A robotic/mechatronic mammotome system for minimally invasive breast cancer surgery

Ranjan Kumar Mishra

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**A ROBOTIC/MECHATRONIC MAMMOTOME SYSTEM
FOR MINIMALLY INVASIVE BREAST CANCER
SURGERY**

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A thesis submitted to the Nanyang Technological University
in fulfillment of the requirement for the degree of
Master of Engineering

2005

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Abstract

Breast cancer is the second most common cancer and the second leading cause of cancer deaths in women in most of the countries including Singapore. The current mainstay of treatment is either partial surgical excision of breast cancer (lumpectomy) or complete removal of breast (mastectomy) in combination with additional therapies although the method of choice for many surgical procedures has shifted from open surgery to minimally invasive alternatives. Since breast cancer is hypothesized to be a potentially systemic disease from its inception, local control is only one part of the total treatment for most patients. Due to advancement and widespread use of mammographic breast screening technique, many patients are now diagnosed with small cancers, even tumor size of less than 1 cm. In view of this, it would be advantageous to develop a minimally invasive surgical (MIS) method for patients diagnosed with early cancer (typically Stage-I & II) that will lead to less morbidity and less cosmetic deformity.

This report describes the details of work done based on the novel objective of developing a minimally invasive surgical alternative for breast cancer treatment. The potentiality of the directional vacuum assisted biopsy (Mammotome breast biopsy device from Johnson & Johnson) enabling multiple tissue excision in a single incision has been considered as the surgical modality in the present research work. A dual arm robotic/mechatronic system having independent manipulation of the ultrasound imaging probe and mammotome biopsy needle has been developed. The surgical planning software developed along with a user-friendly interface (GUI) has features such as system initialization, image acquisition, tumor volume estimation, needle incision and tissue excision process control.

Functionality tests and feasibility trials using animal tissue phantoms were conducted on the laboratory prototype. The error in volume estimation module was found to be less than the volume of a single excised tissue. The positional accuracy of the needle tip of the excision arm is found to be ± 0.5 mm. The oscillatory tissue removal was

found to be more accurate compared to the progressive tissue removal. The objective of removing the entire piece of tissue embedded inside a piece of thick muscle simulating as the tumor have been successfully tested during the feasibility trials. The overall trials conducted on the laboratory prototype show that the proposed methodology can be implemented for animal trials with integration of a complete imaging arm and 3D rendering of tumor volume.

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List of Symbols and Abbreviations

α	Manipulator joint parameter
θ	Manipulator joint angle
ρ	Density of air
μ	Viscosity of air
a	Manipulator link parameter
d	Manipulator joint offset parameter
l	Manipulator link length
P	Air pressure
Re	Reynolds number
F	Force
ABBI	Advanced Breast Biopsy Instrumentation
CIS	Computer Integrated Surgery
DCIS	Ductal Carcinoma-In-Situ
DVAB	Directional Vacuum Assisted Biopsy
FEM	Finite Element Modeling
FNA	Fine Needle Aspiration
GUI	Graphic User Interface
HIFU	High Intensity Focused Ultrasound
IDC	Infiltrating Ductal Carcinoma
ILC	Infiltrating Lobular Carcinoma
LCIS	Lobular Carcinoma-In-Situ
MIS	Minimally Invasive Surgery
MRI	Magnetic Resonance Imaging
TNM	Tumor Node Metastasis
PID	Proportional Integral Derivative

Chapter 1

Introduction

Breast cancer is the second leading cause of cancer-related mortality in most of the countries including Singapore, among women aged between 45–64 years [1, 2]. Increasingly, women are participating in mammographic screening, which results in earlier detection of non-palpable lesions and small breast carcinomas. Once an abnormality or lump is detected, the patient needs to go for biopsy, which involves taking sample tissue from the suspicious area to determine whether it is cancerous and a biopsy is currently the only way to establish an accurate diagnosis. There are couples of breast biopsy options available ranging from an open surgical procedure [3] to minimally invasive techniques [4]. Based on the biopsy results further treatment is decided.

When the results of the diagnosis are benign, the abnormality is non-cancerous and then no further treatment is necessary. If the result shows that the abnormality is cancerous, based on the analysis of the stage of the cancer, a surgical or other treatment procedure is planned accordingly.

Present methods of breast cancer treatment are either radical mastectomy (complete removal of the tissue) or lumpectomy (only the affected part is carefully removed by surgery) [5, 6]. Women with smaller lesions, more specifically ‘carcinoma in situ’ have more choice in terms of breast conservation versus mastectomy with similar survival rates, and are less likely to undergo a mastectomy than those with large tumors. Additionally, women diagnosed with small carcinomas are less likely to have positive auxiliary nodes and adjuvant chemotherapy than women who present with symptomatic disease [7].

1.1 Minimally Invasive Surgery

Minimally Invasive Surgery (MIS) is the practice of performing surgery through small incisions or ports using specialized surgical instruments in order to reduce the size of incisions required to access internal tissues during surgery. During conventional open surgery, the access wound is typically greater than at the operating site. Therefore, the procedures performed using MIS eventually results in reduced bleeding, discomfort, patient recovery time, and cost.

However, MIS is technically more difficult for the surgeons. Therefore, surgeons must be trained extensively, and there still remains an increased risk of surgical complications, which must be traded off against the opportunity for reduced morbidity. MIS is therefore limited to a number of relatively simple procedures such as, cholecystectomy (gall bladder removal) for which there seems to be a consensus within the medical community that it is in fact beneficial. Due to the changing landscape of medical reimbursement in the United States, there is a substantial push from medical payer organizations (insurance companies, health maintenance organizations, and hospitals) to introduce MIS to other procedures in order to reduce hospital stays and thus the costs. As recoveries are typically faster and less painful, more and more patients are asking for these procedures [8].

1.2 Robotics in Surgery

Surgery now uses robotic and image processing systems in order to interactively assist the medical team, both in planning the surgical intervention and in its execution. The objective of this technique is to enhance the quality of surgical procedures by minimizing their side effects (smaller or no incisions, lesser trauma, more precision), thus increasing patient benefit while decreasing the surgical cost. These techniques are being successfully deployed in several areas of surgery such as neurosurgery, orthopedics, microsurgery, cardiovascular and general surgery [9].

Computer Integrated Surgery (CIS) systems typically include preoperative planning, intra-operative registration and pre-surgical planning, robotic assistance and manual

tools for guidance, post operative verification and follow-up. In general, medical robots are used for performing various functions, for instance, assisting in data acquisition (as part of pre-operative surgical planning), surgical execution and control (as in intra operative assistance). Based on their functionality they are categorized into three types such as Passive, Passive-constrained and Active robotic devices. Typically, devices used for surgical simulation, surgical tool navigation or aiming are under the passive category. These devices normally do not have any integrated actuators and enable the comparison between the simulation of the surgery plan and its actual implementation. For guidance and surgical execution, both passive-constrained and active type devices are used. Passive-constrained devices are similar to the passive types but have features capable of physically constraining user action to follow a pre-defined strategy. However, with active systems, which have integrated actuators and redundant sensors some or all subtasks of the strategy are performed autonomously under surgeons supervision. Details on these systems are discussed in section 2.9 of Chapter-2.

Overall robotics technology integrated with the medical imaging systems such as ultrasound can provide localized information of the suspected region or tumor in the body while manipulating the imaging devices and subsequently using this information for accurate positioning of surgical tools for surgical manipulations. Due to these potential advantages, increasingly new applications of medical robots are being explored by researchers worldwide in the field of surgical interventions [10].

1.3 Purpose and Objectives

There are several biopsy devices available capable of performing biopsies minimally invasively. These devices are only for extracting breast tissue samples [11, 12]. Whereas considering the present treatment procedures for breast cancer based on the biopsy results, typically patients undergo either invasive lumpectomy or mastectomy. The surgical excision of breast cancer ("lumpectomy"), in combination with additional therapies, is the current mainstay of treatment. Although conventional surgical lumpectomy is not a major procedure, it is invasive and cosmetically undesirable. It involves open surgery and makes a large scar on the breast tissue.

Alternative surgical modalities such as Focused Ultrasound Surgery (HIFU), Microwave Surgery, and Cryosurgery are being researched for non-invasive and minimally invasive breast cancer treatment. The present research work promises a system for minimally invasive surgery of localized breast cancer. In the proposed approach, Mammotome breast biopsy device manufactured by J&J is adopted as the surgical tool.

Currently Mammotome is a widely accepted and preferred breast biopsy technique [4]. This device uses Directional Vacuum Assisted Biopsy (DVAB) technique for collecting tissue samples from the breast and offers certain advantages over other biopsy devices such as multiple excisions in a single insertion and a pre-defined volume of excised tissue samples. This is done under online ultrasound image as an outpatient basis. Considering the advantage of multiple excisions, surgeons (e.g. Tan Tok Seng Hospital, Singapore) practicing on Mammotome system tried the possibility of complete removal of the tumor by multiple excisions until it disappears from the ultrasound image.

However, it is possible to remove the tumor visible under ultrasound image completely, after multiple excisions using the handheld Mammotome system, but this cannot be justifiable as a surgical treatment for cancer. As there is no information available on the tumor size/volume and its location, it is not possible to quantify how much tumor has been removed and from where? Furthermore, once the tumor has disappeared from the image the location of the tumor is lost, resulting into the uncertainty of removing the margin tissue. This is very essential as even in breast conservation surgery (Lumpectomy) a margin tissue around the tumor is removed to ensure complete removal of cancer tissue. These challenges and problems of adapting Mammotome for surgery eventually formulated the current research.

As part of this research work, a project on studying the feasibility of introducing a MIS procedure by extending the use of omni-directional vacuum assisted surgery was conducted as a Final Year Project at NTU [14]. A pre-calculated volumetric approach was introduced for predictive and precise excision of tissue while being monitored on-line using diagnostic ultrasound. A modified cutter, thus designed, however, has

concerns for spearing through the affected mass, which might result into increased seeding effect in surrounding tissue.

There are however, no systematic studies conducted to alleviate such concerns. Breast being a soft tissue, collapses unpredictably with the removal of tissue in steps, thus making it difficult to find and ascertain the position of serial cuts. In order to extract the affected tissue and a specific boundary surrounding it, it is required to develop a system, so that a calculated amount of tissue volume can be extracted in each step. Further to this, the location of the tissue/lump extraction should also be known.

This report embodies an alternative approach for developing a new minimally invasive surgical system by adopting Directional Vacuum Assisted Biopsy (DVAB) technique for complete removal of the tumor along with a predefined margin tissue. The goal of using the available Mammotome breast biopsy system, integrated with a novel positioning system for accurate and predefined complete removal of breast tumor/lumps has been reported. Collapse of the tissues after each removal, a typical behavior of the soft tissue has been taken in to consideration while developing the systematic method of tissue removal.

The objective of this research is to develop a minimally invasive surgical system using the existing Mammotome, directional vacuum assisted biopsy system. In addition, on-line monitoring of the surgery helps the surgeon for on the spot intervention and alteration in the surgical planning for case-to-case basis.

The objectives of this project are as listed below

1. The development of a mechatronic manipulation system for ultrasonic diagnostic imaging probe and DVAB probe,
2. Pre-surgical planning system including target region imaging, user selection of points and target volume computation,
3. Surgical control system for real-time imaging, DVAB probe localization, real-time surgery controls.

1.4 Scope

The scope of the research work accomplishing the objective of developing a minimally invasive surgical system for breast cancer is explained below. The details of the work includes:

- Development of robotic/mechatronic manipulation system for imaging probe for registration, scanning and image acquisition of the tumor,
- Development of a robotic manipulation system for the DVAB probe for localization, incision, and excision of tumor,
- Surgical planning including:
 - Target volume computation from user/surgeon input as delineated in a series of ultrasound images,
 - Incision point determination (surgeon/user guided manually),
 - Real-time surgical controls.
- Formulating and conducting laboratory trials on phantoms and tissue specimens for
 - Functionality and Feasibility test.

The proposed system is intended for human patient, however trials of the system were restricted to in-vitro (supermarket meat, not the actual targeted tissue) as safety, sterilization and adaptability issues are yet to be solved. The real-time surgical control is also intended to include the image acquisition, axis control and over all excision control. The successful implementation of the procedure and the system will largely rely on further extensive clinical trials.

1.5 Overview of the Dissertation

The thesis reports on the development of a minimally invasive surgical alternative for breast cancer treatment using a directional vacuum assisted biopsy tool available commercially as Mammotome. The proposed methodology and the scope of the project involving development of a mechatronic manipulation system for ultrasonic

diagnostic imaging probe and Mammotome probe, a pre-surgical planning system and a real-time surgical control system are described in details.

Overall, the dissertation is organized as follows.

Chapter 2 reviews background literature on breast anatomy and breast cancer, minimally invasive surgery, robotic surgery and its current state. A review on cancer types, staging, screening and current treatments available, and the various breast biopsy options, in particular the vacuum assisted biopsy device developed by Johnson & Johnson is also included. Chapter 3 describes the DVAB as the MIS. It outlines the objectives, constraints, and focuses on the tumor volume calculation and needle localization. Chapter 4 outlines the constraints and describes the design of the robotic system, breast-immobilizing device, and imaging system for the minimally invasive surgery. It also includes the method of tissue extraction adopting the DVAB technique, localization and registration of the tumor using ultrasonic diagnostic system, tumor volume calculation. In Chapter 4, which describes the system, layout and proposed clinical set-up, includes details of surgical planning, and detailed process description. The prototype development is also described along with 3-D models of the manipulation system. Chapter 5 describes the various feasibility tests followed by the functionality trials conducted on the prototype system during the laboratory trial phase. The results of these tests and trials are reported and discussed in this chapter. Finally, Chapter 6 summarizes the work done and describes the further works to be done including the future enhancements and research.

Chapter 2

Literature Review

2.1 Background

This chapter covers the findings of the background study done on areas as identified based on the novel objective of the proposed research work covering details on breast cancer and state of robotics in surgery. Initially study on the breast cancer starting from the overviews of the breast anatomy followed by the breast cancer screening, cancer diagnosis, various imaging methods, breast biopsy options and available cancer treatments are described in details. Since the proposed work is to extend the existing directional vacuum assisted biopsy (DVAB) for complete removal of the tumor, a detailed report on the Mammotome breast biopsy system has been included. Emphasis has been given on the findings related to the breast cancer staging, corresponding tumor size, related risk factor and respective treatments. Comparative studies have been done on the two major surgical procedures Lumpectomy and Mastectomy and are reported. However, findings related to the breast cancer statistics and its facts are attached separately in Appendix-1. As the present research work is dealing with needle intervention of soft tissue a detailed study has been done on the its physical properties and are reported in this chapter and a scheme for modeling the breast tissue using Finite Element Method (FEM) based on reported work by various researchers is attached as appendix-2. Finally, the review done on robotics/mechatronics in surgery has been included along with detail descriptions on typical procedures involved in robotic surgery and issues related to robotics in surgery are described. Studies have been done on the popular commercially available surgical robots and brief descriptions on some systems are also included in this chapter.

2.1.1 Anatomy of the Breast

The female breast as shown in Fig-1 is composed of 15-20 sections, called lobes, [11] with each lobe ending in many smaller lobules. These lobules further end in dozens of tiny bulbs, which produce milk during lactation. The lobes are shown in the picture as clusters of smaller yellow circles, which represent the smaller lobules. The three components, lobes, lobules, and bulbs, are all linked together by thin tubes called ducts that are shown as small brown tubes running throughout the breast. All the small ducts eventually come together to form larger ducts that empty to the outside through the nipple. The bulbs are too small to be seen on this diagram. All ducts lead to the nipple, which is centered in the areola, a dark area of skin in the middle of the breast. The actual breast is composed of fat and breast tissue. There is no muscle in the breast, but muscle does lie underneath the breast, covering the ribs (Fig-1).

Fig-1: Anatomy of female breast (Adopted from [12])

2.2 Breast Cancer Overview

Cancer is not just one disease, rather a group of diseases. All forms of cancer cause cells in the body to change and grow out of control. Most types of cancer cells form a lump or mass called a tumor. Cells from the tumor can break away and travel to other parts of body where they can continue to grow. This spreading process is called metastasis. When cancer spreads, it is still named after the part of the body where it started [2]. Another word for cancerous is malignant, so a cancerous tumor is referred

to as malignant. But not all tumors are cancer. A tumor that is not cancer is called benign. Benign tumors do not grow and spread the way cancer does. They are usually not a threat to life. A few cancers, such as blood cancers (leukemia), do not form a tumor [15].

As most kinds of cancer are named after the part of the body where the cancer first starts, breast cancer begins in the breast tissue. Inside the breasts are glands that produce and release milk. The breast as shown in Fig-2 is made up of milk producing glands called lobules, ducts, and fatty, connective tissues [12]. Lymph is a clear fluid that contains immune system cells. The fluid is carried in lymph vessels that lead to small, pea-sized collections of tissue called lymph nodes. Most lymphatic vessels of the breast lead to lymph nodes under the arm. They are called auxiliary nodes.

Fig-2: Lobules and ducts of the female breast (Adopted from [12])

If breast cancer cells reach the under arm lymph nodes, they can continue to grow, causing the nodes to swell. When cancer cells have reached these nodes, they are more likely to spread to other organs of the body as well. There are several types of breast tumors. Most are benign: that is they are not cancer. These lumps are often caused by fibrocystic changes. Breast cancer on other hand, involves malignant tumors. Here are some terms that describe the most common types of breast cancer [5, 13]:

- a. **Ductal carcinoma in situ (DCIS):** This is breast cancer at its earliest stage (stage 0). It is confined to the ducts. Nearly 100% of woman with cancer at this stage can be cured. The best way to find DCIS is with a mammogram.

- b. **Infiltrating (invasive) ductal carcinoma (IDC):** This cancer starts in a milk passage or duct, breaks through the wall of duct, and invades the fatty tissue of the breast. From there it can spread to other parts of the body. IDC is the most common type of breast cancer. It accounts for nearly 80% of breast cancer.
- c. **Lobular Carcinoma in situ (LCIS):** A tumor that hasn't spread beyond that area where it began is called in situ. Although not a true cancer, LCIS increases a woman's risk of developing cancer later.
- d. **Infiltrating (invasive) lobular carcinoma (ILC):** This cancer starts in the milk glands (lobules). It can spread to other parts of the body. Between 10-15 % of breast cancers are in this type.

2.3 Breast Screening

In case of regular self-examinations followed by examination by trained personnel at clinics, any suspicious abnormalities in breast are detected then the screening mammogram is conducted. Screening mammography is a low-dose x-ray examination of the breast that is performed on women with no complaints or symptoms of breast cancer (asymptomatic).

The typical mammogram images of both the breasts of a patient are shown in Fig-3 & Fig-4 [6].

Fig-3: Side-to-side mammogram

Fig-4: Top-to-bottom mammogram

The goal of screening mammography is to detect breast cancer when it is still too small to be felt by a physician or the patient. Research has shown that the early detection of small breast cancers by screening mammography greatly improves a woman's chances for successful treatment. For example, if breast cancer is caught and treated while it is still confined to the breast ducts (a type called ductal carcinoma in situ; DCIS), the cure rate is close to 100% [15].

2.4 Breast Cancer Diagnosis

If a breast abnormality is detected with the screening mammography or physical exam, additional breast imaging with diagnostic mammography, ultrasound, or other imaging tests are conducted. Depending on the results of these imaging tests, the patient may be referred for a breast biopsy. Biopsy is the only definitive way to determine whether cancer is present [16].

2.4.1 Diagnostic Mammography

Diagnostic mammography is an x-ray examination of the breasts that is performed in order to evaluate a breast complaint or abnormality detected by physical exam or routine screening mammography. Diagnostic mammography is different from screening mammography in that additional views of the breast are usually taken, as opposed to only two views (Fig-3 & 4) typically taken with screening mammography. The goal of diagnostic mammography is to pinpoint the exact **size and location** of breast abnormality and to image the surrounding tissue and lymph nodes. In many cases, diagnostic mammography shows that the abnormality is highly likely to be benign (non-cancerous). However, if an abnormality seen with diagnostic mammography is suspicious, additional breast imaging (with exams such as ultrasound) or a biopsy is ordered.

2.4.2 Ultrasound Breast Imaging

Breast ultrasound, also known as sonography or ultrasonography, is frequently used to evaluate breast abnormalities that are found with screening or diagnostic mammography or during a physician performed clinical breast exam. Ultrasound allows significant freedom in obtaining images of the breast from almost any

orientation. Ultrasound is excellent at imaging cysts: round, fluid-filled, pockets inside the breast. Additionally, ultrasound can often quickly determine if a suspicious area is in fact a cyst (mostly non-cancerous) or an increased density of solid tissue (dense mass), which may require a biopsy to determine if it is malignant (cancerous) [16].

2.5 Breast Biopsy

If there is any suspicious breast abnormality, a biopsy is carried out. A biopsy is a procedure that removes a tissue sample from the body, to be examined for a precise diagnosis in pathological studies. It is desirable that the procedure be as accurate, non-invasive, and non-traumatic as possible. This process determines if a lesion is benign or malignant. While physical breast exam, mammography, ultrasound, and other breast imaging methods can help detect a breast abnormality, biopsy followed by pathological (microscopic) analysis is the only definitive way to determine if cancer is present. [3]

Table - 1: Biopsy Options

Palpable	Non-palpable
<ul style="list-style-type: none"> • Open excisional biopsy • Fine Needle Aspiration (FNA) • Core-needle biopsy 	<ul style="list-style-type: none"> • Open excisional surgical biopsy with needle localization • Fine Needle Aspiration (FNA) • Stereotactic core-needle biopsy • ABBI (Advanced Breast Biopsy Instrument) • Mammotome (Vacuum-assisted breast biopsy)

Fig 5: Different Biopsy Procedures

There are several methods of breast biopsy (Fig-5) available. The options are based upon whether the lesion is palpable or non-palpable (whether or not felt by human touch). Current Biopsy Options based on palpability are given in Table - 1. The main difference between biopsies, which are performed on palpable and non-palpable lesions, is that image-guidance (mammography, stereotactic or ultrasound) will be necessary for the non-palpable lesion because it cannot be felt or seen externally. The following sections describe each of these procedures. The selection of method of biopsy depends on a number of factors, including how suspicious the abnormality appears; the size, shape, and location of the abnormality; the number of abnormalities present; the patient's medical history; the patient's preference; the training of the radiologist or surgeon who is performing the biopsy; and the breast imaging center or surgical center where the biopsy is performed [13].

2.5.1 Open surgical (excisional or incisional) Biopsy

In the past, surgeons used an open surgical biopsy method to remove samples of lumps and cancerous cells. It requires general anesthesia and is carried out in an operating room. For a non-palpable lesion the surgeon inserts wire needle localization into the abnormal breast to identify the area to be cut out during the biopsy. For palpable lesion the surgeon does not need needle localization since the surgeon can feel the lump that is to be removed.

The patient may be left with a large scar and potential permanent disfigurement of the breast. It is also more costly as it involves pre-surgical tests by the surgeon, the anesthesiologist, the hospital, and the laboratory.

2.5.2 Fine Needle Aspiration (FNA)

A fine hollow needle that is attached to a syringe is used in this procedure. The procedure is performed under local anesthesia and there is no need to make a cut in the breast. The doctor uses ultrasound or mammogram to assist in locating the specimen to be removed [3, 13].

After the needle is placed into the breast in the region of the lesion (abnormality), a vacuum is created and multiple in and out needle motions are performed. Several needle insertions are

usually required to ensure that an adequate tissue sample is taken. FNA does not require stitches and can usually be performed on an outpatient basis. A very small bandage is placed over the area after the procedure. Many patients resume their normal lifestyle and routine the same day of the FNA procedure.

2.5.3 Core needle biopsy

Core-needle biopsy is the removal of the whole mass or core of the lesion using a 14-gauge needle. The needle is placed (Fig 6) next to the lesion and inserted into the breast.

Fig 6: Diagram showing steps of core-needle biopsy

The needle is removed from the breast and a small piece of tissue is removed from the sampling notch. The needle is reinserted into the breast several times in order to extract sufficient amount of tissue for diagnosis.

The procedure can be applied to both palpable and non-palpable lesions using the assistance of either ultrasound or x-ray guided stereo-tactic means. The procedure leaves no big scar and is done on an outpatient basis. It only takes half an hour for the procedure to be completed and the patient can return home on the same day [3].

The advantage of using the core needle biopsy is that it removes a reasonably large amount of tissue. This gives the pathologist more to work with. Scarring is also

minimal. However the major concern in this procedure is the displacement of tumor cells into normal tissues during needle insertion and extraction [13].

2.5.4 Large core surgical biopsy- ABBI

ABBI, which is a brand name that stands for Advanced Breast Biopsy Instrumentation is a large core breast biopsy surgical technique that involves removing an entire intact breast lesion (abnormality) under image guidance [11]. During the ABBI procedure, local anesthetic is injected while the breast is maintained in compression. A wire is then guided into the breast lesion using stereotactic mammography. Next, a narrow tube with a cutting device (a cannula, also called the large core needle) is inserted into the breast, using the wire as a guide. The core specimen of the breast tissue is then removed with a looped wire and taken to the pathology laboratory for diagnosis.

Additional mammograms of the breast after the removed specimen are performed to confirm the biopsy. Due to the size of the large biopsy section, stitches are usually required. Large core biopsy (ABBI) takes approximately one hour, often followed by several hours of recovery.

Fig 7: The ABBI procedure on a stereotactic table

The patient lies face down on a specially equipped table with a window opening at the chest area (Fig 7). Using stereotactic techniques, the surgeon pinpoints the lesion with the aid of a computer, which calculates the precise location of the lesion.

2.5.5 Mammotome - A Directional Vacuum Assisted Biopsy System

Since the objective of the present research is to adopt the existing Mammotome breast biopsy probe as the surgical tool a detailed study has been done on it. The vacuum-assisted breast biopsy is a percutaneous ("through the skin") procedure that relies on stereotactic mammography or ultrasound imaging. Stereotactic mammography involves computers to pinpoint the exact location of a breast mass based on mammograms (x-rays) taken from two different angles. The computer coordinates help the physician to guide the needle to the correct area in the breast. With ultrasound, the radiologist or surgeon will watch the needle on the ultrasound monitor to help guide it to the area of concern. The patient is normally positioned in the upright or prone (face down) position for a vacuum-assisted biopsy [3,4]. Vacuum-assisted biopsy is a minimally invasive procedure that allows for the removal of multiple tissue samples through a single incision in the breast. It can be completed in an hour and local anesthesia is used. Patient positioning depends on the imaging method that is used. If the procedure uses ultrasound imaging, a doctor will obtain images of the breast tissue while the patient lies on her back. In stereotactic procedures, patients lie facedown on a special table. The woman's breast protrudes through a hole in the table's surface, where it is lightly compressed and immobilized while a computer produces detailed images of the abnormality.

Fig-8: Schematic of the Mammotome Biopsy Needle

Once the area to be biopsied has been located and mapped, the Mammotome probe is inserted through a small ~6 mm incision in the breast (Fig-8). When the probe is positioned at the area of concern, it gently vacuums, cuts and removes tissue samples for examination (Fig-9).

Fig 9: Number of steps involved in Mammatome biopsy procedure

The samples are passed through the hollow chamber of the probe into a collection chamber. Because the Mammotome probe is directional, multiple specimens can be collected without removing and reinserting the device. Presently, to monitor the breast health following a breast biopsy using the Mammotome system, the doctor places a small stainless steel MicroMark II (Fig-10) tissue marker to identify the biopsy site. While this tiny marker is undetectable to the patient, it enables a physician to keep track of an abnormality in future mammograms. The Mammotome probe Fig-11 is removed after the samples have been collected, and the incision is closed with a small tape.

Fig 10: MicroMark II marker

Fig 11: Mammotome probe by Johnson & Johnson

The present mammotome biopsy device is a hand-held type (Fig-12) comprising a probe that is disposed once the procedure is completed. There are three sizes of mammotome probes based on the diameter of cutting tube available. The detail mechanical dimensions of these three sizes of Mammotome probes are tabulated and presented in Appendix-3.

Fig 12: Mammotome Hand-Held Biopsy System

2.6 Breast Cancer Staging

The breast cancer staging, also known as tumor staging, predicts outcome, planning therapy and comparing results among institutions. The staging is done based on TNM system (tumor size, status of lymph nodes, and presence of distant metastases) as in Table - 2. There is a distinctive correlation among increasing tumor size, probability of axillary metastasis, and decrease in long-term survival [17]. The details of the TNM system as adapted from “American Cancer Society” are given below [18].

Table-2: Staging of Breast Cancer Adapted from (AJCC)*

Stage	Tumor (T)	Nodes (N)	Metastasis (M)	Five Year Survival Rate
Stage 0	TIS	N/A	M0	100%
Stage I	T1	N0	M0	98%
Stage II	T0	N1	M0	88%
	T1	N1	M0	
	T2	N0, N1	M0	
Stage IIIA	T0	N2	M0	56%
	T1	N2	M0	
	T2	N2	M0	
	T3	N0, N1, N2	M0	
Stage IIIB	Any T	N3	M0	49%
	T4	Any N	M0	
Stage IV	Any T	Any N	M1	16%

* Note: American Joint Committee on Cancer 4th Edition 1997

- **Tumor Size or Characteristics:**

TX = Primary tumor cannot be assessed

TIS = Carcinoma in-situ

T0 = No evidence of primary tumor

T1 = Tumor less than 2 cm in greatest dimension

T2 = Tumor larger than 2 cm in size but less than 5cm.

T3 = Tumor larger than 5 cm in size

T4 = Tumor of any size extending to the chest wall or skin

- **Lymph Nodes:**

N0 = no metastasis to auxiliary nodes

N1 = Metastasis to moveable auxiliary nodes

N2 = Metastasis to fixed or matted auxiliary nodes

N3 = Metastasis to supraclavicular, infraclavicular or internal mammary nodes

- **Metastasis:**

M0 = no distant metastasis

M1 = distant metastasis

2.7 Breast Cancer Treatment

Breast cancer as a tumor can have serious consequences [6] but at the same time it is also one of the most treatable cancers. However, it has the capacity to grow indefinitely and to spread into and affect other parts of the body thus characterized as malignant or metastasize and cause death. Some forms of breast cancer can be cured at a rate above 99% [13].

Based on the study of the breast cancer and its classifications, an overall block diagram is shown in Fig-13 for various stages involved in breast cancer management [6, 12]. This is the initial phase of treatment plan, which is the early detection of breast cancer through Breast self-examinations, Clinical Breast Examinations and Screening Mammography [5, 13, 16]. These are essential steps in helping to detect breast cancer at an early stage when there are greatest chances of complete cure.

Different types of treatment are available for patients with breast cancer and it depends on a variety of factors such as the size of the breast tumor, location of the tumor, the stage of the cancer and results of laboratory tests (such as hormone receptor tests). It is found that for every stage of breast cancer, there are three broad types of treatment: *Local/regional treatment* is directed to the breast and to lymph nodes around the breast. In the case of metastatic disease, local treatment is considered to specific areas of metastasis (places where cancer may have spread, such as bones or lungs). *Systemic treatment* is directed to the whole body or “system”. *Alternative and Holistic Therapies* are directed to the whole person, including mind and spirit as well as body [6, 17].

Fig 13: Various Phases of Breast Cancer Treatment

Some treatments are standard (the currently used treatment), and some are being tested in clinical trials. However, surgery followed by various adjuvant therapies as described in the following sections is found to be the standard options available.

2.7.1 Surgery

Most patients with breast cancer have surgery to remove the cancer. Some of the lymph nodes under the arm are usually taken out and looked at under a microscope to see if they contain cancer cells. Breast-conservation surgery, an operation to remove the cancer but not the breast itself, includes the following [21]:

Lumpectomy

The procedures used to cure cancer while avoiding removal of the entire breast are called Breast Conservation Operations [9, 21]. The classic breast conservation operation is the lumpectomy. This refers to the removal of the tumor in the breast along with a rim of normal breast tissue to achieve a clear margin. Most doctors also take out some of the lymph nodes under the arm. Lumpectomy may also be called wide excision biopsy, breast conserving therapy or quadrantectomy (the latter term is used when up to one fourth of the breast is removed). The procedure is often performed on small or localized breast cancers and can be an attractive surgical treatment option for breast cancer Stage-I and Stage-II because it allows women conserve most of their breast after surgery. Lumpectomy is usually followed by radiation therapy to the breast.

In Fig-14, lumpectomy is shown by removing the tumor and margin of surrounding normal breast tissue. Some of the axillary (underarm) lymph nodes may also be removed. A separate incision is required to include a sampling or removal of the axillary (underarm) lymph nodes. In this part of the surgery, which may be a sentinel node biopsy, an axillary lymph node sampling, or an axillary lymph node dissection, is performed to determine whether the cancer has begun to spread out of the breast.

Mastectomy

This procedure involves the removal of the entire breast and the lymph nodes under the arm through one large incision across the chest [6, 21]. This incision typically measures

15-20 cm and is made in a transverse fashion unless the tumor is located high in the breast. The chest wall muscles are not removed and left intact. The procedure can sometimes be performed through a minimal incision 5-8 cm centered on the nipple-aerolar complex, the so-called skin-sparing mastectomy. The advantage of this technique is that more skin is preserved for possible later reconstruction [21].

Fig-14: Lumpectomy procedure

A modified radical mastectomy has the provision of reconstruction of the breast mound which usually accomplished with one of two methods, either a breast implant or the process of moving tissue from other part of the body to the chest wall to reconstruct the breast mound. Fig-15 shows the typical mastectomy procedure. General anesthesia is administered during mastectomy, and an ECG monitor (electrocardiogram) is connected to the patient to monitor heart rates. Blood pressure and vital signs are also monitored throughout the surgery.

Fig 15: Mastectomy procedure

Several types of mastectomy procedures are available such as:

- **Partial or segmental mastectomy:** Removal of the cancer, some of the breast tissue around the tumor, and the lining over the chest muscles below the tumor. Some of the lymph nodes under the arm are usually taken out. In most cases, partial mastectomy is followed by radiation therapy.
- **Total or simple mastectomy:** Removal of the whole breast. Sometimes lymph nodes under the arm are also taken out.
- **Modified radical mastectomy:** Removal of the breast, many of the lymph nodes under the arm, the lining over the chest muscles, and sometimes, part of the chest wall muscles.
- **Radical mastectomy:** Removal of the breast, chest muscles, and all of the lymph nodes under the arm. This surgery is used only when the tumor has spread to the chest muscles.

Even if the doctor removes all of the cancer that can be seen at the time of surgery, the patient may be given radiation therapy, chemotherapy, or hormone therapy after surgery to kill any cancer cells that may be left. Table-3 shows the results of both lumpectomy and mastectomy conducted in USA [20].

Table-3: Lumpectomy vs Mastectomy

	Radical mastectomy	Lumpectomy	Lumpectomy plus irradiation
Number	589	634	628
Outcome [number, (%)]			
Local recurrence	60 (10)	58 (8.8)	17 (2.7)
Contralateral breast cancer	50 (8.5)	56 (8.8)	59 (9.4)
Distant metastases	132 (22)	158 (25)	163 (26)
Other primary cancers	43 (7.3)	32 (5.0)	49 (7.8)
All cause death	371 (63)	408 (64)	391 (62)

2.7.2 Adjuvant Therapies

Treatment given after or prior to surgery to increase the chances of a cure is called *adjuvant therapy* [18, 21]. The various available adjuvant therapies are:

- **Radiation therapy**

Radiation therapy is the use of x-rays or other types of radiation to kill cancer cells and to shrink tumors. Radiation therapy may use external radiation (using a machine outside the body) or internal radiation. Internal radiation involves putting radioisotopes (materials that produce radiation) through thin plastic tubes into the area where cancer cells are found. Radiation may be used after surgery in addition to chemotherapy, and hormone therapy. Breast cancer is treated with external radiation [6].

- **Chemotherapy**

Chemotherapy is the use of drugs to kill cancer cells. Chemotherapy may be taken by mouth, or it may be put into the body by inserting a needle into a vein or muscle. Either type of chemotherapy is called systemic treatment because the drugs enter the bloodstream, travel through the body, and can kill cancer cells throughout the body [6].

- **Hormone therapy**

Hormones are chemicals produced by glands in the body and are circulated in the bloodstream. Estrogen and progesterone are hormones that affect the way some cancers grow. If tests show that the cancer cells have estrogen and progesterone receptors (molecules found in some cancer cells to which estrogen and progesterone will attach), hormone therapy is used to block the way these hormones help the cancer to grow. This may be done by using drugs that block the way hormones work or by surgically removing organs that make hormones, such as the ovaries.

2.7.3 Treatment Options by Stage

The treatment of ductal carcinoma in situ (DCIS) normally includes breast-conserving surgery with or without radiation therapy or hormone therapy and sometimes-total mastectomy, with or without hormone therapy. In case of Lobular Carcinoma *In Situ*

(LCIS) treatment includes biopsy to diagnose the LCIS followed by regular examinations and regular mammograms to find any changes as early as possible. This observation is to reduce the risk of developing breast cancer [11].

1. Stage I, Stage II, and Stage IIIA Breast Cancer

Treatment of stage I, stage II, and stage IIIA breast cancer that is confined to the breast and lymph nodes under the arm may include the following [18, 19]:

- Breast-conserving surgery or lumpectomy.
- Modified radical mastectomy, with or without breast reconstruction surgery.
- A clinical trial evaluating sentinel lymph node biopsy (removal of the first lymph node(s) to which cancer is likely to spread from the tumor) followed by surgery.

Adjuvant therapy includes:

- Radiation therapy after a modified radical mastectomy to the lymph nodes near the breast and to the chest wall,
- Systemic chemotherapy with or without hormone therapy,
- Hormone therapy.

2. Stage IIIB, Stage IV, and Metastatic Breast Cancer

Treatment of stage IIIB breast cancer is carried out by [18, 19]

- Systemic chemotherapy,
- Systemic chemotherapy followed by surgery (lumpectomy or total mastectomy), with lymph node removal followed by radiation therapy.

Treatment of stage IV or metastatic breast cancer may include the following:

- Hormone therapy and/or chemotherapy with or without trastuzumab,
- Radiation therapy and/or surgery for relief of pain and other symptoms.

2.8 Physical Properties of Breast Tissue

As discussed in the previous section, and breast being a soft tissue, the issue of registration of the breast with respect to the robotic system and imaging system is a challenging topic. In order to achieve accurate and correct surgical intervention using robotic technology a study on the mechanical properties of the breast tissue is essential. Research on soft tissue related to predictable tissue deformation is an active issue and various research groups are involved to model the soft tissue to study the mechanical properties [22, 23, 24]. There are two difficulties involving breast surgery such as fixation of the breast and prediction of tissue behavior during needle intervention. Most popular way of fixing the breast is by compressing it between two plates as used in the stereotactic biopsy (Fig-7 shows the fixing of breast while the patient is laying face down). Recently SIEMENS has introduced the latest mammogram system where the patient either can seat up right or lay down

Overall, the major concerns due to soft tissue related to needle based procedures are, inaccuracy in tumor volume estimation due to tissue deformation, movement of tumor inside the tissue while piercing the needle, uncontrolled collapsing of tissue after sampling. As noted in [24] real-time guidance during needle breast procedures is still not possible even with high-field strength MR imaging. Physician can calculate the approximate location and extent of a tumor in the compressed patient breast before inserting the needle, and tissue specimen removed at biopsy may not actually belong to the lesion of interest due to the movement of the lesion inside. This is due to the movement of tumor inside the tissue. For this it is required to know the properties of the breast tissue to predict the movement with respect to the insertion force applied. Similarly after removal of each sample, the tissue collapses which is unpredictable.

All these lead to the requirement of a breast model. Considerable efforts have been made to create a deformable model of the human breast. Studies have been done to determine the mechanical properties of tissue in the breast.

Soft Tissue Modeling

There are many approaches available for soft tissue modeling; most are based on surface models typically for breast tissue. The geometry of the breast can be constructed using high-fidelity image data such as MRI [25] and the mechanical properties can be modeled using a non-linear material model. Breast tissue has complex tissue properties as it consists of layers of different tissues interlaced with ligaments and the superficial layer or fascias. The fascia is separated from the skin by 0.5 to 2.5 cm of subcutaneous fat where the diameter of the ducts varies from 2 to 4.5 mm. In order to develop a model for deformation of the breast, geometric description of breast, a mathematical model of the elastic deformation (typically a finite element model, FEM), and a solution algorithm are required. However, for a realistic model of a breast the finite element model becomes very complex making the model not useful clinically [25]. This resulted in the requirement of developing a reasonably simpler and application specific finite element model of breast by balancing the accuracy of deformation against the requirement and speed for computation. The two major stages in modeling the breast are *3D Mesh Creation* and *Integrating Material Properties*. Because of high variability of breast shapes and its deformations during imaging and incision, breast models are built following the breast contour [25]. Using these series of breast contours either manually or automatically demarcated on each 2D image using standard graphics programs 3D wire mesh is generated. These models containing the definitions of volume elements, boundary conditions and different material properties are exported to standard FEM software such as ABAQUS or NASTRAN. Studies conducted by researchers [22, 24] show that very complex models would be needed to model breast realistically and thus their complexity and the required computational time would keep them from being useful clinically. Finite element models of breast have actually been implemented with the commercial software packages; most have been used in phantom studies [22, 24].

A generalized scheme for building a realistic model based on Finite Element Method (FEM) has been included in Appendix-2. However, the proposed methodology uses a simplistic approach to tackle these issues, which will be discussed in details in the following chapters.

2.9 Robotics/Mechatronics in Surgery

While industrial robots have been readily available for nearly 40 years, medical robots designed to support surgeons have existed for only a decade and a half. The development of robotic assistance for surgery has been a slow process with safety being a primary consideration. However, medical robots now exist which offer intelligent assistance with routine tasks; highly accurate minimal-access surgical interventions; reductions in radiation exposure; and improvements in training. Recent advances in control, intelligent manipulation and computer technology, collectively known as Mechatronics, currently exploited to provide higher positioning and accuracy in surgery. The tools developed based on these techniques are fully automatic and operated by surgeons while providing additional sensing through electronics sensors, experience in the form of a prior knowledge, and skills to interpret the data produced by the process.

An increasing number of robot and robotic devices are in clinical use [26]. Applications are as diverse as neurosurgery, urology, orthopaedics, E.N.T., general surgery and ophthalmology. Initially medical robots were modified industrial robots, but due to incompatibilities modern medical robots are specially developed user-friendly, task-specific machines, which perform the designated procedure with high safety consideration such as limited speed and force, and restricted range of motion within the safe area. Medical robots are designed for human control rather than autonomous as instead of replacing surgeons, they provide assistance. Self-monitoring of its own performance and redundant critical components provides multiple levels of failure protection to surgical robots. One critical feature of success for a medical robot is its user friendliness [27].

Robotic Surgery Procedure

The term Robotic surgery is the process of carrying out a surgical procedure by a robot under the control of a computer system [10]. The planning of such a process is performed by or with close co-operation of a surgeon. The surgeon observes the implementation of the plan, however mainly the robot accomplish the execution of the plan. The advantages gained through automation using robots are numerous such as:

precisely controlled and constrained motion through programming, fast and accurate trajectory planning and follow up, high accuracy with predictable velocities and accelerations with no overshoot and overall highly repeatable and reliable. In addition, the planning of the surgical procedure and the imaging requirements are necessary steps of any proposed surgery and, thus, the time saved due to quicker performing of the surgical task and in the reduced recuperation time will outweigh any increase in the pre-operative stage.

Considering the currently available surgical robots, they are categorized in two groups such as: *tele-manipulators* and *image guided robots* [9]. Tele-manipulators are master/slave systems in which the surgeon operates a master control that causes a slave robotic arm to respond. These devices simply respond to instructions from a desk-based simulator. Image guided robots take advantage of the medical imaging enable a surgeon to specify a path to choose target point or volume of tissue. Since our proposed research work falls into the category of image-guided surgery a details on the issues related to this is described as follows.

Image Guided Robotic Surgery

The decision of executing a surgery by the robot is made by the surgeon by planning from a medical image during the pre-operative planning stage, and the corresponding instructions are then downloaded to the robot, thus making the surgery an Image-guided one. However, the different issues involved in the robotic fulfillment of an operation and are outlined here.

- ***Planning***

Surgical planning is defined as a process consisting of three main parts, namely imaging the patient, creating a satisfactory three-dimensional (3D) model of the imaging data, and planning/rehearsing the operation. Two-dimensional images typically from CT, MRI and ultrasound are converted into a 3D model of the patient or of the area of interest based on the imaging modality to get the spatial information such as volume, position in 3 dimensional spaces. The conversion into a three dimensional model are typically done through computer graphics. However, the processing requirements of these modeling systems are very large. As the next step, the plan is

developed which involves, the determinations of the movements and forces of the robot and the path planning of the robot.

- ***Registration***

The registration of the robot and the patient is the correlation of the robot's data about the patient with the actual patient, in terms of positioning. A critical aspect of image-guided surgery is the need for accurate registration of the robot, the patient and the image, so that all three are brought into the same frame of reference. The registration process consists of two main parts: fixation of the patient and the robot, and intra-surgical registration. In traditional surgery, fixation of the patient, that is fixing the patient in position on the operating table, is achieved through strapping and clamping of the areas pertinent to the surgery. It works best in orthopedics and cranial surgery, where bony landmarks can be used to check position. For example, the patient's head is fixed in position during neuro-surgery through the application of a head-fixation device known as a 'stereotactic unit'. In case of soft tissue surgery, this becomes more challenging to correct for movements of the target due to deformations. Considering breast cancer surgery, which falls into the soft tissue category, a preliminary literature survey on the mechanical properties of the breast tissue has been done and is included in Appendix-2.

Fixation of the robot is achieved through analogous methods. The task of fixation plays a vital role in a successful robotic operation. Robots perform their actions namely based on re-defined (i.e. programmed) paths.

- ***Plan Execution***

This phase is the actual implementation of the surgery. Once the robotic procedure is initiated, sensors collect real-time data from the operating site and pass this to a display, via which the surgeon observes the operation. The patient is sensed by sensors positioned appropriately with respect to the area of interest. Typical sensors in robotic surgery use infrared transmitters on the robot's joints, which are detected by cameras in the operating theatre. Typically, emergency stop or redo type controls are provide to the surgeon overseeing the automated surgery for immediate intervention in case of any unwanted or incorrect instances.

- **Evaluation**

Similar to traditional surgery tasks, evaluation is an integral part of robotic surgical operation. Due to the automatic nature of the operation, it is not possible always for the surgeon to check everything before proceeding with the subsequent steps. If it is found that something is not completely satisfactory, then the surgeon has the option to either repeat the whole operation or to carry out a manual procedure to complete the work.

Currently, as defined in section 1.2 of Chapter-1, robotic systems used for medical surgery are also categorized based on their functionality [9]. A passive type of system enables the comparison between simulation of surgery plan and its actual implementation. Usually these systems are utilized with intra-operative sensors (3D localizers), which allow the surgeon to control his actions with respect to the available information, including pre-operative data. Some passive systems are also called *Navigators*, which enables the surgeon to follow the location of the tip of a tool on pre-operative images. The tool can also be displayed using a 3D rendering technique. In contrast to navigators, there are *Aiming Systems*, which enables the user to do the surgical plan and strategy and then to reproduce the plan. Aiming systems are necessary when the choice of a strategy is too long or too difficult to be performed directly on raw data. Passive robotic devices are also used in some cases for surgical simulations during intra-operative phase [60].

Both passive-constraint and active robots are used for surgical execution. In some cases, passive constrained robotic systems also known as semi-active systems capable of physically constraining the manipulation are used as surgical assistive devices. Complete autonomous robots under the active medical robots categories are used for automatic manipulation of the surgical tools. Such systems begin to exist and are very popular such as da Vinci minimally invasive surgical robots from *Intuitive surgical, Inc.*, *ROBODOC* orthopedic surgical robot from *Integrated Surgical Systems, Inc.*, and *Cyberknife* whole body robotic radiation surgery from Accuracy Inc [43].

Chapter 3

The Proposed Methodology and Design Formulation

This chapter describes the directional vacuum assisted biopsy procedure in further details (in continuation to Chapter-2, section-2.5.5). The need for choosing DVAB as a MIS procedure for breast cancer treatment is due to its significance and potential to be adopted as Minimally Invasive Surgery (MIS). A method to determine the tumor volume and its location using off-line/online ultrasound image, a sequential tissue removal procedure and the overall system are discussed. The design specific constraints related to positioning and manipulation of the DVAB tool are described.

3.1 Directional Vacuum Assisted Biopsy (DVAB)

At present, the commercial system for directional vacuum assisted tissue removal is limited to breast biopsy procedure, including microcalcifications, masses, speculated masses, asymmetric, multifocal disease and diffuse tissue. As the name suggests, vacuum is directed to suck the tissue near the suction port of the cutting mechanism. The sucked tissue is then excised and retrieved by a rotary cutting tube. Mammotome system is a handheld breast biopsy device. A closer look of the Mammatome probe and description of its functions is as follows.

3.1.1 Needle System

The Mammotome biopsy needle is manipulated under image guidance (such as ultrasound and X-ray) and can be mounted or hand held. The Mammatome needle components include an outer trocar cannula, a sliding inner hollow coaxial cutter and knockout shaft. The needle (Fig-16), which incorporates a distal sampling notch and proximal tissue retrieval chamber, has a thumbwheel, which is used to manually turn and orientate the sample notch [28]. A tissue cassette body slides into the retrieval

chamber to receive the biopsy specimens. Additionally, an aspiration conduit is integrated into the probe, which allows connection to an aspiration source.

Fig-16: Schematic Diagram of the DVAB System (as adopted from the commercial J&J device)

3.1.2 Imaging System

The conventional Mammotome biopsy procedure is performed under image guidance either using x-ray imaging or ultrasound imaging. X-ray guided biopsy or stereotactic biopsy uses multiple coordinates to precisely determine the location of a tumor or nodule to obtain a tissue sample. In this case, the patient lies facedown, [3, 11] with her breast projecting through a hole in the table (Fig-17).

Fig-17: Stereotactic Biopsy

Unlike the conventional X-ray, in stereotactic biopsy, the image is displayed on the computer and the lesion can be located precisely in three dimensions by calculating its

apparent change in position on angled x-ray images [13]. The first x-ray locates the abnormality in the breast, after which two stereo views are obtained; each angled 15 degrees to either side of the initial image. The physician then marks the lesion electronically on the stereo images. The computer calculates how much the lesion's position has changed on each of the stereo views, and in this way is able to determine its exact site in three-dimensional space.

Ultrasound (US) imaging [13], also known as ultrasound scanning or sonography, is a method of obtaining images from inside the human body using high frequency sound waves. The sound waves' echoes are recorded and displayed as a real-time, visual image. No ionizing radiation is involved in ultrasound imaging like X-ray. In case of ultrasound imaging the patient lies on her back and the doctor scans the breast through the handheld ultrasound probe (typically 7-15 MHz transducer is used for breast scanning) and gets the 2D image of the breast [13]. Either pulsed or continuous sound waves are directed at the area of interest using a hand-held device called a transducer. It also receives echoes of the sound waves whose pattern reflects the outlines of the mass. There are certain advantages of ultrasound imaging for which most of the biopsies are ultrasonic guided. In the following section, this procedure will be explained in further details.

3.1.3 Mammotome Biopsy Procedure

Breast biopsy using the Mammotome system is conducted under local anesthesia on out-patient basis. The patient position is supine and the surgeon performs the biopsy by manipulating the Mammotome needle in one hand and holding the ultrasonic diagnostic probe in other hand. The detailed steps (as explained in the website of this commercial device [3,4]) are as follows:

1. The precutaneous site is incised or punctured with a scalpel before introduction of the probe and then advanced through the lesion visible under the image,
2. Proximal to the piercing tip of the probe is an aperture through which tissue is drawn into a sampling chamber by means of vacuum line located underneath the chamber,

-
3. Once tissue has been pulled into the sampling chamber, the motorized rotating hollow coaxial cutter advances through the sampling chamber. Tissue in the sampling chamber is cut away from the breast and is stored in the lumen of the cutter,
 4. Once the cutter has traversed the length of the sampling chamber, it is pulled back to the tissue retrieval chamber,
 5. By rotating the aperture, tissue can be excised by repeating the steps 3 & 4 and a required number of samples can be collected.

Generally, a sample weighing 35–45 mg (using 14-gauge probe), 90–100 mg (using 11-gauge probe) and can be retrieved. Typically, about 1 g of tissue (27 samples if using the 14-gauge probe; 10 samples if using the 11-gauge probe) is sufficient for diagnosis of benign breast disease, atypical ductal hyperplasia, atypical lobular hyperplasia, ductal carcinoma in-situ or invasive breast carcinoma [28]. Additionally, the probe can be used to place a radio-opaque clip for surgical, radiological and pathological localization. In the following section, the proposed minimally invasive surgical system based upon DVAB is described.

3.2 DVAB as a Minimally Invasive Surgery

It is evinced that through the Mammotome system a multiple number of samples can be excised in a single incision. This can lead to complete removal of tumor visible under ultrasound image [29, 30, 31]. During the attempts to remove the complete tumor as reported visible in ultrasound image using the handheld Mammotome biopsy (DVAB) system based on the visual feedback, the surgeon repeats the steps 3 & 4 (of section 3.1.3) by rotating the aperture until the tumor disappears completely from the online 2D ultrasound image. Results during the attempts show that complete removal of non-palpable and palpable breast abnormalities and localized lumps visible in ultrasound image is possible with the manual DVAB procedure. However, as mentioned earlier (section 3.1.3) this procedure is still not defined as a surgical treatment of the breast cancer. The limitations of this procedure as a surgical treatment are analyzed and are listed as follows.

-
1. It is possible to position the cutting window of the needle just below the tumor visible under ultrasound image but the actual size and volume of the tumor is not known in 2-D images,
 2. The objective is to remove the tumor visible under the ultrasound but there were no clear guidelines to cross check whether the tumor is completely removed or not,
 3. Once the visible tumor is removed in multiple biopsies by rotating the cutter window under ultrasound the location is completely lost,
 4. As the location of the tumor after removal is lost, the removal of the margin tissue is also not accurate.

3.3 Proposed Methodology

In this research, as described in Chapter-1, (section-1.3) a MIS system, based upon the DVAB system is devised. This system would use multiple predefined excisions, thus effectively making an outpatient ambulatory MIS procedure, performed under local anesthesia. The limitations and constraints of adopting the DVAB technique as a surgical modality can be summarized into three main classifications such as 1) Determination of the tumor size/volume, 2) DVAB probe localization and 3) A method for accurate removal of tissue. Following sections describe these preoperative steps in details.

3.3.1 Tumor Size & volume estimation

Instead of creating a mental reconstruction of the three dimensional anatomical structure of the tumor/lump based on the skill, experience and knowledge of the surgeon, a method needs to be adopted to get the exact location of the tumor and its volumetric information. The system is required to provide localization information of the tumor by reconstructing 3D structure from 2D images. This 3D reconstruction is still an active research topic [32, 33, 34]. There are couple of 3D ultrasound diagnostic machines available enabling the surgeon to determine the tumor size/volume/location, such as *GE Voluson 730 Pro*, *SIEMENS Sonoline Sienna*, and *Philips SONOS 7500*.

Nevertheless, in the proposed system a simplified approach has been adopted considering the easy availability, portability and cost effectiveness of the conventional 2D ultrasound system. A series of 2D images of the breast scan are used as shown in Fig-18 to extract a 3D volume of the tumor.

Fig-18: Schematic arrangements of 3D Volume Rendering

Fig-19 shows a tumor visible in a 2D image. In order to re-construct 3D model of the tumor there are two constraints (1) identifying tumor boundary with a predetermined margin on each 2D images and the 3-D position, (2) angular orientation information of each image for getting the correct depth information.

Fig-19: A typical ultrasound image of breast showing a non-palpable mass (Source SIEMENS)

Various image-processing algorithms are derived for automatic and accurate contour detection for the breast tumor in ultrasonic images such as edge based segmentation methods, watershed segmentation [35], [36] non-rayleigh statistics [37], neural networks [38] and texture analysis [39]. Some of these methods (such as edge based segmentation methods) do not perform well for ultrasonic image, whereas some methods are very sensitive to the noise and contrast in the image (such as region-based segmentation methods). In addition, the excessive variety of tissues always creates difficulties in extracting the accurate tumor's contour in breast images. Considering the limitations in both automatic identification and manual methods, we present an optimized solution by some trade off between the computerized contour detection and manual outlining without sacrificing the accuracy as explained in the following sections.

In the DVAB, procedure (section 3.1) the resolution of the excised tissue is limited to a cylindrical shape. It is proposed to fit an optimized regular geometrical shape encapsulating the tumor. Simple geometrical approach has been adopted to find out the most optimized shape considering the average shape and size of both tumor and excised tissue sample. In this case, the actual volume of tumor and the volume of either a cylindrical or a rectangular block encapsulating the tumor (Volume of Interest-VOI) have least significance. As there is no control over the shape and size of the excised tissue sample (due to limited size of cutter), it is not possible to either geometrically fit a stack of these cylinders inside the tumor or remove tissue exactly within the tumor boundary. The excised tissue sample using mammotome biopsy probe is cylindrical in shape. This is primarily due to a rotating cutter (refer to Appendix-3 for the mechanical dimensions of the mammotome probe).

Also explained in Chapter-2, initially it is feasible to consider only Stage-I cancer because the tumor size is less than 2 cm with no lymph node metastasis with prognosis factor of five-year survival (90%). Recent studies shows the complete removal of benign palpable mass using either the 8-gauge probe for lesions larger than 1.5 cm and 3.0 cm or less in greatest dimension, or 11-gauge probe for lesions 1.5 cm or less in greatest dimensions using hand-held Mammotome breast biopsy system [30, 31]. Typically, an average tumor can be expressed in two major dimensions (such as

25.9mm width and 12.5mm height of a malignant tumor) [32]. A collection of pathology-proven result showing the sizes of the breast tumor from 20 ultrasound images are given in Appendix-1. Thus, a typical tumor can be expressed with three dimensions in a Cartesian co-ordinate frame and geometrically a cylindrical VOI is more appropriate to encapsulate the tumor than a rectangular volume, thus adopted in our procedure. The dimensions of the VOI are derived from the localized boundaries from all 2D images, as explained in the following steps: -

- A. The image where the tumor is best visible showing the largest dimension is considered as the reference image,
- B. Selecting four extreme points on the visible tumor on the first reference image identifies the boundary of the tumor as shown in Fig-19,
- C. A series of 2D images with a known internal spacing till the full maximum length is taken along the plane normal to the reference image (cross-section plane perpendicular to reference image plane) plane,
- D. Similar four extreme points representing the boundary of the tumor on these images as shown in Fig-20 are used to find the maximum dimension of the tumor. It provides the third dimension (depth) for volume estimation. From reference image the maximum dimension is used as the length for the tumor,
- E. Tumor localization is done based on the position and orientation of the image probe with respect to the reference frame (world co-ordinate).

The parameters for the cylindrical tumor volume calculation are

Length → Maximum dimension from reference image

Diameter → Maximum dimension among all 2D cross-sectional images

The parameters for the Total-Volume, which includes the margin amount, are

Total-Length → Length + 2 x margin

Total-Diameter → Diameter + 2 x margin

3.3.2 DVAB Probe Localization

This is the second step of our methodology addressing accurate placement of the DVAB probe with respect to the tumor position achieved in the previous step. To achieve this it is necessary to adopt the same reference frame as of the imaging probe with respect to the world co-ordinate and manipulate the DVAB probe accordingly. The parameters for the manipulation of the DVAB probe will be taken from the tumor localization information. Considering this similar to the requirement of imaging probe manipulation, a multi degrees of freedom manipulation system for DVAB probe is envisaged.

Fig- 20: Selection of points and the optimum incision axis (thick line)

3.3.3 Method of Accurate Removal of Tissue

After accurate placement of the suction window of the DVAB probe with respect to the tumor, it is essential to adopt a systematic method of sequential removal of the tissue based on the number of cuts required. During the manual hand-held biopsy procedure as explained in section 3.1, the suction window is normally placed below the tumor and tissue samples are taken by orientating the suction window by rotating the biopsy probe. Since tissue can be removed consecutively either starting from the center of the suspicious mass or below the tumor mass (similar to the manual approach), two methods have been proposed considering the placement of the needle either at the center or below the tumor.

Progressive Tissue Removal

In this method, the cutting needle is placed at the center of the tumor and the tissue is progressively removed from all around in a symmetrical manner by rotating the needle about its axis. This method assumes collapsing of tissue from all around (filling the cavity) under an external compression force generated by the breast holding cup. As shown in the Fig-21 the outer two circles are tumor boundary and margin boundary while the inner dotted circles show stages of tissue removal after every full rotation of the needle along the axis.

Fig-21: Cross-sectional view of the excision probe at the center of the tumor

However, for the lower half of the circles, difficulties in pulling of tissues into the aperture may occur as the effect of gravity and external compression due to the breast holding cup resulting in the collapsing of tissue is not in the direction of suction. This method may not be accurate if the tumor size is too large (~larger than 2cm as the largest dimension) and the vacuum system may need to be appropriately changed to generate sufficient suction in order to pull the tissue into the aperture window under unpredictable collapsing. A schematic representation of the cavity created for a given index angle at each stage is shown in Table-4. The index angle needs to be re-tuned based on feedback from the clinical trials.

Oscillatory Tissue Removal

This method adopts the mammotome's conventional approach of tissue removal. Instead of positioning the needle at the center, the suction window is placed at the lower boundary of the total tumor as shown in the Fig-22 (a). This method takes the

advantage of the collapsing of tissue due to gravity as well as the external compression. However, instead of rotating the suction window by 360° in each stage, in this case it is required to oscillate within a range of angle, which is less than $\pm 180^\circ$.

Table 4: The Progressive tissue removal with 90° step angle

Step	Orientation Angle	Action	Probe Status	Action	Probe Status
1	0°	Incision		Suction and tissue removal
2	90°	Rotation of the excision needle		Suction and tissue removal
3	180°	Rotation of the excision needle		Suction and tissue removal
4	270°	Rotation of the excision needle		Suction and tissue removal
5	360°	Cavity after tissue removal

Typically, as shown in Fig-22 (b) the effect of gravity over the suction window is 100% when the window is facing upwards ($T = 0^\circ$). It reduces to minimum (zero) when the window rotates by 90° both clockwise and counter-clockwise. At these orientation angles, there are possibilities that the suction force due to vacuum at the suction window may not be sufficient to pull the tissue into the needle. Thus, the oscillatory tissue removal method, which is derived from the mammotome's conventional approach of tissue removal, has reduced probability of false or no tissue excision. In this case the suction window is restricted to oscillate between $\pm 75^\circ$ which has gravitational effect of $\sim 25\%$ of the total effect at 0° .

3.4 Overall System Design Requirements

A “system requirement model” which is listed below has been developed based upon the above findings.

1. A device to manipulate the ultrasound probe for tumor localization and volume estimation,

2. A device to restrain the movement of the soft tissue of the breast,
3. A device to position and manipulate the DVAB probe as per the tumor registration information,
4. Surgical planning system to plan and control the number of cuts and volume to be excised.

3.5 Proposed Clinical Setup

As per the system requirement model independent imaging module and excision module is desirable to enable independent image acquisition and registration of the tumor as well as positioning of the DVAB probe with respect to the image registration information. For this, an innovative approach has been formulated by integrating the mechatronic & robotic technology with computer imaging to the existing ultrasound diagnostic and DVAB system. A breast immobilizing cup and a dual arm design has been proposed and are described in the following sections. The overall system components are as follows:

1. Manipulation System
 - I. Imaging Arm
 - II. Excision Arm
2. Surgical Planning & Control System
 - I. Breast Immobilizing Cup
 - II. Execution and Control System

Fig-23: Proposed Clinical Setup

In the proposed system layout as shown in Fig-23 the patient will lie on her back (supine condition) on the surgical bed with the proper flatness and comfort (normal operating table). The affected breast is first marginally immobilized by the cup and then registered to the manipulation system. The details of design concepts for the proposed system are explained in the following sections.

3.6 Manipulation System

3.6.1 Dual Arm Design

As derived from the methodology explained earlier two independent manipulation arms capable of achieving and maintaining position and orientation of both ultrasonic imaging and DVAB probe has been proposed. In addition to this it is also required that both the manipulation arms should have a common frame of reference for ease of co-ordinate transformations.

Fig-24: Position of the tumor in the breast

In the conventional mammotome procedure, as explained in Chapter-2 (section-2.7), while holding the diagnostic probe in one hand, the surgeon places the mammotome probe and inserts the needle according to the location of abnormality as seen in the diagnostic image. The surgeon carries out the tissue excision steps by rotating the mammotome probe in one hand with guidance from the online image in the other hand.

Kinematically, it is proposed to adopt the approaches of the two arms similar to the conventional procedure and would require small amount of vertical movement. Further to this, as both (imaging probe and excision needle) require vertical approach with respect to the patient and the target area (the tumor location Fig-24) and require an overlapping work area, the most suitable configuration for the manipulator can be two-serial chain [42, 43, 44] type and vertically articulated.

The other option can be a single arm capable of gross positioning of two independent micromanipulation units (wrist) for imaging and surgery may be suitable. However, a single arm can reduce dexterity as compared to a dual-arm type. Similarly, an anthropomorphic configuration can also be adopted for the arms. However, as the manipulation system is required to work closely with the humans it is essential to consider the safety aspects during configuration design [45]. The case of a vertically articulated manipulator, which is unstable during power malfunction, can be completely avoided in a horizontally articulated planner configuration. A SCARA (Selective Compliance Assembly Robot Arm) manipulator which is a planner robot, widely adopted for precision-positioning tasks in industrial applications, has tremendous potential (the base positioning arms of *da-Vinci* [43] surgical robotic system from Intuitive Surgical Inc. USA, configuration of EndoAssist [46] from Armstrong Healthcare Systems, UK) as a surgical assistive device due to the safety factors associated with its vertically constrained configuration.

Thus, a planner configuration has been chosen for the manipulation of both the tools i.e. imaging probe and excision needle. This kinematically selective compliance manipulator has the ability to position any object in 3D-space using two vertically articulated rotary joints coupled with vertical linear joint. As one joint corresponds to the positioning in vertical plane, it greatly enhances the safety factor by restricting its

work area vertically [42]. Depending upon the required maneuverability of the Imaging arm and the mammotome probe/excision needle arm, the basic kinematic design, has been finalized and is explained as follows.

3.6.2 Excision Arm

The Incision Point Constraint

The fundamental requirement of MIS is that the incision tool must pass through a small incision into the breast as shown in Fig-25. This shows that the incision point constraints the motions of incision tool to two degrees of freedom after positioning with respect to body.

In order to give an intended reach to any point in the remote target, the manipulator holding the excision tool should have at least six degrees of freedom (three linear motions along X, Y and Z and three rotary motion roll, pitch and yaw about X, Y and Z respectively). Adding the two degrees of freedom for incision and rotation for rotary tissue removal makes it eight in total. However, total degrees of freedom are optimized to seven as shown in Fig-26, by removing the redundant roll axis (rotation about x-axis) out of the three orientation axes.

Fig - 25: The incision point constraints

Even though there are no space constraints for the positioning mechanism, it is always recommended to have a compact mechanism from safety aspects. The wrist unit must be carried by the remainder of the manipulator in order to be positioned relative to the surgical site and should have additional three degrees of freedom for positioning in the 3-D space. Thus, the whole system is divided into three units according to their respective functionality and named as Base Positioner Unit, Wrist Unit and Excision Tool Unit. The proposed configuration is shown in Fig-26 considering the

requirements, constraints and intended actions. A typical serial chain arm, whose base is fixed relative to ground, positions the wrist unit. The wrist unit holds the excision tool unit and orients it in a desired orientation.

Fig-26: The kinematic constraints on the incision tool define its overall structure.

Proposed Kinematic Design of Excision Arm

Functionally the excision arm requires a cylindrical workspace with a planner arm configuration. Apart from the basic three degrees of freedom the excision needle requires both the yaw and pitch axis. Additionally for independent rotation of the needle about its axis as needed either for “progressive” or “oscillatory” tissue removal as explained in section 3.3.3, one redundant axis is required. It is also realized that for incision and positioning of the cutting window with respect to the tumor another linear axis along the axis of the needle is required.

The first five degrees of freedom (Fig-27) allow the excision tool to position at any co-ordinate in the Cartesian co-ordinate system with the yaw and pitch at the end for required orientation along horizontal and vertical plane. The next two degrees of freedom have different features comprising of the rotation of the needle about the needle axis to rotate the position of the aperture window. The linear motion of the excision tool along the needle axis is for incision and position of the aperture window inside the tumor. The last two axes known as the DVAB probe drive system are required for the excision procedure to rotate the cutter and translate it independently.

However, these two axes are localized to the excision tool and do not affect the kinematics of the manipulator.

Fig-27: Line diagram of Excision Arm

3.6.3 Imaging Arm

Image Manipulation Constraints

In case of imaging arm, which will manipulate the imaging probe needs to maintain a close contact with the body surface. As the probe manipulation is outside the body the constraints are quite different in comparison to the incision point as shown in Fig-28. The *in and out* motion of the incision tool is a redundant degree-of freedom for imaging probe which can provide linear translation to the imaging probe. In addition, the roll motion (rotation along X-axis) is not very helpful, and thus omitted.

Proposed Kinematic Design of Imaging Arm

The imaging arm will hold the diagnostic ultrasound probe and its functionally required workspace is a cylindrical one similar to the excision arm. For basic positioning of the imaging probe in 3D space, it has two rotary axes for movement on the horizontal plane (X-Y plane) and to travel along the vertical Z-axis has one vertical linear axis with very small range.

Fig-28: The imaging manipulation constraints

The imaging arm has seven degrees of freedom as shown in Fig-29 including the two redundant degrees of freedom. The first five degrees of freedom (T1, T2, d1, T3, and T4), enable the imaging probe to be positioned in any required configuration in the Cartesian co-ordinate system with the yaw and pitch at the end for required orientation.

As suggested in section 3.6.1, a redundant linear axis similar to the d2 axis of the Excision Arm can be considered. This will help to get a series of 2D images parallel to each other by indexing it along the axis of d2. Similarly, the extra yaw T5 as shown in Fig-29 will provide the required redundancies to the imaging probe for rotating the

Fig-29: Line diagram of Imaging Arm

image plane about its axis. Overall, these two joints will eliminate the gross movement of the first five axes once the position and orientation is fixed by selecting the *Reference Image*. Moreover, the proposed kinematic configuration enables any type of scanning including rotational scanning, fan scanning, free hand scanning and linear scanning.

Thus, the overall system design will consists of dual manipulators having planner configuration coupled with two wrist units for individual tool (in this case the imaging probe and the excision probe). The summary of the dual manipulator systems is shown in Table-5. Further detailed design on dual manipulating arm, surgical planning, and needle localization and excision control will follow in the next chapter.

Table-5: Summary of the System Counterparts of Dual Arm

Specifications	Imaging Arm	Excision Arm
Task	Positioning	Positioning
Payload	Ultrasonic diagnostic probe (< 1 kg)	DVAB Probe (< 3 kg)
Payload type	Static load with no dynamic loading	Both static and dynamic load
Kinematic Configuration	Vertically articulated planner arm	Vertically articulated planner arm
Work volume	Cylindrical	Cylindrical
No of Degrees of Freedom	3 Base Positioner + 2 Wrist	3 Base positioner + 4 wrist +2 Excision
Required Range	Nearly similar to human arm	Nearly similar to human arm
Speed	Not critical	Not critical
Accuracy:	~ +/- 0.1mm	~ +/- 0.1 mm
Repeatability	~ +/- 0.05 mm	~ +/- 0.05 mm

Chapter 4

System Design and Prototype Development

This chapter describes the overview of the system and system layout with proposed clinical set-up. It includes system design such as the robotic system, breast-holding device and surgical planning system followed by the prototype development. Finally, a detailed description of each sub-system as part of the process description is included.

4.1 Overview of the Proposed System

As per the system requirement model explained in section 3.5, a dual manipulator comprising of an imaging arm and an excision arm is required to enable independent image acquisition and registration of the tumor as well as positioning of the DVAB probe with respect to the image registration information. Based on the functionality, the overall system is divided into the following sub-systems.

- System Hardware: - **Dual Manipulating Arm & Patient Registration**
 1. Imaging Arm
 2. Excision Arm comprising of the following:
 - Vacuum source, tubing and accessories
 - Disposable mammotome biopsy probe
 3. Breast Immobilization Cup
- System Software: - **Surgical planning & Execution Module**
 1. 2D Image Acquisition
 2. Tumor Volume estimation
 3. Needle Localization and Excision

4.2 Dual Manipulating Arm

The design of a robotic system requires a specific approach. In our design process, we have adopted an approach based on SRI International [41], according to which the design process starts with formulating configuration design followed by the detailed design. During the detailed design phase, the major steps involved are kinematic modeling, actuators & transmission system design and control system design. These steps will be explained in further details in the following sub-sections. The summary of the system counterparts and their relative functionality are detailed in Table-5. During the detailed design process some of the contemporary design techniques are also considered [41]. Both arms are designed based upon modular concept. Apart from the last two degrees of freedom associated with the excision tool viz. rotary tissue removal axis and incision axis, all other modules of both arms are interchangeable. To reduce the error in registering both the arms with respect to patient, a common reference frame-based design approach has been considered, with overlapping workspace.

4.2.1 Manipulator Kinematics

Kinematic Modeling

As per the kinematic design, (Chapter-3, section-3.6) each of the arms have a pair of links connected serially through a revolute joint. In order to get a common reference both the arm are hinged to a single revolute axis. The distal end of each arm has a prismatic joint holding the wrist unit and each arm has a modular wrist unit having two degrees of freedom. For developing the inverse and forward kinematic model and dimensioning, the Denavit & Hartenberg (DH) based system modeling is adopted [42].

The dimensions of the basic structure of both arms are listed in Table-6. The four basic parameters as per DH conventions namely, the link lengths (a), link twist (α), link offset (d) and joint angle (θ) for each is finalized based on the system requirements. The length of each link is set to 300 mm (similar to human arm) and to simplify the design as well as the kinematic model the joints are kept free of offsets. The resultant DH parameters for both Imaging and Excision arms are shown in Table-6.

Table-6: DH Parameters of Dual Arm

Angular Joint (θ)	Link (d)	Linear Offset (a)	Angular Offset (α)	Remarks	Joint Ranges (Overall range)
T ₁	300	0	0	Rotary joint (EA) (IA)	$\pm 90^\circ$
T ₂	300	0	0	Rotary joint (EA) (IA)	$\pm 90^\circ$
0°	d1	0	0	Linear joint (EA) (IA)	150 mm
T ₃		0	0	Rotary joint (EA) (IA)	$\pm 135^\circ$
T ₄		0 mm (IA) 20 mm (EA)	0	Rotary joint (EA) (IA)	$\pm 90^\circ$
0	d2	0	0	Linear joint (EA) (IA-optional)	120 mm
T ₅	20	0	0	Rotary joint (EA)	600°
T ₆	0	0	0	Rotary joint (EA)	Continuous
0	d3	0	0	Linear joint (EA)	130 mm

[Note: IA- Imaging Arm and EA: Excision Arm]

Both imaging and excision arms have identical kinematic model up to wrist pitch and yaw (Fig-31). Excision arm has four extra joints, out of which two joints d2 and T₅ are part of the wrist unit. The remaining two joints are for the excision tool where T₆ is the rotation of the cutter (which is endless) and d3 is the *in and out* motion of the cutter. To simplify the dual arm manipulator kinematics, it has been divided into two separate sections: base joint kinematics and wrist joint kinematics. Same approach has been adopted during programming the manipulator, i.e. enabling initial positioning through base joint controls followed by wrist joints control.

• **Base Joint Kinematics**

Base joints are represented by the first three axis of motion such as T₁, T₂, and d1. Here, the prismatic joint is kinematically decoupled from the first two revolute joints as it directly corresponds to the variability in one plane. In Fig-30 the links are represented as vectors P₁* and P₂* which start from the proximal (closest to the coordinate frame origin O) to the distal (closest to the end effector B) points. Here, O is the origin of the robot co-ordinate for both the manipulator and the axis of joint 1 perpendicular to the plane of the paper. Similarly, point A is the axis of joint 2 and B is the axis of the joint d1. θ_1 and θ_2 are the values of the joint 1 and joint 2. l_1 and l_2 are the link lengths; in our case they are both 300mm.

Fig-30: Kinematic diagram showing the 2-axis of the planner manipulator on X-Y plane

Matrix expressions for the link vectors for the manipulator are,

$$P_1^* = l_1 \begin{pmatrix} \cos \theta_1 \\ \sin \theta_1 \end{pmatrix} \quad \text{.....1.1}$$

$$P_2^* = l_2 \begin{pmatrix} \cos(\theta_1 + \theta_2) \\ \sin(\theta_1 + \theta_2) \end{pmatrix} \quad \text{.....1.2}$$

Link position vectors in the stationary reference frame with their origin at the first joint (joint-1) are designated as P_i for the i th link.

$$P_1 = P_1^* \text{ \& } P_2 = P_1^* + P_2^* \quad \text{.....1.3}$$

The position of the end point of the arm is the output of the direct kinematic analysis, or input of the inverse kinematics, expressed as:

$$P_2 = \{x, y\}^T, \text{ or}$$

$$P_2 = \begin{pmatrix} x_B \\ y_B \end{pmatrix} = \begin{pmatrix} l_1 \cos \theta_1 + l_2 \cos(\theta_1 + \theta_2) \\ l_1 \sin \theta_1 + l_2 \sin(\theta_1 + \theta_2) \end{pmatrix} \quad \text{.....1.4}$$

The inverse problem can be solved as follows:

Considering $x = x_B$ and $y = y_B$ and using the law of cosine

$$\cos \theta_2 = \frac{x^2 + y^2 - l_1^2 - l_2^2}{2l_1 l_2} \quad \text{.....1.5}$$

Thus, each solution from $\cos \theta_2$ represents two values for θ_2 characterized by equal magnitude and opposite signs represented as the dotted lines (Fig-30). Since there are two arms of identical geometry, these two solutions (inward arm and outward arm with respect to the origin) are used independently for each arm. As a default condition and considering an anthropomorphic configuration the inward arm solution is used for excision arm where as the outward arm solution is for imaging arm (the dotted line represents Imaging arm).

Now substituting expressions in eq. 1.4 and subtracting it further, θ_1 is calculated as shown in eq. 1.6:

$$\tan \theta_1 = \frac{-(l_2 \sin \theta_2)x + (l_1 + l_2 \cos \theta_2)y_B}{(l_2 \sin \theta_2)y + (l_1 + l_2 \cos \theta_2)x_B} \quad \text{.....1.6}$$

These equations are used to compute the image position reference in XY plane in case of imaging arm and later fed to the excision arm for positioning. Arm position in Z-direction is a direct calculation of the vertical joint variable.

- **Wrist Joint Kinematics**

As suggested during the conceptual design stage the objective of the wrist unit for both the arms are to provide a spherical workspace for the end-effectors. To simplify the

kinematic model each joint is decoupled to generate pitch, yaw and linear axis. In case of imaging arm, in addition to the XYZ values these three joint values are stored directly in joint co-ordinate system. However, for the excision arm, the joint angles for the wrist unit are calculated based on the axis of incision and position of tumor (Chapter-3, Section-3.3.2). The combined kinematic diagram of the imaging arm and excision arm wrist units is shown in Fig-31.

Fig-31: Excision & Imaging Arm Wrist Unit Kinematics and its projections

The yaw (T3) and pitch (T4) angle for the excision arm is calculated from the projection of the axis of incision on XZ and YZ planes. The detail calculation for finding the corresponding X, Y and Z values with respect to the T3 and T4 values required during positioning of the excision arm will be explained in section-4.5.3 in this chapter.

Joint Velocity Calculation

Typically, the Jacobean J can be expressed according to the vector-matrix method as:

$$J = \begin{pmatrix} \frac{\partial x}{\partial \theta_1} & \frac{\partial x}{\partial \theta_2} \\ \frac{\partial y}{\partial \theta_1} & \frac{\partial y}{\partial \theta_2} \end{pmatrix} = \begin{pmatrix} -l_1 \sin \theta_1 - l_2 \sin(\theta_1 + \theta_2) & -l_2 \sin(\theta_1 + \theta_2) \\ l_1 \cos \theta_1 + l_2 \cos(\theta_1 + \theta_2) & -l_2 \cos(\theta_1 + \theta_2) \end{pmatrix} \quad \dots 1.7$$

Based on the above expression, the relation between joint velocities and the Cartesian velocities of the tip is derived by differentiating equation 1.4.

$$\dot{P}_2 = \begin{pmatrix} \dot{x}_B \\ \dot{y}_B \end{pmatrix} = \begin{pmatrix} -l_1 \sin \theta_1 - l_2 \sin(\theta_1 + \theta_2) & -l_2 \sin(\theta_1 + \theta_2) \\ l_1 \cos \theta_1 + l_2 \cos(\theta_1 + \theta_2) & l_2 \cos(\theta_1 + \theta_2) \end{pmatrix} \begin{pmatrix} \dot{\theta}_1 \\ \dot{\theta}_2 \end{pmatrix} \quad \dots 1.8$$

The Jacobean has a zero determinant at $\theta_2 = 0^\circ$ and 180° , which is physically not possible in our design as both the arms has a common joint 1 axis (both imaging arm and excision arm has a common origin “O” since the joint 1 for both the arms are coaxial). The equation for acceleration of the arm tip is derived in terms of the time derivatives of θ_1 and $\theta_1 + \theta_2$ as follows:

$$\begin{pmatrix} \ddot{x}_B \\ \ddot{y}_B \end{pmatrix} = \begin{pmatrix} -l_1 \sin \theta_1 & -l_2 \sin(\theta_1 + \theta_2) \\ l_1 \cos \theta_1 & l_2 \cos(\theta_1 + \theta_2) \end{pmatrix} \begin{pmatrix} \ddot{\theta}_1 \\ \ddot{\theta}_2 \end{pmatrix} - \begin{pmatrix} -l_1 \cos \theta_1 & l_2 \cos(\theta_1 + \theta_2) \\ l_1 \sin \theta_1 & l_2 \sin(\theta_1 + \theta_2) \end{pmatrix} \begin{pmatrix} \dot{\theta}_1 \\ \dot{\theta}_1 + \dot{\theta}_2 \end{pmatrix} \quad \dots 1.9$$

The joint velocities and accelerations are propagated from the base to the tip of each link, while computing link velocities, accelerations, and inertial forces and moments for each link along the way.

4.2.2 Manipulator Dynamics

At present, our goal is to provide additional degrees of freedom to the surgeon, for which dynamic constraints are far less important. However, the recommendations for the wrist unit and base-positioning unit, joint frictions are calculated based on previous experiences and prior art.

Servo Response of the Manipulator

The purpose goal of the base positioner of the excision arm is to move the wrist unit to reach of targeted organ of the human body (in our case the breast) with desired positioning bandwidth and accuracy. Any errors in tracking of the imaging arm will be perceived as errors in tumor volume calculation. Eventually error in tumor location will

introduce error in desired position for the excision arm in addition to its own positional error.

To minimize this servo error the actuators' inertia need to be matched with the arm inertia. Also sufficient overall stiffness needs to be generated by each actuator to compensate for disturbances due to external forces such as those caused by movements of the body and during manual incision. Overall, servo performance will depend on the servo parameters such as K_p , K_d and K_i values of PID servo systems. These parameters will be defined during servo tuning test as part of the parameter identification phase.

Structural Dynamics

Structural dynamics should be minimized in order to achieve good position servo response of the base platform. In addition, the overall stiffness of the connection between the imaging and excision arm will be limited by the structural stiffness of both. Since two manipulators are pivoted at one shaft, the vertical column holding the dual arm is made to be rigid (100mm x 50mm cross-section aluminum profile) with a larger base (400mm x 400mm foot print and 1200 mm height).

Counterbalancing

Counterbalancing as one of the design considerations has been addressed by selecting the planner configuration in section 3.6.1. Because of the planner configuration, both the arms are restricted in vertical plane avoiding the need to be gravitationally counterbalanced. This will help reduce the torques required for the base positioner actuators and to provide additional measure of safety. This vertically constrained manipulator with all back drivable joints will not have a tendency to "fall over", as in case of a vertically articulated manipulator, if motor power is lost.

Sizing of the System

Based on the size of current mammotome biopsy needle (1.7mm cutter diameter with 17mm long aperture), the stroke of an instrument in and out of the patient is on the range of 5-8 cm. and the depth of penetration into the body is 9 cm. The volume of the

workspace should be consistent with these requirements. However, these values will vary with different patients and with different procedures and provide typical estimations for a generic system. The work volume of both arms is independent of the wrist unit shown in Fig-32.

Fig-32: Overlapping work envelope of Excision & Imaging Arm independent of wrist

As the basic objective is to position and hold the imaging probe and excision needle within the reach of surgeon, the work envelope has been chosen considering average size of human arm (average length of arm when fully stretched is $\sim 600\text{mm}$). The length of each link is set to be 300 mm and the joint ranges are limited to $\pm 90^\circ$. As shown in Fig-32 both the arms have an overlapping work envelope. However in order to avoid collision between links but as each are pivoted onto a common axis, the minimum angle between each arm's link-1 is set to 20° .

4.2.3 Actuators & Transmission System Design

The major driving factors for drive system design are actuator and transmission system selection. Moreover, the major consideration during the drive system design in the

present case is to make all joints “back-drivable”. This is to enable the surgeon to move the arm by hand whenever required.

Since, both the arms are primarily functioning as positioning devices with a fixed payload; the dynamics on the manipulator is simple and straightforward. There is no change in dynamics once the required position and orientation is achieved. It is also possible and recommended to lock each joint using manual mechanical locking to make it more stable from safety consideration during excision. For this the required joint torque for each joints are only to overcome the joint friction [44], which can be achieved by using low torque motors with medium gear ratio (typically 100:1). But to make it back drivable it is essential to use back drivable transmission system with very low backlash. We have selected precision planetary gear-heads integral with the motors. Further to this for rotary joints, motor to joint transmission through bevel gears and linear joints through rack and pinion has been adopted.

The adopted transmission system for the first two rotary axes of both the arm is shown in Fig-33. For sterilization requirements, the equipment should be at least splash proof. In some cases, a waterproof jacket is wrapped around the equipment, which prevents the equipment from any damage during the sterilization. Another major requirement is minimum exposed moving parts to reduce the accidental hazard of the surgeons or patient during use. Considering these requirements, the actuators are encapsulated inside the hollow links of the arms preventing any accidental direct contact with the electric motors [47, 48].

Fig-33: The Vertical Joint Transmission System

Also the gear system is such that a flexible bellow can be wrapped around each joint to make it water proof. The transmission system adopted for the vertical linear joint is shown in Fig-34. The design is modular to adopt either cable drive type or rack and pinion type transmission system achieving the back drivability [8, 48]. However, in the present prototype, rack and pinion system has been adopted based on the availability of the components.

Fig-34: Z-axis transmission

Fig-35 (a) shows the transmission system for the wrist unit. A two-axis gimbal has been adopted for giving the dexterity of human hand. Pitch and yaw axis, as shown in Fig-35 (b), are intersecting and perpendicular to each other, resulting in the pivotal motion of the excision tool at the intersecting point. This wrist design has enabled both the imaging probe as well as the DVAB probe to orient in a spherical workspace [41, 42]. The motion sequence is achieved through a set of three miter gears and shown in Table-7.

Fig 35 (a): Two-Axis Gimbal for Wrist Unit

Fig-35 (b): The incision axis and rotary tissue removal axis

Table-7: Differential Motion Sequence of Wrist

Sl. No.	Left Miter Gear	Right Miter Gear	Central Miter Gear	Resultant Motion
1	CW	CW	No movement	Pitch Up
2	CCW	CCW	No movement	Pitch Down
3	CW	CCW	CW	Yaw Right
4	CCW	CW	CCW	Yaw Left

A rack and pinion transmission has been adopted for the incision axis as well as the redundant linear scan axis of excision arm and imaging arm respectively. For the rotary tissue removal, a DC servomotor is attached to the linear slide of the incision axis as shown in Fig 35 (b). The solid model of the linear and rotary joint of the Excision tool is shown in Fig-36. A detailed design of the commercial mammotome probe drive system as explained in Chapter-3, (section-3.3.2) part of the excision arm is included in Appendix-3.

Fig-36: The Solid Model of the Excision Tool System

4.3 Vacuum System

The proposed system utilizes vacuum assistance to prolapse the tissue into an aperture, and is cut-off by an advancing and rotating cutter. The process of prolapsing the tissue through the suction technique is already established (prevalent from the product available from J&J). Since, a similar system is adopted, a theoretical study was done to establish the requirements of the suction system to be used. Typically, the suction of tissue occurs due to vacuum created by large inflow of air at the suction port. The suction force is created by difference in pressure and can be expressed by the following equation [50]:

$$F = \frac{\pi}{4} P d^2 \quad \dots 1.10$$

where F is the suction force without considering the influence of air viscosity, P is the pressure difference of both sides of the aperture, and d is the aperture dimension of the suction hole. However, the real suction force is much larger than this and attributed by the effect of air viscosity that is described by *Reynolds Number* [50,51].

$$R_e = \frac{\rho U L}{\mu} \quad \dots 1.11$$

where, ρ is the air density, U is the characteristics velocity, L is the characteristics length and μ is the air dynamic viscosity. Typically the smaller the value of Re , the more viscous is the fluid and since the size of tissue to be pulled by one hole is very small which leads to the small value of L , the value of Re is critical. However, the major factor that contributes to the force is the pressure difference, which is typically achieved through vacuum pumps. As per the reported literature, the mammotome procedure is done under green zone vacuum or rough vacuum [28].

As per the present configuration for the mammotome probe two independently controlled (on/off) vacuum lines are needed. This can be achieved by one single vacuum source (a vacuum pump) with two solenoids controlled vacuum valves. However, based on the availability of resources the present prototype is integrated with two independent vacuum systems (due to unavailability of vacuum valve for toggling the vacuum supply line). For tissue suction at the aperture, a vacuum pump based on the “Rotary Vane Type Pumping” and for suction of the excised tissue compressed air based vacuum ejector is used. The Model 15120A - 10 CFM has free air displacement of 10 CFM (2.8×10^4 CCM) through two stage pumping. It is driven by a 400 watts induction motor and weighs 17 kg. Though the vacuum has not been measured but as per the conversion factor it generates nearly 22” Hg (~ 500 mm of Hg) vacuum. The pump is connected to the relay drive for programmable control. However, at present only ON/OFF control is enabled. The vacuum pump is shown in Fig-37. The vacuum ejector generates suction using positive pressure from a compressed air line. The compressed air type generator is based on the principle of venturi flow.

Fig-37: The Vacuum System

The SMC vacuum generator is a multistage ejector and operates at 7 kgf/cm² and generates suction up to –630 mm of Hg. The control for this is through a 24 VDC valve with the appropriate pneumatic fittings to attach to the vacuum source.

4.4 Prototype Development

As explained earlier during the design phase, the prototype development consists of two major sub-systems. In this section the hardware development consisting of the robotic system, DVAB probe drive system, Vacuum system, and the Controller system are described. The Software development will be described in the next section.

4.4.1 Manipulating Arm

In order to test the feasibility of the desired system, only a fully functional excision arm was built, whereas a manually adjustable fixture is fabricated to move Imaging Probe in 3D space. The excision arm base unit holding the wrist unit is pivoted onto a vertical column mounted on a base frame as shown in Fig-38. The modular DVAB probe drive system, which is a part of the excision unit explained in Appendix-3, is shown in the Fig-39. The DVAB probe drive system is integrated into the *excision arm* at the *rotary tissue removal* joint as shown in Fig-40.

Fig-38: Excision Arm Prototype

During this stage of the prototype development, a fixture holding the imaging probe is fabricated and fixed to the base frame. The fixture is capable of manual rotation of the imaging probe about its axis for changing the image plane orientation and moving the probe for scanning linearly required for tumor volume estimation as explained in Chapter-3, section-3.2.1. More details about the laboratory setup will be explained in next chapter along with the laboratory trials.

Fig-39: Showing the inline modular DVAB probe drive system

Fig-40: The DVAB drive along with Rotary Tissue Removal drive system

4.4.2 System Controller

The system controller consists of a host computer, motion controller, motor amplifiers, power and safety systems and the necessary inter-connecting equipment [53, 54, 55, 56]. The host computer interfaces the motion controller with the amplifiers. The dual arm has a total of 15 controllable axes comprising of 9 axes in excision arm and 6 axes in imaging arm. Out of these, 14 axes (8 from excision arm and 6 of imaging arm) are to be controlled in close-loop and the last axis of the excision arm needs to be speed controlled. A PC-based Galil motion controller [54] has been chosen which supports extensive C++ classes. As per the prototype system requirement with reduced number of axis as explained in section 4.3.1, one DMC-1842 from Econo Series capable of controlling 4 axes is sufficient for feasibility testing. The two wrist axes, the rotary tissue removal and linear needle incision axes are connected to this controller. As per our prototype requirement, each axis is controlled in trapezoidal profile mode. The maximum speed of each joint is set at the minimum (typically ~ 540 degrees per minute). Similarly, the acceleration and deceleration are also set at minimum value

(500 degrees per second square is the minimum value of Galil Controller). The system controller also has a relay board and digital switches for controlling the mammotome probe drive system, vacuum pump and vacuum ejector. The amplifiers, Galil interconnecting module, relay boards and the connection board are housed in an electrical enclosure unit. The details of the controller are attached in Appendix-5.

4.5 Surgical Planning & Execution Module

The major tasks of this system are image acquisition & storing for image guidance, surgical planning and execution. All the required inputs for each function are done through the GUI, which is explained in section 4.6.

4.5.1 Patient Registration

This is the pre-surgical preparation part, where the patient is referenced to the manipulation system. This stage also involves a breast-immobilizing cup to restrict the movement of the breast while scanning and excision.

Breast Holding Cup

A mechanical means of immobilization of the breast has been adopted similar to other commercial systems. A breast holding cup is designed which applies uniform mechanical pressure around the breast tissue. The design of breast holding-cup is similar to a bra cup. For reinforcement very thin stainless steel, wire cage has been provided. An ultrasound friendly material such as natural rubber is proposed [57]. Natural rubber has similar acoustic impedance as human skin (~1.5). The dimensions of such a cup will vary for different patients. Similar to the design of the bra, elastic straps are provided to put the cup on to the patient. It has one longitudinal strap and one lateral strap with respect to the patient body. The strap ends are fitted with *Velcro* tapes to adjust the tightness. Both the straps are wrapped around the body, thus preventing any relative movement of the breast while scanning. The schematic design of the cup is shown in Fig-41. It is understood that the wrong sampling (excision from incorrect region) due to movement of tumor during needle incision is relative to the number of incision. Since our proposed methodology employs only one incision, the

inconsistencies due to the movement of the tumor during multiple incisions have been eliminated. Thus, the overall objective of the breast holding cup is primarily applying compression.

FIG.-41: Breast Holding Cup

4.5.2 2D Image Acquisition

As explained in Mammotome procedure (Chapter-2, section-2.2.2) a standard commercially available 2D ultrasound diagnostic system is used. For breast scanning linear array diagnostic probe with typically high frequency (7.5 MHz) is used (Fig-42). There are several manufacturers providing ultrasonic diagnostic systems [58]. A portable ultrasonic diagnostic system from Aloka model SSD 900 as available in the laboratory and a 3.5 MHz frequency electronic sector probe is used (Fig-42 (b)). Since the ultrasound, diagnostic probe is designed for hand held use, an attachment is required to adapt to the mechanical arm.

The VGA out of the scanner is connected to a digital frame grabber, which transfers the image to the PC monitor. Once the image is available at the PC level all-necessary image processing and analysis usually are taken care by PC since they are highly customized as per the requirements of a specific system. However, in this project, controls available at the diagnostic machine level such as the zoom factor, intensity, depth control etc. are used.

Fig-42 (a): A typical Linear Probe used for Breast Scanning

Fig-42 (b): The Sector probe used in our experiments

A typical ultrasound image displayed on the ultrasound machine has a set of information that include the actual image boundary, and for a sector probe the radius of scanning as shown in Fig-43. On the machine screen, the size of the image can be measured using the inbuilt measurement features. But with change in zoom factor (Zoom factor R4 as shown in Fig-43 represents 4cm depth along Y-axis) which changes the scan radius, thus changes the depth of scan, the number of pixels on the screen corresponding to the actual dimension of the object in mm also changes. For a selective size of the image window on the PC monitor screen, a suitable pixel to mm ratio was chosen (image size 102mm along X and 80mm along Y axis with an average pixel to mm ratio of 0.242 was used).

Fig-43: The 2D ultrasound image and its specifications

The scanner is connected to the host PC for further processing through a digital frame grabber. A frame grabber from Matrox is used for acquiring the image from the ultrasound machine. Matrox has a dedicated imaging library known as MIL, provides all necessary image handling and processing library of commands including high level tools. As explained earlier the diagnostic probe is mounted on the Imaging Arm and while acquiring and storing the 2D images, this module also stores the position information as calculated using the image arm kinematics (from each joint encoder). The images are stored in windows bitmap format and corresponding position information is stored as an identity of the image.

4.5.3 Tumor Volume Estimation

Volume of the tumor using 2D diagnostic images is estimated and 2D images along with the respective position information are acquired and stored. As explained in section 3.2.1, in order to extract volume information from an acquired set of 2D images, apart from registering the 3D position and angular orientation of each image, tumor boundary information is also required. A simplified approach has been proposed to generate boundary based on surgeon's selection of four extreme points (2 points in each dimension) on the region of interest covering the suspected tumor on each image. Volumetric information is generated by linearly scanning [59] the ultrasound transducer across the affected surface in a given direction as shown in Fig-44. O_i is the origin of the transducer or image co-ordinate frame $X_iY_iZ_i$ and the linear scan direction is along Z_i axis. The perpendicular direction pointing into the object is the positive Y_i axis, and the direction along the surface perpendicular to both of these, forming a right-handed coordinate system is the positive X_i axis of the transducer. The placement of the image co-ordinate frame with the reference robot coordinate frame XYZ whose origin is O is shown in Fig-45. The scanning axis Z_i is initially aligned with the X -axis of the reference coordinate frame.

As described in Chapter-3, section 3.1.3, transducer is moved to the suspected zone and scanned manually by moving the imaging arm (all joints are back drivable to manually move and can be locked at any configuration using mechanical and servo locks) to get the image showing best possible view of the tumor or suspicious mass. The best

possible view corresponds to one that shows the maximum spreading of the tumor horizontally and vertically with respect to the image plane. This image is referred as the *Reference Image*, defines the initial setting of the image plane, referred to as the origin O_i with respect to O along X , Y and Z -axis, tilt angle $T3$ (angle between Y_i and Z about X) and angle of inclination $T4$ (angle between X_i and Z_i about Z).

Fig-44: Tumor Cross-section showing on Y_iZ_i and X_iZ_i plane

After selection of points on the reference image the transducer is rotated by 90° to show the cross-sectional view of the suspected area or tumor. The transducer is moved linearly along the scan axis Z_i with small increments (2 mm) to acquire images showing the cross sectional views of the tumor. Similar to the reference image, four points are selected on each image showing the tumor. Schematically, the selection of points on the reference image and the corresponding cross-sectional images are shown in Fig-44.

As shown in Fig-45, a cylindrical shape encapsulating the tumor is chosen for excision. Each selected point carries x and y values which correspond to the absolute location on the tumor as they are converted from the screen coordinate which is in number of pixel to corresponding millimeter on their respective image. The difference between the

minimum x and maximum x out of all selected points with respect to the screen represents length of spread of the tumor along Z_i -axis. Similarly, the difference between minimum y and maximum y out of all selected points represents the length of spread of the tumor along Y_i -axis.

Fig-45: Schematic arrangements showing the Image plane with respect to base co-ordinate

Out of these two values, the maximum and minimum dimensions are taken as the length and diameter of cylinder respectively and the cylinder volume is calculated. The amount of margin tissue to be removed as per the size of the tumor is specified by the surgeon and added accordingly to the dimensions of the cylinder to calculate the total excision volume. In Fig-45, the tumor boundary is shown in green dotted line. The cylinder encapsulating the tumor is shown in red, where the maximum spread is along Z_i -axis thus the length of the cylinder (L_t). The next maximum spread is along Y_i -axis represents the diameter of the cylinder (D_t). Subsequently, the number of cuts required

for complete excision of the tumor is derived from the total calculated volume and the volume of a single excision (volume of a cylinder of 1.7mm diameter and 17mm height in our case).

4.5.4 Needle Registration and Execution

This module calculates the position and angular orientation required for the excision needle to accurately align with the incision axis. Fig-45 shows the schematic diagram for the incision axis with respect to the needle and excision arm. As shown in Fig-45, the centerline of the cylinder is taken as the incision axis. The needle registration and incision involves a sequence of motions such as (i refers to co-ordinate frame of Imaging Arm):

- Orient the needle axis to align with incision axis in XiZi plane (T1, T2, T4)
- Orient the needle axis to align with incision axis in YiZi plane (d1, T3)
- Move the needle along the needle axis (d2)

The corresponding values for each of the joints of the excision arm are calculated based on the projection of the incision axis on the excision arm co-ordinate frame. The angle of inclination of the incision axis w.r.t YiZi and XiZi plane corresponds to T3 and T4 of excision arm respectively (Fig-45) and are calculated considering the absolute co-ordinate values of any two center points of the cylinder. The projection of the wrist unit of the excision arm with respect to the image frame is shown in Fig-46 in isometric and planner views, where O is the image frame origin, Ow is the wrist origin. Zoff is the offset distance between the image plane and wrist axis. The actual distance between the needle tip and the point A is recorded as d2 value (the d2 axis is initialized as “0mm” at fully retracted condition) during initialization. The point on the incision axis corresponding to the first image is taken as Pt and the corresponding co-ordinate (x, y) are used for calculating M_x , M_y and Z_{off} where, M_x and M_y is the deviation of Ow w.r.t O in X and Y axes. As shown in Fig-46 there is a mechanical offset between the needle axis and the wrist origin along XY plane represented as Yoff and is always perpendicular to the needle axis.

The following direct geometrical calculations are used to determine the above parameters.

$$Mx = OwF - x \text{ and } My = OwB - y$$

$$q2 = \tan^{-1}\left(\frac{d2}{Y_{off}}\right) - T3 \text{ and } \sin(q2) = Z_{off}/OwPt$$

thus

$$Z_{off} = \sin(q2) \left(\sqrt{(Y_{off})^2 + (d2)^2} \right) \quad \dots 1.12$$

so

$$OwB = Z_{off} / \tan(q2) \quad \dots 1.13$$

$$OwF = Z_{off} / \tan(T4) \quad \dots 1.14$$

The depth of incision is the length of the tumor (Lt) added with the initial value of d2.

Fig-46: Projection of Excision Needle on image plane

4.6 Graphic User Interface

The entire surgical process is broadly classified into three major steps such as System initialization, Image Registration & Surgical Planning and Excision. The flow chart for

the control program and graphic user interface (GUI) is developed based on these three steps. The inherent functions during each step are further derived and incorporated in the control program. The detail flow chart of the system, which is being implemented, is shown in Fig-47. The program is developed in Microsoft Visual C++ version 6 to run on Microsoft Windows platform (Windows NT/ 2000). GUI was initially developed and tested by a final year project student [60]. For the sake of clarity, the individual modules of the GUI and their functionalities will be explained in Chapter-5 along with the test results.

Fig-47: Control & GUI Flowchart

As shown in Fig-47 *system initialization* includes a user input for patient identification and hardware and software system initialization. The patient identification is used to set the data structure to store the images and all related information for a particular case. The system initialization downloads the preset conditions for Galil controller and software system Matrox Imaging system including the reference values for each joint along with respective PID values, maximum and minimum values of speed, acceleration and deceleration for each joint, the image buffer, its location, and size. Initialization also enables the display to show online image on the image window. GUI has provision for grabbing and saving images once the required image is available on the screen. While storing the image as a bitmap file it also stores the position information (available from the position encoders of the imaging arm) with respect to the base frame (world co-ordinate system) of the robotic system is stored. Provision for automatic scanning through the imaging arm is not included in the present prototype. As part of the surgical planning to determine the tumor volume, selection of points are done through PC mouse on each stored images. The mouse co-ordinates are stored and used for tumor volume estimation and the incision axis generation. Total volume calculation including margin and the required number of cuts are calculated based on the margin value given as input data by the user. In the present version of GUI, the generated boundary is shown superimposing the tumor either in lateral and longitudinal cross section.

As part of the GUI, independent control buttons in a separate control window have been provided for moving the excision arm, executing manual incision and automatic excision. In case of any emergency, in the present version emergency stop and auto recovery is limited to immediate shut down of the process while storing the current position information of the excision arm.

The required functional parameters for controlling the excision arm, mammotome probe drive system and actual testing of the overall system including the feasibility trials will follow in the next chapter.

Chapter 5

Results & Discussions

A systematic approach has been adopted for the laboratory trials, which were arranged in two, stage viz. 1) Functionality tests and 2) Feasibility trials. The first stage is to test the functionality and accuracies of all the sub-components of the system individually and then integrated together. The second stage is the feasibility trials using appropriate animal tissue phantoms.

5.1 Functionality Tests

This stage was divided into three steps to establish the functionality and parameters of the system independently. The division was done based on the three major sub-systems 1) the surgical planning & volume estimation, 2) manipulation and registration and 3) tissue removal.

5.1.1 Surgical Planning & Volume Estimation

The objective of this test was to verify the methodology of selecting four points on the boundary of the suspected region in cross sectional images for information on depth, volume and the axis of incision. The planning software was used without the controller command (disabling all the motions).

Materials & Methods

Pork muscle from super market was used as the base tissue phantom. The objective was to check the accuracy of the volume estimation cylindrical shape objects of rigid material were chosen instead of a deformable material simulating the tumor. A stainless steel rod of 1 cm diameter and 2 cm length was embedded inside the tissue as shown in Fig-48 (a). The stainless steel sockets were inserted through the cut at the center as shown in Fig-48 (a) in the muscle. This was done to see the embedded steel socket in the ultrasound image while scanning the muscle as ultrasound detects the change in

material properties. For laboratory trials, in order to provide a rigid surface for executing the surgical procedure a wooden board was fixed onto the vertical column just below fixture. Since this will be replaced by the surgical bed in future clinical prototype is named as “surgical board” (Fig-48 (b)). The phantom was finally wrapped with cling film along with Styrofoam plate and fixed on to the surgical board using rubber band.

Fig-48 (a): Pork muscle and the two sizes of the embedded objects

Fig-48 (b): The arrangement showing the surgical board and tissue

Test Procedure and Results

System Initialization

This is the first step of the control software. The GUI shown in Fig-49 is the first control window that appears once the program is executed. Two buttons provided on the top left corner of the GUI window executes this step is shown circled in Fig-49 One button is for patient identification input and the second button is for system initialization. The patient identification is later used to set the data structure to store the images and all related information for a particular case. The second button initializes downloading the preset conditions for Galil controller such as the PID values, maximum and minimum speed, acceleration, and deceleration, maximum software limits for each joint, followed by specifying the image buffer, location, and size for the Matrox Imaging system.

Imaging & Localization

After system initialization the online image appears on the image window. Here the surgeon manually guides and manipulate the image probe to scan the organ or tissue.

Once the required image is available on the screen as shown in Fig-50 can be acquired by clicking the “GRAB IMAGE” on the left hand panel of the window, as shown in Fig-49, a 2D image with the position information (available from the position encoders of the imaging arm) with respect to the base frame of the robotic system is stored.

Fig-49: The GUI with a Pup-Up window for Patient Id input

The surgeon repeats the same operation by guiding the probe to acquire images of the tumor linearly at various positions. Below the GRAB IMAGE button a MOVE button is also provided with an intention to extend automatic movement of the imaging probe with respect to the present position and orientation by specifying the index distance and axis of indexing (not included in the present prototype). This is to acquire a set of 2-D images parallel to each other. All images acquired, either manually or automatically are stored as *.bmp* files in the folder created as per the patient identification.

Fig-50: Diametric cross-sectional view of the socket with four marked points

However, during this trial the diagnostic probe mounted on the jig was manually aligned till a good view of the embedded rod was visible on the image window (Fig-50) showing the longitudinal cross-sectional view of the embedded socket. Considering this as the reference image as described in Chapter-3, section 3.3.1 four points were selected on the image.

Fig-51: The Imaging Probe Fixture

After selecting points on reference image the probe was rotated manually as shown in Fig- 51 exactly 90° (by aligning the index mark with the fixture) to show the cross section view of the rod. Ten images were taken with 2 mm index along the linear slide axis and four points were selected on all images as shown in Fig-50. In the present version of GUI the tumor boundary and the margin boundary are displayed superimposed with the 2D ultrasound image and provision for showing either longitudinal or lateral cross-section is available. Computed tumor volume and margin volume considering 5mm margin (a default amount which can be altered by user) surrounding the tumor is shown in Fig-52.

Fig-52: The Window showing the rendered boundary in cross-sectional view

The estimated volume was compared with the actual volume of the rod. This was repeated for 5 times with different volume of rod and the accuracy of the estimation was found to be less than the volume of one excision sample (56.5 mm^3). In addition, the generated axis was found to be along the longitudinal axis. Though tumor can be of any arbitrary size, here the rod used is only a preliminary indication. In order to get the number of cuts as an integer the calculated number of cuts are rounded up to the next higher number and considered for actual excision. However, the errors shown in Table-8 are not rounded off for better understanding.

Table-8: Computed Tumor Volume

Trials	Computed Tumor Volume (mm^3)	Calculated Number of Cuts	Error of Calculated Volume (mm^3)	Error Number of cut
1	1545.5	27.35	25	< 1 cut
2	1525.5	27	45	< 1 cut
3	1611	28.51	-40.5	< 1 cut
4	1599.5	28.3	-29	< 1 cut
5	1561.5	27.63	9	< 1 cut

5.1.2 Manipulation & Registration

This step was testing of the robotic system, which includes functioning of the Excision arm base unit, wrist unit, mammotome probe drive unit and the test set-up for the imaging arm and finding the accuracy and repeatability of the end-point or the DVAB needle tip. Also finding the best-suited PID parameters for all servo axes was also essential to achieve a smooth and controlled motion of the needle. However, due to the controller limitation (as explained in Chapter-4, section-4.4.2) gross position unit and the wrist unit were tested separately. As shown in the Fig-58, vertical column holding the surgical board and imaging fixture is fixed to the extended base of the excision arm to provide a common and fixed reference.

Test Procedure and Results:

Initially each axis was tested through the Galil's proprietary software "Servo Design Tool". The PID parameters were set using the auto-tuning feature under default tuning method. This was repeated for different load conditions such as arm fully stretched and retracted, pitch down and up with incision in and out to set the optimized parameters

(as shown in Table-9). The first three axes viz. Joints 1, 2 and 3 were tested individually in joint space.

Table-9: Optimized PID Parameters of the Excision Arm

Axis	KP	KD	KI	Speed
Joint-1	120.45	1697.23	6.7	3.75 rpm
Joint-2	118.63	1620.87	6.1	3.75 rpm
Joint-3	70.28	1294.34	6.3	40 mm/s
Joint-4	173.56	1292.23	55.1	5 rpm
Joint-5	173.56	1293.23	55.7	5 rpm
Joint-6	70.46	1139.25	50.3	50 mm
Joint-7	152.48	1294.66	5.2	10 rpm

(Typical performance curve of the PID values for X-axis)

Joint 1 and Joint 2 were tested based on the absolute angle measured between the protractor fixed on to one link and the reference mark on the relative moving link/shaft. Similarly, the up down motion of the third joint was tested by measuring the relative movement from the reference point. As all the three joints are mechanically decoupled, it is possible to manually manipulate each joint independently and fixed them at the required joint position within $\pm 1^\circ$ for Joints 1 and 2, and ± 1 mm for Joint 3. However, this measurement is not very critical for the final positioning accuracy of the needle in the present prototype. To test the orthogonality of the pitch and yaw axis (the linearity of the incision axis and concentricity of the rotary tissue removal axis) of the wrist-unit, a special arrangement was made as shown in Fig-53. The needle was removed from a used mammotome probe and a felt tip pen was fixed at that place.

Base joints with linear scale and protractor

Wrist unit fitted with pen and graph paper

Fig-53: Accuracy & Repeatability Test Setup

An acrylic board holding graph paper of 1 mm resolution was placed perpendicular to needle/pen axis simulating as the image plane. While fixing the paper, the horizontal lines were aligned to the yaw axis plane.

The distance between the image plane origin and excision arm origin (joint 1 axis) along X-axis, Y-axis and Z-axis were measured directly from the origin of the joint-1 axis and used for calculating all joint values through the inverse kinematic routine. After each initialization of the system, the first three joints were moved manually (Fig-53) to the desired position and orientation and manually locked. As all four axes of the wrist unit were connected to the available four servo control from the Galil controller the wrist was moved as per the calculated pitch and yaw angles in servo mode followed by the movement of the needle incision axis as desired. A test program was written to mark eight points representing four corner points of a 4 x 4 cm square and the four mid points of each side of the square. The process of marking the points starting from the center point was repeated for 10 times to verify both accuracy and repeatability of the pitch, yaw and incision axis. The accuracy of marking points with respect to the origin (center of the square) was recorded within $\pm 0.5\text{mm}$. However, it was observed that the system is highly repeatable (less than $\pm 0.5\text{mm}$) as 0.4mm diameter pen tip made marks within four squares ($\pm 1\text{mm}$) along horizontal and vertical lines of the graph paper consistently.

5.1.3 Tissue Removal

This was one of the most vital functionality of the proposed methodology. The objective of this trial is to establish the functionality of the DVAB probe drive system, vacuum system, and controller for rotary tissue removal. Independent macro programs written for the Galil controller were used for these tests. The tissue removal test parameters are shown in Table-10.

Test parameters include:

- Accuracy and repeatability of the tissue excision and cutting efficiency
- Maximum achievable cutting volume
- Step angle optimization

Table-10: Tissue Removal Test Guideline

Parameters	Requirements	Constraints (if any)
Phantoms Tissues	<ol style="list-style-type: none"> 1. Target independent. As it is to establish the functionality. 2. Thick muscle (pork) 	Predefined position and orientation of the excision tool. This is to restrain the movement of the suction window after initial incision except the rotation about its axis. All joints are locked for no movement.
Cutting	<ol style="list-style-type: none"> 1. Progressive cutting: 360° rotation of needle 2. Oscillatory Cutting: $\pm 90^\circ$ oscillation of the needle 	

Tests and Results:

Similar to the previous tests tissue samples such as pork muscle, chicken breast, beef muscle etc were used. The dimensions of the tissue sample were taken as an average of 100mm X 100mm X 40mm. The tissue was wrapped with cling film onto Styrofoam plate that later fixed on to the wooden board using rubber band as shown in Fig-54. A 14-gauge mammotome probe was inserted into the socket of the DVAB probe drive and was aligned approximately at the cross-sectional center of the tissue. A layer of ultrasound jelly was used to couple the tissue with imaging probe. The DVAB probe was guided manually and inserted into the tissue phantom keeping the needle approximately aligned to the image plane such that the location of the needle is visible in the ultrasound image.

Fig-54: A typical setup showing the needle inside the tissue phantom

The DVAB cutter *in-out* motion was under position control and the cutter rotation was under velocity control. To find out the optimized rotation and *in-out* speed, trial motions were performed as per the flow chart shown in Fig-55 and the current drawn by each axis motor was monitored. Ideally, the current drawn by the motor for the *in-out* motion should be minimum ($< 200\text{mA}$) while cutting, which implies the cutting of tissue is primarily due to the rotation of the cutter. The graph in the Fig-56 shows that the change in speed of the *in-out* motion does not affect the torque of the rotary motor while cutting tissue. However, the current drawn by the *in-out* motor varies with variation in the rotary cutting speed (5-60 RPM). The current of *in-out* motor increases below 40 RPM of the rotation speed and remains same above 40 RPM. This indicates that at lower RPM (below 40 RPM) the cutter pushes the tissue before cutting. Thus, the suitable speed for rotary cutter is set at 40 RPM.

Fig-55 DVAB probe operation flow chart

Fig-56: Rotary cutter speed optimization

Optimized speeds (10 mm/sec for in-out motion and 40 rpm for cutter speed) were set for both the drives, and independent tests were conducted to find the accuracy and repeatability of tissue excision for progressive removal and oscillatory removal. Index angle of 45° and 90° for progressive removal and $\pm 45^\circ$ and $\pm 90^\circ$ for oscillatory removal were tested during this step. As shown in the graph (Fig-57) after one full rotation the accuracy and repeatability of the tissue excision drastically reduces particularly when the suction window is facing sideways. As there is only deviation in the length of the excised tissue the graph is plotted considering the deviation from the theoretical/maximum length of the aperture window.

Fig-57: Performance curve of Progressive Removal

The change in index angle was not visible in the accuracy and repeatability as only two rotations were possible. However good repeatability and accuracy was observed in case of oscillatory removal as shown in Fig-58 & 59. There was slight difference in the performance observed between two index angles (deviation in length up to -4 mm in $\pm 90^\circ$ index angle as compared to -2 mm in $\pm 45^\circ$ index). The maximum volume of tumor volume (including margin) that can be targeted with the existing set-up was found to be ≤ 2 cm in diameter. However, this can be improved by a better vacuum system, which can generate more suction to pull tissue beyond 2 cm diameter.

Fig-58: Performance curve for Oscillatory
Removal with $\pm 90^\circ$ index angle

Fig-59: Performance curve for Oscillatory
Removal with $\pm 45^\circ$ index angle

5.2 Feasibility Tests

Feasibility trials were conducted to validate the parameters established during the first stage. Normal animal tissues as in the previous trials were used. The major objectives of this trial were to fine-tune the specifications such as:

- i. The Minimum and Maximum tumor size that can be treated,
- ii. The need of different gauge needle based on the tumor size,
- iii. Safety aspects of the surgical system,
- iv. Sterilization issues.

Similar to the volume estimation trial to simulate the volume of a tumor, an approximately cylindrical shape tissue from a different muscle (chicken, beef etc) was embedded in pork base (instead of stainless steel rod). The dimension of the embedded tissue was maintained within 1-1.5cm in diameter and 2cm in length. The tissue was wrapped with cling film along with styrofoam plate and placed onto the wooden cutting board.

Test Procedure and Results

The imaging probe was fixed with reference to the board and the phantom was aligned to get the best longitudinal image to maintain the reference dimension of the image probe with respect to the Excision arm. The laboratory trial set-up is shown in Fig-60.

Fig-60: The overall setup for the validation trial

After selecting four points on the reference image, imaging probe was rotated 90° to get the lateral cross sectional view of the embedded tissue. While selecting the four points on each image, eight images were taken at 2mm index covering the entire length of the tissue. The volume was computed and displayed in the surgical planning window as shown in Fig-61.

The “Surgical-Execution” button provided at the lower right corner as shown in Fig-61 switch to the excision control by displaying Surgical Control window displaying the real-time online image. The Oscillatory Removal was adopted due to the difficulty of inserting the DVAB probe at the center of the embedded tissue. The embedded tissue was not integral to the base tissue. Therefore, instead of piercing through, the embedded tissue was squeezed inside the base tissue. However, in the real case the tumor is a structurally integral part of the breast tissue. Due to this during incision the surrounding breast tissues restrict the relative movement of the tumor and in turns deform the surrounding tissues. Thus, in the present GUI Oscillating Removal is set as default removal process.

Fig-61: Four points on Reference Image, rendered boundary and incision axis

The incision axis was calculated accordingly and the “POSITION ROBOT” button moved the excision arm to the calculated position and aligned the wrist to the axis. The incision was made through the “INCISION” button which servo locked all the joints and moved the linear incision axis at a slew speed to manually guide the needle along with the movement of the incision axis holding the phantom in one hand. However, the need of holding the tissue in actual clinical trials will be eliminated by the breast-immobilizing cup, as the cup will firmly hold the breast restraining the movement. The real-time position information of the excision arm available in this window was monitored for any change due to manual intervention. As calculated and programmed the process of consecutive removal was enabled by clicking the “EXCISION” button.

The automatic excision was continued for 48 times with real time update of the tumor volume left, margin volume left, and number of cut left after each removal. Fig-62 shows the snap shot of the screen taken during the trial showing nearly half of the embedded tissue along with the needle. The operation was stopped after the required numbers of steps were executed and the needle was automatically retracted and excision arm was moved to a pre-defined position away from the surgical site. After the trial the base tissue was cut apart to see any residual embedded tissue. The cavity created due to the margin tissue removal was, however, not detectable.

Fig-62: The Surgical Procedure showing the online image along with the needle

The feasibility of using the excision arm for a constrained and controllable manipulation of the mammotome probe is shown in the trials as explained in this chapter. Out of the two proposed rotary tissue removal methods, oscillatory tissue removal method is found to be more appropriate with greater tissue removal success. The configuration of the manipulator is found to be suitable for the required manipulation task. In addition, the features and functionalities of the current surgical control software such as image acquisition, the four point selections, volume estimation, incision axis generation, and kinematic calculation were found to be accurate within $\pm 25\text{mm}^3$, which is less than the volume of a single excised tissue.

Chapter 6

Conclusions & Future Work

In this dissertation, a method of extending the presently available mammotome biopsy device (Johnson & Johnson) into a minimally invasive surgical method using robotic technology is presented. Detailed study on the breast cancer staging and available treatment procedure was conducted. However, several problems and limitations are noticed while adopting the mammotome biopsy probe/device for complete removal of tumor and margin area as: -

1. There is no quantitative information available for the tumor volume,
2. There is no predefined procedure for predictable complete removal of the tumor,
3. The registration and location of the tumor is not available,
4. Manual handling of the biopsy probe leads to unpredictable removal of tissue from unknown location.

Two systematic approaches such as the progressive removal and oscillatory removal have been proposed for multiple tissue removal ensuring complete removal of the tumor. As per the requirement of the system based upon the overall constraints of the DVAB procedure a robotic dual-arm system is designed. This system has the ability to manipulate the imaging probe and excision needle independently. Using optimization techniques modular components were designed.

A dual-arm system has been proposed having independent arm for handling imaging probe and mammotome probe. Each arm is based on hybrid configuration comprising of an identical base unit with 3-dofs and two different wrist units for imaging arm and excision arm with 2-dofs and 6-dofs respectively. Considering the budgetary limitations only the excision arm was fully assembled and integrated to a 4-axis PC based servo controller to show feasibility of proposed methodology. A GUI has been developed

incorporating all the required features such as 2D image acquisition, selection and storing of points, volume estimation including margin, positioning and controlling the excision manipulator. A representative number of samples were tested to validate the feasibility of the proposed concept.

6.1 Conclusions

The presented research methodology is based on a simplified approach and efforts are directed towards making it adaptable to the existing mammotome biopsy device, both in operating principle (cutting mechanism is adopted without any modifications) as well as operational features. The present methodology is limited for breast carcinoma-in-situ and where the target region is visible in ultrasound images. As explained in Chapter-3 section 3.3, the tissue sample excised by the mammotome device is cylindrical in shape with fixed dimensions for a given needle size. For target volume estimation, a simplified but crude fitting of linear stacks of this cylinder is considered for defining an encapsulating cylindrical shape. Thus, an over-estimated region of the target region (tumor/lump) is derived instead of accurately defining the boundary of the tumor using various manual or automated boundary detection methods. Though it is understandable that the proposed approach will thus contribute to lower accuracy and precision in excising the tumors, the automated boundary detection and deformable tissue modeling is not explored in this work. The adoption of latter techniques may not have an exact synergy if adopted with mammotome system because it is not possible to excise partial cylindrical regions with a predictable accuracy. The margin region is considered as another cylindrical region (with a user-defined extended diameter) encapsulating the target cylinder. As per the discussions with surgeons involved and considering the relatively lower criticality of breast tissue, it was advised that such an over-excision would be clinically acceptable for small and localized masses only. Based on these discussions, a research objective was initiated in extending the functionality of a commercially available biopsy device (the mammotome), and a part of this objective was entrusted under the present M.Eng. project.

To enhance the functionality of the present mammotome device for surgery, a single incision is adopted with an added provision to rotate (progressive tissue removal) or

oscillate (oscillatory removal) the needle around the needle axis using mechatronic means as explained in Chapter-3 section 3.3. In both the cases, the maximum diameter of the cavity that can be created in a single incision is dependent on the suction force generated by the vacuum system used to pull the tissue into the cutting window for excision. In addition to the suction force, pulling of the tissue is increased due to effect of the gravity during oscillatory tissue removal method. However, this free fall of the tissue under gravity may be unpredictable resulting into imprecise excision. No volumetric modeling/analysis is done in order to study this deformation of the tissue during the excision process, in the scope of this dissertation. A manually guided needle incision is adopted followed by skin incision, which would reduce the initial patient response under local anesthesia.

While conducting feasibility trials using the laboratory prototype system few limitations and shortcomings were observed and are summarized here:

- The manual locking of the base joints are not convenient to operate. It is required to replace them with electromagnetic brakes. Since all the three joints have sufficient space, servomotor with integral brakes could be used.
- The servo locking of the wrist joints (pitch and yaw axes) is not sufficient to maintain the required orientation during manual incision. To ensure maintaining exact yaw and pitch angle, it is required to equip them with electromagnetic brakes. For the wrist, there are space constraints and simple space saving braking mechanism needs to be employed. Instead of using integral brakes with the motor, a mechanism to hold the big spur gears driving the differentials is more suitable.
- The present vacuum system can able to excise up to a maximum of 2 cm diameter of mass through the rotary tissue removal process. This can be improved by increasing the capacity of the vacuum pump generating vacuum of 23" Hg to direct more suction at the aperture window of the needle.
- The yaw axis is found to be not exactly perpendicular to the pitch axis. This can be rectified by improving the manufacturing process.
- Manual retrieval of the excised tissue after each excision is tedious and sometimes leads to damaging the excised tissue sample, which is crucial to the histological studies.

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- The present system cannot detect any false excision (empty retrieval), which leads to error in the total volume excised.

The present methodology promises the defined excision of tissue from a defined location, though for a restricted class of breast tumors/cancers. In order to establish the functionality and feasibility of the proposed approach, laboratory studies were done on trial phantoms. The aim of conducting these trials, as reported in Chapter-5, was for testing the mechanical functionality and excision feasibility of the system. However, since the laboratory trials may not bear any clinical significance (the phantoms lacking cancerous/visible targets may not be a representative of actual target tissue), the need of a statistically large number of such trials was not considered. It is found that the volume estimation error is less than the volume of one single excision. Even though the trials have shown better accuracy, repeatability of tissue excisions with 2cm diameter of cavity formation during oscillatory tissue removal, the progressive tissue removal method has been incorporated as an alternative option. It may be suitable and only feasible option to place the needle axis at the center of the target region where the target is too close to the chest wall.

6.2 Future Work

Based on the limitations as described in the previous section, and in addition to the suggestions for locking mechanisms, further work can be continued on the following aspects:

Design improvements:

The imaging arm as proposed in Chapter-3 needs to be developed along with servo controls for all axes to exploit the full functionalities. It will be more adoptable and modular by developing two identical arms. This will enhance the dexterity of the imaging arm and a generic manipulation system enabling linear, rotary scan pattern in any spherical configuration for further exploitation leading to 3D imaging. The breast immobilizing cup wherein the three steel wires used for reinforcement may impose constraints in accessing and scanning the breast needs to be re-designed. Developments should be done to suitably improve the design of the mammotome outer case to

incorporate sensor as well as the automatic retrieval system. Feasibility trials need to be improved for arbitrary shapes and more realistic boundary conditions.

Safety precautions:

A thorough study needs to be done to implement various safety aspects, such as integrating fail-safe brakes along with redundant end limit sensors and software limits in all joints. A robust software design by incorporating safety interlocks features is needed. Hardware and software emergency buttons for instantaneous stopping of the manipulator are required. The emergency stop should activate automatic storing of the current needle position information for further re-positioning including a safety strategy for safe retrieval of the mammotome needle from the body under emergency conditions. The proposed methodology suggests local anesthesia, hence, the change in registration caused by patient movement as well as the movement due to breathing needs to be studied and an accurate tracking system needs to be integrated for compensation.

Representative Clinical Trials:

It would be desirable to introduce some mechanisms for online monitoring (besides 2-D diagnostic image) in order to monitor the surgical progress during of the tissue excision. As found in our preliminary literature studies, the unpredictable behavior of a soft tissue (such as breast tissue) is a concern area while dealing with soft tissue surgery. For understanding the deformation/collapse under defined excision conditions and thus to make the procedure more precise and predictable, a separate study needs to be initiated, which would probably be effective with a suitable/refined and variable cutting mechanism (instead of using mammotome). Besides establishing the feasibility of the suggested configuration of this work, trials under defined clinical settings having clinical applicability need to be done to establish the clinical feasibility and statistically proven efficacy of the proposed research methodology. Following these, type, stage and size of tumor that can be targeted for this methodology can also be deduced.

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Appendix-1

Breast Cancer Facts & Figures

Estimated Cases and Deaths (Case Study during year 2001 conducted at America)

- Excluding cancers on the skin, breast cancer is the most common cancer among women, accounting or nearly one of every three cancers diagnosed in American women.
- In 2001, approximately 192,200 new cases of invasive breast cancer were forecasted to be diagnosed among women, with 47,000 additional cases of in situ breast cancer (Table-1).
- Also in 2001,40,200 women were expected to die from this disease (Table-1). Only lung cancer accounts or more cancer deaths in women.

Gender

- About 1,500 cases and 400 deaths from breast cancer are expected to occur among men in 2001, accounting for about 1% of all breast cancers.

Table-1: Estimated New Breast Cancer Cases and Deaths in Women by Age, United States, during year 2001

Age	In Situ Cases	%	Invasive Cases	%	Deaths	%
<30	100	0.2	900	0.5	100	0.2
30-39	1,600	3.4	8,000	4.2	1,200	3.0
40-49	10,800	22.9	35,400	18.4	5,000	12.5
50-59	12,500	26.5	46,800	24.3	7,300	18.3
60-69	9,400	19.9	33,100	17.2	5,900	14.6
70-79	9,400	19.9	43,000	22.4	9,800	24.3
80+	3,300	7.0	25,000	13.0	10,900	27.2
Total	47,100	100.0	192,200	100.0	40,200	100.0

Source: American Cancer Society, Surveillance Research, 2001

Incidence Trends

Much of the underlying increase in incidence is attributed to changes in reproductive patterns, such as delayed childbearing and having fewer children. The more rapid increase between 1980 and 1987 is due largely to increased detection through greater use of mammography screening, with diagnosis of smaller, more easily treatable cancers than would have occurred otherwise.

During this short period, incidence rates of smaller tumors (<2.0 cm) more than doubled, while rates of larger tumors (3.0 cm or more) decreased 27%. The much slower increase in rates in the 1990s reflects the leveling off of mammography screening utilization, with incidence trends returning to baseline, and tumors continuing to be diagnosed at an earlier stage.

Fig-1: Female breast cancer incidence and death rates, by race and ethnicity

Fig-2: Female Breast Cancer—Invasive by Age,

Fig-3: Female Breast Cancer—Ductal Carcinoma In-situ by Age

Fig-4: Female Breast Cancer Incidence Rates* by Race and Ethnicity

Fig-5: Female Breast Cancer Death Rates* by Race and Ethnicity
Data source: NCI Surveillance, Epidemiology, and End Results Program, 2001

Table-2: A collection of pathology-proven result and size of breast tumor for 20 ultrasound images

(Source: Y. L. Huang and X. Y. Lin, "Contour Detection for the Breast Tumor in Ultrasonic Images Using Watershed Segmentation" in Proceedings of the 2002 ICS: Workshop on Artificial Intelligence, Hualien, Taiwan, G2-5, Dec. 2002. (NSC 90-2213-E-029-011))

Image No.	Benign/ Malignant	Tumor Size (mm)	
		Width	Height
1	M	18.9	10.6
2	M	25.6	12.5
3	M	16.1	10.4
4	M	11.8	9.0
5	M	5.064	4.6
6	M	14.6	5.8
7	M	14.6	12.8
8	M	16.6	13.5
9	M	23.3	25.4
10	M	20.6	10.2
11	M	19.4	10.6
12	M	10.1	9.2
13	M	23.3	18.0
14	M	15.4	12.7
15	B	13.5	6.3
16	B	0.90	4.2
17	B	13.2	5.6
18	B	15.2	7.8
19	B	15.2	5.9
20	B	19.0	8.3

Appendix-2

Breast Tissue Modeling

There are many approaches available for soft tissue modeling; most are based on surface models typically for breast tissue. As explained earlier breast is an inhomogeneous structure contains many layers of many different kinds of tissue. Due to this breast has a complex tissue property as the layers of different tissues are interlaced with ligaments and the superficial layer or fascias. The fascia is separated from the skin by 0.5 to 2.5 cm of subcutaneous fat where the diameter of the ducts varies from 2 to 4.5 mm. In order to develop a model for deformation of the breast, geometric description of breast, a mathematical model of the elastic deformation typically a finite element model (FEM), and a solution algorithm are required. However, for a realistic model of a breast the finite element model becomes very complex making the model not useful clinically [25]. This resulted in to the requirement of developing a reasonably simpler and application specific finite element model of breast by balancing the accuracy of deformation against the requirement and speed for computation. The two major stages in modeling the breast are

1. 3D Mesh Creation

Because of high variability of breast shapes and its deformations during imaging and incision, it is advisable to build the model following the breast contour [25]. Typically, the geometry of the breast is constructed using high-fidelity image data such as MRI. Using a series of breast contours either manually or automatically demarcated on each 2D image using standard graphics programs a 3D wire mesh can be generated which can be scaled to any size. The typical guidelines for this program and its contents are given below.

- Contains the definitions of volume elements
- Solid eight-node (hexahedral) (Fig-1) tri-linear iso-parametric elements to model all breast tissues except for the skin and assigned non-linear material properties

Fig-1: Elements to build the deformable model (8 node on left and 3-node on right)

- Three-node tri-angular iso-parametric elements to model the skin and assigned non-linear elastic properties in the plane of their triangular surface and no axial stiffness
- Boundary conditions
- Different material properties

A file containing above information written as per the standard format can be exported into any standard FEM software such as ABAQUS or NASTRAN. It is also possible to incorporate the tumor by changing the density of the mesh at the particular location. A typical 2D mesh generation scheme using 2D image data is shown in Fig-2.

Fig-2: Typical 2D mesh generation

2. Integrating Material Properties

Most biological tissues display both a viscous (velocity dependant) and elastic response. Since our requirement is for slow displacement, the great majority of forces developed can be attributed purely to the elastic response. All tissues in the breast can be considered isotropic homogeneous, and incompressible with non-linear elastic properties.

Based on these assumption it is possible to define the mechanical behavior of the breast tissue with a single elastic modulus E_n , which is a function of strain ϵ_n for tissue type n (σ_n is the stress):

$$E_n = \frac{\partial \sigma_n}{\partial \epsilon_n} = f(\epsilon_n) \quad \dots 1$$

This non-linear relationship can be calculated for every tissue type from uniaxial stress-strain experiments using tissue samples [25]. To model in every element a typical steps are followed after every small deformation increment;

- Calculating the Lagrangian strain tensor, E at the center of the element where E is a measure of the deformation of a point in the model with respect to its initial position [29]

$F_{pq} = \frac{\partial x_p}{\partial X_q}$ where F is the 3x3 deformation gradient tensor, and its components

can be written as: $F_{pq} = \frac{\partial x_p}{\partial X_q}$

where x_p is one of the three elements of x , the final position vector, and X_q is one of the three components of X the initial position vector.

- The maximum principal strain component, e_{max} , can be given by the largest eigenvalue of the strain tensor E .
- Based on the experimental stress-strain curve for the particular tissue type, the assigned Young's modulus value for the corresponding element can be

$$e_{max} : E_n = f(e_{max})$$

So after every deformation increment, the element's stiffness value is updated to model the material's non-linear behavior resulting into a continuously differentiable stress-strain curve as a continuous step-wise linear curve. To determine the non-linear stress-strain curve the mechanical properties of breast tissue has been established through experiments.

$$F_{pq} = \frac{\partial x_p}{\partial X_q} \quad \dots 2$$

where σ_n and ϵ_n are the nominal stress and strain respectively for tissue type n. b and m are the fit parameters experimentally determined for every tissue type such as

$$b_{glandular} = 15100 \text{ N/m}^2 \text{ and } b_{fat} = 4460 \text{ N/m}^2$$

$$m_{glandular} = 10.0 \text{ (within 1 standard deviation)}$$

$$\text{and } m_{fat} = 7.4 \text{ (within 1 standard deviation)}$$

As reported, the mechanical properties of skin have been studied more thoroughly. A piecewise linear stress-strain curve is available derived from typical experimental stress-strain curve, that can be used in this to model the skin. The skin elasticity modulus E_{skin} , function of strain ϵ_{skin} can be given as

$$F_{pq} = \frac{\partial x_p}{\partial X_q} \text{ (I - 1 to 3)} \quad \dots 3$$

Typically the values for a_i (in N/m^2) are 3.43×10^6 (for $0 \leq \epsilon_{skin} \leq 0.54$), 2.89×10^7 (for $0.54 < \epsilon_{skin} \leq 0.68$), and 1.57×10^8 (for $0.68 < \epsilon_{skin} < 1$). Experiments shows that skin tissue becomes very stiff (third range of values) due to the presence of the collagen fibers, whose effect is more than the elasticity, which during our intervention will not occur. Experiments also established that it is not possible to compress out the fatty tissue since it remains there inside under compression. A typical model dynamics is given here as a guideline for our above proposed scheme. The finite element method is used through which all quantities necessary for the Lagrange equations of motion are

derived from same quantities computed independently within each finite element. Thus the Lagrange equation of motion can then be written for each and every node I in the model as follows:

$$\alpha I \frac{\partial q_i}{\partial t} = f_{i, total} = f_{i, internal} + f_{i, external} \quad \dots 4$$

where I = the identity matrix, q_i = the three dimensional nodal displacement at node I, $f_{i, internal} = [-Kq]_i$ = an internal stiffness force, and $f_{i, external}$ = an external force combining the body forces. The elemental stiffness matrix, K_e , incorporates the geometry and material properties of the element, which can be computed from the equation below

$$K_e = \iiint_{V_e} B^T D B dV \quad \dots 5$$

This is an triple integral over the volume V_e of the element. Matrix D contains the material property information (which includes the value of material's elastic modulus) and relates nodal stresses σ to nodal strains ϵ ($\sigma = D\epsilon$). Matrix B relates nodal strains to displacements and incorporates the strain tensor formula ($\epsilon = B d_e$). Once the element forces are calculated, each element contributes to the total internal nodal force for each of its nodes. However, for every displacement iteration the equation needs to be integrated using an Euler method with adaptive step sizing until the difference between the sums of all displacements from one time iteration to the next is less than a predetermined threshold.

Similar scheme has been tried using MR data of the breast. The above figure (Fig-3) shows the deformable wire mesh model generated through NASTRAN software superimposed with MR image. The deformation due to the plate compression as used in stereotactic procedure is clearly seen along with the image. In addition, localized deformation is also seen at the needlepoint.

Fig-3: A deformable breast model superimposed with 2D MR image

The proposed scheme using finite elements with the non-linear material properties of the breast can be used to generate a realistic deformable model. This scheme can directly programmed to any FEM analysis software to generate the model. This will help accurately locate the tumor and estimate the volume under typical compression and during needle insertion.

Appendix-3

Mammotome Biopsy Probe Specifications & Drive System

(Source: Johnson & Johnson Inc.)
(<http://www.jnj.com/>)

Mechanical Specifications of the available Mammotome biopsy probes

Table-1: Mammotome probe comparative table

Specifications	14 gauge probe	11 gauge probe	8 gauge probe
Needle Length	89.7 mm	92.4 mm	89.7 mm
Dead Space	5.6 mm	7.9 mm	9.5 mm
Aperture	16.3 mm	19.4 mm	23.0 mm
Tissue Collection	N/A	N/A	N/A
Needle Height (Cutter + Vacuum)	3.1 mm	4.6 mm	6.0 mm
Needle Width	2.1 mm	3.1 mm	4.3 mm
Inner Diameter of Rotating Cutter	1.9 mm	2.7 mm	3.9 mm
Average Sample Weight	40 mg	110 mg	300 mg
Fluid fill Space	1.5 cc	1.8 cc	2.4 cc

Mammotome Probe Drive System

The mammotome probe drive system is already explained in the kinematic design in Chapter-3. As explained earlier the mammotome probe requires independent driving systems both for rotation and translation of the cutter. The basic design parameters such as the axis of motion, speed, torque, and accuracy of the drive system are tabulated in Table-2. The dynamic parameters are derived from the mechanics of tissue cutting. Soft tissue excisions demand control of bleeding and minimal thermal injury.

Based on the standard mammotome procedure, after identifying the incision point the physician manually insert the needle into the patient breast and positions the suction window covering the tumor. As it has already been concluded that the force required and deformation of tissue in the initial incision is not critical and thus ignored. However, the requirement here is simulating the incision of the rotating cutter into the tissue, which is pulled inside through the suction window. Here as the cutter only rotates and moves along its axis without any deflection, all other forces except the forces applied by the cutter to the soft tissue are canceled.

Table-2: Design Parameters of the Mammotome Probe Drive System

Specifications	Translation	Rotation
Task	Moving cutter In-Out	Rotating cutter
Kinematic Configuration	Along the cutter axis	Around the cutter axis
Required Range	125 mm	Continuous
Speed Consideration	Should not push the tissue	Sufficient to cut the tissue without heating the tissue
Torque	Sufficient to overcome the tissue friction and force required to cut tissue	Sufficient to overcome the tissue friction and force required to cut tissue
Accuracy:	~ +/- 0.1mm	NA
Repeatability	~ +/- 0.05 mm	NA

A stationary cutter with a sharp cutting edge sufficient for enforcing shear force has been considered to study the parameter of cutting where the cutter exerts force on the tissue at the edge of the circumference, where the cutter is displacing and cutting the tissue, and frictional forces are applied along the tube.

Then the relation between the displacements of tissue with the shear force can be written as

$$f(F_a) * S_f \Rightarrow f(d) f(E) f(F_r)$$

Where,

S_f = Factor for shearing force or cutting force

F_i = Forced applied

F_r = Friction force on tube

E = Tissue displacement without cutting or Error

d = Positive cutter movement after cutting

This relation shows that, the shearing factor has direct effect on the error. To improve this in DVAB a rotating cutter is used which independently cuts the tissue using the shearing force generated by the rotation and the force applied for translation is to overcome the friction (F_r) and (d). However, F_s depends on following factors

- Cutting speed
- Sharpness of the circumference of the tube
- Tissue properties

The sharpness of the cutter is inversely proportional to the amount of force required to cut the tissue. Assuming constant tissue properties, sharper cutter cuts through the tissue more easily reducing the displacement. It is also reported that increasing the insertion velocity decreases the error due to damping and friction effects between tissue and cutter. But greater the tissue stiffness less is the error as cutter exerts proportionately greater forces, this was established during the Laboratory Trial explained in Chapter-5.

Fig-1: The Schematics of the DVAB Probe Drive Mechanism

However, at this stage a generalized approach has been adopted for selecting the motors for driving the probes as shown in the above figure (Fig-1). The objective was to have a variable speed control with current limiting torque control to be used for empirical studies for parameter identifications. To make the design modular and compact inline approach has been adopted instead of remote cable transmission as in case of the Mammutome hand held system. Both motors for the drives are placed inline with the

DVAB probe at both side and coupled to the driving shaft through a set of spur gears with 3:1 ratio. The design of the shaft ends is such that any gauge probe module can be attached to the drive. The modular design is shown in above figure.

Appendix-5

(Source: Galil Motion Control, Inc.)

(www.galilmc.com)

Details description of the GALIL DMC-1842 Controller

The DMC-18x2 for the PCI bus (Fig-1) is designed for extremely cost-sensitive applications. Performance specifications are similar to the Optima series, but with some features removed for reduced cost such as uncommitted analog inputs, a secondary FIFO, optical isolation and auxiliary encoders. Designed to fit in a single PCI slot of a PC, the DMC-18x2 controllers accommodate 1- through 4-axis formats and allow control of step or servomotors on any combination of axes. Any mode of motion can be programmed including linear and circular interpolation, contouring, electronic gearing and e-cam. Programming the DMC-18x2 is simplified with two-letter, intuitive commands and a full set of software tools such as WSDK for servo tuning and analysis, ActiveX Tool Kit for Visual Basic users and a C-Programmers Tool Kit.

Fig-1: The PC-add-on board (PCI version)

Features

- Accepts up to 12 MHz encoder frequencies for servos and 3 MHz for steppers
- Advanced PID compensation with Velocity and Acceleration feed forward, integration limits, notch filter and low-pass filter. Sample times to 62.5 microseconds per axis

- Modes of motion include jogging, point-to-point positioning, contouring, linear and circular interpolation, electronic gearing and ECAM
- Multitasking for concurrent execution of up to eight application programs
- Non-volatile memory for application programs, variables and arrays
- Home input and forward and reverse limits accepted for every axis
- 8 Uncommitted inputs and 8 outputs
- Expansion for 64 I/O available with DB-14064
- High speed position latch and output compare
- Sinusoidal commutation for brushless servo motors
- High-density shielded cable minimizes EMI with Ceramic Motor Option allows precise control for all Ceramic Motors.

Accessories

Each set comprises of one PCI add-on card, one 3 meter high density d-type connector cable, one interconnecting module and the device drivers and libraries for C++.

Encoders

Optical Encoders

Features:
100 or 180 Lines per revolution
2 Channels
Digital output

Series 10B, 09B, 10BP, 09BP

		10B	09B	10BP	09BP	
Function		speed control		position control		
Lines per revolution	N	100	180	100	180	
Signal output, square wave		2		2		channels
Supply voltage	V_{CC}	4.5 ... 5.5		4.5 ... 5.5		V ⁺ DC
Current consumption, typical ($V_{CC} = 5V$ DC)	I_{CC}	12		12		mA
Pulse width	P	180 ± 30		180 ± 30		°e
Phase shift, channel A to B	φ	90 ± 30		90 ± 30		°e
Logic state width	S	90 ± 30		90 ± 30		°e
Cycle	C	260 ± 10		260 ± 10		°e
Signal rise/fall time, typical	ts/TF	2.5 / 0.1		2.5 / 0.1		µs
Frequency range ^{a)}	f	0.05 to 50		up to 50		kHz
Inertia of code disc	J	0.3		0.3		gcm ²
Operating temperature range		-20 ... +85		-20 ... +85		°C

^{a)} Velocity (rpm) = f (Hz) x 60/N

Output signal information

Encoder type	number of channels	lines per revolution	10B/09B	09B/09BP	In combination with DC-Mikromotors, brushless DC-Servomotors and DC-Motor+Tacho units (preloaded on bearing request)
10B2, 10BP2	2	100	180		free standing for independent use
10B12, 10BP12	2	100	180		series 1628
10B2, 10BP2	2	100	180		series 2228, 2229, 2251, 2256
10B16, 10BP16	2	100	180		series 2228, 2242
10B24, 10BP24	2	100	180		series 2006
10B17, 10BP17	2	100	180		series 2444
10B14, 10BP14	2	100	180		series 2042, 2042
10B4, 10BP4	2	100	180		series 2537

Features

These incremental shaft encoders in combination with the FAULHABER DC-Mikromotors and brushless DC-Servomotors are designed for indication and control of both, shaft velocity and direction of rotation as well as for positioning.

Type 10B and 09B are for shaft velocity and direction of rotation control only.

Type 10BP and 09BP are in addition for position control.

Two LEDs across transparent light through a low inertia metal disc to give two channels with 90° phase shift.

The supply voltage for the encoder and the DC-Mikromotor as well as the two channel output signals are interfaced with a 150 mm ribbon cable and a 10-pin connector.

The total axial and radial shaft play of the motor and the free standing encoder for independent use is eliminated with preloaded ball bearings.

Details for the DC-Mikromotors and suitable reduction gearheads are on separate catalog pages.

Output signals / Circuit diagram / Connector information

for motor series see data sheet for motor and microcontroller

specification subject to change without notice

for motor and cable strain relief

specification subject to change without notice

Appendix-6

Details of MATROX Frame Grabber

MATROX Meteor is a low-cost color/monochrome frame grabber with integrated display for AGP or PCI (Fig-1).

Key Features

- AGP or PCI form factor
- Composite, S-video, or RGB NTSC/PAL
- Video capture composite RS-170/CCIR & video capture up to 8 video inputs
- Arbitrary video scaling trigger input
- VGA display up to 1280 x 1024
- Non-destructive overlay of true-color graphics on live video
- Separate and independent composite, Y/C or RGB NTSC/PAL
- Video output NTSC/PAL & is synchronized to video input
- 32 MB graphics and video buffer
- Available software is sold separately and includes Matrox Imaging Library (MIL support for Microsoft® Windows® 98, Windows® Me, Windows NT® 4.0, Windows® 2000 and Windows® XP

Fig-1: The PCI Matrox frame grabber board

Related Information

- Matrox Orion Installation and Hardware Reference Manual (PDF - 168Kb)
- Matrox Orion PC Compatibility List (PDF - 97Kb)
- Rapid Switching between Multiple Video Inputs (PDF - 353Kb)
- Hardware/Software Cross-Reference Table (PDF - 81Kb)
- Download Area

Connector pin outs

- Expanded video I/O connector
- VGA output connector
- Video input and TV output connectors