tricity could have serious implications if less than total mastectomy is performed.

Four per cent of patients had complications; wound infection occurred in 3% of patients, which corresponds to a 2% infection rate requiring hospitalization reported by Homer et al.[6] We believe that the slightly increased infection rate is due to the patient having to be transferred from radiology to surgery during which sterility can be disrupted. The four hematomas were due to the biopsy and not the localization procedure. The one patient with a vasovagal reaction was the only complication due directly to the localization procedure, which is a complication reported by others.[4]

In our series the main risk factors for breast cancer of increased age, a family history of breast cancer, and previous breast cancer history were associated with an increased incidence of breast cancer. Patients with these risk factors should be screened carefully. Mammographic screening of asymptomatic women is an important step in reducing mortality from breast cancer. It has been shown to have reduced mortality rates from breast cancer by 20–30% and to have decreased the percentage of patients with Stage II disease or higher by 60%.[3,14] Mammographic screening will reduce breast cancer mortality only if the abnormalities identified are managed aggressively. A biopsy should be performed on any nonpalpable suspicious lesion. If cancer is identified, then appropriate surgery should be performed, usually a total mastectomy with axillary dissection in this series.

Although mortality can be decreased by mammographic screening, three issues on breast screening of asymptomatic women remain: expense, labor, and compliance. The major cost component is the mammogram, which accounts for 90% of the cost; however, costs will also be increased by the number of biopsies generated by abnormal mammograms. The cost projection for the annual screening of 50 million women over the age of 50 by 1990 is overwhelming.[1] Obviously, some efforts to reduce this cost have to be made. A Swedish study showed improved survival rates from a single-view mammogram taken every 2–3 years,[1] an approach that has not been well accepted in the United States. Also, even if the American Cancer Society (ACS) guidelines were followed by all, there would not be enough radiologists to analyze the mammograms. Currently, compliance rates with the ACS guidelines among surgeons is about 11%.[1] As the use of screening mammography increases, it may become necessary to use paramedical personnel to screen the mammograms, which may also decrease the costs.

Patient compliance is also a problem. Many women do not understand the importance of breast cancer screening, how effectively early breast cancer can be detected, and the increased treatment options if cancer is discovered early. Because some women fear a mastectomy if cancer is found, they will not comply with screening. These components of noncompliance should be addressed by public education.

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Discussion

DR. RONALD COY JONES (Dallas, Texas): I believe Dr. Roberts and Symmonds have brought to our attention the importance of the liberal use of mammography for the early detection of breast cancer. Only 11% of their patients had positive nodes, which is much lower than the usual 40–50% that is quoted if the mass is first detected by the patient or by the physician. Therefore, these patients in their series should have a 5-year survival rate in excess of 90%.

I believe it is also important for the surgeon to remember that one of every four or five patients with cluster microcalcification will have carcinoma on biopsy.

In their manuscript, only 2% of all cancers were in patients under the age of 50, which seems to be rather low, and I wonder if they have an explanation for this, perhaps an excellent physical examination may have excluded some of those patients. Secondly, 82% of patients had invasive carcinoma when detected by mammography alone, and this seems rather high since several reports have emphasized that the value of routine mammography in at least half to more than half of those patients is that they have an *in situ* lesion or a noninvasive lesion. Thirdly, how do you examine the margins of the excised specimen at the time of biopsy, and if you do not, how do you treat the patient who has microscopically involved margins and desires in the postoperative period to have lumpectomy and radiation? Lastly, what percentage of patients treated at your institution have had their cancer detected by mammography alone?

DR. MORTON C. WILHELM (Charlottesville, Virginia): As a new member, I thank you for the privilege of membership in this group and tell you that I look forward to participating in both the scientific and social activities in the future. I enjoyed looking at the authors' paper. We have had a particular interest in this in Charlottesville.

I believe that the authors are to be congratulated for looking at their information in detail, and I encourage each of you if you are going to do this procedure to look at what you are doing, and only if you look at it carefully, will you know your yield. You should include your pathologist and radiologist in this because I believe you might find that you will improve your results.

We, too, use the hook wire. We have found it very satisfactory. I have even had it put in the day before on some patients, and this works well.

We use local anesthesia. In looking at the last 100 local anesthetics, we used an average of 11.5 mL of local anesthetics. You can see that this can be done easily under local anesthesia.

We generally do not perform frozen sections except when there is a specific nodule where we might get receptor studies.

We do specimen mammography on all patients with calcifications. We frequently do not do them in patients of density because they rarely help. One word of caution. When you are operating on these patients for a nodule, you should be sure that you have the nodule in the specimen you remove. Sometimes what we have found happens is the needle and the wire will slip off of the nodule, which is firm, and when you take out the area, you will miss the nodule; therefore, look at your specimen. See whether the nodule is there in the case of a true nodule, and if it is not, feel around because you may have missed it.

I would like to look at a group of patients we have examined that have had (slide) biopsies for nonpalpable lesions. This came about by having a physician's wife who was 55 years old come to me last year with a change in her mammogram. She had had a mammogram the year before, then developed a nodule. I took it out, and it was a fibroadenoma. I believed that is not supposed to happen in a 55-year-old, but obviously it does; therefore, we started looking at people of this age group.

We looked at 195 women who had a previously considered normal mammogram within 1–4 years before this biopsy was carried out. The majority of them were benign as you will note. Yet, we did have a pickup rate of carcinoma in 17% of patients.

(Slide) This is a breakdown of these lesions, and you will notice the number of perimenopausal and menopausal women in whom benign changes develop that take place in the breast.

You see fibroadenomas. You see fibrous areas and you see a lot of fibrocystic disease. These are the lesions that are giving us a hard time as far as mammography. They are developing in these older women. I believe we might see more of these lesions as the vanishing menopause has arrived. As you know, many women today are going to use Premarin®, and I believe that we may be plagued with more women having these changes, which will make it difficult for us to separate these from malignant lesions on mammography.

If we look at the interval cancers, that is, those women who have had a previously considered normal mammogram and subsequently had an abnormality that led to the diagnosis of cancer, we can see that we picked up 35 cancers in these women. The nice thing about this was the majority were "*in situ,*" certainly in the 2–4-year follow-up period.

You can see the benefits then for the recommendations of the American Cancer Society that people have yearly mammograms.

(Slide) This demonstrates that in our initial group about 50% of our lesions were invasive. In those in which we did interval biopsies and found cancers, we found a 30% incidence of invasive cancers. This certainly makes it worthwhile that we carry out repeated mammography and that we carefully examine this for any change and perform biopsies on these women.

(Slide) There is no question this is going to have a significant impact on your practice, and we looked at this in our institution. We ran along for a 6-year period of doing about 80 every 3 years, and suddenly from 1982–1985 we jumped up to 371. I am sure if you look in your own series, you will find this to be true. In 1986 it looks like we are going to have about 200 in our institution, so this is going to have a significant impact on all of us as far as our surgical practice is concerned. However, if, as the authors say, we can pick these lesions up when they are early, if we can find individuals who have negative nodes and only 13% with invasive cancers, then I believe we can have a significant impact on helping these women.

DR. RICHARD T. MYERS (Winston-Salem, North Carolina): We also have been interested in the occult breast lesion and our recent experience has been published (Surg Gynecol Obstet August 1986).

(Slide) Our technique parallels that of Doctors Symmonds and Roberts in that the radiologist places a needle into the breast tissue by mammographic guidance with the point into or closely adjacent to the suspicious lesion allowing its easy removal. More often than not, a repeat roentgenogram of the excised tissue is done for verification (Slide).

(Slide) In our series of 195 patients, the incidence of malignancy was 13.7%, which corresponds closely with the 14% reported today by Doctors Symmonds and Roberts. In suspicious lesions, calcified or not calcified, the incidence is practically identical at about 14%. Furthermore, if the lesion is malignant, over 90% will be Stage 0 or I. This represents a significant improvement in early detection of breast cancer.

I commend Dr. Symmonds and Roberts on their excellent presentation on a timely subject.

DR. ERLE E. PEACOCK, JR. (Chapel Hill, North Carolina): I have two comments. The first is that I foresee a problem if we continue to take 86% of patients to the operating room for a biopsy under general anesthesia who have only fibrocystic disease. Fourteen per cent cancer means to me that radiologists are over-reading films and that too many people are being operated on unnecessarily. Have you discussed this problem with your radiologist?

The second comment is based on the question of whether a needle is needed. Nearly 5 years ago it occurred to me that preoperative needle placement was unnecessary. Since that time I ask the radiologist to give me two coordinates and the calculated depth of the lesion. As an outpatient surgical procedure performed under local anesthesia, I have the nurse hold the patient's breast in the exact position for mammography while I plot the two coordinates on the surface. I then excise a core of tissue, which admittedly is perhaps 1 cm greater in diameter than when a needle is used. In only one of 26 patients have I failed to remove the lesion. While I am closing the wound the radiologist x-rays the specimen. In the occasional patient in whom I have missed the lesion, the radiologist is always able to tell me where it is in relation to the specimen I removed. By following his directions I have been able to remove the lesion the second time.

It seems to me there are a number of significant advantages. The patient is spared the psychological and emotional trauma of having to go to x-ray and have a needle placed in her breast. The surgeon is spared delay in the operating room because there was a hold-up in x-ray. The breast is spared another dose of radiation and the pathologist receives a very small specimen because the radiologist removes 90% of it and places a needle in the remainder when he has the specimen on a cork board. It does not seem to me necessary to use a preoperative wire. Would the authors please comment.

DR. SALLY MATTINGLY (Lexington, Kentucky): We, too, at the University of Kentucky have been involved in this technique, particularly over the last 5 years and have found in our series of about 150 patients

a 12.5% cancer rate. Interestingly, all of these women had no positive nodes; therefore, all had Stage I disease.

I would like to comment on the technique, and then focus on another aspect, that is, what type of benign disease was removed when the lesion was benign.

We recently got a new mammogram unit that allows the radiologist to use the compression grid technique for inserting the needle wire localization before operation, and we found that this did change our surgical approach somewhat because you are dealing with yet another plan. When compressing the breast, it gives a more direct shot to stick the needle in. However, it also means that the needle may be in deeper than it was when it was done more in a free hand method, and I wonder what type of technique your radiologist is using.

We also x-ray all the specimens removed even though it is not as accurate when you are dealing with a mass or density that has been removed as with microcalcifications. However, we have found that this has helped considerably in ensuring the removal of the lesion.

Now on to what kind of benign disease you are removing. An article in the *New England Medical Journal* that appeared almost 2 years ago by Dr. David Page from Vanderbilt, focused on the risk of development of breast cancer in women who had had the diagnosis of atypical hyperplasia of the breast. It turns out that in many series, including his, this diagnosis is present in about 4% of women. In our series of biopsies after needle localization, we had a 9% incidence of atypical hyperplasia and have been very careful in our surgery group to follow these patients up as a high-risk group and have found in the last 2 years one patient in whom an interval cancer developed in the same breast from which the biopsy specimen had been taken.

I wondered if you had looked at this in your series, and I believe that this may be another advantage of this type of screening of the breast in women because this does seem to put the woman at a very high risk.

DR. CARL SUTHERLAND (New Orleans, Louisiana): This paper introduces one of the major health issues of the day.

The American Cancer Society will have breast screening as its major goal for 1987. For that reason, the Field Liaison Program of the American College of Surgeons has also adopted the same goal. Some of us are going to be directly involved in coordination of those programs and will be responsible for the policies and recommendations of these two major organizations.

Although several questions of major importance have already arisen, two are the most frequently asked and, as far as I am concerned, are going to be the major problems and questions needing resolution.

The first is quality control of the radiologist, alluded to earlier. Major differences continue to exist between radiologists in their interpretation of these films, to the point of some radiologists not interpreting any film without adding a conclusion like, "Malignancy cannot be excluded; biopsy is recommended."

Are we, therefore, to reward women for screening by having a biopsy in almost every case? Who should establish the rules and guidelines for mammographic interpretation, and what are we going to do about facilities that fall outside of these guidelines on either side (*e.g.*, a biopsy for everybody, or only on those patients found to have malignancy)?

The second question is the appropriate therapy for these patients. Certainly, considerable concern exists among some people involved in this project that if we convince women to participate in the programs and cancer is found, some of them will be treated by modified radical mastectomy. Some believe this is no reward for participating in screening programs, when at least two clinical trials find no difference in survival rates in women who have more advanced disease and poorer prognosis than usually found during screening programs, and are being treated with less than modified radical mastectomy (*i.e.*, local resection with radiation therapy plus axillary dissection). In this group of patients with excellent prognosis, perhaps not only mastectomy but radiation therapy may not even be necessary.

I see the resolution of these issues as having a major impact on success of the programs, and determining whether routine screening will become a reality for substantial proportions of these women.

I enjoyed this paper. It raises many important issues, and is well done. We would welcome any help you can give us regarding these questions.

DR. ROBERT P. HUMMEL (Cincinnati, Ohio): I apologize for prolonging things but would like to share some data with you. Our experience is very similar at the Breast Consultation Center of the University of Cincinnati to that presented here today.

Of the 740 needle localizations for nonpalpable lesions, we had an overall incidence of carcinoma of 19% with approximately 80% being in the Stage 0 to Stage I group and the remainder in the Stage II group. We also had a 6% incidence of atypical hyperplasia as mentioned by other discussants and a 10% incidence of fibroadenoma.

I would like to mention one other factor, which looks at this problem from a slightly different perspective. The question that has been raised is the value of mammographic signs. We looked at 205 patients with breast carcinomas who had mammography at the University of Cincinnati Breast Consultation Center. We split them into a negative physical examination group and a positive physical examination group. Results of positive physical examination may have been no more than a thickening on one side or an actual breast mass that might be palpated.

With the negative physical examination (the group that we are talking about in this paper), we had 41 cases of carcinoma diagnosed by punctate calcifications alone. The predictive value for this group was 11.5%. When the radiologists said, "You had better biopsy these calcifications because they might be malignant," 11.5% were. Interestingly enough, the predictive value was less if a mass was felt, but I believe that many patients with masses have biopsy due to the mass rather than the suspicious nature of the calcifications. When the radiologist said that the mammogram showed a mass that was possibly malignant, that statement had a 5% predictive rate with a negative physical examination. If the radiologist said the mass was possibly malignant and you palpated something, then the predictive value went up to 11%. If the radiologist stated the mass was malignant and you could not feel anything, 74% of these cases were malignant. If you did feel something, that finding was 100% predictive. We should remember that many people who have an obviously malignant mass do not even have mammography done.

When the mass was questionable radiographically (there was some asymmetry between one breast and the other) and you couldn't palpate anything abnormal, all of those biopsy results were negative, and we have stopped doing biopsies based on that radiologic finding.

I have just one comment about the use of local anesthesia and the hooked needle. We previously used general anesthesia most of the time when we used hypodermic needles because of the fear that injecting a lot of local anesthesia would move the needle away from the area you are interested in biopsying. Since we now use the hooked needle, there is less worry about the use of local anesthesia.

DR. MARSHALL M. URIST (Birmingham, Alabama): At the University of Alabama we have also been concerned about some of the developments related to needle localization biopsy. We are particularly concerned about patients who have calcifications without a mass and how often a radiologist will see this as a situation requiring biopsy.

At our institution in the last 100 cases of patients who had calcifications alone, 28% were positive. This is higher than the rate observed at several other institutions. Three fourths of the patients had *in situ* lesions. Twenty-five per cent were invasive and none of the invasive lesions have had positive axillary lymph nodes. We believe that this is an optimal detection ratio, but it requires close communication among the surgeon, radiologist, and patient. Patients with calcifications that are not clustered and not microcalcifications can often be observed using serial mammograms and in that way avoid biopsy.

I would like to ask, what were the characteristics of the calcifications that were observed without biopsy in your series? Also, were there any patients who had what appeared to be fibroadenomas (by mammography and ultrasound) who did not have a biopsy performed?

Another major problem regards patients who have localization biopsies performed without concern for what type of treatment may follow. Needle localization biopsy should be performed in a manner that removes a

specimen large enough to ascertain negative margins and also show the histologic condition of the tissue surrounding the calcifications. This will reduce the necessity for re-excision of the tissue surrounding the calcifications. This will reduce the necessity for re-excision of the biopsy site, a procedure that requires removal of the entire previous wound, including the overlying incision. Re-excision may result in an unnecessary cosmetic defect. In your series, what percentage of patients had residual tumor in the specimen when re-excision was performed? I enjoyed this detailed presentation of your large clinical experience.

DR. LOREN J. HUMPHREY (Tulsa, Oklahoma): I want to make a quick point following up the line about hyperplasia and atypical hyperplasia that two of the previous discussants made.

There are benefits such as Dr. Letton's paper made last year with a 30% increased survival rate compared with those not in screening for this type of patient.

The second point I want to raise relates to atypical hyperplasia, the lesions that you did not report. For instance, Victor Gilbertsen in his 25-year follow-up of patients in the colorectal screening program at the University of Minnesota reported a greater than 30% decrease in the incidence of colorectal cancers compared with the expected rate. My question relates to hyperplasia in the lesions that you are removing, notwithstanding multifocality and multicentricity. Don't you believe another expected benefit will be that you will lower the incidence of carcinoma over 25 years in those patients who are followed in screening?

DR. R. ROBINSON BAKER (Baltimore, Maryland): I rise to give another minority opinion similar to Dr. Peacock's.

I have done 100 consecutive cases of nonneedle localization in conjunction with one radiologist. We would measure out the lesion on the mammogram, *i.e.,* the lesion is at the 2 o'clock position in the left breast 6 cm from the nipple, and make the appropriate incision. In three of these cases we did not localize the lesion. In eight of these cases the lesion was not totally excised, but we believed on the basis of a postoperative film that we had excised at least 60% of the lesion and nothing further has been done. These eight patients have been followed for a mean of 36 months, and no palpable masses developed in the area of the biopsy and there has been no change in the radiographic appearance of the lesion.

Furthermore, I also agree with Dr. Peacock that a 3–6 cm segment of breast tissue can be excised and the incision closed without significant deformity. The dimensions of the biopsy specimen as reported by the surgical pathologist in the 100 consecutive patients ranged from 3–7 cm, mean: 5.5 cm. There was no significant deformity in any of these breasts secondary to the biopsy procedures.

I disagree with Dr. Peacock in one respect as to the management of these nonpalpable mammographic lesions. It is much easier to have the radiologist localize the lesion because then all you have to do is excise the area, and if the x-ray abnormality is not in the operative specimen it is the radiologist's fault rather than yours.

My experience with 100 patients indicates that nonpalpable x-ray lesions can be accurately localized without the use of needles in most cases, particularly in patients with small and moderate-sized breasts and central lesions. Nonneedle localization is more difficult in women with large breasts with peripheral lesions. Localization without the use of needles avoids the inherent disadvantages of needle localization, *i.e.,* additional radiation exposure, the potential for infection and hemorrhage related to needle localization, and the additional cost of the localization procedure. These factors are going to become increasingly important as an increasing number of women are referred with nonpalpable x-ray abnormalities.

DR. R. E. SYMMONDS, JR., (Closing discussion): We certainly appreciate all the discussants comments and their interest in this paper.

Dr. Jones pointed out that about 20% of the lesions that have the punctate clusters of calcifications were malignant and that is what we found in our series as well. He commented on the low rate of carcinoma in our series of just two patients in the group comprising patients who were less than 50 years old. I do not have a good explanation of why this was except we eliminated all patients who had palpable lesions or we suspected that a palpable lesion was the lesion that was seen on mammography.

Our 82% rate of invasive carcinomas was higher than we had hoped to find. However we included in this group all patients who had any type of invasion listed on the pathology report. Frequently this was listed as "carcinoma *in situ* with early invasion." This was a retrospective review of our needle localization biopsies, and perhaps a prospective study would have yielded different results.

As regards the margins, our pathologists do not use an India ink stain. We do use frozen sections on all of them at the time of the biopsy. One reason is to get estrogen and progesterone receptors if cancer is identified if there is enough tissue. If there are inadequate margins identified, and the patient is under general anesthesia, and the plan has been made to have axillary dissection and radiation therapy, then we re-excise that site. If the patient is under local anesthesia, and is going to have an axillary dissection at a subsequent operation, then we re-excise that biopsy site later.

At Scott and White we have done approximately 27,000 mammograms over the course of this study. It is interesting that of all those mammograms only slightly less than 2% had malignancy identified. Twenty-five per cent of the malignancies were identified by mammography alone. We had a false-negative rate of 9% by mammography.

Dr. Wilhelm, we now use local anesthesia almost exclusively for our biopsies. We started out using general anesthesia and have gradually switched to local anesthesia. I do not use general anesthesia any more for breast biopsies. All biopsies are done with local anesthesia or local anesthesia with intravenous sedation. In fact, we do them in the clinic treatment room rather than the operating room. Hopefully, this will decrease the cost, which is about 30% less in an outpatient treatment room facility as opposed to being an outpatient in the operating room, and that is about 30% less than what it is in the operating room under general anesthesia.

As I mentioned, we use frozen sections so that we can identify the lesion and allow for preliminary discussion with the patient. If it is definitely benign we do not even require the patient to come back until their follow-up mammogram in 2–3 months.

To avoid missing the lesions that are calcified, we try to take a little wider biopsy just at the tip of the wire, and if the pathologist or radiologist calls back and says that there is not a lesion there, then we do further biopsies before we close the incision.

Dr. Myers, we have not had any experience in leaving the needle in after it has been localized. That is an interesting technique. We just have not used that. We make an incision adjacent to the wire, follow the wire down near the tip, and then take a piece of breast tissue that surrounds the tip.

Our series similarly showed about a 90% incidence of Stage I lesions which we believe, hopefully, is going to help improve survival.

It is slightly more difficult to do the biopsy under local anesthesia than under general anesthesia. With deep lesions, we have a tendency to add intravenous sedation a little more frequently. I do not even use that much any more. I just infiltrate widely and go slowly, and if it starts to hurt, I give more local anesthesia. This has been well tolerated by the patients as a general rule.

Dr. Peacock, thank you for your comments. I certainly cannot disagree that many of these lesions are also able to be removed without needle localization. Our initial approach to the nonpalpable mammographic abnormalities before starting this study was to do them somewhat as you mentioned. We have not had good experience with blind biopsy or perhaps the correct technique as you described but we found a number of lesions that we either failed to remove or had to rebiopsy to remove an additional portion. Therefore, we were dissatisfied with our results with blind biopsies, and that is why we changed to the needle localization biopsy.

Occasionally during this study, if the patient has a small breast and we could localize it or triangulate it by using the method that you dis-

cussed, we would do the biopsy without needle localization. On patients with large breasts and deep lesions it is difficult to tell how much distortion has been produced by the compression for the mammogram. It is difficult enough to find the deep lesions that have been localized if the wire is not adjacent to the lesion.

Certainly we may be doing too many biopsies with needle localization, and there may be some psychological trauma attendant with that, but we currently believe that needle localization increases our ability to find the lesion using a small incision and we are continuing to use this technique.

Dr. Mattingly, our technique for localization is actually the Kopans needle localization technique. We had tried some of the other techniques and had not found them as useful as this. As the slides show, a bend in the wire at skin level avoids it migrating in any further.

We did not look at the benign tissue too critically since we were more concerned about the cancers in the study. Although if a potentially premalignant lesion was identified pathologically, we discussed it with the patient.

Certainly we are all dependent on the radiologic interpretation as several discussants mentioned, and that can be a problem. We are frequently operating when they say operate. At our institution this has not been a problem because we use the same radiologists year after year, and they leave the final decision on operating to us. Nevertheless, if they say something is suspicious, we recommend that it be biopsied. We may be doing too many benign biopsies, but with our low rate of positive nodes, perhaps we are biopsying the correct amount.

I certainly cannot disagree that in our series perhaps more patients could have had less than a modified radical mastectomy, and perhaps in the future that will occur. The reasons for more patients having modified radical mastectomies is a combination of physician and/or patient preference.

The types of calcifications that we had that were worse, were the clusters of multiple, tiny calcifications, and as I mentioned, 20% of those were malignant.

Many patients had adenomas or mammographically benign calcifications, and if the radiologists believed they were definitely benign, we did not biopsy those lesions.

We did not look too closely at the patient who had residual carcinoma in the mastectomy specimen; therefore, I do not have that answer for you.