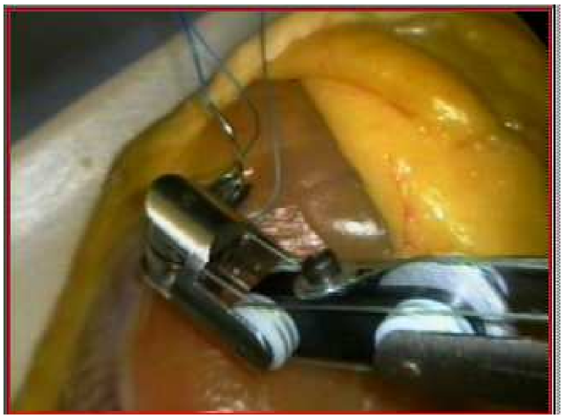

Figure 6-47: Suturing along a line perpendicular with the instrument shaft. Beginning another stitch.

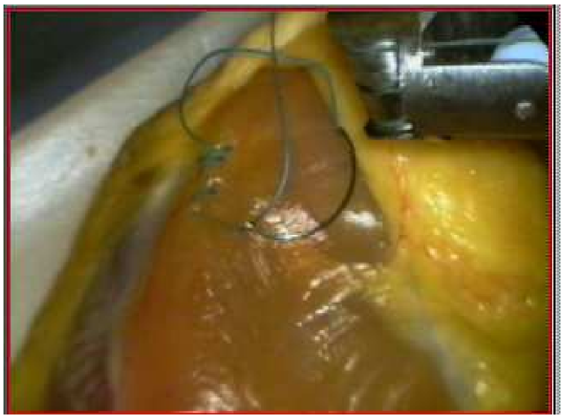

Figure 6-48: Suturing along a line perpendicular with the instrument shaft. A completed row of stitches.

can be felt that most forces which are applied simply cannot be felt. Based on our discriminations tests, forces below roughly .39 N to .58 N cannot be felt.

To give an idea of how soft our "tissue" (the chicken) is, we depressed it with a force sensor (Mark 10 model BG) with a cone shaped attachment with a 60° included angle. To depress the cone approximately 6 mm required anywhere from 0.22 N to 0.6 N. Since we can easily see deflections of less than 1 mm, we will see deflections and hence force being applied long before we feel them.

- Another way of stating this is that we can already do this task fairly well visually. Whether or not force reflection is necessary (better force reflection than we are able to provide) is questionable. It is unclear whether or not vision or touch is more important during the suturing task even when performed during open surgery.
- Motion scaling makes force scaling necessary in order to have reasonable compliance to sense transitions bewteen hard and soft. However, some of the force are fairly large. For example it can take as much as one or two lbs of force (4.4 N- 8.8 N) to push our needle through the chicken. We might use a similar amount of force to draw a suture tightly. These forces, scaled up by a factor of two, almost require two hands to apply while simultaneously controlling three positions, three orientations, and a gripper. I found it convenient to use my left hand to support the end of the master while using my right hand to control fine motions. Again, this is a bit fatiguing and we would like one hand operation.

Figure 6-49: Sliding a tygon tube along a metal “S” shaped metal wire.

Figure 6-50: Sliding a tygon tube along a metal “S” shaped metal wire.

6.6.2 Tube and Wire Test

Another qualitative demonstration is a task where a plastic (tygon) tube is slid over a curved wire which is mounted in a small piece of wood. Figures 6-49 through 6-52 show this task begin performed. This task is actually somewhat more difficult than suturing for several reasons:

- The range of wrist motion required is greater.
- The contact between the instrument and the wire is stiff. This means large forces can be generated which cannot be resolved using visual feedback. Force reflection is therefore more important during this task than during the suturing task.
- Substantial torques can be applied to the wire through the gripper, however we have no torque feedback. Again large forces can be applied to the stiff contact without the user knowing.
- The grip force must be modulated to successfully complete the task. If the tygon tube is gripped too strongly, it will bind on the wire and is unable to slide. Again, we have no gripper feedback (we are not using our actuated gripper here.) Thus grip force can only be modulated through visual feedback, that is by watching the tygon tube deflect.

With force reflection off, I found I could perform this task. However, I had to watch the instrument very carefully for deflections in the instrument in order to determine binding between the tubing and the wire.

Figure 6-51: Sliding a tygon tube along a metal “S” shaped metal wire.

Figure 6-52: Sliding a tygon tube along a metal “S” shaped metal wire.

With force reflection on, I found that when the tube binds, forces are fedback which stop the master from moving, so it becomes clear that the tube is stuck. However, because there is no torque feedback to tell me which way to reorient the wrist to free the tube, I could only watch very carefully and jiggle the tube in order to free it. In all fairness, this task is very difficult. I found it difficult to slide the tube over the wire when using a standard pair of open surgical needle holders (hemostats), largely because it is difficult to modulate grip force with these instruments due to their large mechanical advantage. I could only slide the tube naturally when using my bare fingers.

6.7 Areas for Improvement

There are a number of areas where the Black Falcon can be improved:

6.7.1 Base Unit

- Raise the natural frequency by increasing structural rigidity. While each link was designed to be very stiff, the bearings which connects them were underdesigned from a stiffness point of view. Larger bearings, appropriately preloaded would increase the overall stiffness.
- The “spindle” and “base” pieces should also be redesigned for increased rigidity. In fact, after the unit was constructed, I reinforced the spindle uising two $3/8\times$

1×11 in aluminum bars to reduce torsional deflections about the x axis. This helped, but the base could still use reinforcement.

- I continue to dislike gears and would suggest a redesign where the base motors (axes 0 and 1) used two stage cable reductions instead of a single stage cable reduction and a gearhead reduction. The additional backlash may be contributing to an inability to raise base gains further during force reflecting master/slave operation.

6.7.2 Wrist Unit

- The wrist unit needs to be in general stronger. We do not use the full actuator potential of the base at this time. Partially because we have found that we do not need it in order to securely hold needles. But I am also wary of pretensioning the system more than we do due to strength of the wrist unit and the spectra cable we are using. More pretension would require stainless steel, or better yet, tungsten cable. This however tends to preclude a non-alpha wrist design due to the extra friction created by alpha wraps when used with metallic cable.

- The attachment between the wrist unit and the base unit is inconvenient and not 100% reliable. Currently, we clamp the wrist unit and base unit cables together using screw clamps.

- We would like to further miniaturize the wrist.

- It is critical that we focus on reducing friction in the wrist if we intend to go forward with macro-micro type controllers for implementing force reflection.

- Finally, the geometry of the wrist must be studied in more detail. The kink introduced by our four degree of freedom wrist design is inconvenient during suturing. It seems to get in the way and rub on the tissue. If correctly oriented, it actually helps keep the instrument shaft out of the tissue, but not this in not always the case. While the concept is sound, we feel that the best way to design the wrist to allow macro-micro control is still an open question.

Chapter 7

Conclusions

7.1 Summary

This thesis addresses teleoperator manipulator slave design for Minimally Invasive Surgery, (MIS).

There are several problems in current MIS, specifically:

1. The surgeon is deprived of three-dimensional depth cues and must learn the appropriate geometrical transformations to properly correlate hand motions to tool tip motions.

2. The surgeon's ability to orient the instrument tip is reduced. The incision point/cannula restricts the motions of the instrument from six DOF to four. As a result, the surgeon can no longer approach tissue from an arbitrary angle and is often forced to use secondary instruments to manipulate the tissue in order to access it properly or to use additional incision sites. Suturing become particularly difficult.

3. The surgeon's ability to feel the instrument/tissue interaction is nearly eliminated.

This work is based on the premise that despite surgeons' considerable skill and ability to work within the constraints of current MIS technology, the expansion of minimally invasive medical practice remains limited by the lack of dexterity with which surgeons can operate while using current MIS instruments.

We propose teleoperation as a solution, specifically, this thesis focusses on the the design of teleoperator slave manipulators. Chapter 3 discussus control algorithms within the context of a three degree of freedom testbed consisting of a two degree of freedom slave and one degree of freedom master. The slave is designed with a low inertia distal micro freedom mounted to a large inertia macro freedom. We study several forms of macro-micro control which take advantage of the discrepancy in inertia.

In Chapter 5 we present the Silver Falcon telemanipulator slave, a seven degree of freedom arm consisting of a two degree of freedom base which pivots the device about the remote center of rotation created by the surgical incision. This base is coupled to a five degree of freedom non-removable wrist unit. The wrist unit consists of actuation and transmission elements for a wrist and gripper which is attached to an instrument shaft which passed into the body. This system was tested using a Phantom haptic interface, modified with an instrumented gimbal and gripper to measure positions of seven degrees of freedom. Three directions of force feedback are available with this master.

There were a number of areas where the Silver Falcon was limited. The wrist kinematics allowed us to use macro-micro control in only two out of three directions meaning that there was always one direction in which the surgeon could not feel forces. There were also practical issues such as excessive structural flexibility, insufficient base servo performance, and the lack of sufficient grip strength to hold needles securely. Finally the wrist was designed as an integral part of the system and is not interchangable with other instruments or sterilizable.

Our second teleoperator slave, the Black Falcon, is described in Chapter 6 and was designed to address some of these issues. This eight degree of freedom arm is structurally stiffer and considerably stronger in terms of actuator capacity. The system is counterbalanced for safety by placing all of its actuators at its base and using cable transmissions to actuate the wrist and gripper. This also allows the wrist unit to be detatchable to allow future development of wrist-units which perform other functions, such as cutting, grasping tissue instead of needles, and cauterizing. This basic concept also allows the actual portion of the instrument which enters the body to be sterilized. The wrist was redesigned with an additional degree of freedom to allow macro-micro control in all three linear degrees of freedom with the goal of allowing forces to be felt equally well in all three directions.

We found that the system had the appropriate kinematics and range of motion to allow suturing along aribitrarily oriented suture lines. Force reflection was however inadequate to help the suturing task. Force reflection is more useful during rigid contact tasks where force information is not available to the operator via visual cues. One such task, although not surgical, is sliding a plactic tube along a curved metal wire, a task which is difficult using direct manipulation with open instruments. We could perform this task using the Black Falcon, albeit with difficulty. The lack of torque feedback from our master manipulator was a noticable limitation during this task. Tests were carried out using both the Phantom haptic interface and the Tool Handle (a scaled up version of the Phantom) as a master each mounted with an instrumented gimbal and gripper.

7.2 Comments on Master Design

A few comments are warranted on the design of master manipulators for minimally invasive surgery, and in particular on the suitability of the Phantom haptic interface to be used for such purpose. In general we very much like the Phantom, a three degree of freedom arm which is nearly counterbalanced mechanically (the remainder can be done in software using motor torques) and which has low friction and no backlash in the tranmissions. There are several areas where we might improve this system however:

- To have similar encoder resolution to the Black Falcon, resolution needs to be improved by roughly $100\times$. This would improve master-slave teleoperation by giving the slave a much smoother command to track.
- Continuous force levels need to be increased by about $10 - 20\times$ to allow scaled force reflecting teleoperation.
- The structural stiffness of the master is low and could easily be increased by several times through improved design, especially bearing design at the joints.
- A higher degree of freedom wrist is required. One of the most annoying problems while using the system was running into rotational limits of the master well before running into such limits on the slave. One solution is to use a kinematically identical master and slave. However reorientation of the slave would then required reorientation of the master to keep this benefit. The other solution is to inrease the range of motion of the master wrist, most likely through the use of a four degree of freedom wrist, that is through the addition of an output roll. In order to take advantage of this however, the gimbal must have at least one controlled joint (the input roll) in order to ensure that singularities are avoided.
- There is another reason to power the wrist joints. When the surgeon lets go of the master (which they have a surprising tendency to do), the master wrist will simply fall. Even if it were balanced one could bump it easily. The slave wrist will then track this motion potentially causing damage to tissue. If sensors

are incorporated which determine whether or not the surgeon is holding the master, then we have two options. First we can disconnect the two in software, so that when the master wrist falls, the slave wrist does not move. In this case reengaging the system becomes a problem, in that the surgeon would have to realign the two (with some sort of visual cues displayed on the video monitors for example) before the controller would reengage the system. The second option is that we power the master gimbal so that when the surgeon lets go, it simply freezes in position so that misalignment between the master and slave never occurs. Another advantage of this approach is that if the slave manipulator is repositioned with respect to the patient, the master manipulator can reposition and reorient itself automatically in order to maintain visual correspondence between the two.

The disadvantage is that powering wrist comes with a substantial increase in design complexity and possibly weight.

- Finally, we may want to go one step further and not only power the wrist but design these degrees of freedom to allow precise application of forces in order to give the surgeon torque, as well as force, feedback. Our feeling at this stage is that the the need for torque feedback, while certainly useful in some tasks, has not proven itself sufficiently useful during surgical tasks to warrant incorporating it into the surgical master.

7.3 Future Work

7.3.1 Force Reflection

The quality of force reflection needs to be improved. How this may best be done is unclear. One way is to pursue our current track and further improve the transmission characteristics of these systems, primarily in order to reduce friction. Brushless motor technology which typically has had many problems when applied to force control may have improved sufficiently to help here as well.

Another is to incorporate additional modes of sensing into the system. This is not meant as carte blanche to remove the good qualities (low friction and backlash free transmissions, lightweight distal joints) which we have strived to incorporate, but rather to augment them in order to further improve the system. Force sensing in particular has for many years been a subject of much interest. Perhaps improvement in the quality of sensing available will make the addition of force sensing a reliable, robust, and accurate way to augment the quality of our force reflection.

7.3.2 Enhanced Modes of Teleoperation

Replacing hand-held instruments with teleoperators open the door to enhances modes of surgery. In particular, we have a way of giving more information to the surgeon in a fairly natural way.

7.3.2.1 Visual Overlays

The first way is to include visual overlays into the surgeons view of the operating site. Since this view is already planned to be in 3D, why not have images, MRI images of tumors for example, directly overlaid onto this view? This would be an incorporation of work such as (Grimson et al., 1996) into teleoperated MIS.

7.3.2.2 Visual Overlays

The second is to add haptic overays onto the workspace of the master manipulator. We can easily place walls or funnels within this workspace in order to guide the surgeon or to protect sensitive areas from accidental contact. The difficult part of both of these problems is actually getting the information accurately and registering it to the actual anatomy. Displaying it is relatively easy.

7.3.2.3 Beating Heart Surgery

Another example is operating on moving tissue. The classic example is operating on a beating heart, in order to avoid the need for a heart lung machine and the trauma associated with circulating blood through it. If the motion of the heart can be measured, the slave can track this motion. In the reference frame of the slave, the heart is now still. The same thing can be done to image of the heart, either by having the arm which holds the camera track the heart, or by nulling out motions in the image using the measured position of the heart. Then the illusion can be created for the surgeon that he is operation on a still heart, when it is in fact beating. The difficult part of this problem of course is measuring where the heart is. For the slave to track this, we need information at servo rates, preferably at better than servo rates so that we may filter noisy data. How then can we determine six degree of freedom motion at say 4000 Hz? It will be difficult or impossible to to this using a video image. It may be much more feasable to do this using a small instrumented mechanical arm which is placed directly onto the heart. This arm would then both partially stabilize the heart and measure its motions precisely at rates limited only by computational speed.

Appendix A

Will minimally invasive CABG be worthwhile? Lessons from laproscopic cholecystectomy, coronary angioplasty and open CABG.

A.1 Introduction

There is a great deal of interest currently in minimally invasive coronary artery bypass graft surgery (CABG), (Winslow, 1997). As these procedures and technologies are introduced, some questions will naturally arise: Will patient outcomes be improved? Will there be an increased risk of complications? Will MIS CABG save money or will it be more expensive than traditional CABG? Will surgeons accept these procedures? Will patients demand them? Are these procedures really necessary, or is the primary push coming from the medical instrument industry? To better understand some of these questions and what the relevant costs and benefits might be, we take an historical look at the use of minimally invasive surgery (MIS) for cholecystectomy, comparing laparascopic and open techniques, and for cardiac surgery, comparing open CABG to percutaneous transluminal coronary angioplasty (PTCA).

MIS procedures have been touted as directly reducing costs to payers in terms of decreased hospital stay. However, there have also been higher reported comlications and questionable improvements in efficacy. At the same time, we have seen and surgeons have predicted for several years the increased use of MIS techniques, (Bloom et al., 1995).

We find that in the case of laparascopic cholecystectomy, a consensus has been reached by the medical community that this is a useful and viable procedure which patients prefer, (NIH, 1993). However the actual quantitative savings in terms of hospital costs and long term outcomes appear to be slight with estimates ranging from essentially 0% to 20%, (Bass et al., 1993), (Fisher et al., 1991). The primary cost savings is in reduced hospital stay which is offset considerably by the higher cost of instruments. The consensus seems to be that the increased cost due to increased risk of bile duct injury apears to have diminished as surgeons have become more experienced with the procedure. Patient satisfaction and cost due to reduced time away from work, while important, do not typically enter the published studies.

When comparing CABG to medical therapy alone to treat coronary artery disease, it is clear that CABG improves quality of life, but unclear that it increases life expectancy except in severe cases such as triple vessel disease or occlusion of the left main coronary artery. Given their large number (roughly 400,000 annually in the United States) the procedure is clearly well accepted.

When comparing angioplasty to CABG, it is unclear as to which is in fact less expensive. The primary reason is that the rate of restenosis in angioplasty is high requiring subsequent angioplasty or CABG. It is likely that the less invasive nature of angioplasty drives surgeons to administer it (and patients to request it), despite published comparisons of costs and effectiveness.

Finally, it is too early to make clear statements about the cost effectivenes of new MIS cardiac procedures. A preliminary estimate indicates that the cost saved due to reduced hospital stays is not sufficient to offset additional instrument costs. The cost savings to the patient or their employer due to a faster return to work (in the case they are working) could be substantial, but is unlikely to drive the technology since the hospital or payer do not see these savings. The desire to improve outcomes and to keep abreast with the latest technology may well be the deciding factors in driving these techniques into the market.

A.2 Laparascopic versus Open Cholecystectomy

A.2.1 Introduction

Until 1991, the primary treatment of symptomatic gallstones was surgery to remove the gallbladder, which resulted in a roughly 5-day hospitalization and 3-6 week period of convalescence. Alternative treatments have since been developed including oral bile acid dissolution, contact solvent dissolution, mechanical extraction through a catheter, and fragmentation by shock wave lithotripsy combined with oral bile acid dissolution. These treatments all leave the opportunity of recurring gallstones since the gallbladder is left in place, (NIH, 1993).

Laparascopic cholecystectomy was first performed in the U.S. in 1988. Using this technique, the abdomen is first inflated with CO_2, an endoscopic camera and surgical instruments are inserted through small incisions (.5 inch) in the abdomen to view the operating site and to perform the necessary manipulations to remove the gallbladder. It was estimated in 1993 that 80% of cholecsystectomies were performed this way, and today the percentage is most likely above 95%.

A.2.2 Published Comparisons

A number of studies compare cost effectiveness and efficacy of laparoscopic cholecystectomy with that of open cholecystectomy. We find that despite the much publicized potential for cost savings, the actual cost advantage of laparascopic over open cholecystectomy is slight and could be easily subsumed by additional costs due to complications. There is evidence that patient satisfaction and a desire to keep abreast of technology as opposed to economic benefits to paying orgainzations or hospitals appear to be a prime motivator for the widespread acceptance of the procedure, (Escarce et al., 1995).

Bass et al performed a cost-effectiveness analysis comparing laparascopic cholecystectomy with open cholecystectomy, (Bass et al., 1993). They used a decision analysis type approach, estimating probabilites of outcomes, made quality-of-life adjustments, and estimated costs of different health states. Reviewing the results is interesting in order to find where the potential costs and benefits are for MIS procedures in general.

They first assigned probabilities to clinical events and gave references regarding how these probabilities were assigned, see Table A.1. Base estimates are for 45 year old women. These probabilities indicate that 1) a major non fatal complication is 3 times more likely in open cholecystectomy, and yet 2) biliary stricture formation is 2.5 times more likely in laparoscopic cholecystectomy. This indicates the basic tradeoff between the increased potential for complication due to the surgical wound in open surgery versus the increased possibility of making mistakes during MIS procedures.

They then identified types of morbidity and assigned utility values, Table A.2. This confirms our notion that morbidity due to the open procedure is higher than that for the laparoscopic procedure. Using their probability and quality of life estimates, they found the expected gain in quality adjusted survival with laparoscopic cholecystecomy over open cholecstectomy for 45 year old women to be just 0.29 months (52.16

Type of Clinical Event	Open Chole Probability	Lap Chole Probability
Operative mortality	0.002	0.0008
Major nonfatal operative complication	0.10	0.033
Postchelecystectomy syndrome	0.05	0.05
Retained gallstones	0.01	0.01
Successful T-tube extraction	0.95	-
Mortality from T-tube extraction	0	-
Recurrent stone in bile duct	0.01	0.01
Succesful removal of bile duct stone by endoscopic sphincterotomy	0.90	0.90
Mortality from endoscopic sphincterotomy	0.01	0.01
Mortality from re-exploration of billiary tree	0.018	0.018
Biliary stricture formation	0.01	0.025
Mortality from choledochoenterostomy	0.02	0.02
Stricture recurrence after repair	0.20	0.20
Conversion from open to lap surgery	-	0.042

Table A.1: Probabilites of Clinical Events During Cholecystectomy (Bass et al., 1993)

Type of Morbidity	Utility Value
Complications	
Complications of surgery	0.77
Postcholecystectomy syndrome	0.79
Surgical scar	0.988
Procedures	
Laparoscopic chole	0.91
Open chole	0.77
Endoscopic sphincterotomy	0.95
T-tube extraction of stone	0.83
Reexploration of biliary tree	0.77
Biliary stricture surgery	0.64

Table A.2: Utitility Estimates (Bass et al., 1993) versus 51.89), or just a fraction of a percent of the total gain due to either procedure. So based on quality alone, this analysis does not show a significant difference between either procedure.

Bass et al. estimates costs from their experience in the state of Maryland. For a 45 year old individual with acute or chronic biliary pain and documented gallbladder stones, the differences in projected average total charges at the end of 1 month were less for the laparoscopic procedure than for open procedure by $651.00 ($4431 vs. $5082) for women, and $1271 ($5118 vs $6389) for men. Though it is not stated explicitly, I believe the estimates are given in 1993 dollars. Over 5 years the savings due to the laparoscopic procedure were $171 for women and $794 for men. The difference is greater if only patients with acute cholecystis are considered ($1019 for men and women combined). However if they considered using a preoperative retrograde cholangiography and sphincterotomy (raising charges by $667), then for 45 year old women charges were increased on average by $496.

To summarize, the differences are slight. The addition of cholangiography, which is standard in teaching hospitals, can make laparoscopic procedure more expensive than the open one, not less. The primary complication is bile duct injury which has a substantial effect on the analysis because of the high costs associated with it. In support of the laparoscopic procedure, however, we note that Bass et al uses a 2.7 day average hospital stay for the lap chole, whereas most reports today estimate a 1 day stay. Also, the analysis does not include indirect costs such as time lost from work which might make a substantial difference in favor of lap chole.

Another perspective on the likelyhood of complications is given by Bernard et al, (Bernard and Hartman, 1993). Complications which are not discussed in Bass et al are: major vascular injury (aorta, vena cava), hematoma or hemorrhaged bowels, bladder perforation, and incarcerated bowels (through the instrument ports). Apparently these totaled 158 for New York State between August 1990 and March 1992. Almost 72% resulted in open surgical repair. 18% resulted in conversion to open cholecystectomy during the same procedure. This data was available because N.Y. State health law requires such incidents to be reported to the State Health Department.

Until January 1992, a seperate identification code did not exist for laparoscopic cholecystectomy. (The Statewide Planning and Research Cooperative System, SPARCS, processes data from N.Y. state hospitals). So the total number of laparoscopic cholecystecomies during that time was not reported in Bernard et al, but they do report that between January 1 1992 and October 29 1992, 19,697 cholecystectomies were reported and 13,159 were coded as laparoscopic cholecystectomies. Due to time delay in reporting, they expect the numbers to be much higher. They also show, between April and October 1992, that there were 22 major complications reported due to open cholecystecomy vs. 90 complications during laparoscopic cholecystectomy, with 5 major bile duct injuries or leaks during open chole compared to 44 during lap chole. This data contradicts the results found by Bass et al. Both studies were published in the same April 1993 issue of the American Journal of Surgery.

We might suppose that New York State is different. However the data presented is real (albeit retrospective and using fairly small sample sizes). Bass et al estimated complication rates because they found actual data to be difficult to acquire as no randomized trials had been done to that time.

Despite this one fairly negative report, most other reports support the view that laparascopic cholecystectomy is a valid and useful procedure. For example the NIH formed a Consensus Development Panel on Gallstones and Laparascopic Cholecystectomy which supports this view, (NIH, 1993). They state that: "Laparascopic cholecystectomy provides distinct advantages over open cholecystectomy. It decreases pain and disability without increasing mortality or overall morbidity. Although the rate of common bile duct injury appears to be increased, this rate is still sufficiently small to justify the use of laparascopic cholecystectomy in the treatment of symptomatic gallstones."

Williams et al (Jr. et al., 1993) also supports this view and states: "LC appears to be a safe procedure with a low incidence of complications including bile duct injury when performed by adequately trained surgeons".

Steiner et al (Steiner et al., 1994) states that using data from 1985-1992, "In Maryland, although the adoption of laparoscopic cholecystectomy has been accompanied by a 33 percent decrease in overall operative mortality per procedure, the total number of cholecystectomy-related deaths has not fallen because of a 28 percent increase in the total rate of cholecystectomy". In other words, in terms of overall societal costs, there has been an increase in the rate of cholecystectomes, which likely offsets any savings due to individual procedural costs.

The question of costs for MIS procedures is a subject of debate with much arguement concerning the costs of the specialized instruments used to perform laparascopic surgery. For example, Traverso (Traverso, 1995) studied costs for laparascopic surgery over a one year period and found that 28% of OR costs could be attributed to disposable instruments. He recommends that reusable instruments be used to decrease costs (Traverso, 199). In constrast, Reichert (Reichert, 1993) suggests that when the full costs of labor and time required to maintain and sterilize reusable instruments are considered, that disposables justify their cost and decrease risks associated with the difficulty in sterilizing these complicated instruments. Voyles in fact reports published hospital costs for laparoscopic cholecystectomy which vary by a factor of 4 between different hospitals, (Voyles, 1993)

We note finally that, despite a lack of quantitative evidence at the time, laparascopic cholecystectomy was rapidly adopted and accepted amongst general surgeons. Diffusion of the procedure amongst general surgeons went from several % in 1990 to 81% in 1992, (Escarce et al., 1995). More than three fourths of the adopters questioned in this report stated a "desire to keep up with the state-of-the-art and improved patient outcomes as very or extremely important reasons for adopting laparoscopic cholecystectomy."

A.2.3 Summary

A consensus has been reached by the medical community that laparascopic cholecystectomy is a useful and viable procedure which patients prefer. However the actual quantitative savings in terms of hospital costs and long term outcomes appear to be slight. All of the following issues are relevant:

- Decreased morbidity and improved patient satisfaction with laparoscopic cholecystectomy.
- Decrease time lost from work with laparoscopic cholecystectomy.
- Increased risk of complications such as bile duct injury with laparoscopic cholecystectomy.
- Increased risk of complication due to wound trauma due to open cholecystectomy.
- Decreased cost of hospitalization in laparoscopic cholecystectomy.
- Increased cost of instruments in laparoscopic cholecystectomy.
- Technological imperative - the feeling in the surgical community that one must remain current with the technology.

A.3 Coronary Artery Disease

The second area we look at is cardiac surgery, in particular we look at the comparisons which have been made between coronary artery bypass grafting surgery (CABG) and medical therapy and also comparisons between CABG and percutaneous transluminal coronary angioplasty (PTCA). In the near future, I expect the introduction of minimally invasive CABG will produce similar comparisons. Below we discuss published reports on the efficacy of CABG versus medical therapy, and of angioplasty versus CABG.

The methods of assesment for CABG, in addition to the procedure, have gone through a period of evolution according to Preston (Preston, 1989). CABG was developed in the late 60's, and early assesments in the early 70's were largely anectodal. The first large randomized study, the Veterans Administration Study, was reported in 1976 (Murphy et al., 1977), followed by the European Coronary Surgery Study (ECSS) (Varnauskas, 1988), and the NIH-sponsored Coronary Artery Surgery Study (CASS) (CASS, 1983a; CASS, 1983b), discussed below. It is interesting that, as Preston states, initially cardiologists asked cardiac surgeons to support their claims that CABG was an efficacious treatment when compared to medical therapy. But the tables turned after the introduction of angioplasty, with cardiac surgeons asking cardiologists to justify the recommendation of angioplasty.

A.3.1 Efficacy Studies

A.3.1.1 CABG versus Medical Therapy

The first question is whether or not CABG prolongs life, or whether the primary benefit is to improve quality of life when compared to medical therapy. Weinstein et al (Weinstein and Stason, 1982) states that the Veterans Administration (VA) Cooperative Study and the European Coronary Surgery Study Group indicate that surgery prolongs life in patients with coronary artery disease involving three vessels or the left main coronary artery. In contrast, the CASS reports surivival data which states: "In contrast to the European Collaborative Study, the CASS does not show a significant decrease in survival rates for patients with three-vessel disease and ejection fractions greater than 0.50, or in patients with two- or three-vessel disease involving the left anterior descending coronary artery.", (CASS, 1983a).

The CASS reported specifically on both survival data (CASS, 1983a) and on the quality of life (CASS, 1983b) associated with CABG as compared to treatment with medication alone. This study followed 780 patients with $\geq 70\%$ stenosis of one or more operable vessels for a mean of 5.5 (3.8-7.7) years and used the following factors for comparison:

- Chest pain: classified as occurring during four different cases ranging from strenuous physical activity to occuring with any activity or at rest.
- Activity limitation: classified by levels of limitation during normal daily activites.

- Heart failure: recorded if patients reported ankle edema, dyspnea, or orthopnea.
- Graded excercise tests: a series of treadmill excercises.
- Employment status: unemployed, part time employed or full time employed.
- Recreational status: classified as strenuous, moderate, mild, or sedentary.

While there were no significant differences noted in heart failure, employment status, or recreational status between the surgical or medical groups, there was marked difference between chest pain status, activity status, and graded excercise tests. For example, roughly 20% more patients who underwent surgery reported no chest pain after five years than did those who underwent medical therapy alone averaged over patients with one, two, and three vessel disease. The need for extensive drug therapy causes problems with compliance, may itself reduce quality of life, and adds cost for the life of the patient.

The conclusion is that CABG definitely improves quality of life when compared to medical therapy alone, but most likely does not improve life expectancy in one and two vessel disease. There is still some question as to whether or not it improves life expectancy in left main disease or in three vessel disease.

A.3.1.2 CABG versus Coronary Angioplasty

For reference, there have been a number of trials comparing angioplasty with CABG. These include the Randomised Intervention Treatment of Angina (RITA) trial (Hampton et al., 1993), the German Angioplasty Bypass Surgery Investigation (GABI) (Hamm et al., 1994), the Coronary Angioplasty Bypass Revascularization Investigation (CABRI), the Argentine Randomized Trial of Percutaneous Transluminal Coronary Angioplasty versus Cronary Artery Bypass Surgery in Multivessel Disease (ERACI) (Rodriguez et al., 1993) and the Bypass Angioplasty Revasularization Investigation (BARI) (BARI, 1991).

The main points of comparison between angioplasty and CABG can be seen by looking at data from Hamm et al, (Hamm et al., 1994). In this study, patients with at least two major vessels supplying different myocardial regions of the heart were studied. Hospitalization was 19 days for CABG versus 5 for PTCA. Q-Wave myocardal infarction was more common in CABG (8.1%) than in PTCA (2.3%). In hospital mortality was 2.3% in CABG versus 1.1% in PTCA. 93% of CABG patients were free from angina at discharge versus 82% for PTCA. 6% of CABG patients required further intervention within one year (1% CABG and 5% PTCA) versus 44% of PTCA patients (18% CABG and 3% PTCA).

	Gone	Improved	Same or Worse
Medical	16%	32%	52%
Surgical			
year 1	63%	20%	17%
year 2	45%	11%	44%

Table A.3: Outcomes for Medical Therapy vs. CABG, from Weinstein et al, (Weinstein and Stason, 1982)

	1vd	2vd	3vd	LMD
surgical	20.7	20.3	20.4	19.5
medical	20.9	19.7	17.2	12.6
difference	-0.2	+0.6	+3.2	+6.9

Table A.4: Expected Increase in Life Expectancy for CABG over Medical Therapy, from Weinstein et al, (Weinstein and Stason, 1982)

It is clear, from this study and others, that while CABG is a substantially more traumatic experience for the patient, the likelyhood that the patient will be free from angina is much higher.

A.3.2 Cost-Effectiveness Studies

A.3.2.1 CABG vs. Medical Therapy

Weinstein et al (Weinstein and Stason, 1982) performed a cost-effectiveness analysis of coronary artery bypass surgery versus medical therapy in 1982 which tries to measure cost-effectiveness in terms of quality-adjusted life years (QALY's) and assigns a net cost per added QALY. They consider the following outcomes for life expectancy: operative mortality, survival after surgery, and survival with medical management. They try to asses quality by assigning a weight to each level of angina in order to derive a measure of quality adjusted life-years. Based on the data in Table A.3 on relief from symptoms and life expectancy, they find values for quality-adjusted life expectancy for surgical versus medical therapies for one, two, three vessel disease and left main disease, Tables A.4, A.5.

Essentially, their quality of life assesments serve to modify their survival data, but

	1vd	2vd	3vd	LMD
surgical	17.1	16.8	16.9	16.2
medical	16.6	15.7	13.7	10.0
difference	+0.5	+1.1	+3.2	+6.2

Table A.5: Quality Adjusted Expected Increase in Life Expectancy for CABG over Medical Therapy from Weinstein et al., (Weinstein and Stason, 1982)

	1vd	2vd	3vd	LMD
$000	30	17.5	7.2	3.8

Table A.6: Net Cost per Quality-Adjusted Life Year Gained Using Surgery instead of Medical Therapy for Q = 0.7, from Weinstein, (Weinstein and Stason, 1982)

do not seem to have a large effect on overall advantage, in life years, of one procedure over the other.

Weinstein defines four sources of costs:

- Cost of surgery itself.
- Differences in the cost of medical management with and without surgery.
- Savings due to the prevention of coronary artery disease, especially myocardial infarction.
- Differences in costs of repeated or subsequent operations.

He then finds the net cost per quality adjusted life year gained by using surgery instead of medical therapy for various levels of angina. For example, for patients with severe angina (Q = 0.7), Table A.6. The majority of the cost difference is due to the cost of surgery as opposed to savings on medical therapy. If increased quality-adjusted life expectancy is in question, the above analysis is meaningless. This is likely to be the case in one and two vessel disease.

To summarize this information, if a substantial increase in life expectancy exists, then cost effectiveness based on this study turns out to be essentially the cost of surgery divided by the increase in life expectancy. Of course, if the efficacy of two treatments is equal in terms of QALY's, then while differential cost-effectiveness is undefined, the lower cost treatment can still be selected.

A.3.2.2 CABG vs. Coronary Angioplasty

Reeder (Reeder et al., 1984) compares the cost of percutaneous coronary angioplasty with that of bypass surgery. This is a one year retrospective study of 79 patients who underwent PTCA and 83 patients who underwent CABG in order to compare costs and to some degree reported benefits between the two.

Costs included those due to initial hospitalization, follow-ups, later procedures and hospitalization for restenosis either using PTCA or CABG. Over the course of one year, the average cost for PTCA was found to be 15% lower than for CABG (not adjusted for quality of life). However, the costs for PTCA ranged from a roughly 50% lower cost for patients who did not require subsequent restenosis to a 52% higher cost for those who required subsequent restenosis via CABG. An overall 33% restenosis rate (both via PTCA and CABG) was reported.

The authors suggest that a substantial savings could occur if the percentage of patients requiring restenosis were reduced. At the time this seemed likely because the procedure was still young. However, other more recent studies (King et al., 1994) report the levels of restenosis required in PTCA over the course of three years is over 50%, suggesting this is unlikely.

Quality of life was reported as essentially equal between PTCA and CABG treatments. Patients seemed equally satisfied (or dissatisfied) with their health status. However, the percentage of patients who returned to work (who were working prior to treatment) was significantly higher amongst PTCA patients (95% for PTCA versus 75% for CABG). We can speculate that the trauma induced by CABG is sufficient to deter patients from returning to work even after (or perhaps because of) a relatively long period of post operative convalescence.

A.3.3 Summary

We have looked at some published comparisons between treatments of coronary artery disease via medical therapy, percutaneous transluminal coronary angioplasty (PTCA), and coronary artery bypass grafting (CABG) surgery.

It is clear that CABG improves quality of life when compared to medical therapy alone, but unclear that it increases life expectancy except in severe cases such as triple vessel disease or occlusion of the left main coronary artery. This comes at a substantial monetary cost, and while it is the subject of debate, it appears to be the consensus among physicians that it is worth the cost.

When comparing angioplasty to CABG, it is unclear as to which is in fact less expensive. The primary reason is that the rate of restenosis in angioplasty is high requiring subsequent angioplasty or CABG. The obviously less invasive nature of angioplasty compared to CABG likely drives surgeons to administer it (and patients to request it). It is unclear whether a real comparison of costs and effectiveness is made during these decisions.

A.4 New Cardiac Technology

This finally brings us to new minimally invasive techniques for cardiac surgery. Up to this point we have found that minimally invasive technology was rapidly accepted in the case of laparascopic cholecystectomy and coronary angioplasty prior to any controlled trials to prove efficacy and cost effectiveness. The decrease in recovery time and trauma to the patient seem like clear advantages. Surgeons cite a desire to keep abreast with the technology and to improve patient outcomes, and the perception that these techniques decrease costs to the payer, typically insurance companies, primarily through a reduction in hospital stay.

In fact, the decrease in cost was not that initially perceived in either case. The costs during MIS procedures could be greater due to the cost of follow up procedures and costs associated with complications, and the cost of instrumentation is typically higher for instruments used in MIS procedures.

For new MIS cardiac procedures, we find that these same tradeoffs exist. The cost of instruments is very high, but at this point it is difficult to say whether or not it will be worth it because complications data has been difficult to find in the abscence of controlled trials. The procedures are in fact less than a year old, and the companies making instruments in the area have not released specific complications data.

It is clear though that the promise of CABG which does not require a standard (split ribcage) sternotomy is in high demand. (Winslow, 1997) The promise is to have a procedure with the effectiveness of open CABG, but with a recovery closer to that of angioplasty. It is difficult to assess whether the cost of decreased hospital stay and recovery time will sufficiently offset the cost of instrumentation, though I will briefly estimate this below.

A.4.1 New Technology

There are two different approaches which are currently being called "Minimally Invasive Cardiac Surgery" at this point in time. The first is done through a mini-thoracotomy, whereby a relatively small (6 cm) incision is made in the chest wall and short (1-2") portion of rib is removed to create access to the heart. CABG's have been done through this approach both on cardio-pulmonary bypass (CPB), and while the heart remains beating.

Cardio Thoracic Systems (or CTS, in Cupertino, CA) specialize in beating heart CABG using a mini-thoracotomy. This is often called MIDCAB (Minimally Invasive Direct Coronary Artery Bypass). About 1400 CTS MIDCAB procedures have been performed to date, 900 of which were done in the first quarter of 1997. There is essentially no new technology involved in this procedure. The enabling device is essentially a horseshoe shaped spatula used to physically stabilize the heart so that the surgery may be done on the beating heart.

The second approach, which I am more interested in, is known as "port-access" and is closer to what we think of as MIS surgery where instruments are inserted through trocars (or ports) as in laparascopic cholecystectomy. The primary company involved with this type of surgery is Heartport, (Redwood City, CA). Heartport prefers to use CPB while performing CABG. Without physically stabilizing the heart, as done by CTS, it is very difficult (even through open visualization) to operate on a beating heart. Heartport also states that doing CABG under CPB is the "gold standard" and allows the entire heart to be accessed in order to perform multiple bypasses.

The Heartport product line is considerably more extensive. Their products include:

1. A system for doing MIS CPB consisting of catheters and a balloon aortic clamp.
2. A Port-access MVR (mitral valve repair) system consisting of a thoracoscope, specialized instruments and a tissue retractor.
3. A Port-access CABG system consisting of a thoracoscope, specialized instruments, and a tissue retractor.

A.4.2 Complications and Efficacy

The data regarding procedures done with Heartport systems consists of press reports with a few preliminary reports from surgeons using the system. There have been no controlled trials to date. As of March 31, 1997, approximately 650 cardiac surgery procedures had been performed using the various systems above. 300 of these were performed in the first quarter of 1997. About 250 of these were mitral valve procedures. Until January 1997, approximately 20% of the CABG operations were double- or triple-vessel. The first Heartport quadruple bypass was reported on March 20, 1997.

According to a press report dated October 8, 1996 (http: //www.pslgroup.com /dg/cdf6.htm) the Heartport systems are becoming routine at the Cardiovascular Institute at the Dresden University Hospital. Data based on the first 30 patients to undergo port-access surgery had hospital stays of 5 days on average as compared with 7 to 10 day stays after the open procedure. Operating room time was 4.5 hours, “slightly longer” than during the open procedure. 3 to 6 months after the procedures, there was no mortality and one patient required reoperation with the open-chest approach.

In a letter sent to the New England Journal of Medicine, surgeons (Reichenspurner et al. (Reichnspurner et al., 1997)) from the same Dresden institution reported that based on experience with 12 patients, “minimally invasive bypas surgery appears to be feasible without and increase in risk to the patient,” and that “safety and efficacy of cardiopulmonary bypass and cardioplegic arrest are the same as in conventional bypass surgery.” Obviously at this stage, without controlled trials, we must assume some level of opinion is involved in these statements.

Heartport themselves state only that post-surgical hospitalization may be shortened “from about six days to about three or four days” and that “patients may experience less pain and trauma, have a reduced risk of complications, and have only minimal scarring from the small ’port’ incisions.”

A.4.3 A Brief Cost Assessment

It is difficult to assess costs given the limited data available. Based on experience with laparascopic cholecystectomy and coronary angioplasty, we would expect that the primary cost savings results from reduced hospital stay, and the primary additional cost is price of new instrumentation. Additional costs which are more difficult to measure are the cost of increased or decreased complications and costs which are saved (by the employer or employee) by a faster return to work.

In the case of Heartport, each kit for femoral artery catheterization for CPB costs $5000.00, one of which is required per procedure. Heartport supplies reusable instruments to the hospital, trains the surgical team, and gives out educational and promotional materials in return for a contract to purchase 30 kits. Let us assume, based on comments by Reichenspurner that hospital stay may be reduced from 7-10 days to 5 days using the Heartport system. (Heartport themselves give a similar estimate of “6 or more to three or four days”.) We then have a 3-5 day savings in hospital stay. Further assume that ICU stay is the same in either procedure so this savings occurs in regular bed savings at a cost of $800/day. This gives a hospital stay savings of $2400.00 - $4000.00. Considering that the Heartport instruments may replace some other instruments, then this savings may roughly offset the higher cost of the Heartport instruments. A major cost savings does not seem to exist here.

The other major factor which is typically not included in cost analyses of laparascopic cholecystectomy and coronary angioplasty is the cost to the employer or employee of lost days at work. The main reason to perform MIS CABG is to avoid sternotomy. Heartport states that normal activity might be resumed in 1 - 2 weeks instead of 4 - 12 weeks, which represents a savings of 2 - 11 weeks. If we assume a savings per day of $100.00, then for 10 - 55 reduced days of convalescence, we have a $1000.00 - $5500.00 savings. If the daily savings are $1000.00, we have $10,000.00 - $55,000.00 savings, and for $3000.00 a day the savings would be $30,000.00 - $165,000.00. This represents a substantial savings, though of course it depends on the value we attribute to lost days of work. While this cost is real, it is difficult to see it driving the use of the technology since neither the hospital nor the payer see it.

If we consider models for laparoscopic cholecystectomy and coronary angioplasty however, I would speculate that patient satisfaction, the desire for surgeons to improve patient outcomes despite lacking appropriate data, and the general desire to keep abreast with the latest technologies will be sufficient to drive the diffusion of these techniques into the market.

A.5 Conclusions

Our original question was “Will minimally invasive CABG be worthwhile”. The answer is yes, though not for the reasons I originally expected.

The first assumption is that the overall complication rate will not be substantially different than in the open case. We might expect fewer wound related complications in MIS CABG, but possibly greater procedure related complications as well which will diminish as surgeons become more skilled and the procedures become further developed.

The main cost will then be due to increased cost of MIS instrumentation, and the main savings will be due to decreased hospital stay. This is from the perspective of the hospital or payer organization. While the perception might initially be different, I believe these costs will essentially cancel. A hidden savings, not seen by the hospital or payer, but rather by the patient or their employer due to the reduced period of convalescence. If the patient is not employed, this still represents a measure of patient satisfaction.

Therefore, the introduction of these techniques, even if they financially break even from the point of view of the hospital/payer, they appear to be worthwhile from a societal perspective because of the decreased convalescence times involved.

Based on our experience with laparoscopic cholecystectomy and coronary angioplasty, patient satisfaction (while correlates with decreased convalescence) and doctors' desire to improve outcomes and to stay abreast with the technology will drive this technology into the marketplace.

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