ABSTRACT

The purpose of this literature review was to survey available information and research related to routine three-dimensional (3D) ultrasound technology in obstetrics, with an emphasis on current medical uses, safety, and availability issues. Several data bases, including Cochrane, WHO, NIH, CINALH, Blackwell Synergy, ERIC, PubMed, and Medline, were used along with information from Internet search engines. Although fetal 3D ultrasound is used in both medical and commercial settings, recent studies focus on its possible uses rather than the more difficult issues of safety and commercial applications. Professional organizations associated with ultrasound technology support limiting ultrasounds in pregnancy to medically necessary events, whereas commercial venues use “direct to consumer” marketing to promote this technology as a way to “see” the baby before it is born. How safe is routine or frequent use of 3D ultrasound? Further research is needed to address these important questions.

Key Words: Fetal ultrasonography; Ultrasonography, fetal; Ultrasonography, prenatal.
Since the early 2000s, opportunities for capturing the lifelike image of a developing fetus have emerged in shopping malls around the world (Gordon, 2003). Parents can now purchase three-dimensional (3D) ultrasound images by merely entering a mall and leaving with pictures suitable for framing; no physician involvement is needed for this event (Capitulo, McClintock, & Armour, 2005). These commercial businesses, with names such as Fetal Foto, 3D Baby View, American Baby, Baby Insight, and Baby’s First Image, perform 3D ultrasounds and provide a photo package similar to any commercial photographic enterprise currently available.

The subject of private fetal ultrasound has been debated in the nursing literature (Capitulo et al., 2005) and recently found its way into Hollywood when it was reported that celebrities were purchasing ultrasound machines to monitor their developing babies themselves. This underscores the dilemma with this available technology. According to the American College of Radiology (2005), fetal ultrasound should be performed only by certified technologists for medical purposes and with a prescription from an appropriately licensed provider. The United States Food & Drug Administration (USFDA, 2005) stated on August 30, 2005 that casual exposure to ultrasound, especially during pregnancy, should be avoided. Obstetrical ultrasound is a common procedure, and yet the machines can be purchased by any private citizen. What are the implications of this? Can fetal 3D ultrasonography be safely practiced by anyone, at any time, outside the confines of a health visit with a provider?

According to Woo (2005), ultrasound technology has been termed the most important diagnostic tool in the field of obstetrics, because by using sound waves to form images of the body, it replaces the need for ionizing (x-ray) methods to obtain the same information. Fetal scanning with two-dimensional (2D) ultrasounds, which depict length and width, has been used routinely in obstetrics since the 1960s, but these images are black and white, flat and grainy, and need an expert to interpret the results. With the advent of 3D ultrasound in the early 2000s, the added dimension of depth resulted in a clearer photographic image that is easily recognizable by the untrained eye (Woo, 2005). Four-dimensional (4D) ultrasound, which captures movement, recently was added to the ultrasound possibilities, resulting in a more complete representation of the developing fetus. Some nonmedical mall ultrasound businesses include this as an optional service or part of the photo package.

Initially, ultrasounds were confined to hospital settings with centralized control and regulation. In the early 1980s, because of a reduction in cost and added mobility, ultrasound scanners decentralized from the hospitals into physicians’ clinics and offices (Woo, 2005). As the technology has evolved, regulation and control have become problematic, and concerns are now emerging about the safety of this procedure in nonmedical/commercial venues. There is no regulation of the commercial application of this; the USFDA is responsible for the verification of maintenance of the ultrasound machines, but not where the machines can be used (Volker, 2005).

The purpose of this article, therefore, was to analyze available information and research related to fetal 3D ultrasound technology use, safety, and DTC marketing. The following databases were used in this analysis: Cochrane, WHO, NIH, CINALH, Blackwell Synergy, ERIC, PubMed, and Medline. Inclusion criteria for reviewed articles included text in English, professional journal articles, professional organization standards, published re-
search, and direct to consumer marketing of fetal 3D ultrasounds. Nine recent studies (2000-2005) that addressed current uses were reviewed, and two older (1993, 1998) landmark studies identifying possible side effects from ultrasound exposure were also included. Consumer marketing and related professional organizational information was accessed using the Internet search engines Google, Yahoo, and Ask Jeeves.

**Studies About Medical Uses of Fetal Ultrasound**

No research studies were found directed at fetal 3D technology use in commercial venues. Therefore, medical use of fetal ultrasound research was used to examine current practice, shown in Table 1. Recent medical studies demonstrate the desirability of fetal 3D ultrasounds when compared to the traditional 2D standard. Schield, Fimmers & Hansmann (2000) compared 2D and 3D ultrasound for EFW (estimated fetal weight) in 190 scans completed at 7 days before birth with the actual birth weight, demonstrating that 3D ultrasounds were superior in determining fetal weight.

Rotten and Levaillant (2004) studied more than 10,000 women who received standard 2D ultrasounds during pregnancy, examining the number of 2D views necessary to identify facial deformities when compared to 3D technology. Their findings supported 3D technology, which required fewer views, was easier to use, was more efficient, and resulted in a clearer image. Merz and Welter (2005) had similar results and demonstrated that in 70% of the cases with abnormalities, 3D ultrasounds provided more information about the severity of the abnormality.

Several studies have focused on abnormalities during pregnancy and birth, such as nuchal cord. Hanaoka, Yanagihara, Tanaka, and Hata (2002) compared 2D and 3D ultrasound in a convenience sample of 85 pregnant women with evidence of a nuchal cord and demonstrated that 3D ultrasound was superior in nuchal cord identification at term. Chaoui, Kalacheand, and Hartung (2001) studied 3D ultrasound to identify abnormal fetal development, finding that it could verify the abnormality in the fetus in 64% of the abnormal cases.

In recent years, concerns over cervical length and the incidence of PTD (preterm delivery) have been addressed with the use of ultrasound to measure the length of the cervix during pregnancy. Severi et al. (2003) studied this in 103 high-risk women and found that 3D ultrasound technology was superior in identifying women who would deliver early.

Pregnancy ultrasound information about the first trimester has been limited by standard 2D views, but 3D ultrasound offers new opportunities in this area. Early 3D use in pregnancy has now been studied. Michailidis, Papa-georgiou, Morris, and Economiers (2003) compared the ability to determine gender identification between 2D and 3D ultrasound, finding that 3D ultrasound technology was superior. Ohman, Saltvedt, Grunewald, and Waldenstrom (2004) examined the anxiety felt by women when early ultrasounds were used to detect Down syndrome and found that early use of 3D ultrasound did not increase anxiety levels in women.

Because of the clarity of 3D and 4D ultrasounds, innovative uses are still being developed. Kurjak et al. (2004) used 4D ultrasound to compare observed fetal behavior in utero with subsequent behavior after birth, noting that movements and facial expressions were the same for individual infants before and after birth. This finding suggests that there could be a potential for identifying neurological problems before birth, thus adding to the literature on whether neurological problems are caused by birth trauma.

**Studies About Safety of Fetal Ultrasound**

In the early 1980s, the National Institutes of Health (NIH, 1984) convened an expert panel to determine possible safety concerns related to exposure to ultrasound technology. This panel recommended against the routine use of prenatal scanning (embryonic and fetal), suggesting that although there are no known hazards, caution should be exercised regarding developing organisms. In June 1988, a subsequent professional group was convened by the NIH to start a 3-year process to develop standards for operation at higher levels of exposure to increase diagnostic capabilities. One result was the “output display standard,” which gives the operators information about possible temperature increases.

Parents-to-be can now merely enter a shopping mall and obtain 3D ultrasound images of their fetus, with no healthcare provider involvement.
<table>
<thead>
<tr>
<th>Study</th>
<th>Sample</th>
<th>Design</th>
<th>Outcomes</th>
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<tbody>
<tr>
<td>Chaoui et al. (2001)</td>
<td>133 pregnant women; n = 45 normal; n = 87 abnormal; convenience sample from hospital clinic in Germany</td>
<td>Visualization of fetal vasculature; abnormalities with 3D U/S</td>
<td>64% of abnormalities could be visualized. Lack of visualization due to fetal movement and differentiation between other vascular structures. Superior to 2D U/S in visualization of vascular abnormalities in fetus.</td>
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<td>Fatemi et al. (2001)</td>
<td>N = 9; 3rd trimester fetus</td>
<td>Fetal reactions to U/S; clinical study, prospective</td>
<td>Demonstrated reaction by the fetus to U/S.</td>
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<td>Hanaoka et al. (2002)</td>
<td>85 pregnant women in Japan; convenience sample</td>
<td>Identification of nuchal cord with 3D U/S in pregnancy compared to 2D and color Doppler</td>
<td>No overall differences between compared modalities, although subjective visualization was deemed better with 3D U/S by the operators.</td>
</tr>
<tr>
<td>Kurjak et al. (2004)</td>
<td>n = 10, 3rd trimester; n = 10, newborns; convenience sample from Croatia</td>
<td>Compare fetal behavior/ movements with newborns; Real time Video/4D U/S used for fetal observation.</td>
<td>Demonstrated the same movements, facial expressions newborns and fetus. 4D U/S as powerful tool for assessing fetal behavior. Possible use for assessing CP-type perinatal impairments.</td>
</tr>
<tr>
<td>Ji et al. (2005)</td>
<td>n = 50, 2D; n = 50, 3D</td>
<td>Compared bonding measures between 2D and 3D; randomized, control trial</td>
<td>3D may have greater bonding potential.</td>
</tr>
<tr>
<td>Michailidis et al. (2003)</td>
<td>N = 200 pregnant women, 1st trimester; convenience sample from England</td>
<td>1st trimester 3D U/S for sex determination; prospective</td>
<td>Demonstrated effective identification of gender at an earlier stage than 2D U/S.</td>
</tr>
<tr>
<td>Merz &amp; Welter (2005)</td>
<td>N = 3,472 high-risk pregnancies</td>
<td>Convenience sample in Germany. Compare identification of fetal anomalies between 2D and 3D U/S; prospective</td>
<td>3D U/S was advantageous in 70% of the identified cases. Provides &gt; information about a normal fetus and anomalies.</td>
</tr>
<tr>
<td>Ohman et al. (2004)</td>
<td>N = 2,026 pregnant women; multicenter in Sweden</td>
<td>Early U/S (12-14 weeks) for Down syndrome identification in pregnancy: Does this increase anxiety?</td>
<td>Did not cause more anxiety during pregnancy.</td>
</tr>
<tr>
<td>Rotten &amp; Levaillant (2004)</td>
<td>N = 10,500 2D U/S exams 2nd trimester, France</td>
<td>Determine the number of views to identify facial anomalies and compare 3D; retrospective</td>
<td>3D superior to 2D in identifying fetal facial deformities. Need 2+ views in 2D to identify abnormalities. 3D easier, rapid, and more precise.</td>
</tr>
<tr>
<td>Schild et al. (2000)</td>
<td>N = 190 pregnant women, 7 days &lt; EDC, Germany</td>
<td>EFW comparisons between 2D and 3D U/S at term; prospective, cross-sectional</td>
<td>3D U/S was more effective at determining fetal weight at term.</td>
</tr>
<tr>
<td>Severi et al. (2003)</td>
<td>N = 103 pregnant women; 2nd and 3rd trimester; convenience sample from Italy.</td>
<td>Comparison between 2D and 3D examination of cervical length; prospective</td>
<td>Demonstrated superiority of 3D U/S in determining cervical length and subsequent PTD.</td>
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(thermal index) and mechanical damage (mechanical index) to use in clinical decision-making (AIUM, 1992). Findings from these groups resulted in the principle of exposure to ultrasound called ALARA (As Low As Reasonably Achievable), which is the current industry standard. This standard implies a level of knowledge about upper (or dangerous) levels of exposure and the effect on living tissue that may or may not be present in clinics and commercial venues.

The lack of scientific knowledge about the safety of multiple ultrasounds in pregnancy stands in stark contrast to the fact that women consistently express the desire to know their babies before they are born. Ultrasound has given them that opportunity. Clement, Wilson, and Sikorski (1998) described three main elements in a pregnant woman's desire to have an ultrasound:

1. Meeting the baby
2. Developing a visual confirmation of the pregnancy
3. Reassurance of fetal well-being

Garcia et al. (2002) confirmed this work and noted that in all of the studies they reviewed from industrialized countries, women rarely expressed fears about the safety of the procedure. Because ultrasound is approached by the medical community as part of normal prenatal care, it seems that few women are aware of the safety concerns that are inherent in this procedure.

The two major effects of ultrasound on living organisms are heat and cavitation. Because tissue heating related to the time of exposure is a major concern in the practice of obstetrics, all professional organizations have supported limits for the maximum exposure time to 20 min for the developing fetus. Cavitation is the formation of gaseous “bubbles” when tissue is exposed to ultrasound (Miller, 1999). Although no studies have demonstrated a direct relationship with complications related to heat or cavitation, the AIUM (1999) suggests that the possibility exists for biological effects to be identified in the future. Many professional organizations and others support lim-

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<th>Organization</th>
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<td>ISUOG (International Society for Ultrasound in Obstetrics and Gynecology)</td>
<td>2002</td>
<td>Limit to medically indicated procedures rather than for purely entertainment purposes <a href="http://www.isuog.org">www.isuog.org</a></td>
</tr>
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<td>BMUS (British Medical Ultrasound Society)</td>
<td>2000</td>
<td>Investigations are in early stages, advise “prudent” use of this modality <a href="http://www.bmus.org">www.bmus.org</a></td>
</tr>
<tr>
<td>AIUM (American Institute of Ultrasound in Medicine)</td>
<td>1999</td>
<td>Limit to medically indicated reasons <a href="http://www.aium.org">www.aium.org</a></td>
</tr>
<tr>
<td>ASUM (Australasian Society for Ultrasound in Medicine)</td>
<td>2003</td>
<td>No convincing evidence that diagnostic ultrasound causes adverse health effects but does not recommend non-medical use <a href="http://www.asum.com.au">www.asum.com.au</a></td>
</tr>
<tr>
<td>FDA (Food and Drug Administration)</td>
<td>2005</td>
<td>Discourage nonmedical use of ultrasounds <a href="http://www.fda.org">www.fda.org</a></td>
</tr>
<tr>
<td>ACOG (American College of Obstetrics and Gynecology)</td>
<td>2005</td>
<td>Fears about the qualifications of providers, inaccuracy of findings, and increased exposure ultrasound technology <a href="http://www.acog.org">www.acog.org</a></td>
</tr>
<tr>
<td>MOD (March of Dimes)</td>
<td>2005</td>
<td>Casual use during pregnancy should be avoided <a href="http://www.marchofdimes.com">www.marchofdimes.com</a></td>
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</table>
iting ultrasounds in pregnancy to medically necessary events (see Table 2)

Although recent studies are difficult to identify, three studies that demonstrate possible health effects on the developing fetus were found related to neurological changes, increased incidence of growth-restricted infants, and hearing impacts on the developing fetus. Kieler et al. (1998) studied data collected from a cohort of children whose mothers had participated in an earlier study (1985-1987) in Norway, comparing women who received ultrasound in pregnancy with women who did not. This study focused on the possible neurological impact of routine ultrasounds as reported by the mothers involved in the previous study. No evidence of neurological impairment was reported, but an increase in left-handedness in boys was demonstrated. Although this finding could not be connected to any impairment, the authors recommended that further studies be directed at this finding, because it may indicate a subtle influence on the developing neurological system of the fetus.

The question of effects from repeated ultrasound was the subject of Australian research by Newnham, Evans, Michael, Stanley, and Landau (1993), who randomized women into receiving only one ultrasound during pregnancy or a total of five ultrasounds during the pregnancy. Birth outcomes were compared, and there was a higher incidence of IUGR (intrauterine growth restriction) in the group that received five ultrasounds. This study would be difficult to repeat because of ethical considerations but is worth noting.

Finally, two studies (Fatemi, Alizad, & Greenleaf, 2005; Fatemi, Ogburn, & Greenleaf, 2001) have reported that the developing fetus responds to pulsed ultrasound directed at the head during routine examinations. Although no untoward effects were noted, this finding underscores our current lack of understanding about this common practice in obstetrics. Fatemi et al. (2005) also stated that ultrasound can no longer be viewed as a passive procedure.

Availability of Fetal Ultrasound

In the early 1970s, direct-to-consumer (DTC) marketing exploded when the USFDA stated that consumer marketing was legal if companies disclosed the major risks and “made adequate provisions for information regarding side effects, contraindications and effectiveness” available to the public (Rosenthal, Berndt, Donohue, Frank, & Epstein, 2002). In 1997, this policy was clarified by the USFDA to address broadcast advertising concerns about information to consumers. This clarification stated that DTC marketers should include a referral to a toll-free number, referrals back to their clients’ physician providers, summaries of risks, and related Web sites to fulfill any obligations to consumers regarding use and product safety.

Consumer marketing has been used by pharmaceutical and medical companies for the past 35 years, but the growth in this “new market” of 3D ultrasound technology is unprecedented (Gordon, 2003). DTC bypasses the normal physician interface between consumers and medical services and supplies. Readily available in this and other countries, commercial providers of 3D ultrasounds offer photographic services for unborn children of all interested parents.

Public availability of fetal ultrasound empowers consumers with the ability to access services that bypass their personal medical provider plus enjoy the convenience of scheduling to include other family members. These appealing aspects for 3D ultrasound services are driving the burgeoning market place.

Unfortunately, there are problems inherent in DTC marketing of these services. It is unknown whether consumers understand the results of a commercial 3D encounter, whether there is follow-up for treatment, and whether medical providers even know that such encounters are taking place. By taking the medical provider out of the service dynamic, the consumer assumes the responsibility for any results that emanate from the service. In the case of fetal ultrasound, what if a problem is detected? How this is identified and what is the follow-up? Is the information obtained from a commercial enterprise available to the patient’s medical provider to develop a plan, or will all of the information have to be reinvented with a new ultrasound, thus incurring additional exposure to the fetus? All of these questions are relevant to modern DTC marketing and 3D ultrasound commercial venues.

Clinical Implications

Clinical implications of the ever-increasing use of fetal ultrasound are broad and encompass medicine, nursing, consumers, safety, government/regulations, and marketing/business.

Education of Women and Healthcare Providers

Consumers and providers need more information regarding this new technology. Professional and commercial providers may have limited educational backgrounds for performing
ultrasounds. Because the operators of ultrasound machines are not regulated, consumers have no safeguards about who performs ultrasounds on their fetuses. Minimally, consumers should be apprised of their right to know the professional training and licensure of anyone attempting to perform an ultrasound on them during pregnancy, especially in commercial venues.

Most consumers are woefully unaware of any possible side effects from this procedure (Garcia et al., 2002). Obstetric ultrasounds in a healthcare setting are offered sparingly during pregnancy, and few women forego the opportunity to “see” their baby before the actual birth. With the emergence of DTC marketing, consumers need scientific information based on the best available medical evidence as they consider 3D ultrasound opportunities. Ji et al. (2005) have demonstrated increased maternal-fetal bonding when comparing 2D and 3D ultrasound experiences, but does this bonding experience outweigh the potential risks related to ultrasound technology? According to Capitulo et al. (2005, p.9), we don’t consider having other procedures for fun, so “why would we want to subject a fetus to testing at an unregulated site by an unregulated practitioner?” When the individual consumer has no information about safety or experience of the operator, how can she make a determination about what to do?

**Practice Standards**

In the United States, individual states may regulate the providers of ultrasound through licensing (Volker, 2005), but it is extremely difficult to even obtain information about which states have done so. Some of the issues surrounding this lack of regulation are as follows:

1. Licensing: Currently, providers may have limited or no training related to individual state requirements.
2. Possible side effects: Professional organizations suggest no more than 20 minutes of exposure during fetal ultrasounds, although information about this caution is not readily available to consumers (Garcia et al., 2002).
3. Informed consent: Consumers typically sign a release form stating that they have been advised of the possible risks and benefits of medical procedures, but have they really been advised when so little is actually known?
5. Linkages: Developing communication between the commercial venues and the medical community is critical.
6. Medical history: Should records be required that document the number of ultrasounds and level of exposure during each pregnancy?

The American Institute of Ultrasound in Medicine (AIUM) has addressed practice standards in its 2005 statement on “keepsake imaging”:

> “The AIUM advocates the responsible use of diagnostic ultrasound for all fetal imaging. The AIUM understands the growing pressures from patients for the performance of ultrasound examinations for bonding and reassurance purposes largely driven by the improving image quality of 3D sonography and by more widely available information about these advances. Although there is only preliminary scientific evidence that 3D sonography has a positive impact on parental-fetal bonding, the AIUM recognizes that many parents may pursue scanning for this purpose.

The AIUM recommends that licensed medical professionals (either physicians or registered or registry-eligible sonographers) who have received specialized training in fetal imaging perform all fetal ultrasound scans. These individuals have been trained to recognize medically important conditions, such as congenital anomalies, artifacts asso-

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**Clinical Implications for Providers**

- Following the AIUM guidelines, ultrasonography providers should be licensed medical professionals.
- Patients should be educated to ask ultrasonography providers about their expertise and license before submitting to ultrasound.
- Formal communication linkages should exist between commercial and medical providers.
- Patients who receive any commercial ultrasound should be instructed to discuss this with their healthcare provider.
- Nurses can work with professional organizations to help develop standards for fetal ultrasound.
- Consideration should be given to a true informed consent process for ultrasound procedures.
associated with ultrasound scanning that may mimic pathology, and techniques to avoid ultrasound exposure beyond what is considered safe for the fetus. Any other use of "limited medical ultrasound" may constitute practice of medicine without a license. The AIUM reemphasizes that all imaging requires proper documentation and a final report for the patient medical record signed by a physician." (AIUM, 2005)

Implications for Further Research
Fetal exposure to ultrasound is not easy to study because of ethical and legal considerations (Woo, 2005). Long-term biological effects are difficult to connect to individual medical occurrences in fetal development. Currently, 3D ultrasound is a relatively new, very promising technology being used in some venues without consideration of future effects on developing babies; women are told that there are no known adverse effects, yet few research endeavors have been directed at exposure levels or long-term problems. Research is needed not only concerning the beneficial effects of ultrasound in pregnancy but also its possible negative consequences before women should submit to unlimited ultrasound scans during pregnancy.

Claudia S. Wiseman is a Doctoral Student, School of Nursing, College of Health and Public Affairs, University of Central Florida, Orlando. She can be reached via e-mail at cwiseman@cfl.rr.com.

Ermalynn M. Kiehl is an Associate Professor, School of Nursing, University of Louisville, KY.

References


