Safety Clearance and Artifact Testing of a Nitinol Breast Biopsy Clip in an Ultra-High Resolution (7 Tesla) Magnetic Resonance Imaging Environment

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Abstract

Background The lack of safety clearance of several metallic breast biopsy clips in 7 Tesla (T) poses a significant hurdle to using advanced magnetic resonance imaging (MRI) techniques in clinical management or cancer research.

Aims This article assesses the Ultracor Twirl clip for safety and imaging artifacts in a 7T MRI scanner.

Setting and Design This study can be categorized as a phantom study.

Materials and Methods Tests for magnetic susceptibility (translational attraction and torque), MRI-related heating, and artifacts were conducted based on the American Society for Testing and Materials standards. The magnetic susceptibility tests evaluated the scanner's magnetic force that can cause clip movement and rotation. The heating test was conducted with customized MRI parameters of short TR and maximum echo-train length, designed to induce temperature change. The artifact test, using T1-weighted spin and gradient echo imaging sequences, evaluated potential image misrepresentations (localized signal loss) caused by the clip's metallic properties.

Statistical Tests None.

Results and Conclusion The magnetic susceptibility tests indicated no noticeable translational or rotational force exerted by the MRI scanner. The heating test indicated no significant temperature change ($<0.3^{\circ}C$) in the testing gel when the clip was absent/present, both within the safety threshold ($<1^{\circ}C$). The artifact test's clip images all contained an artifact (largest radius = 10.7 mm). These cumulative results indicate that this clip is safe in 7T scanners. Scanning at least 10.7 mm away from the clip avoids potential signal loss in the region of interest.

Keywords
- 7T MRI
- safety test
- artifact test

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Introduction

Breast biopsy clips used in clinical management and research involving breast cancer patients and survivors, imaged in 1.5T (Tesla) and 3T field strength magnetic resonance imaging (MRI) environments,[1,2] have been tested and cleared for safety. With the Food and Drug Administration's approval and application of 7T MRI,[3,4] ultra-high resolution imaging may be utilized in clinical management and research studies in these groups. Higher field strengths such as 7T offer a higher intrinsic signal-to-noise ratio with resultant superior spatial and/or temporal resolution[5] as compared to 3T and lower field scanners. Novel imaging techniques for accurate diagnostics are possible in 7T[6] with magnetic resonance spectroscopy being one of the modalities, which has clear benefits at higher fields. 7T provides excellent image quality of malignant breast mass lesions with a significant increase in reader confidence.[7] Fat-corrected relaxation-compensated and chemical exchange saturation transfer MRI in 7T shows promise in contrast-free, noninvasive differentiation between breast cancer and normal-appearing fibroglandular breast tissue,[8] and serves as a noninvasive biomarker to assess the early-stage efficacy of neoadjuvant chemotherapy.[9] Dynamic contrast-enhanced MRI of the breast is feasible,[10] providing the ability to differentiate between benign and malignant lesions. Thus, 7T MRI shows promise in advancing noninvasive, accurate, contrast-free diagnostic imaging in breast cancer.

Magnetic forces, heating, and artifact effects are greater at 7T as compared to lower-field MRI systems.[11] A limited sample of biopsy clips have been tested in 7T,[12,13] and many clips remain untested at this high field strength. If the safety of breast biopsy clips is demonstrated in 7T scanners, it will allow the use of ultra-high field MRI in routine clinical management or research studies of breast cancer.

A nitinol[14] breast biopsy clip (Ultracor Twirl, Becton, Dickinson and Company, Vernon Hills, Illinois, United States) was tested in this investigation since the clip is metallic and has received safety clearance for 3T[13] but not 7T MRI. The clip, frequently used in breast cancer biopsies due to its good ultrasound visibility,[15–17] is ring-shaped, 4-mm in diameter, 1-mm thick, and weighs 0.0196 g. This project aims to determine the safety and artifact size of the clip via translational attraction, torque, induced heating, and artifact tests in 7T MRI (GE 950 Whole Body Scanner).

Materials and Methods

This study did not require oversight from the Institutional Review Board, because no human subjects were involved. This is not a rater study and all images collected in this study were obtained in phantoms. The translational attraction,[18] torque,[19] induced heating,[20] and artifact[21] tests were all performed according to the American Society for Testing and Materials (ASTM) standards. The setups for testing were illustrated in the figures (►**Figs. 1–234**) since close-up photos were unsafe to obtain in the magnetic environment of the scanner.

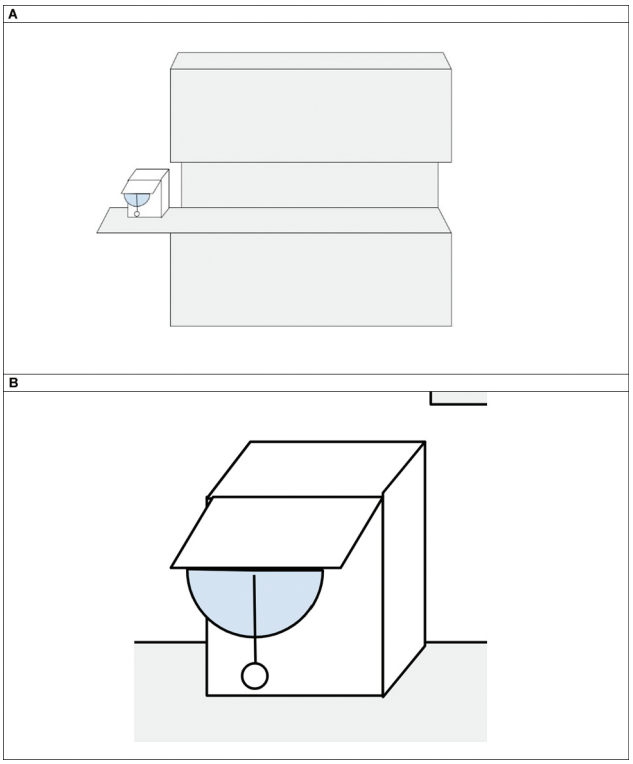

Fig. 1 Translational attraction test setup. (**A**) The clip was suspended at the scanner entrance, adjacent to a protractor. This location has the strongest human subject-accessible spatial field gradient. The black circle is the clip. (**B**) Close-up view of (**A**).

Translational Attraction Test

This test measured the 7T MRI scanner's magnetic force on the biopsy clip. The Ultracor Twirl clip was suspended by a 10-cm string (Meiyi Nylon Monofilament Non-Absorbable Synthetic Suture [0.00174 g]) next to a protractor mounted on a cardboard box. The setup, placed at the scanner's opening (1.82 m from the isocenter; ►**Fig. 1**), indicated the string's deflection angle toward the scanner bore. The deflection angle allowed the estimation of the magnetic force relative to the gravitational force. The chosen test location was estimated to have the highest spatial gradient magnetic field (►**Supplementary Fig. S1**, available in the online version) and force, thus representing the most stringent conditions for translational attraction.

Torque Test

This test measured the torque exerted on the biopsy clip by the 7T MRI scanner. The Ultracor Twirl clip was placed on a low-friction acrylic sheet and inclined to the maximum angle that the clip could stay in place without sliding off (►**Fig. 2A**). The incline angle was used to calculate the maximum torque.[19] The clip was then inserted into the scanner's isocenter (►**Fig. 2**), following the ASTM standard's method.[19]

Since the clip did not move during the torque test procedure, the maximum torque derived from the incline test was compared to the gravitational torque on the clip. The gravitational torque about the clip's longest edge is the cross product of the distance from the clip's longest edge to the center of mass and the gravitational force (weight). Since the

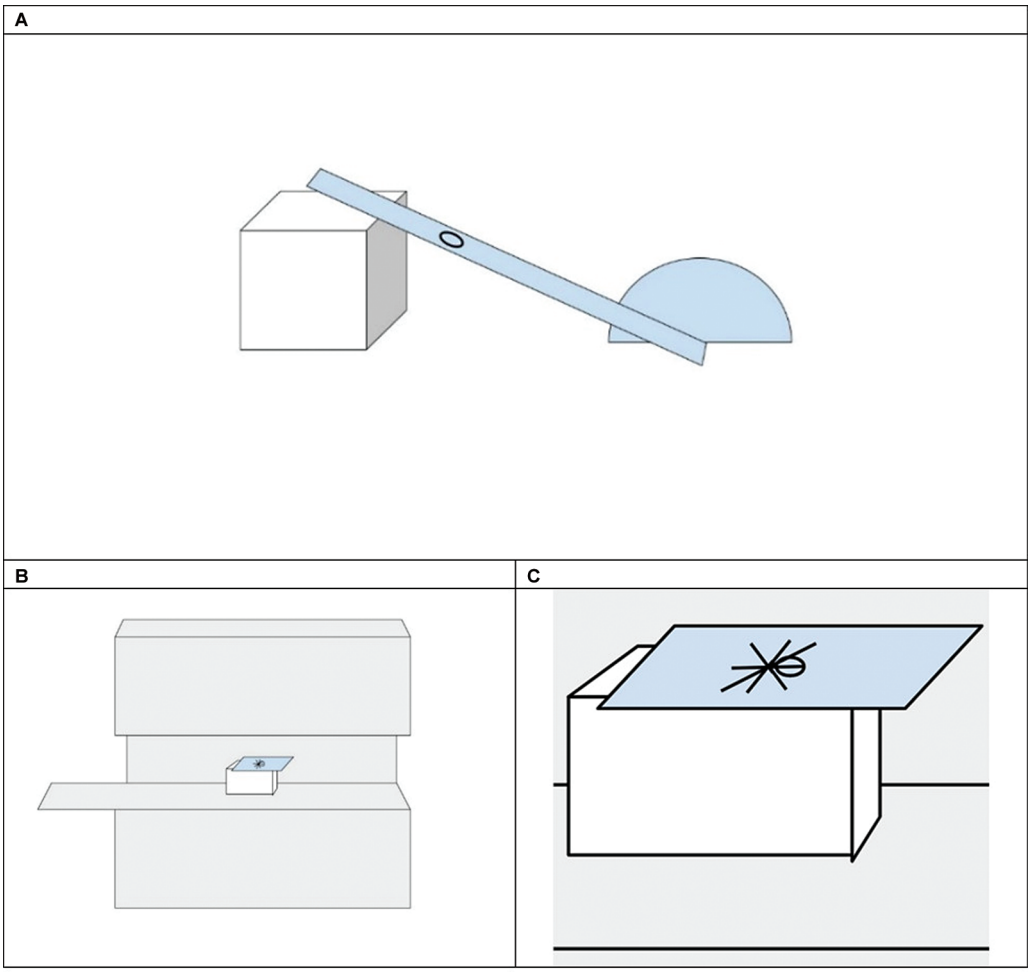

Fig. 2 Torque test setup. (**A**) The acrylic sheet was inclined until the biopsy clip almost slipped. (**B**) The clip was assessed in all 8 orientations at the center of the scanner by rotating the clip at each 45-degree increment about the center. (**C**) Close-up view of (**B**).

clip is a ring, the center of mass and distance were estimated to be at the center of the ring and half the clip's length, respectively. The torque peaks when the gravitational force is perpendicular to the length. Therefore, the maximum gravitational torque was estimated with the following equation:

$$\tau = mg\frac{L}{2} \text{ (Eq. 1)}$$

where τ is the induced torque, m is the mass of the clip, g is the gravitational acceleration constant, and L is the longest length across the clip.

Induced Heating Test

This test measured the radiofrequency coil's (2Tx/32Rx head radiofrequency coil) heating effect on the clip in a gel medium comprising of 1.32 g/L NaCl, 10 g/L partial sodium polyacrylic acid, and 1 L water. The gel conductivity was verified to be within $0.47 \pm 10\%$ S/m, which simulated human body conditions. This test was performed inside the scanner, using a fiber optic thermometer. Three temperature probes were placed in a line parallel to the bore inside the gel (►**Fig. 3A**). A test run measured the temperature change over time at each probe. The probe where the greatest radiofrequency exposure (greatest temperature change) occurred was designated as the heating probe. During the heating test, the clip-present and control (clip-absent) runs measured the temperature change over time at the heating probe. The other two (middle and edge) probes served to validate that both runs received similar radiofrequency exposure. The heating test (►**Fig. 3A** and **C**) was performed with a modified duration of 8 minutes 36 seconds for each round. The following MRI parameters maximized heating effects[20]: two-dimensional fast spin-echo, field of view (FOV) = 220 × 198 mm, slice thickness/spacing = 5/1 mm, TR = 4,000 ms, TE = 5.5 ms, echo train length = 16, matrix = 416 × 256, NEX = 8, bandwidth = 781.25 Hz/pixel, time = 8:36. The specific absorption rate (SAR) of each run was calculated using the slope of the temperature versus time graph and evaluated for safety based on Eq. (1) in the ASTM standard.[20]

Artifact Test

This test measured the size of the artifact, caused by the metallic properties of the clip. A 3.7-L solution of 1.5 g/L $CuSO_4$ was created and separated into three plastic containers (10 cm·10 cm·10 cm) to immerse the biopsy clip. The first container had a nylon rod (reference object) suspended from the top of the container. The second and third containers had clips suspended with their longest length parallel and perpendicular to the scanner's static field. During the test, the second

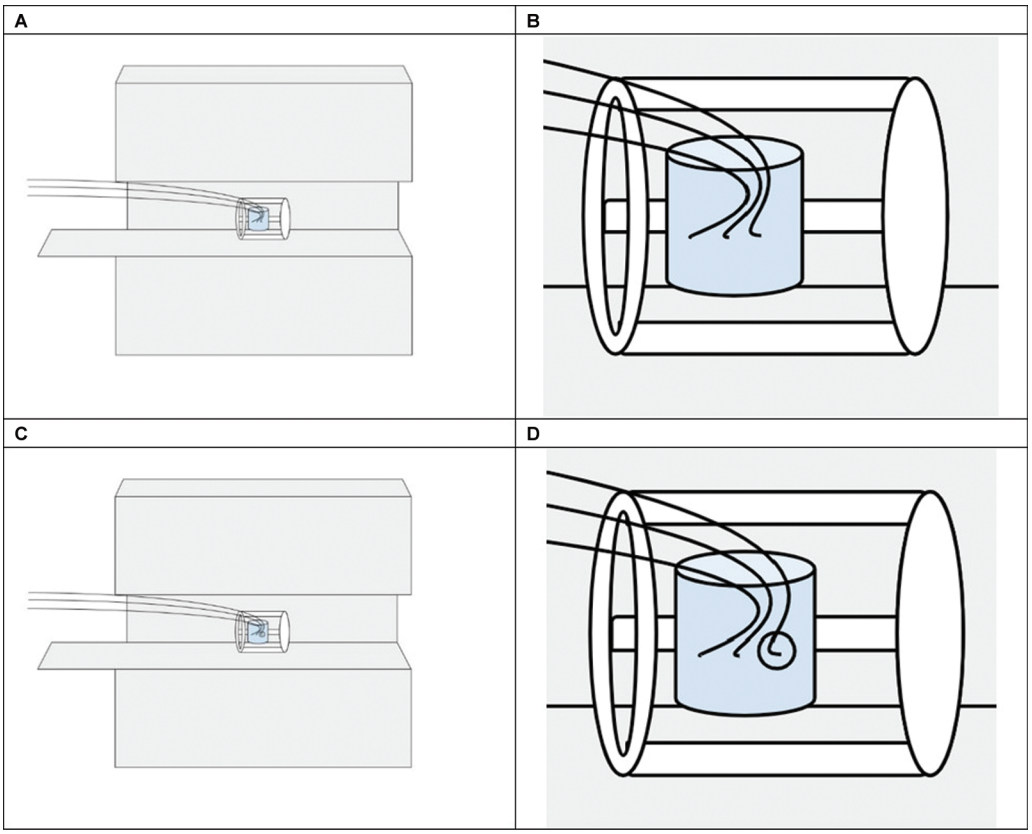

Fig. 3 Induced heating test setup. (**A**) The first run determined the probe location with the greatest temperature change. The second run (control, same setup) observed the gel's temperature change at the test location. (**B**) Close-up view of (**A**). (**C**) The third run (clip-present) observed the clip's temperature change at the test location. (**D**) Close-up view of (**C**).

or third container was placed above the first (►**Fig. 4A** and **C**). The artifact test was performed inside the scanner by imaging the clip in orientations and conditions (►**Tables 1** and **2**) described by the standard (perpendicular/parallel to the static field, frequency/phase encode directions, spin/gradient echoes, and presence/absence of the clip).[21] The MRI scans included spin-echo (TR = 500 ms, TE = 20 ms, FOV = 120 mm, matrix = 256 × 256, bandwidth = 244.141 Hz/pixel, slice thickness = 3 mm) and gradient-echo (TR = 200 ms, TE = 5.5 ms, FOV = 120 mm, matrix = 256 × 256, bandwidth = 244.141 Hz/pixel, slice thickness = 3 mm).

The clip-present images were compared to clip-absent (control) images based on the same image view, clip orientation, and echo type. For example, image set 1 was compared with image set 12 (►**Tables 1** and **2**). Image registration using the Advanced Normalization Tools Software[22] corrected minor image misalignment between the compared images. The registration settings utilized rigid transformation and artifact masking. Histogram matching between the compared images was performed in MATLAB R2022a-Image Processing Package (The MathWorks, Inc., Natick, Massachusetts, United States) using 64 bins, to address the signal intensity variations between the images. Comparisons between artifact-present and artifact-absent images were made for each voxel on every slice, generating binary images based on a 30% difference threshold defined by the standard.[21,23] The artifact size was measured in signal-loss radius and volume. The radius was measured from the artifact centroid to the artifact's furthest edge on each slice. The largest of these radii was selected for each image. The volume was measured by summing the image set's artifact volume in each slice.

Results

Provided below are results from the translational attraction, torque, heating, and artifact tests.

Translational Attraction Test

The fringe field map indicated that the highest spatial gradient magnetic field location was 8.26 T/m at 1.82 m from the isocenter along the *z*-axis, which determined the testing location. The test resulted in a 0-degree deflection angle, indicating that the marker was not impacted by the scanner's magnetic force. This demonstrated the clip's safety since the ASTM standard indicates that if the test's deflection angle is less than 45 degrees, the magnetically induced force on the clip is less than the gravity and therefore generally safe.[18]

Torque Test

The torque test demonstrated no clip movement in all 45-degree increment orientations. Since the torque test was performed on a surface with a coefficient of friction of 0.364, the maximum magnetic torque was 2.80×10^{-6} Nm. The ASTM standard defined safe torque induced by the scanner as less than the torque from regular daily activities such as

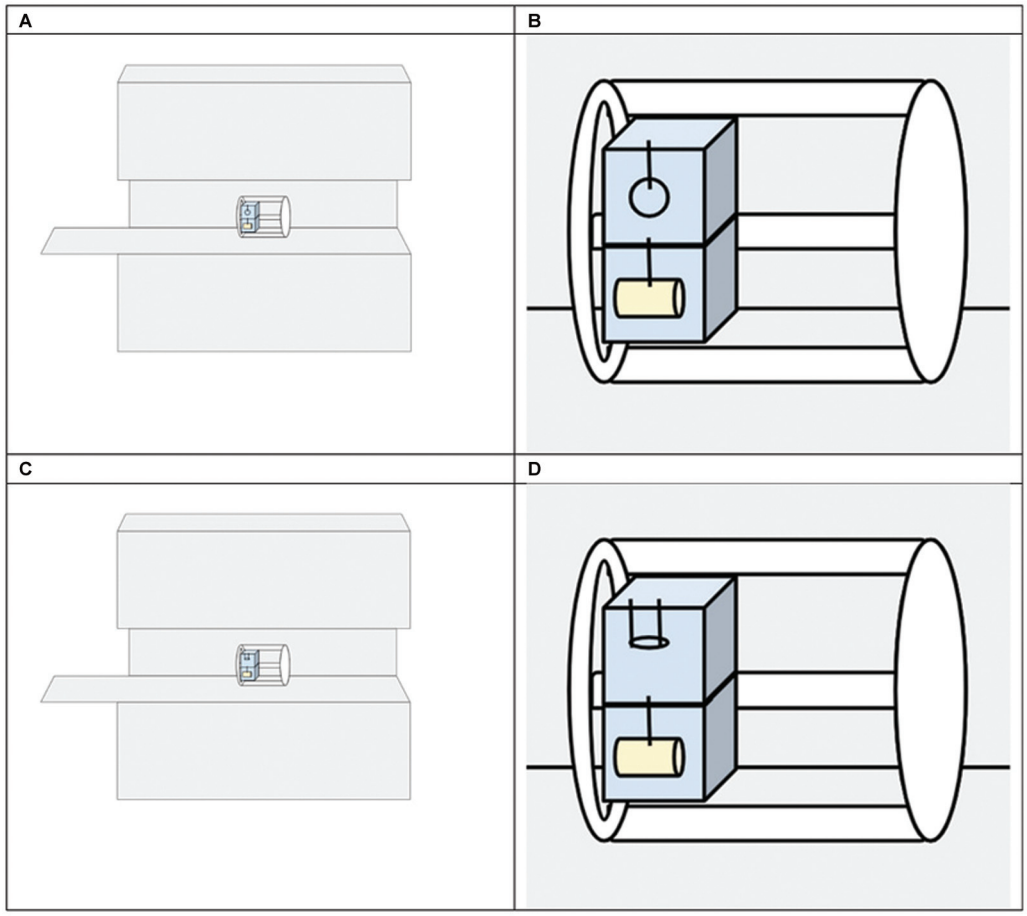

Fig. 4 Artifact test setup. (**A**) The clip was imaged in the parallel configuration. (**B**) Close-up view of (**A**). (**C**) The clip was imaged in the perpendicular configuration. (**D**) Close-up view of (**C**).

riding vehicles or amusement park rides.[19] The Food and Drug Administration defined safe torque as less than gravitational torque.[24] The maximum magnetic torque was less than the gravitational torque about the axis perpendicular to the clip's edge (3.85×10^{-6} Nm), which demonstrated the clip's safety.

Induced Heating Test

Prior to the heating test, the test run recordings from the probes indicated that the greatest radiofrequency exposure occurred at the probe located closest to the radiofrequency coil's center (heating probe). The induced heating test resulted in temperature changes of less than 0.3°C in 8 minutes 36 seconds for both the control and clip-present runs. The heating test probe's SARs for the control and clip-present runs were 2.02 and 1.84 W/kg, respectively. In the temperature change versus time graphs, the slope of the curve is consistent throughout the test (►**Fig. 5**). This consistency was expected if the test were to continue to 15 minutes (the standard duration of the test), justifying the reduction in test duration. A conservative safety criterion for the induced heating test is that the clip heating should not exceed 1°C. If the test were to continue to 15 minutes, the projected temperature change would be less than 0.6°C (less than the safety threshold), indicating the clip's safety. The heating probe's similar temperature changes in both the control and clip-present runs (►**Fig. 5A**) also indicated the clip's negligible effect on heating. The middle probe experienced a different temperature change between runs (►**Fig. 5B**), and the edge probe experienced consistent, low temperature change in both runs (►**Fig. 5C**).

Artifact Test

The artifact test indicated that the clip causes a minor signal-loss artifact in MR images (►**Supplementary Fig. S2**, available in the online version). The spin echo images produced smaller artifacts (up to 342.8 mm^3 in volume and 6.0 mm in radius), compared to the gradient echo images (up to 2,235.9 mm^3 and 10.7 mm in radius; ►**Table 3**).

Overall, the translational attraction, torque, and induced heating tests indicated that the clip is safe in terms of magnetic susceptibility and radiofrequency heating effects. The artifact test indicated that the clip could produce a small signal-loss artifact in the surrounding area.

Discussion

This research suggests that 7T MRI scanning is safe for human subjects with the Ultracor Twirl implant, while also demonstrating signal-loss artifacts associated with the clip. In a

Table 1 Artifact test conditions

Image set	Image view	Clip orientation relative to static field	Frequency encode direction	Echo	Clip presence	Compared to image set(s)
1	Sagittal	Perpendicular	SI	Spin	Present	12
2	Sagittal	Perpendicular	AP	Spin	Present	12
3	Sagittal	Perpendicular	SI	Gradient	Present	11
4	Sagittal	Perpendicular	AP	Gradient	Present	11
5	Axial	Perpendicular	AP	Gradient	Present	9
6	Axial	Perpendicular	RL	Gradient	Present	9
7	Axial	Perpendicular	AP	Spin	Present	10
8	Axial	Perpendicular	RL	Spin	Present	10
9	Axial	Perpendicular	AP	Gradient	Absent	5, 6
10	Axial	Perpendicular	AP	Spin	Absent	7, 8
11	Sagittal	Perpendicular	AP	Gradient	Absent	3, 4
12	Sagittal	Perpendicular	AP	Spin	Absent	1, 2
13	Coronal	Perpendicular	SI	Gradient	Present	17
14	Coronal	Perpendicular	RL	Gradient	Present	17
15	Coronal	Perpendicular	SI	Spin	Present	18
16	Coronal	Perpendicular	RL	Spin	Present	18
17	Coronal	Perpendicular	RL	Gradient	Absent	13, 14
18	Coronal	Perpendicular	RL	Spin	Absent	15, 16
19	Sagittal	Parallel	SI	Gradient	Present	27
20	Sagittal	Parallel	AP	Gradient	Present	27
21	Sagittal	Parallel	SI	Spin	Present	28
22	Sagittal	Parallel	AP	Spin	Present	28
23	Axial	Parallel	AP	Gradient	Present	29
24	Axial	Parallel	RL	Gradient	Present	29

Abbreviations: AP, anteroposterior; RL, right-to-left; SI, superoinferior.

similar study by Shellock and colleagues,[12] 8 metallic breast biopsy clips (titanium or stainless steel) were tested and cleared as safe in 7T. The methods used in the current research are similar, except for the torque test. Shellock and colleagues[12] classified torque via observation and rating the torque from 0 to 4, with 0 indicating no torque and 4 indicating strong torque. In contrast to Shellock and colleagues,[12] the current research compares the maximum magnetic torque with the Food and Drug Administration-defined safety threshold (gravitational torque).[24]

Translational Attraction Test

In the translational attraction test, the ASTM standard recommends the string material for clip suspension to be less than 1% of the clip's mass. However, finding a string light enough was impractical, thus motivating the use of a 10% threshold. This has been previously used in a lightweight implant safety test in 3T scanning.[1] With this modification, the deflection angle measured was 0 degrees, indicating that no magnetic force was detected. The positional setup of this experiment represents the most stringent conditions of the magnetic force that may be experienced by a human subject. The force peaks at the entrance of the scanner.[11]

Torque Test

In the torque test, safety is determined by comparing the maximum magnetic torque and the gravitational torque of the clip. The gravitational torque of the clip represents the scenario where one side of the clip is attached to the tissue and the rest of the clip dangles downward. It is greater than the greatest torque from the 7T scanner, which fulfills the conservative safety criterion. Additionally, using the torque classifications from Shellock and colleagues,[12] this clip has a 0 rating since no movement was observed during the test. This rating is consistent with the translational attraction test result, supporting the clip's safety in magnetic susceptibility.

Induced Heating Test

As highlighted in the heating test results, the heating and edge probes experienced similar temperature changes in both the control and clip-present runs, whereas the middle probe experienced different temperature changes. The

Table 2 Artifact test conditions

Image set	Image view	Clip orientation relative to static field	Frequency encode direction	Echo	Clip presence	Compared to image set(s)
25	Axial	Parallel	AP	Spin	Present	30
26	Axial	Parallel	RL	Spin	Present	30
27	Sagittal	Parallel	AP	Gradient	Absent	19, 20
28	Sagittal	Parallel	AP	Spin	Absent	21, 22
29	Axial	Parallel	AP	Gradient	Absent	23, 24
30	Axial	Parallel	AP	Spin	Absent	25, 26
31	Coronal	Parallel	SI	Gradient	Present	35
32	Coronal	Parallel	RL	Gradient	Present	35
33	Coronal	Parallel	SI	Spin	Present	36
34	Coronal	Parallel	RL	Spin	Present	36
35	Coronal	Parallel	RL	Gradient	Absent	31, 32
36	Coronal	Parallel	RL	Spin	Absent	33, 34

Abbreviations: AP, anteroposterior; RL, right-to-left; SI, superoinferior.

Table 3 Artifact test size results

Image set	Artifact volume (mm^3)	Artifact width (mm)
1	221.5	3.9
2	203.0	4.8
3	1,943.3	8.5
4	1,938.0	8.6
5	2,088.3	8.1
6	2,032.9	8.2
7	232.0	4.1
8	195.1	4.2
13	2,011.8	10.0
14	2,011.8	10.1
15	150.3	4.1
16	137.1	4.3
19	1,922.2	8.7
20	1,898.4	8.9
21	60.6	2.6
22	18.5	1.4
23	2,235.9	8.3
24	2,209.6	8.3
25	342.8	4.7
26	327.0	4.9
31	2,148.9	10.7
32	2,048.7	9.9
33	242.6	6.0
34	187.2	4.7

middle probe region is expected to receive consistent radiofrequency exposure in both runs. The deviation may be due to the movement of the probe away from a radiofrequency hotspot when the clip was being inserted during the clip-present run. The edge probe's consistent, low temperature change in both runs is expected since the region received the same radiofrequency exposure in both runs. The induced heating test has not been performed in the 7T environment for breast biopsy clips in prior research[12] because body coils are not available for these scanners. Hence, we opted to perform this test using a 2Tx/32Rx head coil. Parallel transmission was not used during this test, so the clip may require reevaluation for MRI applications utilizing parallel transmission. This test simulates the highest heating in neuroimaging applications since the clip is located inside the head coil. Normally, the clip is located inside the breast and away from the radiofrequency exposure, and thus would experience less heating.

Artifact Test

In the artifact test, the image processing registration settings (rigid registration and masking) improved the accuracy of artifact size measurement by avoiding artifact deformation and registering only the relevant features. The histogram matching using 64 bins reduced the signal intensity variation in the images attributed to the scanner avoiding signal clipping. This allows the 30% threshold comparison to represent the signal-loss artifact size more accurately. The results indicate that the largest signal-loss artifact occurs when using gradient echo. If the clip is located at least 10.7 mm away from the region of interest, potential signal loss would not affect the region of interest. Artifact size is independent of the 7T coil type, and hence this result is invariant with both head and body coils.

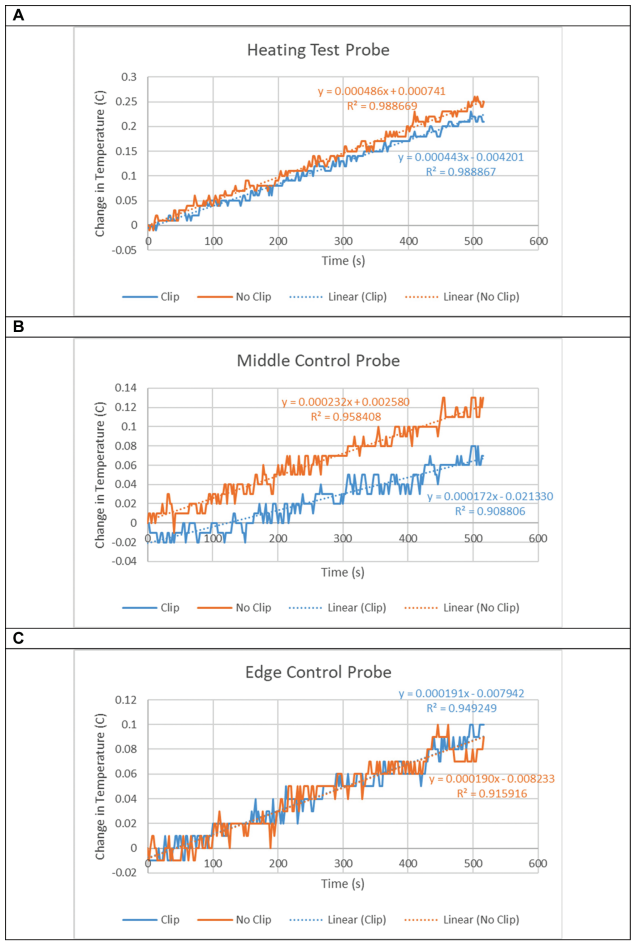

Fig. 5 Change in temperature vs. time graphs of the heating test. (**A**) The heating test probe's temperature vs. time graph indicating similar specific absorption rates. (**B**) The middle control probe's temperature vs. time graph indicating different specific absorption rates. (**C**) The edge control probe's temperature vs. time graph indicating similar specific absorption rates.

Possible Limitations and Future Directions

The translational attraction, heating, and artifact tests in this study have some limitations that may be addressed by future research. In the translational attraction test, using the 10% string weight threshold may underrepresent the measured force since the string's greater relative weight would contribute toward resisting the magnetic force.

A literature search for the artifacts, SAR, and heat indicator at 3T did not yield these details, although the clip's safety clearance is available at.[13] If readily available, this information would have facilitated a comparison of these measures between 3T and 7T, which may be of relevance to clinicians. Our 7T research facility did not have access to a breast coil, and hence these results may bear replication in future studies with a 7T breast coil. In the future, it is necessary for safety and artifact testing of other biopsy clips and related implants at 7T[13] to gain traction, in order for ultra-high resolution imaging to be more accessible to breast cancer clinical and research use.

Conclusion

This research suggests that the Ultracor Twirl clip is safe for use in ultra-high resolution MRI (7T). The safety clearance is significant in allowing human subjects with this clip to be scanned in Food and Drug Administration-approved ultra-high-field (7T) MRI scanners. The artifact test indicates that the clip can produce a small signal-loss artifact to a maximum of 10.7 mm.

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Conflict of Interest
None declared.

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