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Lessons Learned From Kinematics Research Applied to Medical Device Design

Prologue

A passion of mine has been the application of basic engineering principles to practical problems, particularly those that may lead to new products. Grasping the key nuggets of theory without being able to see a real physical embodiment is not one of my strengths. If I can hold the representation of an equation or analytical model in my hands (or see a quality graphic representation) then I am better able to achieve a full understanding of that principal, starting with a high-level analysis and then followed by a more detailed inspection. Without that high-level viewpoint, I am less likely to produce improved theories and optimal results.

I am not alone in this. Many of us learn through our experiences in the physical world. Our visual and kinesthetic learning styles have been heightened by years of practical experience. How much faster and deeper could we learn and dream if the way we learned and explored could match our native style of learning, and feed our imaginations?

I am curious and enjoy learning from talented individuals in adjacent fields. Teaming with experts, whether they be computer scientist or MD's, has provided me a great advantage: my small contribution integrated with a great abundance of others' talents has resulted in a number of instances where the outcome has been an excellent "stone soup." Having been blessed with this skill set and numerous gifted colleagues, I have thoroughly enjoyed a career of attempting to keep pace near the leading edge of new technologies, computation power, and visualization methodologies.

In this paper, I hope to give you a glimpse of what the future can bring, along with a little history of how we came about building the foundation this future vision will be built upon. But first, I would like to start from the beginning, where I was fortunate to find the people who influenced my future and gave their direction.

After college, I attended graduate school at Rensselaer Polytechnic Institute (RPI). It was not because there were a lack of job offers (or due to a high GPA), but because of a strong need to discover my identity as a Mechanical Engineer. I wanted to enter my professional career with an excitement about my chosen subdiscipline within Mechanical Engineering. My search was fulfilled when I took Advanced Kinematics class from George N. Sandor, who later became my Ph.D. advisor, a second father and coauthor on many publications. He taught me so much including professionalism, kindness, how to be a servant leader, the potential of an inquisitive mind, and the excitement of matching mathematical modeling to real engineering systems.

This was during the very early days of engineers using computers for analysis and design. His group of graduate students, including Roger Kaufman, made significant impact on using computers and rudimentary graphics to generate software tools for carrying out engineering design of mechanisms. I believe that the utility of KINSYN and LINKAGE interactive computer analysis and graphically enhanced synthesis package (LINCAGES) were far ahead of other engineering modeling software in the 1970s and 1980s and perhaps introduced user-in-the-loop optimal design. As we will explore in this paper, many of the lessons learned back then, are still being applied today to much more complex systems.

I was privileged in my early years to receive wonderful guidance and mentoring by other esteemed researchers including George Sandor's advisor Ferdinand Freudenstein (recognized as "the father of modern kinematics") and Bernard Roth, also a former Freudenstein student. I have often shared the very same tips with my students that I received as a young man. But not all the advice I received was encouraging as exemplified by advice I received in 1976 from a friend and a vice president of ASME, where he looked me in the eye and said "Art, you are a good guy, but why the heck are you in kinematics?" (insinuation that kinematics was a dead field).

In September 1977, Albert H. Burstein, who established the Biomechanics group at the Hospital for Special Surgery in NYC, was asked to advise me on shifting my research into bioengineering. At that point, I had no training in anatomy, physiology, or biomechanics. Albert advised, "…well you seem like you have a strong career path in kinematics and mechanisms, it would be a long haul to make this move." With that sage advice, I proceeded to seek out strong relationships with colleagues in the medical field, which was fairly easy to do on the University of Minnesota campus.

It is through the journey of being open to the advice from others and seeking to gain a better understanding of myself, that I have been fortunate to collaborate with very talented people in the medical device field and pass along the teachings of those that have come before. The work and learning is not finished. There is more to be achieved, learned, and shared.

The Product Development Process

Whether solving product design problems in the 1950s, 1960s, and 1970s or today, the design processes have remained pretty much unchanged. There have been various publications over the years suggesting improvements in efficiencies, but the foundation for product development have been nearly invariant of the technology available over the decades. Figure 1 shows a flowchart representing the typical steps used in product development, starting with the recognition of an unmet need and expressing the constraints and problem specifications. Once a type of device is selected (e.g., four-bar linkage, cam system, and gear system), a number of input parameters (e.g., thickness, material properties, radius, and lengths) are required in order to define a final solution. Selecting this set of input parameters and deriving potential solutions are referred to as "forward design."

Combining the unmet need with the constraints imposed by manufacturing, marketing, and other functions, an optimal solution can eventually be obtained. In turn, with the optimal solution, a set of output parameters can be derived (e.g., delivered force, maximum acceleration, product cost, size constraints, and/or total weight). With this, we are then able to identify if there is a potential commercially acceptable product.

While the process is straight-forward, there are times when the output is suboptimized, because the input parameters are either arbitrarily selected, or constrained to a fixed value yielding a smaller input parameter set. It is very common for people to accept a set of design parameters either because it is perceived to be prohibitive to build a larger set of parameters and measure the potential outcomes, or worse because someone has used these

DOI: 10.1115/1.4038764
Manuscript received August 3, 2017; final manuscript received December 12, 2017; published online January 18, 2018. Editor: Beth A. Winkelstein.

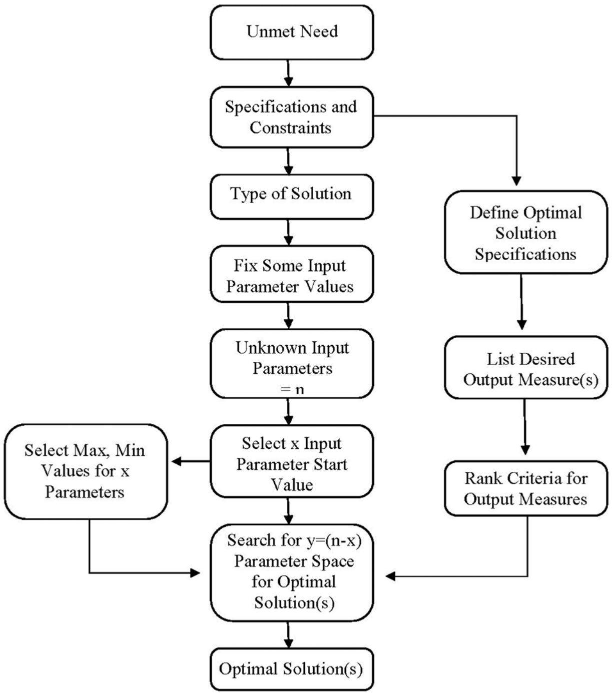


Fig. 1 Flowchart of the product development process

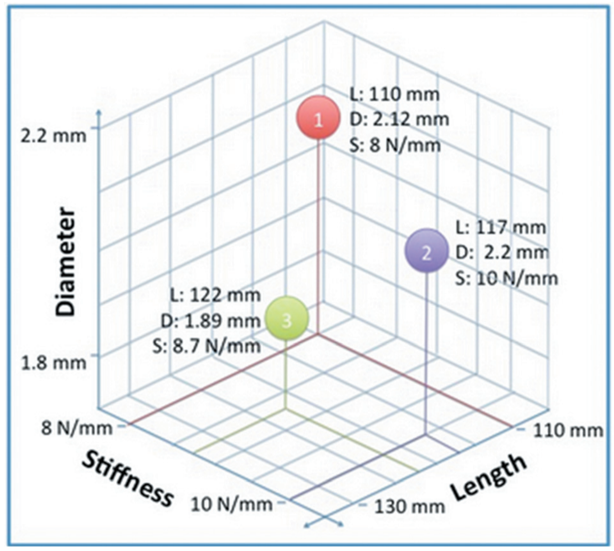


Fig. 2 Selection of Max and Min values of parameters and three instances within a three-dimensional design space

values in the past and now they are considered "gospel." The reality is, by allowing those parameters to be part of the optimization process, there is the potential to reveal truly innovative solutions.

If there are n input parameters and x of them are selected, then, the goal is to determine the optimal set of y parameters to satisfy a majority of the output measures. The potential solution space has y dimensions, where each dimension is defined by the range between the minimal and maximal value of that input parameter. Examples of common tactics include:

(1) Blindly picking a specific set values of parameters y and hoping for a reasonable outcome.
(2) Repetitive application of option #1, keeping track of output measures. This is doing design by pure analysis—very popular throughout the years.
(3) Use analytical or experimental methods to help with narrowing down input parameter selection and Max and Min values.
(4) Use one of many optimization methods for searching through the input parameter design space to yield output measures (with or without visual clues of output parameter performance).
(5) Creation of custom analytical methods for exploring the input parameter design space yielding output measures (with or without visual of output parameter performance).
(6) Mapping out some of or the entire input parameter design space for visual inspection.
(7) Method #6, plus including the user-in-the-loop design decision making.

Table 1 lists several methods for searching a y dimensional solution space. Examples of several of these processes are found later in this paper.

Using Visualization in the Product Development Process

Let's look at the case where a product development problem has been reduced to searching where $y = 3$, as depicted in Fig. 2. To reduce the computational requirements in a solution search, Fig. 1 calls for a narrowing of the input parameter range of possible values. For example, if the goal is to find the optimal parameter selection for an optimized vacuum-assisted biopsy needle system under load (that we will explore later in Figs. 27–30), then the diameter, length, and stiffness (partially determined by the wall thickness) make sense as unknown input parameters.

Figure 2 illustrates this by the ranges of these variables along the axes. For example, based on the desired maximum clinically acceptable incision diameter and the minimum size of acceptable biopsy diameter for useful diagnosis, the values of 1.8–2.2 mm were selected for the search range.

Also shown in Fig. 2 are three potential solutions along with their input parameter selections. What is not very appealing is to determine all the other alternative potential solutions one-by-one,

Table 1 Methods for optimal search

Unstructured	Repetitive analysis	Experimental
• Blind luck • Intuition • Copy others	• Select parameter(s) and see what happens • Compute all or most possible solutions	• Build and test • Design of experiments • Test subsystems
Structured search	User in the loop	Inverse design
• Optimal mathematical based searches	• Computer graphics based search • Sparsely populated solution space search	• Mathematical • User in the loop

and thereby losing the incredible powerful secondary and tertiary clues explored by traversing the entire solution space—or looking for the "needle in the haystack," particularly when there are more than three unknown input parameters.

In contrast, if the solution space is displayed to the user as in Fig. 3, then the effort required to find a "best solution" is vastly reduced. The solution volume shown represents where only "acceptable" solutions exist. In addition, the color scales provides the values of one of the output measures (let's say delivered torque), while the topological map can identify regions of a constant output value (with other additional projections providing additional critical information). Once a graphic like this is generated, the task is relatively easy for the user to identify the optimal solution(s). In fact, multiple such graphs can be generated using different "fixed" parameter selections (step 4 in Fig. 1) allowing one additional variable input parameter, or a test of the sensitivity of the selected value of that fixed parameter, on the resulting solution space. The user can explore these types of solution spaces in sharp contrast to a "batch-like" process of Fig. 2 that offers little insight into the global solution space, other than a finite set of potential solutions.

In the early years, solving for one input parameter set at a time was normal. This strategy is still in place today for most, more complex FEA- and CFD-based solutions, because computational time can take hours to days for a single set of parameters. The last example in this paper demonstrates a method to help bridge this gap.

The observations made above are somewhat independent of the calendar, starting in the 1970s. What is very different from the early years is the computational capability, which significantly enhances speed and other opportunities to create a much more effective design process. As will be illustrated below, interactive computer graphics and simulation now allow more sophisticated optimal design methods in tackling difficult problems.

If one has a "map" of the design space as a function of input parameter selection, then inverse design can also be achieved—an inverse mapping and/or by user-in-the-loop real time exploration. In that case, an ideal set of output measures are specified and the sets of input parameters that yield solutions closest to those goals are then systematically determined. The map or maps can be in a variety of forms (see Figs. 8(*b*), 22, 29, and 31).

Overview of Kinematic Synthesis

Kinematics is defined as the science of motion [1,2]. This fundamental discipline finds application in all that we do and experience. A mechanism is a mechanical device for transferring motion and/or force from an input source to an output. Understanding how a mechanism works (kinematic analysis) can be relatively easy, but understanding how an existing mechanism originated, and why it is in that particular form is more difficult. The fundamental task of conceptualizing mechanisms is still a mixture of art and science, intuition and engineering.

Applications of kinematic theory and/or mechanical linkages can be found in nearly every medical specialty. There are many examples of mechanical linkages being used to improve the human condition, and hundreds of other mechanisms found in medical, surgical, and human-assist devices. In kinematic synthesis (as opposed to kinematic analysis), a user specifies a number of positions (often three or four) that a mechanism must traverse. Kinematic synthesis is the process of designing mechanisms to guide rigid bodies through prescribed motions. With synthesis techniques, particularly Burmester theory [2], one can design many types of linkage mechanisms that have relative motion in a plane. Burmester theory, developed in the 1880s, states that there are points in the moving plane whose four consecutive prescribed positions fall on a circular arc. There are an infinite number of these points whose loci form a cubic curve—the moving pivot curve. Correspondingly, there is an infinite number of points on the fixed plane.

Planar 4-bar linkage mechanism synthesis involves finding two pairs of pivots, one in the fixed plane and one on the moving plane, which can be connected by rigid, binary links. These links along with a portion of the coupler link form dyads that represent grounded pivot locations (see Fig. 4). Two dyads make up a four-bar, three dyads make up most six-bars, and so on. Joining two dyads as seen in figure allows the moving plane to be able to be assembled in each of the four prescribed positions.

In many standard methods for kinematic synthesis, there are free input parameter choices in the kinematic equation set that can be manipulated to create numerous solutions. For example, a free choice of an angle can be broken up into infinite number of segments between zero and 360 deg. Various techniques have been developed to sort through the infinite number of solutions to yield the best designs. This sorting, however, can be done with different purposes and mind. For example, if using compliant joints [3], one may sort by finding those solutions that have the relative angle during motion between links at the compliant joint having a smaller value to minimize the stress and strain on these connections. However, when one adds to the constraints associated with a medical application, there will be other concerns that need to be included in the optimal search process. To calculate all of the outcomes, even for a simple design can be very consuming. What is needed to advance from simple designs is the ability to perform a greater number of calculations with less effort.

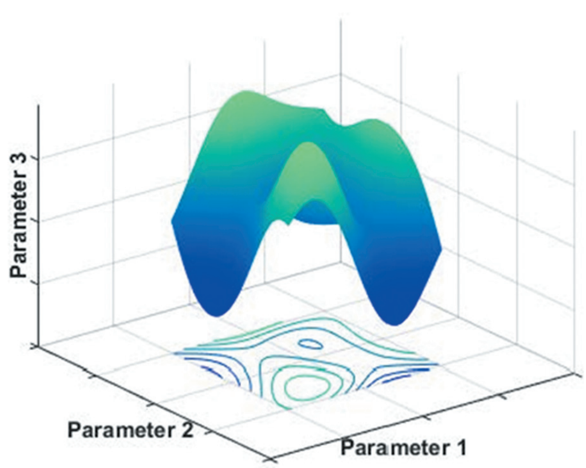


Fig. 3 Potential solutions within a three-dimensional design space

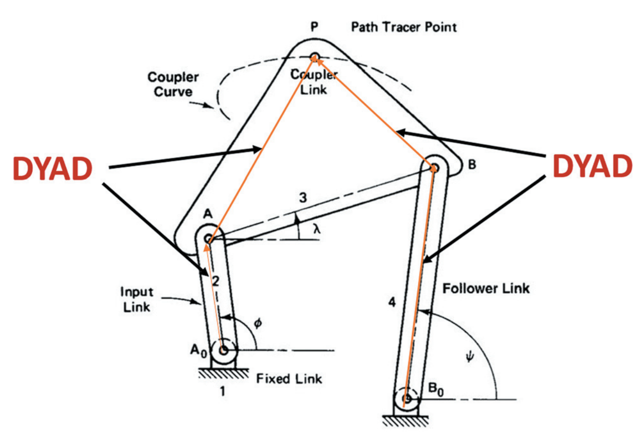


Fig. 4 Kinematic synthesis of linkage mechanisms

History of Computer Aided Mechanism Synthesis

Kinematic Synthesis—The Early Days. The age of computer-aided mechanism synthesis began in the late 1950s, as Freudenstein and Sandor published the first paper on the topic [4]. Many exciting developments occurred based on this development resulting in several intriguing mechanism synthesis software packages at several leading research institutions. One of the main features of these packages was to help the designer choose the most desirable solutions from among the many that result from the input parameter selection. In addition, it provides an environment that will allow the designer to obtain a good or near optimum solution quickly without needing an in-depth knowledge of theoretical kinematics. The software packages provided assistance by producing graphical interfaces, design charts, and other cues that guided the designer by incorporating sophisticated mathematical optimization routines, or by incorporating pattern matching and/or knowledge-based systems that narrow down a large number of solutions to a small number (perhaps one) that the user can easily evaluate.

Freudenstein and Sandor [5–7] were the first to publish a paper on the use of a "digital computer" to synthesize a linkage. Their program was setup to design fourbar linkages for path generation, with prescribed timing for five precision positions. Their program was written for a specific computer, the IBM 650. Freudenstein and Sandor's pioneering synthesis program was also the first to attempt to identify the best of multiple synthesis solutions.

Roger Kaufman (first at Yale, RPI, then MIT, and now at George Washington University) pioneered mechanism synthesis using interactive computer systems using his "KINSYN" programs [8] that were the truly revolutionary interactive computer-aided engineering (CAE) packages. In an e-mail (on June 29, 2013) sent to Tom Chase, Garry Kinzel, and Art Erdman, Roger revealed significant detail about his genius-level contribution to interactive design optimization. Below are interesting quotes from this email:

> KINSYN 1 was a home-made dynamic display made from a bare-bones Tektronix scope with a hybrid computer system cobbled together from a 16K IBM 1620 computer, an EAI 680 analog computer, a wire wrapped interface card, and a hand-built 3DOF *bowling ball* input device you might be interested in the first attached photo circa 1969 or 1970 (see Fig. 5). I believe the photo was taken while I was using KINSYN 1 to design the first polycentric knee joint done interactively in real time to match actual X-ray data for a particular patient (see Fig. 6). By twisting and turning the bowling ball, you could position objects on the display. Screen images were built up from static objects displayed in storage mode and dynamically moving objects which were kept from storing by the home-made circuitry invented by my colleague Dick Seidell. His magic box was driving the Tektronix storage tube using vector data coming from the digital computer via the monster analog machine you see in the background.

Fig. 5 KINSYN 1 was a home-made system user in the loop design system

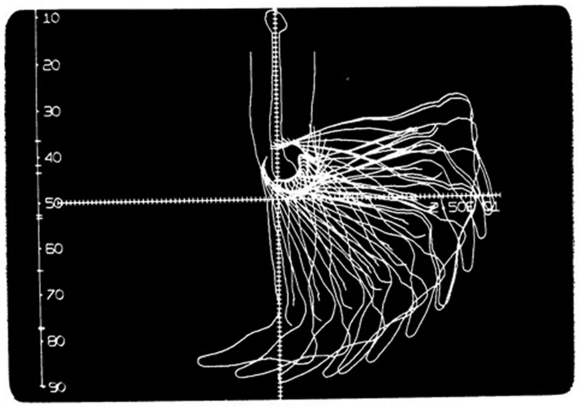


Fig. 6 Potentially the first interactive patient specific medical device designed—a polycentric knee

> KINSYN 1 was the first interactive mechanism synthesis and analysis program that I know of. It could synthesize and analyze four bars and slider cranks of various inversions and for motion or function generating requirements. Depending on the inherent limitations of the mechanism being designed it could deal with two through five position synthesis. It could even synthesize certain six bars such as the Watt 1 and it could analyze a variety of other topologies such as Peaucellier mechanisms and the like.
>
> It certainly wasn't the first interactive CAE program, however, but it was the first synthesis program. Ivan Sutherland's Sketchpad developed in the 60's at Lincoln Labs was probably the first general purpose interactive CAE program and it developed most of the fundamental data structure principles for things like doubly linked lists, etc., that most of the following systems are based on to this day. Sketchpad was based on a huge optimization code that tried to minimize errors while satisfying constraints such as "make these lines equal" and "keep this line vertical."
>
> To get a sense of time scales, I believe George Sandor's original IBM 650 programs at Columbia took about a day to generate a single set of Burmester curves. My early four and five position synthesis programs at Yale on the IBM 7040-7094 system could get in three runs in a week. I would generate a huge 7 track mag tape and then get a set of curves out on a huge flatbed plotter in about an afternoon. KINSYN 1 probably took a minute to generate a set of Burmester curves, and showed the output as it was calculated. KINSYN III was really zippy and may have taken around 15 s per problem, Microkinsyn (on the Apple 2) took perhaps a minute but it didn't require $50.00 or $100.00 per hour for computer time (see Fig. 7). The last

Fig. 7 The KINSYN III hardware. The human user was utilized as an integral part of the synthesis procedure. The user observed the current state of the design on the CRT screen and input directions for continuing the synthesis by way of a data tablet. (From Ref. [9]; used by permission of ASME.)

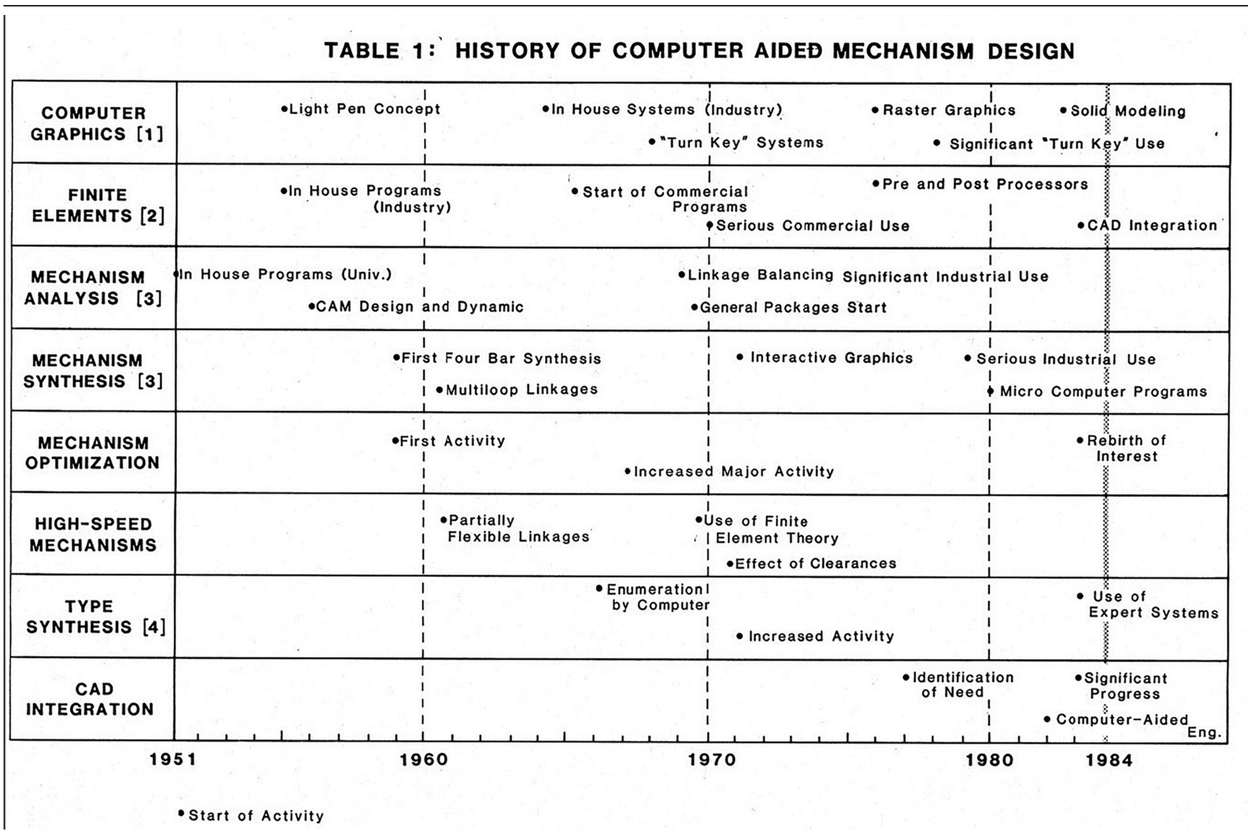
> version we developed, KINSYN 7 generated new Burmester curves faster than the flicker frequency for your eye (maybe 30 times a second) so the curves squirmed around on the display like a pair of courting octopus (octopi?) as you changed your design parameters.

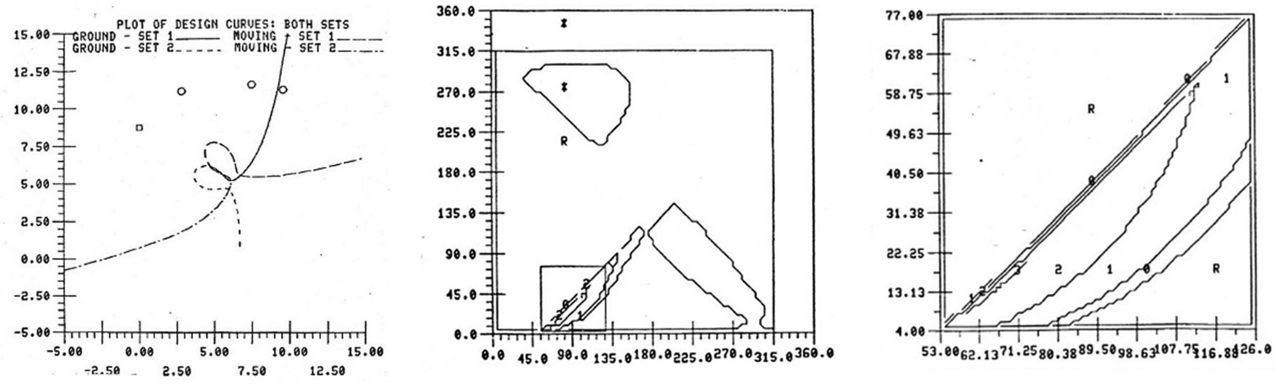
The University of Minnesota group [10–14] developed another early interactive mechanism synthesis package, the Linkage Interactive Computer Analysis and Graphically Enhanced Synthesis Package (LINCAGES). The LINCAGES project was initiated only because KINSYN was not available outside of MIT at the time, and the creation of LINCAGES was necessary to expose University of Minnesota students to Kaufman's groundbreaking interactive synthesis strategy. LINCAGES overcame the need for specialized hardware by using either a commercially available "storage tube" graphics display or a teletype, for both input and output to a mainframe computer operating in "time sharing" mode. While the teletype option was slow and had poor resolution, it made the program accessible where linkage synthesis tools had been previously unavailable.

1984 View of Mechanism Design. The following is an excerpt from a paper titled "The Role of Supercomputers in Mechanism Design" [13]. Although the term "supercomputer" is used in this paper, we must point out the 1984 Supercomputer is significantly different than a Supercomputer we use today. Despite this, some of the design insight below is noteworthy.

> Summary
>
> The last 25 years (1959–1984) has seen a significant evolution in machine design. Although the basic principles of mechanism analysis and synthesis have not change significantly, the design tools have undergone dramatic iterations. The accelerated pace of software development for analysis and synthesis will continue in the years to come. This paper will address the role of the supercomputer in future mechanical computer aided design systems
>
> *Introduction*
>
> The computer was first used for mechanism design purposes in the early 1950s. Since those early applications, a dramatic evolution has taken place. Table 2 summarizes some of the significant developments in the sub-disciplines of mechanisms which have occurred since the digital computer became available. Subject areas such as mechanism analysis, synthesis, optimization, etc. have steadily evolved over time based on advancements in computer hardware and software.
>
> The future integration of the computer into mechanism design will be very dramatic. The mechanism designer will have an impressive set of tools at his/her disposal for optimal analysis and design of mechanical systems. Several specific areas will see increased activities. These include:
>
> (1) Use of solid modelers for the display and analysis of 2-D and 3-D mechanisms
>
> (2) Integration of mechanism analysis and synthesis, into other facets of computer-aided design and manufacture
>
> (3) Many more custom applications to specific needs of industry
>
> (4) The Use of More Sophisticated Graphics for Discrete and Continuous Process Simulations
>
> The interactive nature of the LINCAGES package is well suited to the mechanism design process. The general style of the program is to provide a menu of optional outputs after the user has entered the necessary input data (design positions). Synthesis and analysis of planar linkages are combined in one package to permit convenient iteration between synthesis and analysis. The human in the iterative design loop learns about the problem from the feedback provided by the graphics. The user retains control of the design and is able to address the design parameters. This provides a potential means of avoiding 'trial and error' methods of linkage design for more than three specified positions. However, analytical solutions for complex graphical solutions was not considered realistic in the pre-computer era.
>
> The availability of the computer has changed the way mechanical systems are designed and analyzed. It is now possible to perform

Table 2 Sources for this figure are acknowledged as follows (1) Dr.'s Chase and Don Riley of U of MN; (2) Jerry Glaser of CDC Corp; (3) Ferdinand Freudenstein of Columbia U and Abe Soni of Oklahoma State; (4) Abe Soni





(a) (b) (c)

Fig. 8 (a) Burmester curves representing all ground and moving pivot locations for the four prescribed design positions (square = 1st design position and circles the other three positions). Not shown are the prescribed angular orientations, (b) design map showing regions where viable solutions are according to minimum transmission angle measure, and (c) a blowup of a region of the map shown in (b).

> very rapidly the previously overwhelming computations required to apply advanced kinematic theories. Further, interactive computer graphics makes it possible to find 'optimal' solutions from among numerous possible solutions.

As noted in this paper, four design positions were selected, and Fig. 8 represent the user interface of that time period (1984). Although crude by today's standards, there is rich information presented to the engineer saving countless hours and days to determine equal information by trial and error methods. Literally infinities of solutions are displayed at a time. By changing one input parameter (say the second angle) a new infinity solution space (set of pivot curves) can be produced.

This synthesis problem was run on a CDC CYBER 825 with output on a Viking terminal. A comparison of the CPU time between generation of dyads, and the map is illustrative of the demand on the computer during that era, even for elementary display of results of parameter variation.

Task	CPU-SEC
Solve for 73 dyads	0.483
Calculate a 73 × 73 map of four-bar solutions	5.200
Plot map on screen (e.g., Fig. 8(b))	4.717

> Note that compared to solving relatively complex Burmester equations for the dyads, an order of magnitude more CPU time is required for both the map calculation and plotting functions. Also note, that optimal search routines have not been used here. The designer will become accustomed to receiving relatively quick responses from the computer during mechanism synthesis. Once more options and optimization is integrated into computer aided mechanism design, the supercomputer may indeed be in the loop.

A Milestone in 1985—Integration of Commercial Software Packages. In 1985, there was a noteworthy event—the first known public demonstration of a fully integrated of design/drafting, kinematic synthesis, rigid-body dynamics, and finite-element analysis software packages in real time—at an ASME Design Engineering Conference in Chicago [14]. These commercial packages were linked for the purpose of designing and optimizing a mechanism for a specific task. At the time (and still today, for the most part), software to help engineers perform mechanical design tasks was developed and sold separately, and the data generated in these programs were often incompatible. This was the first real-time optimal design demonstration, which illustrated the possibility of more fully integrated software tools in the future.

The challenge was to design a linkage mechanism for picking up injection molded parts from a mold, and placing them on a conveyor belt. The mechanism was required to have straight line and nearly parallel motion while extracting the molded part from the molding machine. Other constraints for the mechanism are:

- ground pivots lie completely below the die-cast machine,
- does not interfere with the die during motion,
- is proportional in size to the die-cast machine,
- does not branch or toggle within the desired range of motion (Branching is caused when the centerlines of links become collinear so that the output link may change direction. Toggling occurs when the output link will not move no matter how large a force is applied to the input.), and
- does not have a poor transmission angle. (The smaller the transmission angle, the more likely the mechanism is to toggle.)

Given these significant challenges, a six-bar mechanism was selected as a four-bar would be unable to accomplish this task. Geometries of the die, casting, and conveyor were defined in Control Data's (Minneapolis, MN) ICEM design and drafting package. Four design positions were chosen along the required casting path. The coupler point (where the gripper and extractor meet) needed to pass through design positions so that the die is placed on the conveyor after it is turned 90 deg.

Design positions and geometry were sent to LINCAGES-4, where the mechanism that passes through the design positions was synthesized. Because an infinite number of mechanisms meet this criterion, some additional constraints were placed on mechanism performance (see bullets above) so that the mechanism could be optimized. After a few interactions, a double-rocker mechanism was chosen. A driving dyad was also found by using another feature of LINCAGES-4.

Synthesis data were sent to ICEM, which automatically drew a skeleton diagram of the mechanism (Figs. 9 and 10). The engineer adds link geometry (shape, see Fig. 10), and including link geometries and material density, a solid model is developed. The mass and inertia properties of the model are fed into the dynamics package through the CAD interface. An attribute file that includes input link motion, plus external forces and torques, was written and sent to a preprocessor.

The preprocessor prepared the input data file for rigid-body analysis by ADAMS from Mechanical Dynamics, Inc., Ann Arbor, MI, as shown in Fig. 11. Analysis results included values for input torque and joint forces. The joint forces in the proposed mechanism may cause high stress and too much link deformation.

To determine if stresses and deformation are too high, a finite element analysis was done using ANSYS from Swanson Analysis, Inc., Houston, PA. Geometric information was sent to the ANSYS preprocessor from the CAD program. In addition, ADAMS was sent the joint forces and accelerations. Stress and deformations were

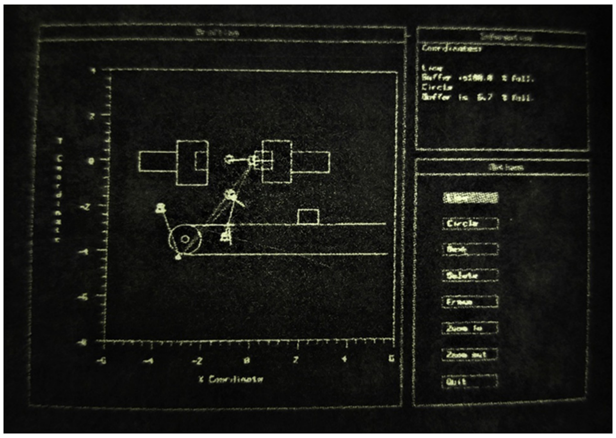


Fig. 9 Integration of ICEM CAE kinematics, LINCAGES, and ADAMS, including skeleton diagram of the six-bar

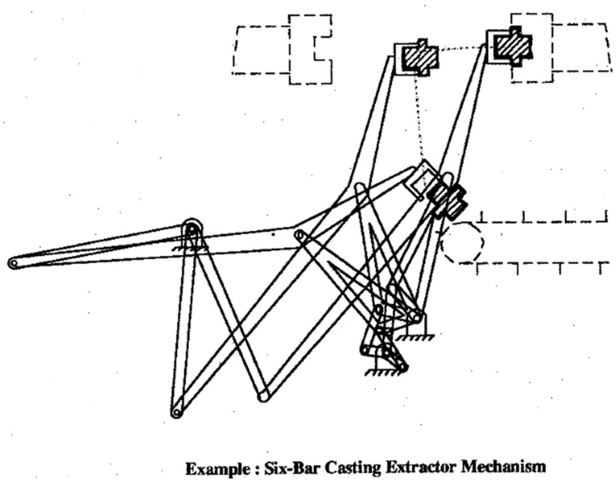


Fig. 10 Multiple design positions of the six-bar extractor

displayed after analysis (e.g., see Fig. 12). Stresses at the middle joint of the gripper link were predicted to be high enough to suggest an increase in the area cross section (Fig. 12). Maximum deflection was determined to be within tolerance. The mechanism geometry is modified, and the analysis rerun. The modified gripper link has larger holes for pivots and larger dimensions in joint areas. The designer also adds fillets. The result was the stresses declined in critical areas near the linkage joint.

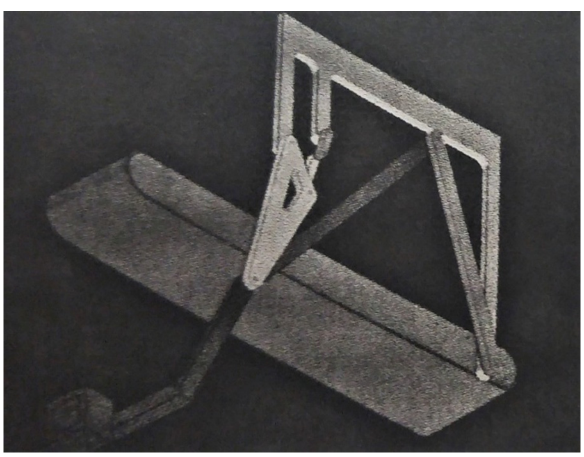


Fig. 11 Six bar solution from LINCAGES animated in ICEM kinematics then used as input into ADAMS

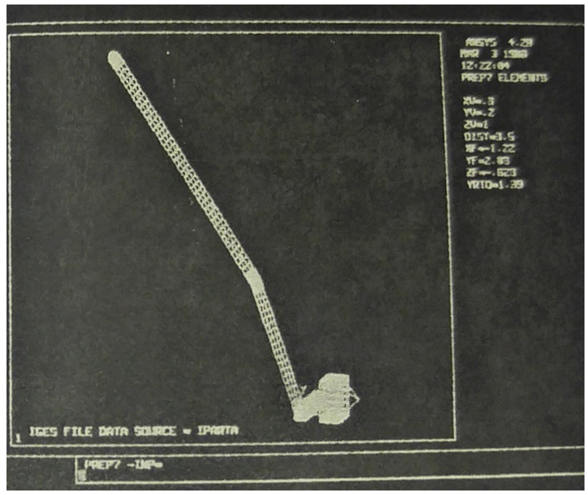


Fig. 12 Maximum stresses in arm shown. Dynamic loads from ADAMS used as boundary conditions in ANSYS.

This real-time demonstration gave attendees a glimpse of what full software integration could look like and how powerful this would be for design engineers.

Design Using Repetitive Analysis

Since 1985 a significant number of products have been optimized using the repetitive analysis strategy suggested in Table 1. Below, are some examples I am familiar with from the University of Minnesota:

Example 1: In-line Skate Boot. *Unmet Need*: The current skate boots require significant ankle torque to overcome the tight rivet connection between the plastic side members of the boot (causing continuous friction between the upper and lower boot during ankle rotation). There is a need for an in-line skate boot design that requires less torque on the ankle while performing the skating motion.

Analysis: Rather than a simple single pivot that was common for in-line skates, the concept was to follow the natural motion of the human ankle in the sagittal plane with a four-bar linkage.

Figure 13 shows the ankle in a flection/extension cycle, and provides the ideal specifications for the output motion. The sketch mode of LINCAGES© [1,12] was used to generate hundreds of solutions, until a solution was found that best matched the natural

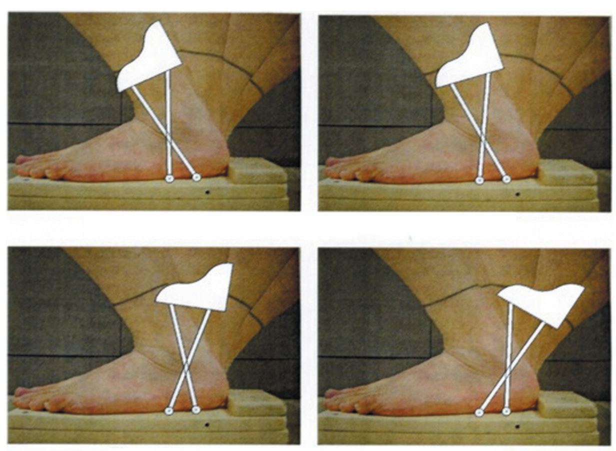


Fig. 13 Natural ankle movement—natural ankle motion in consecutive photographs. One four-bar found to match movement of the joint is included.

Fig. 14 Prototype skate boot

motion of the ankle. This is optimal design by repetitive analysis, but enhanced with interactive graphics where pivot locations could be instantaneously changed while output measures like transmission angle and mechanical advantage simultaneously displayed.

Solution: Figure 14 shows a prototype of this new skate boot mechanism mounted on a set of K2 skates, where the four-bar connects the upper and lower portions of the boot on the lateral sides [15]. The result is a design with significantly reduced ankle motion resistance, while maintaining the lateral stability that recreational skaters require.

Example 2: Nasal Septal Surgery Mechanism. *Unmet Need*: Nasal septal surgery to improve nasal breathing and airflow is one of the most common operations performed by otolaryngologists [16–19] . It is estimated that there are approximately 500,000 septal surgeries performed in the world each year. Nasal septal surgery repair requires making incisions in the nasal cavity, lifting up the intranasal mucosa lining, removing deviated cartilage (and bone blocking the nasal passage) and finished by placing the intranasal mucosa back in its original position. In the past, uncomfortable intranasal packing was placed in the nasal passage to keep the mucosa lining flaps in place and control blood accumulation underneath the flap lining (septal hematoma). The intranasal packing is routinely left in the nose for 24–72 hr. More recently the procedure has been improved by attaching the nasal septal mucosa lining manually with sutures. This operation can be long and tedious (sometimes requiring up to 20–30 min of surgical time).

Analysis: Shortening the time for the procedure could be achieved by using a device to deliver a biocompatible rivet or staple to secure the mucosa lining. The internal mechanism of a surgical hand piece was designed by repetitive analysis steps including solving kinematic loop equations, CAD modeling, and 3D printing. Core to the functionality of the results is a five-bar, dual slider mechanism. Even with modern computational tools, finding an optimal design was a lengthy process because many competing output measurements needed to be satisfied simultaneously which included: fitting the mechanism into the hand piece, yielding reasonable mechanical advantage/transmission angle, and the difficult task of input to output motion requirements.

Solution: The proposed surgical device (see Fig. 15) will fasten mucosa lining together quickly and efficiently with bioabsorbable rivets. The proposed pistol-shaped fastener deployment medical device has two long projections, one for each nostril. An internal mechanism pushes the male portion of the rivet nearly 10 cm down one tube where it pierces the mucosa and mates with the female portion. This is accomplished with one grip motion of the handle, rotating the handle only 30 deg motion for each rivet deployed. It is estimated that it will take less than a minute to attach the nasal septal mucosa lining, significantly improving the patient and healthcare provider experience.

Example 3: Single Port Abdominal Surgery Access System. *Unmet Need*: Surgical procedures are performed by two modalities, "open surgery" and "minimally invasive laparoscopic surgery" with single and multiple points of entry. Both approaches generally require patients to be subjected to intubation and general anesthesia [20,21].

There is a need (especially in developing countries) for an access system that does not require intubation and general anesthesia. A new system between "open" and "laparoscopic surgery," using a single port access with a single incision as little as 8 cm long (for abdominal use) is required. This system should allow for the use of standard, long, or endoscopic instruments, enable direct visualization, eliminate the need for insufflation, and/or in some cases even eliminate the need for general anesthesia and intubation. This system should address the three most important aspects in a surgical setting: access, retraction, and illumination—allowing it to be significantly less expensive, and saving costs for the hospital, patient, and insurer. The system should also provide field retraction, allowing the surgical assistant to support the surgeon as needed, and possibly eliminate the need of an additional surgeon/nurse assistant.

Analysis: The design process consisted of repetitive analysis (CAD and 3D printing) as well as experimentation where prototype testing was carried out in cadavers and in pigs.

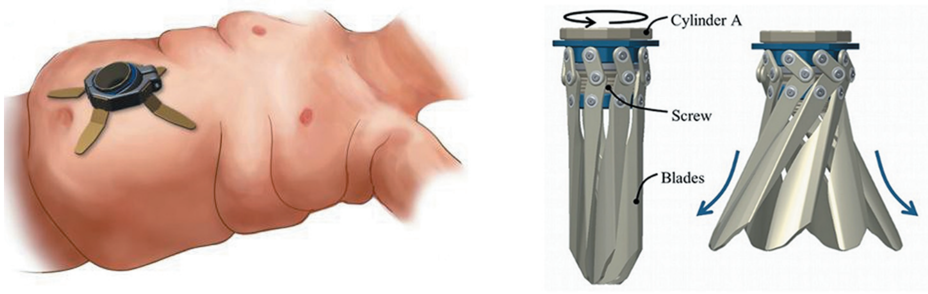
Solution: The surgical access system mechanism has a port-opening on the top with a number of blades below (see Fig. 16). The blades are aligned along the longitudinal axis and terminate at a tip. When the tips are aligned, the system's diameter is less than the diameter when expanded, allowing for a relatively short incision to insert the system into the abdominal cavity. The 3D linkage system is driven by the physician rotating the cylinder with respect to the body, expanding the tips and pushing the other organs out of the way.

Design by Kinematic Synthesis

Example 4—Location of the Origin and Insertions Sites of the Ligaments. *Unmet Need:* A healthy knee is crucial for everyday life. Understanding the motion of each component of the knee

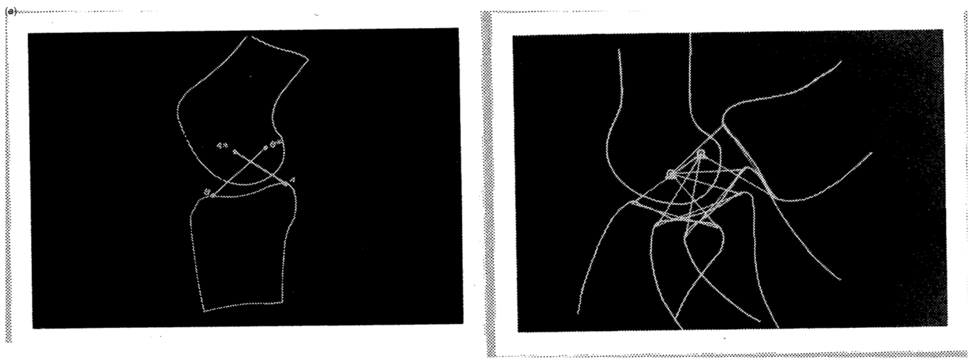
(*a*) (*b*)

Fig. 15 Pistol-shaped fastener deployment hand piece



(*a*) (*b*)

Fig. 16 Surgical system access mechanism



(*a*) (*b*)

Fig. 17 Reproduced from Grood, E. et al. [22]

can provide guidance on how to intervene when the ligaments are damaged [22–24].

Analysis: Given the measurements of the constrained relative motions of the bones and the lengths of the cruciate ligaments with their insertion and origin sites, one can predict the locus of possible locations of the origin and insertions sites and the lengths of the ligaments.

The first step in kinematic synthesis is obtaining accurate measurements of knee motion, such as stereophotogrammetry or laser measurements. With these data, one can begin to understand the unique balance of the knee's kinematic constraints essential for ligament repair or replacement. Using kinematic synthesis, one can determine the locus of potential pivots of constraining links that are consistent with the prescribed motion.

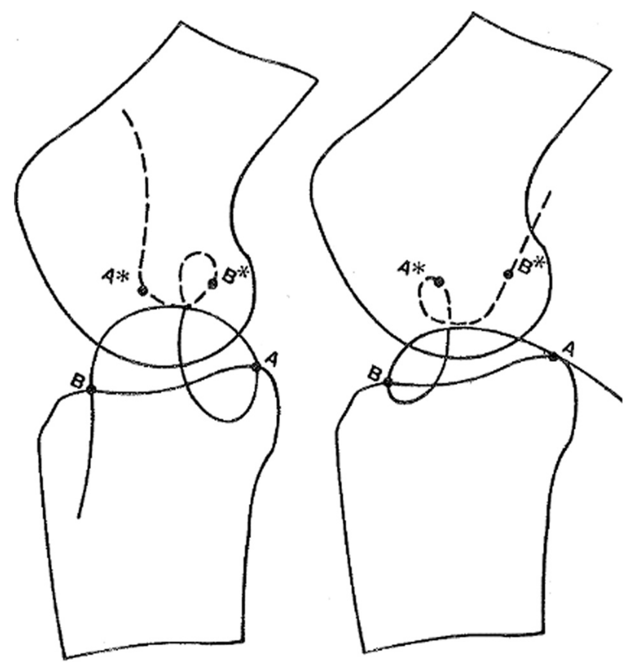
Solution: Curves can be produced by the LINCAGES software showing possible insertion sites and ligament lengths (Figs. 17–19). Note that depending on which knee position is chosen, a different set of Burmester curves are produced. This may help explain the morphology of the ligaments that are composed by numerous individual fibers with different insertion locations.

Example 5—Cataract Surgery Lens Delivery System. *Unmet need*: After the old lens from the eye has been removed from the anterior chamber, a new silicon or acrylic lens will be placed into this space. After the size and strength has been determined, the doctor's assistant will retrieve the correct implant. The difficulty is that these lenses are small (about 8 mm), thin, and difficult to handle [25,26].

Typically, the ophthalmologist or an assistant will open the sterile container and retrieve the lens with forceps (Fig. 20). The lens is then carefully placed into a cassette, causing the lens to conform to the circular shape of the cassette's inner surface. Finally, the cassette is then mounted to the distal end of a delivery tube.

The manual folding process requires a great deal of dexterity and is time consuming even for a skilled professional. An undesirable outcome could include: damage to the lens that may not be apparent prior to the implantation into the eye, or dropping the lens from the sterile field.

Analysis: The LINCAGES package was used for dimensional synthesis. This design process was more challenging due to the



(*a*) (*b*)

Fig. 18 Output from the LINCAGES software, depending on which knee position is chosen. A different set of Burmester curves are produced. Two example sets are shown based on different input parameter sets of four prescribed positions.

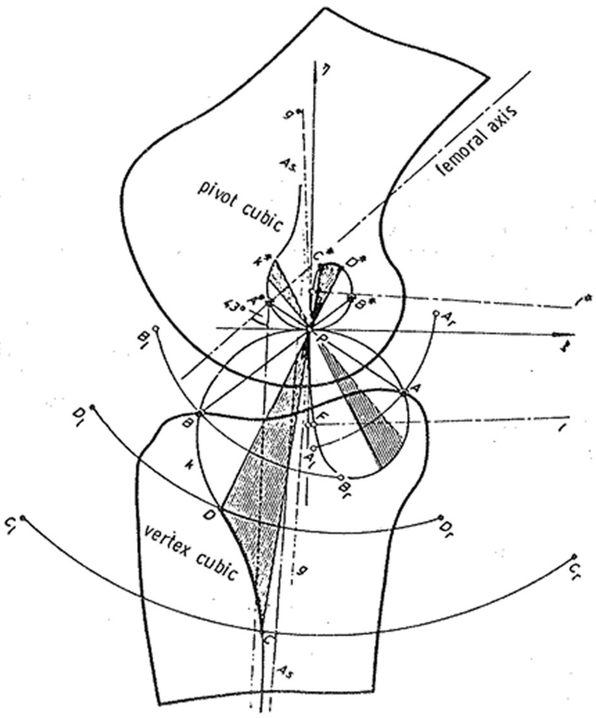


Fig. 19 Reproduced from Ref. [24]

difficulty in finding appropriate pivot locations on or near the corners of a holder. The concept (Fig. 21(*a*)) is to mate a lens holder with a delivery tube, and then transform the lens holder into a movable mechanism (called a compliant mechanism [3]) that will fold and deliver the lens into the tube.

Shown in Fig. 22, are cutaway and side views that depict a portion of the delivery tube, lens holder, and the lens location when the lens holder is initially snapped onto the delivery tube. LINCAGES allows the designer to specify four design positions that a path tracer point on the coupler link will pass through as it contacts the center of the lens, pushes it through a porthole in the top of the delivery tube, and folds the lens into the proper configuration.

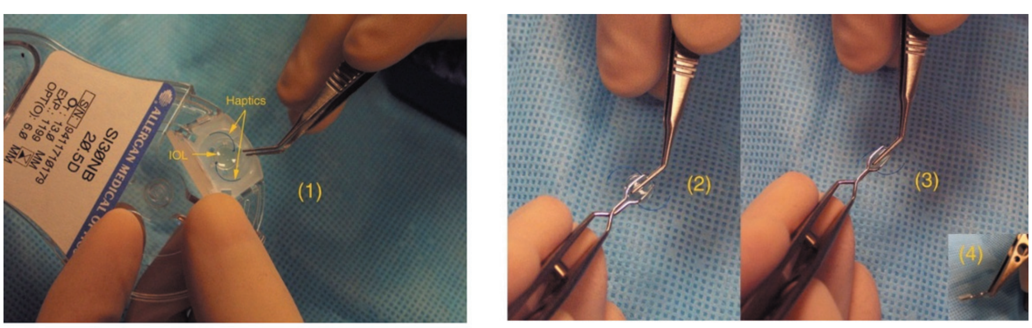
As shown in Fig. 21(*b*), the center of each circle (or square, for the first position) is the specified x, y coordinate, and the arrow represents the relative angle that the coupler link rotates between prescribed positions. Also shown are the cubic (Burmester) curves of allowable ground and moving pivot locations that represent dyads matching all four design positions. The ground pivot curve is the darker curve, and the moving pivots are along the lighter curve.

The goal was to find a mechanism that traced a straight line path and also had its pivots forming a rectangular shape. The LINCAGES design map (Fig. 23) of all available solutions is the second way to enable the user to view the entire solution space. The vertical axis represents one dyad as its ground pivot moves along the cubic curve from $-\infty$ to ∞, while the horizontal axis represents, similarly, all possible locations for the other dyad. Thus, all possible four-bars are depicted in this map, making it very easy to quickly explore the two infinity design space sorted out by the type of mechanism generated. (Other maps would also be possible to allow searches to occur in a similar manner.) The map can be color coded to instruct the designer what type of four-bar mechanism would result by combination of the two dyads. The highlighted regions represent workable solutions, some with fully rotatable input links (crank-rockers, double, or triple cranks), and some with rocker inputs (rocker-crank, double, or triple rockers).

The proposed lens holder is rectangular in shape, with the replacement lens held in the middle. The top of the rectangle and the right side have been designed to uniquely form a four-bar linkage when the seal is snapped by a torque applied on the left handle of the holder. Three of the *living hinge* pivots are designed to be the upper left and right corners and the lower left corner of the lens holder. The fourth pivot of the four-bar is approximately 2/3d's of the way across the top of the lens holder. These pivots were found after many iterations of synthesis using LINCAGES. With the sets of design positions shown, the solid curve (ground pivots) passes through (or near) the upper left and lower right corners of the lens holder, while the moving pivot curve passes through the upper right and top surface of the lens holder. With these corner ground pivots selected, a successful mechanism is generated.

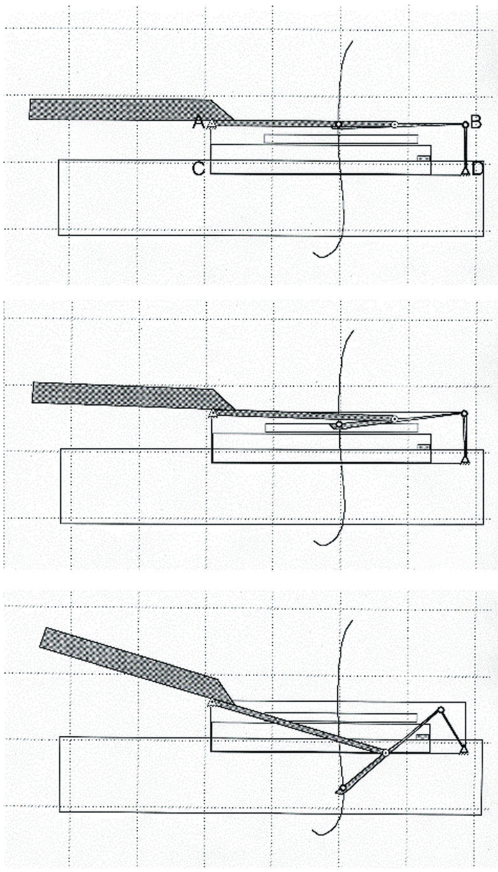
Solution: The result is a lens holder mounted on top of the delivery tube, with a mechanism that performs three functions: to hold, fold, and deliver the lens. A rectangular-shaped lens holder stores the lens in a sterile environment until selected for the patient. The holder is then docked with the delivery tube (breaking the seal), and the sides of the rectangle function as hinges of a four-bar mechanism to deliver the folded lens into the tube as the mechanism is actuated. Without a software aid like LINCAGES, it would have been virtually impossible to find a mechanism solution with pivots at the corners of the lens holder and move thought the four designated positions when deployed.

Future of Medical Device Design. Optimization search methods have been known and used for many years (e.g., see Ref. [27]), but through software packages described above, where even "blind" searches can be complimented by user in the loop strategies, product design will be accelerated. Based on experiences with LINCAGES (where entire solution spaces are displayed in an interactive environment that supports real-time exploration and decisions) could these learnings also be applied to much more complex solution spaces with a larger number of nonspecified parameters? An advantage of Burmester theory is that closed form solutions to produce the pivot curves and the solution maps are

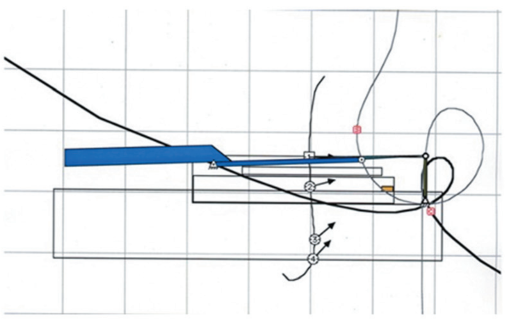


(*a*) (*b*)

Fig. 20 Manual folding of an IOL. The surgeon retrieves the IOL from its container (1) and folds it using both hands (2) and (3). The completely folded IOL (4) is ready for insertion into a cassette.



(*a*)



(*b*)

Fig. 21 (*a*) The linkage in three positions as it is actuated. The top illustration shows the initial position. (*b*) Burmester curves for the four prescribed positions. By choosing pivot locations that were near the corners of the lens holder, then the custom mechanism would be created.

relatively straightforward to compute. The very crude graphical interfaces use in the early days of LINCAGES [13,28] provided a glimpse into the future for illustrating the power of a well-conceived GUI.

We know that advances in high-performance computing makes it possible to construct large parallelized algorithms, and optimally assign computing resources from computationally slow FEA and CFD run times (of hours or days), to faster and more accurate solutions (in some cases just seconds and minutes). Thus, large-scale parallel computing offers a powerful aid to engineers to make large numbers of calculations associated with complex modeling and simulation (M&S) runs, in near real-time.

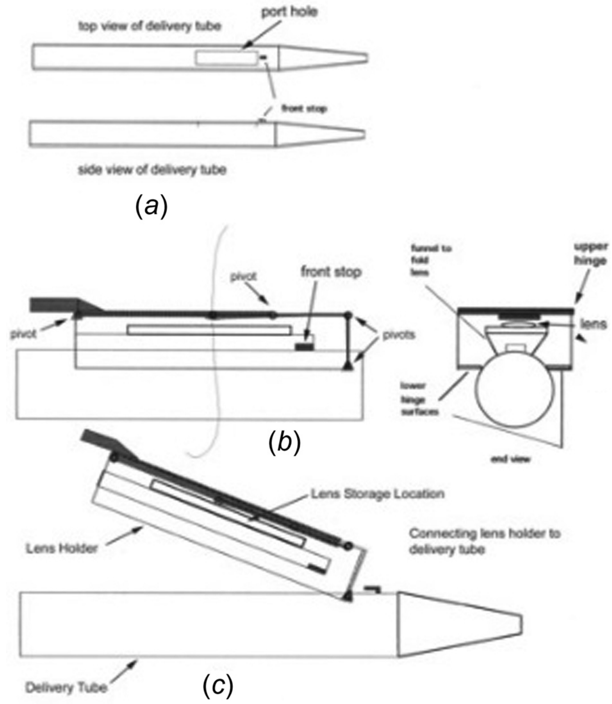


Fig. 22 (*a*) Top and side views of the delivery tube including delivery port. (*b*) Side and end views of the docked holder/folder and the delivery tube. (*c*) Docking the holder/folder onto the delivery tube.

All that remains is to create a map of the design space as a function of input parameter selection, and "inverse design," "inverse mapping," and user-in-the-loop real time exploration should be able to be performed. This allows the engineer to specify the ideal set of output measurements and systematically explore the input parameters until the solution closest to their goal is determined.

Applying Interactive Modeling and Simulation to Healthcare. In 2006, after an ASME FDA workshop on Modeling and Simulation, I made a sketch of a proposed environment for preclinical medical device design (see Fig. 24) [29]. The vision includes combing interactive supercomputing, interactive computer-based 3D data visualization, and human–computer interfaces. This system enables user-in-the-loop engineering design and includes accessing engineering and anatomy databases to customize modeling and simulation specifically for medical device engineering tasks.

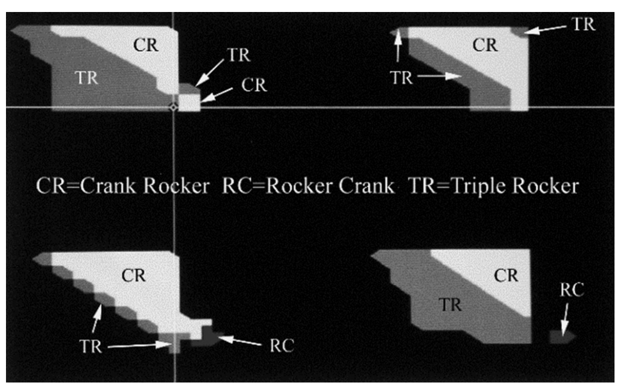


Fig. 23 A LINCAGES-generated design map of all available solutions for the specified design positions

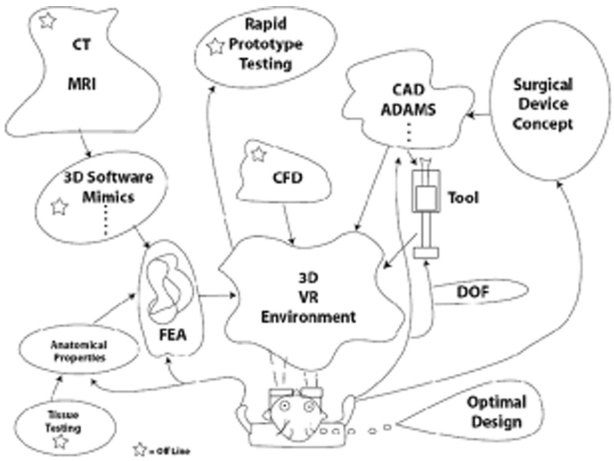


Fig. 24 Sketch of a proposed virtual environment for preclinical medical device design (2006)

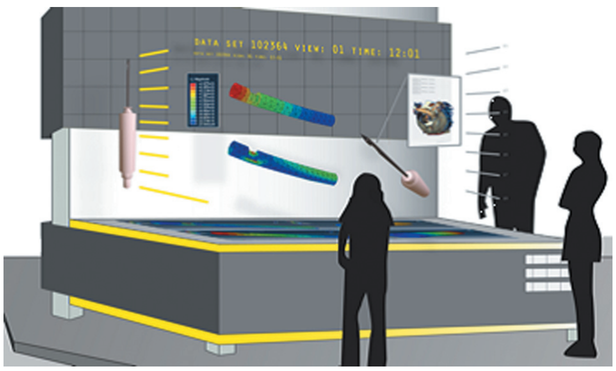


Fig. 25 Artist concept of a virtual design environment (Daniel Keefe's Interactive Visualization Lab, University of Minnesota)

Based on Fig. 24, an artist's concept of a system for using interactive supercomputing in a virtual design environment was created as shown in Fig. 25. This system will assist one or more designers (that may include engineers, medical experts, marketing/sales, etc.) in creating solutions to device needs for healthcare. The goal is to include a combination of hardware and software to enable domain experts to explore large solution sets in real time, gain insights with respect to the solution space quickly, and make decisions based on visual display of data.

By ensuring there are minimum delays associated with complex computations, the designer is continuously immersed in the optimization process, resulting in significantly better insight about parameter sensitivity. This infrastructure includes advancements in computer data visualization tools for observing the results from multiple simulation sources (fluid/thermo/mechanical) in a single environment to support achieving the optimal design(s) in near real-time.

To reduce the delays in response-time and keep the designer engaged, solutions can be based on a finite number of precalculated values. The processor can also execute a routine to determine solutions for an intermediary value. In the absence of intermediary values, the processor can be configured to snap to precomputed solutions and provide performance results accordingly. Design configurations, including design parameters and performance values, can be characterized and parameterized in a particular data format for archival and review purposes. One example of a particular data format can be described as a radar, wheel, or star plot (Fig. 26) [30,31]. The wheel has a number of spokes, each corresponding to an input parameter or output performance measure, and the value of the parameter or performance measure can be depicted by a position along the length of the corresponding spoke. The minimum value of a parameter would be located at the center of the wheel, while the maximum value will be at the largest radius. As instances are selected along each spoke, a "candidate device signature" (the lines drawn between selected points on each spoke) is generated. Dragging one or more of these selections will generate numerous possible solutions.

The input parameters can include traditional variables (such as physical dimensions and material specifications), performance-type inputs (temperature limits, load capacity), and traditional desired outputs (such as temperature profile, stress contour). A robust system would allow for users to manipulate both input and outputs (inverse design).

A particular value or constraint of a value can be user-specified, or determined based on the data associated with a particular model. For example, a user can lock a parameter to have a certain value (as suggested in Fig. 1), or apply weighting to restrict flexibility. In addition, the user or a routine can specify those parameters that are free to move, or impose a cost function with movement of a particular value.

The medical device examples that follow, demonstrate the need for complex FEA and/or CFD analyses to describe the interface between devices and tissue. A powerful optimization tool would be to sparsely populate the input and output parameter space with computed solutions, and allow a designer(s) to explore the entire solution space with algorithms controlling the interpolation between known solutions.

Although modeling calculations only provide an "approximate result," they can be verified and validated with physical models

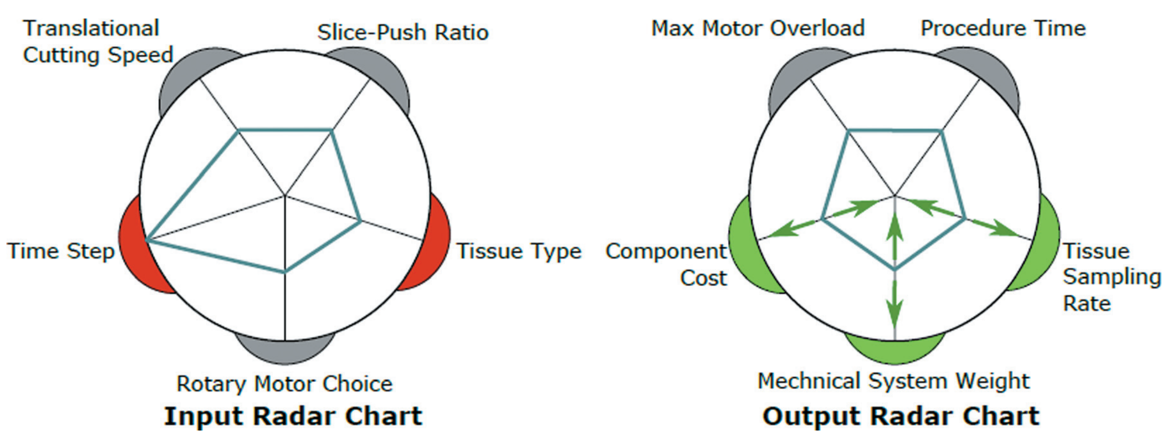


Fig. 26 The radar chart (or wheel plot): input parameters are on the left and output measures on the right. The five-sided shape is one instance of a potential design solution. By dragging along each spoke, new solutions are revealed. This set of plots is related to the next two examples.

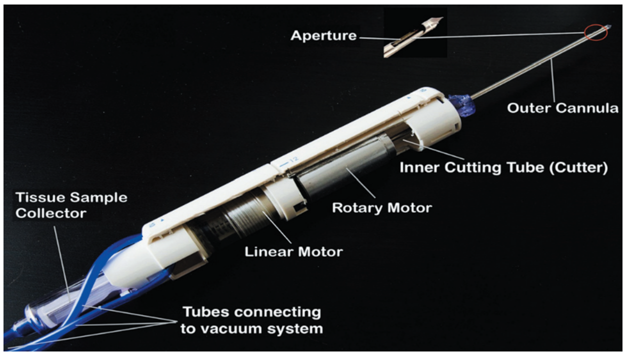


Fig. 27 ATEC vacuum-assisted biopsy device. The inner cutter is both rotated and translated within the outer cannula, causing suspected tissue which has been drawn into the distal aperture in the outer cannula, to be severed from the breast tissue and drawn back into the tissue sample collector.

for a final decision, and the results fed back into the modeling calculations to improve future results. Therefore, it would be advantageous to configure the output device to generate a physical prototype (perhaps using 3D printing, called rapid prototyping in Fig. 24).

Example 1—Virtual Design of a Vacuum-Assisted Biopsy Device. *Unmet need*: A biopsy device that assures proper tissue cutting by progressively slicing until a tissue sample is fully separated from the rest of the breast tissue, in minimal time, with an ergonomically correct tool that is "weighted and balanced," produced at a reasonable cost, and that would enhance the health care providers ability to perform safe and accurate biopsy results [32,33].

Analysis: The tissue cutting mechanism of the vacuum-assisted biopsy system (Fig. 27) was investigated. The goal of the virtual prototyping was to determine the optimal selections of motors, speeds, and aperture geometry (as depicted in Fig. 28) to satisfy a number of output measures (in many cases optimizing one measure yields a suboptimal resulting outcome for another). The challenge was whether such a system could be designed just using modeling and simulation.

As suggested in Fig. 26, five design variables were considered as input parameters: time-step, translational cutting speed, slice-push ratio, breast tissue type and rotary motor selection. Five performance attributes were defined as the output parameters: total procedure time, tissue-sampling rate, maximum motor overload factor, mechanical system weight, and component cost. The total procedure time is related to the level of anxiety the patient may experience during the procedure. Tissue-sampling rate is an indicator of the cutting performance tissue quality and total volume of tissue extracted. The motor overload factor dictates how much rest time between two sampling sequences is required for the selected motor due to potential overheating. The system weight is the total weight of the design components contained in the hand piece, which needs to be minimized for single handed operation by the physicians.

An "inverse design strategy" was chosen, where the engineer chooses an output parameter (e.g., stress contour) and drags it to a new position on the device. The software then computes the best fit for the design variables that would generate the new output stress field intended by the engineer's input. For the biopsy device, the engineer wants to reduce high stress near corners resulting from a perpendicular load applied to the needle tip. (This load is simulating the surgeon or radiologist prying the distal end of the needle against a rib to access a potential lesion location close to the chest wall.)

Figure 29 shows an example of the stress field in the design space for a breast biopsy needle system, where the stress field is modified as a function of input parameters. In forward design, the user drags on an edge of the opening window on the cannula and moves it toward the opposite edge to decrease the window length and observes how the output measures change. In an inverse design, the user manipulates the stress field resulting from a perpendicular load applied to the needle tip. The goal is to find design alternatives where highest stress region is not in the corner of the opening window to reduce a potential failure due to stress.

Solution: With the time-step fixed, four variables were used to generate 900 potential solutions and used to sparely populate a four-dimensional design space with a total of over 10×10^6 possible solutions (if an increment of 0.1 is used for the linear speed and the slice/push ratio). These design points were simulated in a HPC cluster provided by Minnesota Supercomputing Institute (MSI). Each of the simulation jobs was run under 8-core Sandy bridge E5-2670 2.6 GHz processor.

The 900 simulations (tissue cutting + motor) were solved in 28.72 h versus 180 h solution time using a stand-alone workstation. The 900 design points were loaded into the "design by dragging" strategy (a novel interactive design aid introduced in Ref. [32]) to create a spatially populated design space. This is an example of inverse design including user-in-the-loop. Between each pair of the design points, a warp was computed to describe a smooth transition of the von Mises stress field from one to the other.

Example 2—Dry Tap. *Unmet need*:

"Dry tap" means a failure in tissue sampling, caused by the tissue sample not fully separating from the rest of the breast tissue. In order for the breast tissue to be severed by the cutter, either the maximum shear or the maximum tensile damage criterion in the tissue must be satisfied [33].

Analysis: A dry tap problem was detected in a design shown in the upper graphic of Fig. 30 where the deformed mesh shows a failed tissue removal (still connected biopsy distal segment). The lower graphic shows locations of stress in the tissue. The strategy of solving this problem via the inverse design was to replace the still connected tissue (red region) with empty space (in blue

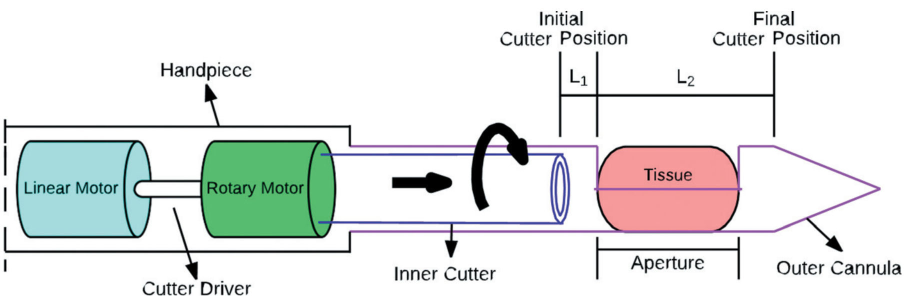


Fig. 28 Virtual design of a vacuum-assisted biopsy tool—schematic of the system showing key variables

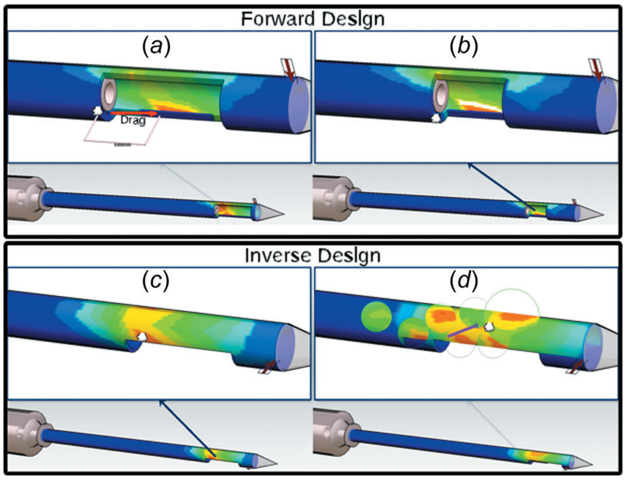


Fig. 29 Examples of designing a biopsy needle using direct manipulation via data visualizations. The colored stress fields are the result of a load (see red arrow) at the tip of the needle representing leveraging the needle against the ribs. In forward design, the user drags an edge of the opening window to the right (*a*). This operation is interpreted as decreasing the window length (*b*). In inverse design, the user attempts to move a high stress region (the cursor location) away from the corner of the opening window. The user right-clicks on the region (*c*), and then, the system suggests design alternatives that have the closest distances (determined by calculating the differences between the parameter values and the weighting) from the current one, shown as preview bubbles (enlarged view in circular windows). Each of the preview bubbles shows a magnified view of local stress distribution, which informs where the high stress region can possibly be moved. The user finally moves into the most-right preview bubble to switch to a new design alternative. This design alternative shows that the high stress region has moved away from the window corner (*d*).

color). Preview bubbles (a novel inverse design strategy introduced in Ref. [33]) were generated to provide approximate stress fields if input parameters were changes in that direction. One of the preview bubbles shown in Fig. 31 (circled in red) showed a possible removal of the tissue connection.

Solution: By switching to the new parameter design point suggested in Fig. 31, the dry tap problem was resolved (Fig. 32). This result includes increasing linear cutting velocity. This was not a unique solution. This example also shows the power of this

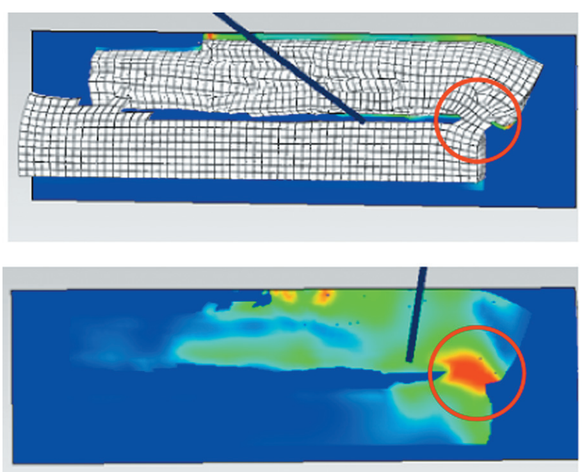


Fig. 30 Locating the dry tap: cutting adipose tissue with low cutting speeds. The deformed mesh is shown on the top while the stress distributions are show on the bottom graphic.

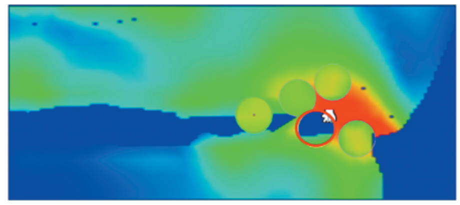


Fig. 31 Preview bubbles are shown near the dry tap area

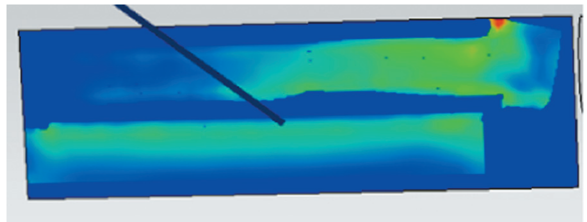


Fig. 32 An optimal design that removes dry tap

simulation tool in avoiding the selection of design parameters (motor selection in this case) that might result in failure of the breast biopsy tool in actual use.

Conclusion

Experiences gained through the evolution and improvements of the various versions of LINCAGES showed how powerful mapping solutions spaces can be. Providing visual clues to output performance measures can dramatically reduce standard timeframes for finding optimal solutions. For example in linkage synthesis, entire solution spaces could be explored in minutes–hours versus days–weeks using trial and error methods. Fortunately these lessons do scale up nicely into much more complicated systems with more varying input parameters. Feedback received from designers, physicians, representatives of FDA, and members of the Medical Device Innovation Consortium (MDIC) are unified in their excitement about application of these user in the loop techniques for preclinical optimization of medical device systems in the future. As computational methods continue to mature, computers become cheaper and faster, and interactive graphics even more mature, the future is very exciting indeed. Design teams will have the opportunity to quickly navigate through solutions spaces thereby gaining continuous feedback on sensitivity of selection of variables.

The power of exploring design spaces using inverse design methods like the ones described above is a true game changer. The engineer will be able to spend more time being creative, developing a deeper understanding of the significant system parameters, and able to easily collaborate with other team members, while bringing about superior designs in a shorter period of time and at lower overall cost. In the seemingly short 40+ years since I was introduced to kinematics synthesis, the impact of M&S has been significant. It challenges the imagination to accurately predict what the next 40 years will bring.

Acknowledgment

The author would like to thank the hundreds of colleagues who have collaborated with me over these years. I have learned so much from each one of you. In particular, I so much appreciate my partnership with Don Riley for his wisdom during those early years of LINCAGES development. I would also like to thank Paul Rothweiler, Lyndsay Stevens, and Sharath Nair for specific assistance on this manuscript. Especially I am indebted to Dan Keefe from Computer Science and Engineering Department at

University Minnesota and Runesha Birali from the Research Computing Center at the University of Chicago, colleagues who I have worked with on modeling/simulation/visualization in recent years and shared support by the National Science Foundation under Grant No. IIS-1251069 and National Institutes of Health under Grant No. 1R01EB018205-01.

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