Comparison of the Gel-SHOT Versus Traditional Ultrasound Gel to Raise Tissue Temperature

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ABSTRACT

The effectiveness of a new ultrasound coupling medium, the Gel-SHOT, compared with ultrasound gel, was assessed by measuring tissue temperature changes in human muscle. Thirty-eight healthy participants were randomly assigned to receive 1- or 3-MHz ultrasound treatments. On different days, participants received ultrasound treatments with ultrasound gel or the Gel-SHOT. Implantable thermocouples were inserted into the triceps surae muscle at a depth of 3 or 2 cm to measure tissue temperature for the 1- or 3-MHz treatments, respectively. At 1 MHz, the Gel-SHOT allowed for a significant temperature increase (3.9°C ± 1.4°C) over ultrasound gel (2.6°C ± 1.1°C) ($P = .045$). However, at 3 MHz, the Gel-SHOT (4.5°C ± 1.2°C) and ultrasound gel (4.1°C ± 1.4°C) allowed for a similar temperature increase ($P = .85$). The Gel-SHOT will allow for higher or similar ultrasound heating compared with ultrasound gel. [*Athletic Training & Sports Health Care*. 2014;6(6):273-279.]

Therapeutic ultrasound is inaudible, acoustic vibrations of a high frequency that produce thermal and/or nonthermal physiologic effects.[1] Ultrasound is a valuable tool in the rehabilitation of many injuries, primarily for the purpose of raising tissue temperature to obtain desired physiological effects.[2] Ultrasound has advantages over nonacoustic heating modalities, such as whirlpools and hot packs. When applied correctly, ultrasound can heat deep tissues that are high in collagen, such as tendons, muscles, ligaments, and joint capsules, without the possibility of overheating tissue surfaces.[3,4]

Transmission of ultrasound occurs only through a medium and does not pass through air or the skin. Optimal ultrasound use requires that a coupling medium be placed between the skin and the ultrasound transducer. Transmission of ultrasound energy through one material to another depends on the physical properties of these materials. Thus, careful selection of the preparations used for ultrasound transmission is required. Some commercially prepared gels, lotions, water, mineral oil, and glycerin are effective coupling agents for ultrasound.[5-9] The 3 most commonly used ultrasound coupling mediums are gels, for direct application; water, for the immersion technique; and 1- to 2-cm thick gel pads, for use over bony surfaces.[4]

Commercially available, water-soluble ultrasound gel is by far the most common coupling agent used for direct contact ultrasound application.[7-10] A layer of gel is applied to the treatment area in an amount sufficient to maintain good contact and lubrication between the soundhead and the skin. How much gel should be used is a question that many clinicians have had for years. Some report using "generous amounts," whereas others suggest that a thin layer be placed between the soundhead and the skin.[11]

Water is a great coupling medium, but it is not suited for surface application because it will not stay in place like gel. However, there are some instances where the clinician might want to use the underwater technique. The immersion technique is recommended if the area to be treated is smaller than the diameter of the available soundhead or if the treatment area is

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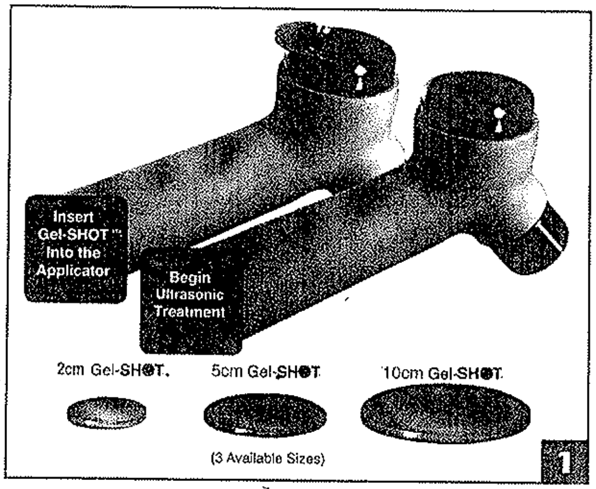

Figure 1. The Gel-SHOT in 2-, 5- and 10-cm^2 sizes.

irregular with bony prominences (such as the hand). With the immersion technique, a plastic container is filled with warm tap water. The ultrasound head is held 0.5 cm away from the skin, and the soundhead is slowly moved.

If the treatment area is irregular but cannot be immersed in water, a gel pad can be used as a medium. A gel pad resembles a gel-filled clear hockey puck. Two studies suggest that ultrasound gel pads are as effective as ultrasound gel.[10,12] In another study,[13] 2 thicknesses of the gel pad were tested against ultrasound gel. The 2 thicknesses were the traditional 2-cm thick pad and the 1-cm thick pad. Ultrasound using the 1-cm gel pad heated the tissue one-third higher than the 2-cm gel pad; however, ultrasound gel still heated the tissue the highest. With this in mind, Rich-Mar Corp (Chattanooga, Tennessee) developed the Gel-SHOT.

The Gel-SHOT is a small disk that comes in 2-, 5-, and 10-cm^2 sizes (**Figure** 1). With an adapter that is attached to the soundhead, the Gel-SHOT fits firmly on the face plate of the ultrasound head. As stated, many clinicians use either too much gel or not enough, and thus the distance between the skin and the soundhead is not consistent. Consequently, the dosage of ultrasound is compromised.[4] The Gel-SHOT is 3-mm thick, which provides optimal coupling between the soundhead and the skin. In theory, this results in a consistent dosage of ultrasound to the treatment site.

The current study aimed to determine how the Gel-SHOT compared with ultrasound gel as a coupling medium. We surmised that the best couplant would deliver more ultrasound energy to the tissue, which would result in higher tissue temperatures. Therefore, the purpose of our study was to assess the effectiveness of the Gel-SHOT as a coupling medium compared with ultrasound gel, by measuring tissue temperature changes in the triceps surae muscle during a 10-minute ultrasound treatment.

METHOD

We used a 2×2×2×20 repeated measures crossover design for temperature heating. The dependent variable was tissue temperature of the triceps surae muscle group measured to the nearest 0.1°C. The independent variables were 2 levels of treatment conditions (Gel-SHOT and ultrasound gel), 2 levels of treatment location (posterior and medial calf), 2 levels of ultrasound frequency (1 and 3 MHz), and time. Time was measured at pretreatment baseline and then at 30-second intervals during the 10-minute treatment (20 points).

Participants

We recruited 38 participants for the study (22 men, 15 women; mean age = 23.1 ± 3.6 years; mean height = 177.4 ± 10.6 cm; mean mass = 78.2 ± 42.0 kg). Each participant was screened for disqualifying conditions that included pregnancy, infection, fever, or injury to the triceps surae area in the past 2 months. During the study, all participants were fully compliant, and we did not have to terminate any treatment. All participants provided written, informed consent, and the study was approved by the institutional review board.

Instruments

Implantable IT-21 thermocouples (Physitemp Instruments Inc, Clifton, New Jersey) were plugged into an electrothermometer (Iso-Thermix; Columbus Instruments, Columbus, Ohio) to instantaneously record tissue temperatures. The reliability and validity of the IT-21 thermocouples and Iso-Thermix electrothermometer have been described previously.[14,15] We used a musculoskeletal imaging ultrasound (LOGIQ e; General Electric Company, Fairfield, Connecticut) to verify the depth that each thermocouple was placed. The therapeutic ultrasound device was manufactured by Rich-Mar Corp and has an effective radiating area of 5 cm^2 and a beam nonuniformity ratio of 5.5:1.

Procedures

The same technique used in several modality temperature studies was used to measure deep muscle tempera-

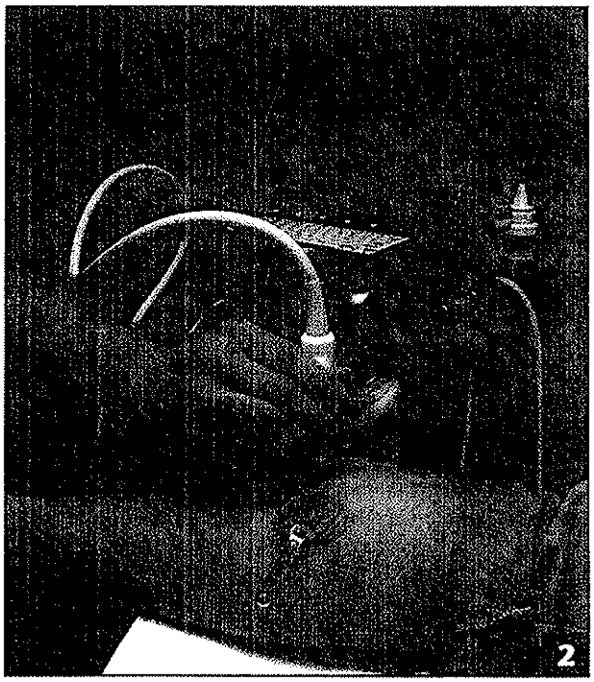

Figure 2. Verification of thermocouple depth via musculoskeletal imaging ultrasound.

tures.[13-19] Participants were instructed to refrain from exercise for at least 4 hours before testing. Participants were randomly assigned to receive either 1- or 3-MHz ultrasound treatments on the posterior or medial surface of triceps surae muscle group throughout their participation in the study. We examined 2 treatment locations to understand whether a difference in muscle heating between the Gel-SHOT and ultrasound gel would occur in both nongravity- and gravity-dependent positions.

Participants lay prone on a treatment table. The calf muscles served as the target tissue. Each treatment was to be 2 times the size of the soundhead. To ensure this, we used a sterile, felt tip marker to trace an area 2 times the size of the soundhead on the posterior aspect of the calf. After this, we used a small carpenter square to measure perpendicularly from an already-marked line on the posterior skin surface to a 2- or 3-cm (actual depth = 1.9 ± 0.1 or 2.9 ± 0.1 cm) posterior-to-anterior distance on the medial side of the calf for the 3- or 1-MHz treatments, respectively. A dot was placed on the skin on the medial side of the triceps surae at the desired distance.

The skin over the insertion site was prepared using an iodine swab and was wiped clean using an isopropyl alcohol preparation pad. A 20-gauge, 1.88-inch

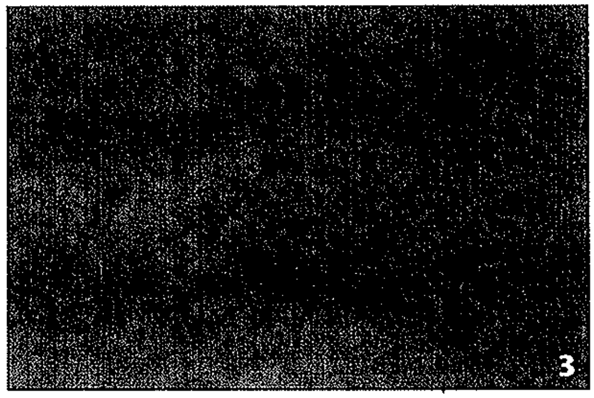

Figure 3. Insertion of thermocouple via the catheter.

(2.54-cm) catheter (BD Medical, Franklin Lakes, New Jersey) was horizontally inserted at the desired depth into the medial aspect of the triceps surae. The depth of the catheter insertion was verified to be within 0.2 cm of the desired depth using the musculoskeletal imaging ultrasound (**Figure 2**). Next, we inserted one IT-21 thermocouple via the catheter. We slowly removed the catheter, leaving the thermocouple intact (**Figure 3**). The catheter was removed to expose the end of the thermocouple so that proper intramuscular temperature could be obtained. If not removed, the catheter would have covered the thermocouple and interfered with its ability to properly measure tissue temperature. The thermocouple was secured to the skin with clear medical tape; it was attached to an Iso-Thermix electrothermometer and set to measure tissue temperature every 30 seconds. The baseline temperature was recorded and reached when the temperature did not change more than 0.5°C over a 1-minute period. For treatments located over the medial triceps surae, the same procedures were used, but the desired depth was measured from a medial to lateral distance on the posterior side. The catheter was then vertically inserted into the posterior triceps surae.

Ultrasound Treatment

We used a random draw to determine which coupling medium was to be used during the first and the second visit. One-half of the participants had the ultrasound gel treatment first followed by the Gel-SHOT treatment at their second visit. The other half had the Gel-SHOT first, followed by ultrasound gel. At least a 48-hour recovery period was between visits. After the baseline temperature was reached, we began the ultrasound treat-

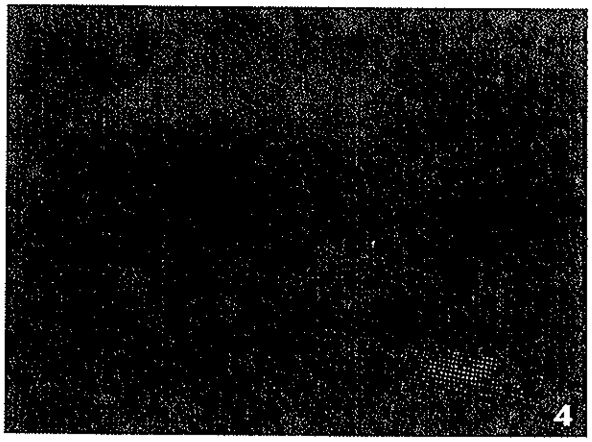

Figure 4. Ultrasound treatment (treating an area 2 times the size of the soundhead at a speed of approximately 4 cm/sec) using ultrasound gel.

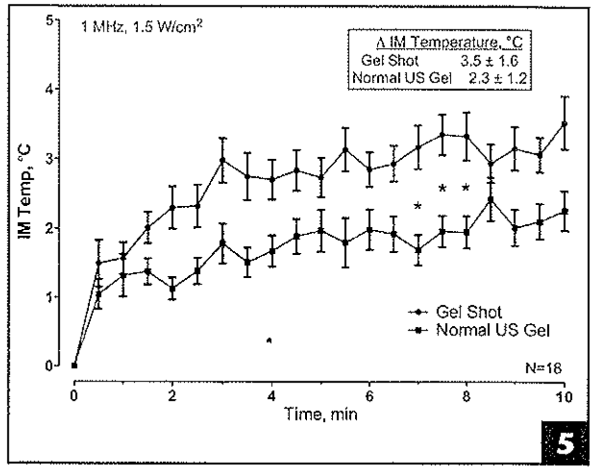

Figure 5. Increase of intramuscular (IM) temperature (mean ± 1 SE) during 1-MHz ultrasound treatments using the Gel-SHOT and ultrasound (US) gel. The Gel-SHOT allowed for a greater tissue heating rate over ultrasound gel ($P = .0002$). * Indicates significant differences at individual time points between the Gel-SHOT and ultrasound gel ($P < .05$).

ment. For 1-MHz treatments, the following parameters were used: continuous mode, 1.5 W/cm^2, 10 minutes. For 3-MHz treatments, the following parameters were used: continuous mode, 1.0 W/cm^2, 10 minutes. Each treatment involved treating an area 2 times the size of the soundhead at a speed of approximately 4 cm/s. For the gel treatment, approximately 5 mL of ultrasound gel was applied to the site (in the tracing) once at the start of the treatment, and a second 5-mL allocation of gel was applied midway through the treatment (**Figure 4**). As the soundhead was moved back and forth in the tracing, the ultrasound gel started to move beyond the margins of the tracing. Therefore, to ensure proper coupling during the treatment, the soundhead was lifted off the skin to retrieve the escaping gel into the treatment area. This happened approximately once per minute. Methods for the Gel-SHOT treatment were identical, except that retrieval of the gel was not needed. After the 10-minute treatment, the thermocouples were removed, the treatment and insertion areas were cleansed, and an adhesive bandage was applied over the insertion site.

Statistical Analysis

For all data, tissue temperature change was calculated as the difference between measured temperatures minus baseline. Initially, a 2×2 (coupling medium × treatment location) mixed model analysis of variance was used to determine whether the heating characteristics of the 2 coupling mediums were different in a nongravity- (posterior treatment location) or gravity-dependent (medial treatment location) position. However, for both the 1- ($P = .99$) and 3-MHz ($P = .46$) treatments, no difference was found in tissue heating at 2 different locations within the same coupling medium. Therefore, we combined the data for the different locations into a single variable.

We used a 2×20 (coupling medium × time) repeated measures analysis of variance to determine statistical differences between the Gel-SHOT and ultrasound gel over the course of the ultrasound treatment. We used a Tukey-Kramer post hoc test to determine individual differences. Different analyses were performed for each ultrasound treatment frequency. We used JMP Pro 10 (SAS Inc, Cary, North Carolina) for all statistical analyses, and alpha was set at $P < .05$.

RESULTS

1-MHz Treatment

On average, the Gel-SHOT allowed for a 3.5°C ± 1.6°C temperature increase, whereas the ultrasound gel treatment allowed for a 2.3°C ± 1.2°C temperature increase. The Gel-SHOT allowed for temperatures 34.3% higher than the gel technique (**Figure 5**). A significant coupling medium × time interaction occurred, where the Gel-SHOT significantly allowed for an increase in temperature at a greater rate than the ultrasound gel ($F_{20,342} = 2.63$, $P = .0002$).

3-MHz Treatment

On average, the Gel-SHOT allowed for a 5.1°C ± 1.4°C temperature increase, whereas the ultrasound gel treatment allowed for a 4.6°C ± 1.3°C temperature increase. The Gel-SHOT allowed for temperatures 9.8% higher than the gel technique (**Figure 6**); however, the Gel-SHOT did not significantly increase tissue temperature over the ultrasound gel during the course of the ultrasound treatment (coupling medium × time interaction) ($F_{20,388} = 0.88$, $P = .62$).

DISCUSSION

The results of the current study found that the Gel-SHOT is more effective than ultrasound gel during a 1-MHz treatment at transmitting ultrasound energy to increase muscle temperature. However, no statistical difference in muscle heating was found when the Gel-SHOT and ultrasound gel were used during 3-MHz treatments. The authors hypothesize that the difference found during the 1-MHz, but not the 3-MHz, treatment is associated with energy transmission.

As ultrasound energy is delivered to the tissue, it is reflected, refracted, transmitted, or absorbed. For the ultrasound energy to be converted into tissue heating, it must be absorbed. No thermal or nonthermal effect will occur during the ultrasound treatment if the majority of the energy is reflected, refracted, or transmitted through the tissues.[4,8] Ultrasound coupling mediums are designed for the ultrasound energy to be transmitted through the medium and absorbed by the target tissue. The Gel-SHOT has 3 main characteristics that may aid in proper transmission of the ultrasound energy.

The first characteristic is that the Gel-SHOT stays in full contact with the treatment area throughout the entire treatment. This is because the Gel-SHOT fits inside a small well on the soundhead face plate. However, ultrasound gel does not fit in a gel well and is constantly pushed out of the way, thus requiring the clinician to lift the soundhead from the target tissue and "scoop" the gel back onto the treatment area. It was hypothesized that this act would reduce the amount of energy transmitted to and absorbed by the target tissue during the treatment. In addition, more energy would be reflected or refracted away from the target tissue. If significant reflection and refraction of the outputted ultrasound energy is detected by the device, it may reduce its power output.[4] This would significantly alter the heating capacity of an ultrasound treatment.

The second characteristic of the Gel-SHOT is that it is a constant 3 mm thick, ensuring that the same

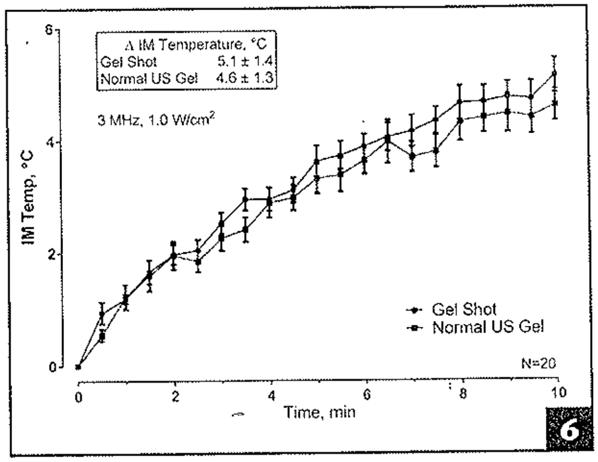

Figure 6. Increase of intramuscular (IM) temperature (mean ± 1 SE) during 3-MHz ultrasound (US) treatments using the Gel-SHOT and ultrasound gel. There was no difference in tissue heating between the Gel-SHOT and ultrasound gel ($P = .62$).

amount of ultrasound couplant is used between the skin and the soundhead. However, ultrasound gel is compressed to a thin amount as the applicator head comes into contact with the gel. This more uniform depth of the Gel-SHOT should result in more uniform heating of the tissue.

The third characteristic of the Gel-SHOT is that it is not as messy as traditional ultrasound gel. This might lead to cost savings in laundering of towels and prevent gel from staining clothing in close proximity to the gel.

On average, ultrasound delivered at 3 MHz is absorbed more in the superficial tissues, and 1-MHz ultrasound is absorbed more in the deeper tissues.[16,20] That is why we had the probe inserted at a depth of 2 cm for the shallow 3-MHz treatment and 3 cm for the deeper 1-MHz treatment. Why did such differences occur in the heat produced from the Gel-SHOT at the 2 frequencies? It may have to do with the beam profile. The 3-MHz beam is collimated, whereas the 1-MHz beam diverges.[21] The authors hypothesize that a statistical difference between coupling mediums (Gel-SHOT and ultrasound gel) during 3-MHz treatments was not found because both mediums maintained an appropriate effective radiating area at the shallower depth (2 cm). However, during 1-MHz treatments, the uniform consistency of the Gel-SHOT (3 mm) produced better coupling than the ultrasound gel, with less reflection or refraction at the deeper depth where the beam diverged (3 cm).

A discrepancy exists regarding how much ultrasound gel should be applied between the soundhead and the skin. Cameron and Monroe[5] used 5 mm of gel thickness when comparing the transitivity of several ultrasound coupling media. However, those authors stated that the amount of gel between the transducer and the skin does not matter. They continued that only a small amount of gel (0.5 mm thick) between the transducer and the skin is needed. Although this hypothesis has never been tested, it seems reasonable to assume that consistent thickness of the coupling medium would result in consistent delivery of ultrasound energy. The thickness of the Gel-SHOT is consistent, never changing its size or uniformity, allowing for consistent transmission of ultrasound energy. In the current study's comparison to the Gel-SHOT, 2 applications of 5 mL of ultrasound gel were used: 1 at the start of the treatment and the other halfway through the treatment. We noticed that as the soundhead was placed on the gel, the gel thickness decreased. It was also noticed that the gel began to run, thus requiring retrieval of the gel back to the target tissue several times during the treatment.

Several other studies have tested the effectiveness of different-thickness ultrasound gel pads on increasing the tissue temperature. Initial studies found that the heating capacity of ultrasound treatments were similar to 2-cm ultrasound gel pads and ultrasound gel.[10,12] However, a more recent study found that a 2-cm gel pad was not as effective as ultrasound gel,[13] less thick ultrasound gel pads (1 cm) allow for greater tissue heating than 2-cm gel pads, and ultrasound gel allowed for the greatest tissue heating. The thickness of the Gel-SHOT (3 mm) allows for at least equal or superior tissue heating during 1-MHz treatments, compared with ultrasound gel.

It has been suggested that the appropriate size of the ultrasound treatment area is 2 to 3 times the size of the soundhead.[18,21,22] As ultrasound is applied using gel, the gel starts to be pushed beyond the borders of the treatment area. This can result in the clinician treating too large of an area as the soundhead is moved to retrieve the escaping gel. The Gel-SHOT's shape and consistency allows for a stable treatment area, thus producing and maintaining ideal treatment sizes.

The authors of the current study chose to compare the thermal effects of ultrasound delivered through the Gel-SHOT, compared with ultrasound gel, by measuring changes in triceps surae temperature. This study provides clinicians with a guide to the Gel-SHOT as a coupling medium when temperature based treatment goals are used. The tissue temperature of healthy human participants was measured, and it was assumed that similar temperature rises would occur with injured patients if blood flow was not compromised. If an institutional review board would approve it, similar studies should be performed on injured patients. Due to the inequality among ultrasound devices, the current results should be inferred only to the Rich-Mar Corp ultrasound device. Future research may determine the effectiveness of the Gel-SHOT on increasing tissue temperature during ultrasound treatments with different devices.

IMPLICATIONS FOR CLINICAL PRACTICE

The ultrasound coupling medium is a factor in the transmission of ultrasound energy to allow for adequate tissue temperature increase during ultrasound treatments. The Gel-SHOT allowed for greater tissue temperature increases during 1-MHz treatments and similar tissue temperature increase during 3-MHz treatments. This study found that the Gel-SHOT is a suitable substitute to ultrasound gel.

Cost is always a concern to clinicians. Each Gel-SHOT can be used only once and costs approximately 25 cents. When shipping of traditional ultrasound gel is considered, the cost is similar. In addition, the Gel-SHOT is housed in a sterile package, whereas traditional ultrasound gel comes in a bottle that may collect germs on its tip. ■

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