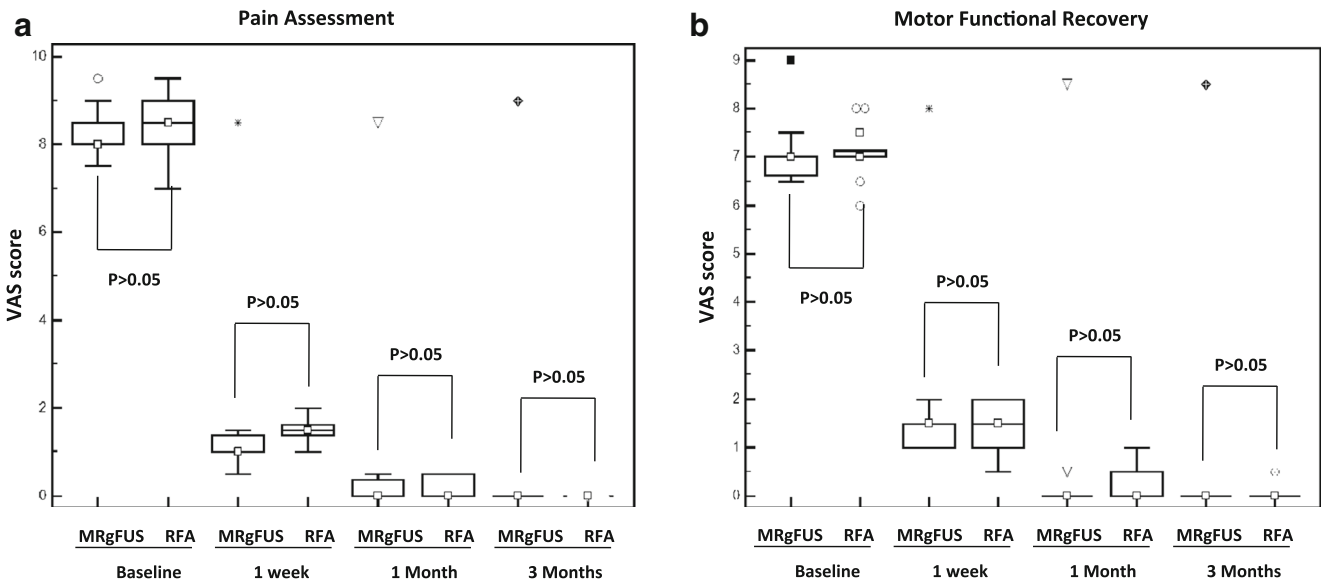


Fig. 4 Comparative analysis of pain changes after MRgFUS or RFA over time (**a**). Comparative analysis of motor functional recovery changes after MRgFUS or RFA over time (**b**)

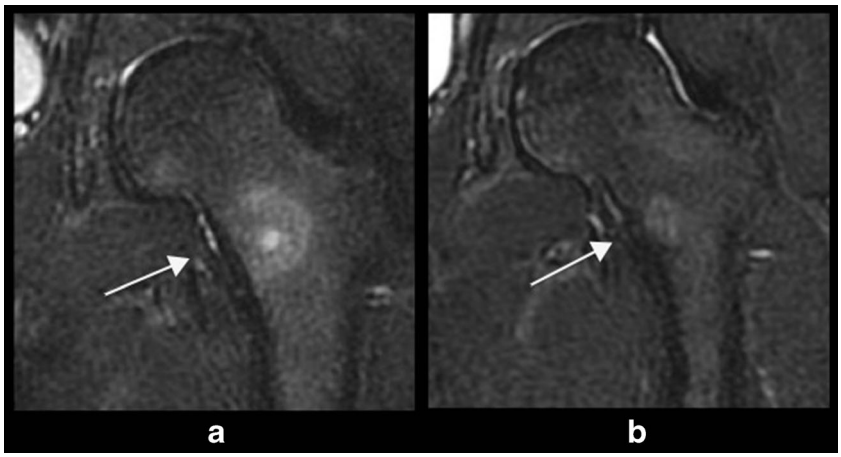


Fig. 5 Coronal STIR images of osteoid osteoma of the neck of the femur before (**a**) and 6 months after (**b**) MRgFUS treatment, showing complete disappearance of bone oedema

Results

Assessment of pain after ablative approaches

The overall number of patients available for follow-up was 30 (100 %) at 12 weeks with no subjects lost during follow-up. A significant decrease in pain perceived by subjects treated with MRgFUS was documented from as early as 1 week after treatment. The clinical success rate of this ablative approach was 93.3 % (14/15) 12 weeks after treatment, which was confirmed at 1 and 3 months, suggesting that when a response was achieved it manifests itself during the first week. The median VAS score of subjects treated with MRgFUS significantly decreased over time with a complete pain relief response observed at 3, 12 and 24 months after treatment in all patients except one (Fig. 2a). The trend in the VAS score observed after RFA treatment was very similar to that observed in MRgFUS-treated patients (Fig. 2b). One week following RFA treatment, the VAS score was significantly lower than baseline. Complete pain relief was achieved 3 months after RFA treatment (Fig. 2b). The clinical success rate of RFA was 100 % (15/15) 12 weeks after treatment. In both groups, all patients (except for one that received MRgFUS treatment) discontinued therapy with NSAIDs following treatment. When the two ablative approaches were compared in terms of pain, no significant difference was found at each follow-up time point suggesting that when technically feasible these two approaches may be considered equally effective (Fig. 4a).

Assessment of functional recovery after ablative approaches

Only one patient treated with MRgFUS showed persistent pain and reduced function. A significant improvement in the functional impairment perceived by subjects treated with MRgFUS was documented from as early as 1 week after treatment (Fig. 3a), which paralleled a reduction in pain. This was maintained over time, with complete functional recovery at 3, 12 and 24 months after treatment in all patients except one (Fig. 3a). The trend in functional recovery observed after RFA

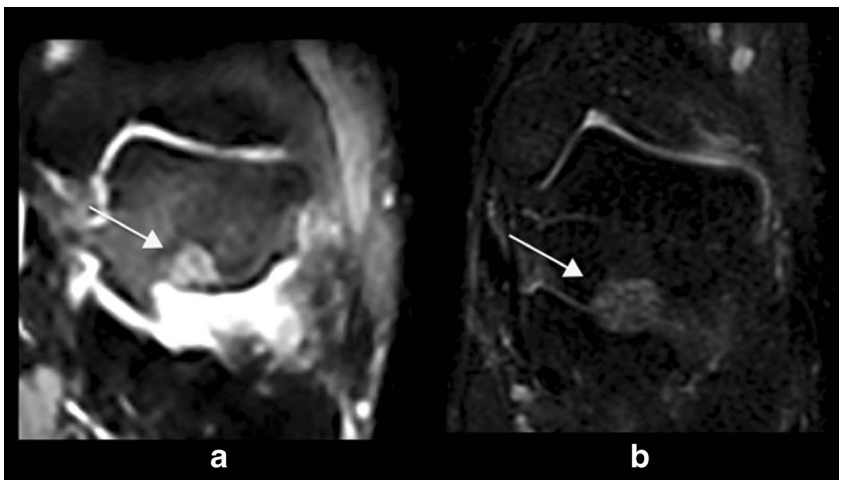


Fig. 6 Coronal STIR images of osteoid osteoma of the talus before (**a**) and 12 months after (**b**) RFA treatment, showing complete disappearance of bone oedema

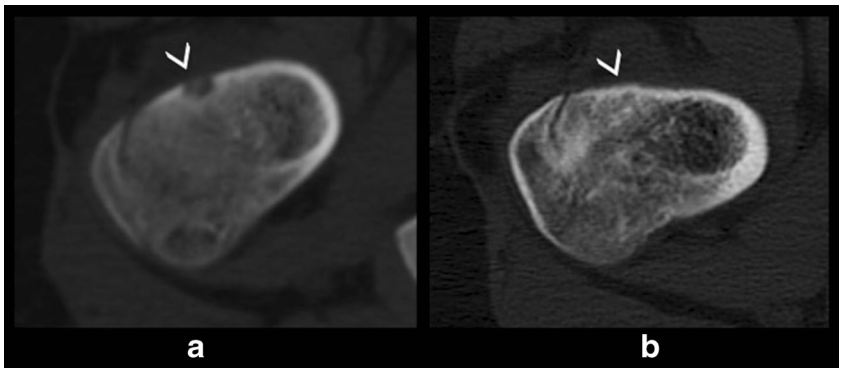


Fig. 7 Axial CT of osteoid osteoma (*arrowhead*) of the neck of the femur (same patient as Fig. 5) before (**a**) and 12 months after (**b**) treatment

treatment was very similar to that observed in MRgFUS-treated patients (Fig. 3b). One week following RFA treatment, functional recovery was significantly increased with respect to baseline. Total functional recovery was achieved 3 months after RFA treatment (Fig. 3b). Similar to what was observed for pain control, there was no significant difference in motor functional recovery at each follow-up time point for MRgFUS and RFA treated patients (Fig. 4a).

Treatment failure rate

Treatment failure was defined as (i) partial response, (ii) no pain relief or (iii) pain progression after a complete or partial response with initial treatment, for either of the two ablative approaches. The rate of treatment failure at 12 weeks was 6.6 % (1/15) in the MRgFUS group and 0 % (0/15) in the RFA group ($p=1.0$). The subject who experienced treatment failure after MRgFUS was successfully treated by RFA, with disappearance of algic symptoms 1 week after the procedure.

Post-treatment imaging findings

The most useful sign of healing in successfully ablated patients was the disappearance of spongious bone oedema (demonstrated by MRI) [14–16], which is related to the therapeutic effect of thermoablation, either with RFA or MRgFUS [17, 18] (Figs. 5 and 6). Post-treatment CT images showed disappearance of central calcification of the nidus, which was present in 4 out of 15 (27 %) ablated lesions before RFA treatment. In these cases, the bone cortex above the lesions was already eroded by the lesion itself before treatment, but no clear correlation between the disappearance of the central nidus of calcification and clinical symptoms was documented. In all radiological evaluations following MRgFUS treatment, a progressive "restructuring" of the bone, with an almost complete disappearance of the signs of the lesion, was seen (Fig. 7). In the patients ablated with RFA, this "restructuring" of the bone developed slower, because of the marks left in the bone following needle perforation (Figs. 7 and 8).

Assessment of morbidity

There were no major complications reported in both treatments; only minor complications were recorded, including thermal insult to the site of ablation (20 %, 3/15), or slight inflammatory reactions of the myofascial structures adjacent to the lesions (0 %, 0/15). Interestingly, modest reactive synovitis was observed when the target lesion was anatomically close to an articulation joint. In this regard, although the joint capsule can be easily crossed without determining anatomical lacerations, reactive synovitis may occur after the procedure. However, target lesions located in positions adjacent to joint capsules may be ablated successfully and be considered suitable for MRgFUS. We recorded only one minor complication (6.6 %, 1/15) after RFA, which was related to thermal injury that caused myofasciitis of the posterior compartment of thigh muscle and affected the sciatic nerve. For this reason, the

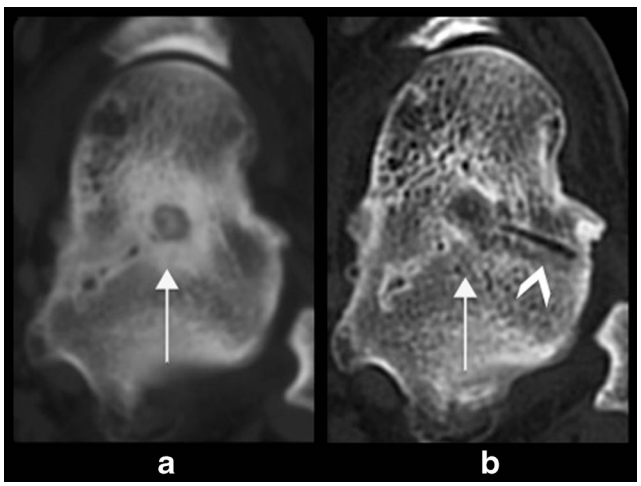


Fig. 8 Axial reformatting of the CT of osteoid osteoma (*arrow*) of the neck of the talus (same patient as Fig. 5) before (**a**) and 12 months after (**b**) treatment; RFA needle track (*arrowhead*)

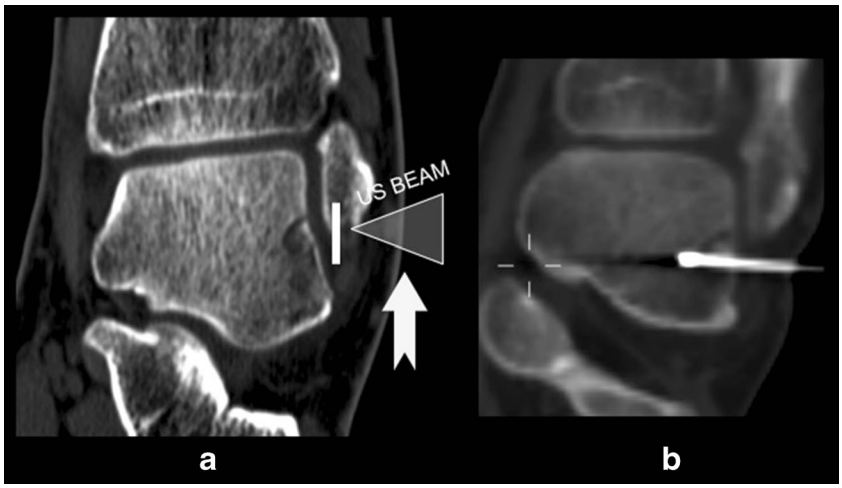


Fig. 9 **a** Example of a case not suitable for treatment with MRgFUS: the presence of the fibula (exemplified by the *thick white line*), which is interposed between the lesion and the skin surface, impedes the ultrasound beam (represented by the *triangle*) from reaching the lesion; **b** same patient treated by RFA: the needle is positioned inside the lesion avoiding the bone of the fibula

patient was hospitalized for an additional 5 days and recovered completely after steroid therapy.

Discussion

HIFU is an innovative, minimally invasive, deep tissue ablative technology [7–9]. The HIFU beam is generated by a transducer on the skin's surface and is concentrated at a focal point within the body where energy is released in the form of heat, resulting in thermal coagulative tissue necrosis. MRI guidance enables accurate anatomical evaluation of the target area and identification of an appropriate acoustic window for accessing the lesion and avoiding damage to sensitive nearby structures. Moreover, MRI allows real-time, pixel by pixel evaluation of temperature rises in the treatment region, enabling adjustments of sonication intensity to achieve optimal temperature levels and tissue ablation. MRgFUS enables treatment of bone lesions without surgical incisions or the need for bone drilling, making it a completely minimally invasive procedure. Since there is no exposure to ionizing radiation, MRgFUS can be repeated if necessary.

The success of MRgFUS treatment depends on the accuracy of the acoustic window and avoiding obstacles in the path of the ultrasound beam. Structures that reflect or refract the ultrasound beam (Fig. 9), such as bone, metal devices or scarring, prevent the concentration of energy at the target point and should be avoided. To maximize the release of acoustic energy at the lesion site and prevent damage to adjacent structures, the acoustic window should be as orthogonal as possible to the target area. Nerve bundles, tendons and ligaments, and areas of tendon insertion should also be excluded from the acoustic window. Moreover, if the lesion is too deep within the bone, the power of penetration of the ultrasound is limited by the bone cortex. The joint capsule can be crossed without lacerations, but reactive synovitis may occur, which can be prevented by treatment with anti-inflammatory drugs (i.e. cortisone) at the end of the procedure.

When treating osteoid osteomas specifically, their location may be a limiting factor. In the majority of cases (75 %) [19], the nidus is located in cortical or subperiosteal bone, which is easily accessible to the ultrasound beam and enables the use of low energy for effective ablation. In other cases, their location is deep, including in the cancellous bone (25 %) [19], or with a

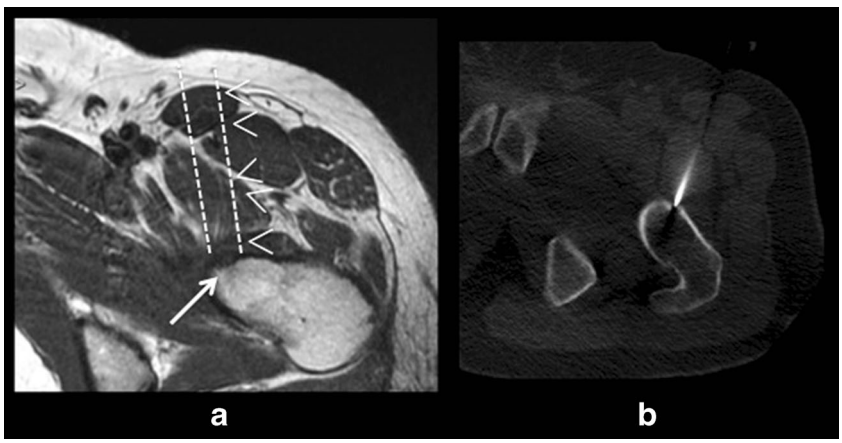


Fig. 10 **a** Pathway (*double dashed lines*) between the lesion (*white arrow*) and the skin is rich of multiple interfaces (*arrowheads*) in this case among soft tissues; **b** same patient treated with RFA

periosteal reaction that limits the penetration of the ultrasound beam. In such cases, the ultrasound beam must be positioned perpendicular to the target area and higher energies are required to achieve an appropriate temperature rise for nidus ablation.

To our knowledge, no existing empirical study has addressed the question of whether MRgFUS treatment achieves the same pain control and functional recovery as RFA treatment in the management of osteoid osteoma. The clinical success rate of RFA treatment is reported to be 89–95 % [5, 17, 19] or, in another study, 96.1 % after the first treatment and 100 % following retreatment [20]. Accordingly, our results indicate that RFA treatment achieves a 100 % success rate, which is comparable to that obtained with MRgFUS treatment (93 %). These data paralleled the improved motor functional recovery observed in subjects treated with RFA and MRgFUS. Interestingly, when RFA was compared to MRgFUS in terms of functional recovery, no significant difference was observed between the two techniques. The treatment failure rate was 6.6 % (1/15) in the MRgFUS group and 0 % (0/15) in the RFA group. The patient that experienced treatment failure with MRgFUS and that was subsequently treated with RFA had an inappropriate acoustic window, since the target lesion was inadequately exposed to the ultrasound beam and could not reach an adequate temperature for ablation. The presence of many interfaces (muscles and fascia) between the skin surface and the lesion likely did not allow adequate penetration of the ultrasound beam to deep tissues (Fig. 10).

Interestingly, no major complications were recorded in both ablative approaches. The most frequently reported minor complication was the inflammatory reaction caused by thermal insult to the myofascial and articular structures adjacent to ablated lesions. This complication occurred in 6.6 % of RFA-treated patients and its occurrence was very difficult to overcome even in the presence of experienced interventional radiologists. This complication was associated with a well-known physical principle underlying ablative therapy, namely ablation due to temperature elevation.

MRgFUS can theoretically require just one or two sonications (taking 1 min each) to treat an osteoid osteoma (if the sonications cover the surface of the lesion). In daily practice, however, as a result of the calibration of the system and, sometimes, also the time required to position the patient on the MRI table, the MRgFUS time of treatment (patient in–patient out) lasts at least 1 h, a longer duration compared with RFA (in our experience, generally about 45 min). However, our opinion is that in the future, the development of the MRgFUS system and the increasing experience with MRgFUS will reduce the time of treatment to make it similar to that of RFA.

On the other hand, the CT-guided intervention requires radiation exposure; in the literature is very difficult to find data about the amount of radiation exposure during this type of CT-guided procedure. The great numbers of variants and parameters (experience of the operators, technique used, type of CT used, characteristics of the lesion, compliance of the patient, etc.) probably impede the standardization of the procedure itself and so it is very difficult to quantify the amount of radiation exposure.

Table 1 reports a mean value of the radiation exposure [21] in our experience: although 5.6 mSv is not a very high absolute value (in RFA treatment), the total absence of radiation exposure (in the MRgFUS treatment) is a very important aspect to take in consideration in the choice of type of treatment especially when dealing with young patients.

The main limitations of the current study include the small sample size and the use of a non-randomized study design. To date, large randomized controlled trials have provided the strongest evidence for the efficacy of therapeutic procedures or treatments in the clinical setting. However, this bias has been substantially overcome by the use of a strategy based on propensity score analysis, which helped us obtain groups of patients randomized for important clinical characteristics. Thus, comparative analysis by propensity-matched pairs minimized methodological biases compared to other common statistical methods.

Despite these methodological limitations our data suggest, for the first time, that MRgFUS favourably impacts pain scores and functional recovery in osteoid osteoma patients, making it a viable alternative ablative approach to RFA. However, our results should be interpreted with caution and only serve as a framework around which to design future large-scale clinical trials.

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Written informed consent was obtained from all patients in this study. Methodology: retrospective, observational, performed at one institution.

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