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RAPID DESIGN AND PROTOTYPING OF CUSTOMIZED REHABILITATION AIDS

Introduction

There is considerable variability in performance, form, and function among the individuals of any population. Such variability creates a critical need for designing products that are specific to an individual. This process becomes even more important when the functional performance of the product is tied to the individual's capabilities, as in the case of rehabilitation devices. In this article, we discuss the emergent technologies and their integration, which will permit rapid customized design and manufacture of products, with some emphasis on the design of rehabilitation aids for individuals with physical disability (e.g., prosthetic devices such as artificial limbs and orthoses).

The customization of the products to an individual has been pursued for centuries in an effort to enhance its usability as well as the comfort of the user. An important first step is to measure and quantify the variability between individuals. This quantification process forms the basis of anthropometry, a branch of physical anthropology that studies measurements of the human body. However, the number of standard anthropometric measurements and their combinations tends to grow exponentially. This makes it difficult to select a limited but adequate number of measurements capable of characterizing the variability. A commonplace example of this process is one of fitting clothing.

Two main paradigms exist for the customization of products, spanning a range of product classes from clothing to rehabilitation aids. *Mass customization* models discretize the variability in the population into a finite set of categories/sizes based on a few anthropometric parameters (like neck size, waist size, arm, and leg lengths). The products are then designed to fit statistically "average" people for each category. Ready-made clothes in stores are a testimonial to this process. Some flexibility of customization is retained by the availability of adjustable features. However, there never are any guarantees of a perfect fit. On the other hand, *individualized customization* models rely on more extensive yet limited *manual* measurement of the user for the design. Tailor-made clothing guarantees a better fit but at a higher cost due to the need for trained professionals for production. Additionally, such individualized customization typically requires repeated "trials" and involves longer manufacturing times.

One should note that the usual caveats for general product development are equally applicable to customized product realization. Production costs have to be kept as low as possible and there is always pressure to provide the product quickly and to be able to respond to the consumers' needs rapidly. Furthermore, it may be necessary to allow for adjustments and maintenance or to rapidly redesign and remanufacture the product due to biological changes that occur over time (e.g., custom-fit eyeglasses).

Over the past decade, there has been a trend for manufacturing enterprises in the United States to transform from low-cost, high-volume producers to organizations capable of producing a wide array of quality products that target specific market needs. This transformation has been fueled by the development of flexible manufacturing technology that is loosely referred to as agile manufacturing (*1*), which makes it possible for a designer to move quickly from a preliminary design concept to a prototype and respond to frequent and unpredictable change. However, neither traditional mass production nor the newer manufacturing techniques specifically address the unique challenges underlying the *rapid manufacture of individualized* one-of-a-kind products in batch sizes of *one*.

In recent years, considerable attention has also been focused on the critical role of information technology in shortening the design cycle and reducing costs (*2*). Virtual prototyping is one of these contemporary technologies offers considerable promise in many arenas, including our efforts in the customization of consumer products.

Virtual prototyping (VP) or simulation-based design (SBD), as it is alternatively called, is the coupling of designs with functional simulations of their performance. It emphasizes the use of parametric designs are refined by interfacing with analysis and manufacturing simulation tools. The coupling to analysis simulations enables functional performance evaluations, and the coupling to manufacturing simulations enables the designer to address issues regarding manufacturability. Bidirectional associativity between the design and analysis gives the designer the ability to perform simulations earlier and more frequently in the design cycle. The ability to verify designs in "what–if" analyses permits the speed-up of the iterative design process. With the growth of confidence in the evaluation process of VP, many traditional functional evaluation/testing procedures are being replaced by their virtual counterparts.

Virtual prototyping impacts every aspect of product development through the extended lifetime: design, optimization, validation, production, product data management, sales, training, and even repair. A number of products serve to emphasize the critical role of simulation-based design in evaluating design alternatives, reducing prototyping costs, and shrinking time to market.

Our research combines and takes advantage of concurrent advances in technology to achieve *rapid individualized product realization.* Specifically, we emphasize (1) an automated in-depth measurement of each individual user and extraction of design specifications, (2) designing products that are customized to these specifications, (3) virtually simulating, testing, and evaluating the product—before and after manufacture, and (4) involving and incorporating feedback from the consumers at all stages of the design process. The automation of the previously manual-labor-intensive stages speeds the process and lowers costs. The VP aids the design process by eliminating the need to evaluate and test intermediary physical prototypes. Finally, the automation of the fabrication using contemporary manufacturing processes permits the rapid physical realization.

Although most of the discussion in this article is limited to rehabilitation aids, there are many other examples of customized products. All products that are worn on our bodies or, more generally, products that depend on prolonged contact with human bodies for their functionality need customization at some level. This class of products includes wrist braces, computer interfaces (keyboards, joysticks), eyeglasses, helmets, and sports equipment.

The level of customization that is justifiable for each product depends on the cost,

FIGURE 1. *The articulated mechanism for feeding in a foot-controlled feeding device (Magpie) designed at the Nuffield Orthopaedic Center in Oxford. (From Ref.* 4.)

time for development and production, production volume, and, ultimately, profitability. A discussion of successful product development (*3*) is beyond the scope of this article. Instead, our main objective is to focus on the crucial engineering component technologies and their integration that are required to support the rapid design and production of customized goods and services tailored to the needs of a specific consumer.

In particular, we examine the role of the integrated approach in aiding the design and prototyping of passive, assistive, rehabilitation aids for people with motor disabilities. We consider as an example, a telethesis, a passive articulated device coupled to the user's body (possibly at a hand or the head) and acts as an "extension" of the person. (By moving his or her hand or head, the person can, e.g., use the telethesis as a manipulator.)

The Magpie (*4*) is a good example of the class of rehabilitation devices in which we are interested. It is a four-degrees-of freedom articulated telethesis that was designed

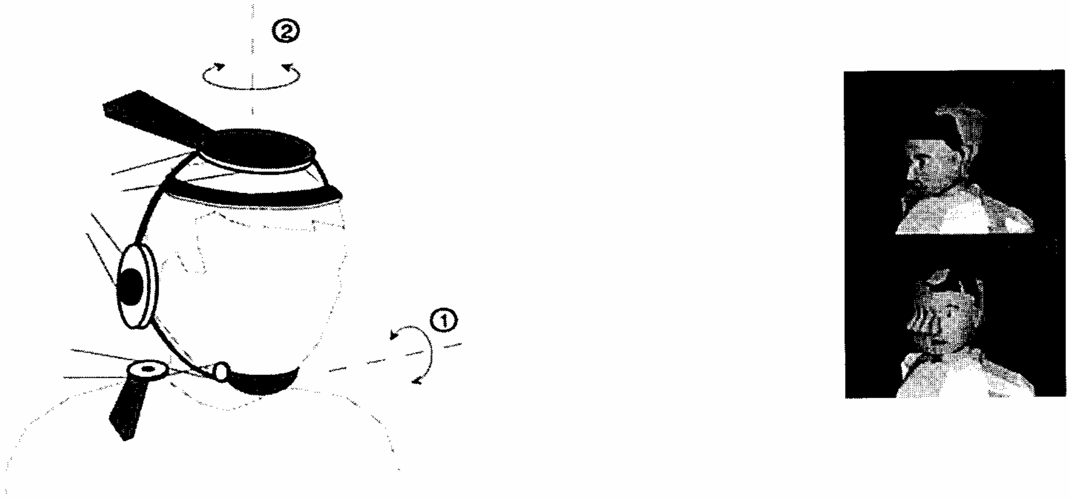

FIGURE 2. *A schematic of a head-control interface. The user can move his head/neck and chin to control multiple (two are shown in the figure) degrees of freedom.*

to permit hand amputees to eat independently. As shown in Fig. 1, the user is permitted to control the motions of a feeding utensil by movements of the leg and foot via a set of cables. However, there is a large group of people with spinal cord injury (SCI) who are paralyzed below the trunk (or neck). This population usually retains some control over head and neck movements, which can now be used to guide the movement of the feeding utensil. Therefore, we consider a modified design with a head-control interface, as shown in the schematic in Fig. 2, to benefit this group of people.

We use the example of the proposed head-controlled feeding device to discuss the basic issues in customized design and prototyping. We examine the process of obtaining user information, extracting design specifications, designing, virtually prototyping, and, finally, physically prototyping a customized telethesis while involving consumers for feedback and evaluation.

The Design Process

The design process for rehabilitation products that are customized to a person will involve a number of steps, as shown in Fig. 3. Of these, there are three stages that are of central interest here

- *Data acquisition:* To measure and observe the user while performing the desired tasks in the appropriate environment and to develop quantitative models for assessment by a therapist or a designer and for providing design specifications
- *Virtual prototyping:* To simulate the user, the product, and their (physical) interaction

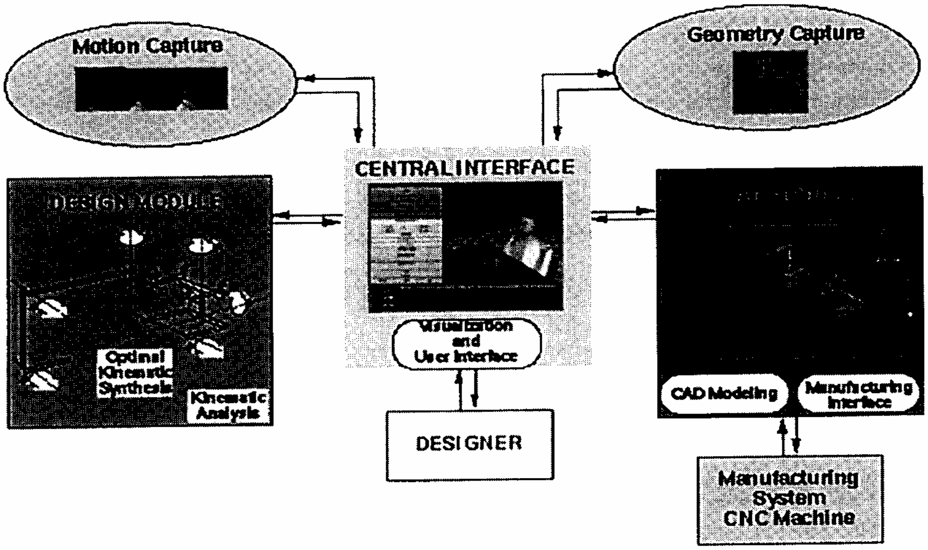

FIGURE 3. *Design and rapid prototyping of a one-of-a-kind rehabilitation product.*

through powerful workstations with high-resolution graphics throughout the different stages of product design

- *Rapid design and prototyping:* To take a preliminary design, convert it into a detailed design, and quickly produce prototypes for evaluation and later for production.

In the rest of this article, we describe each of these steps in greater detail, with particular reference to the computer integration. The end target is to design and prototype a successful customized product.

Data Acquisition: Measurement of the User, Task, and Environment

It is not necessary to measure the capabilities and needs of the individual and his or her environment and to describe the task in quantitative terms in order to generate the specifications for the design problem. For example, the custom design of a head-controlled telethesis for feeding requires the measurement of the geometry of the head, the kinematics of the head and neck, and the forces that the person can apply with his or her head.

Similar measurements may also be required for the feeding task (e.g., the ranges of motion of the spoon or fork and the forces that are encountered during the task). For customized design, we require, in addition to geometric measurements (shape, size), information about the kinematics and dynamics of the individual. Each of these categories is discussed next.

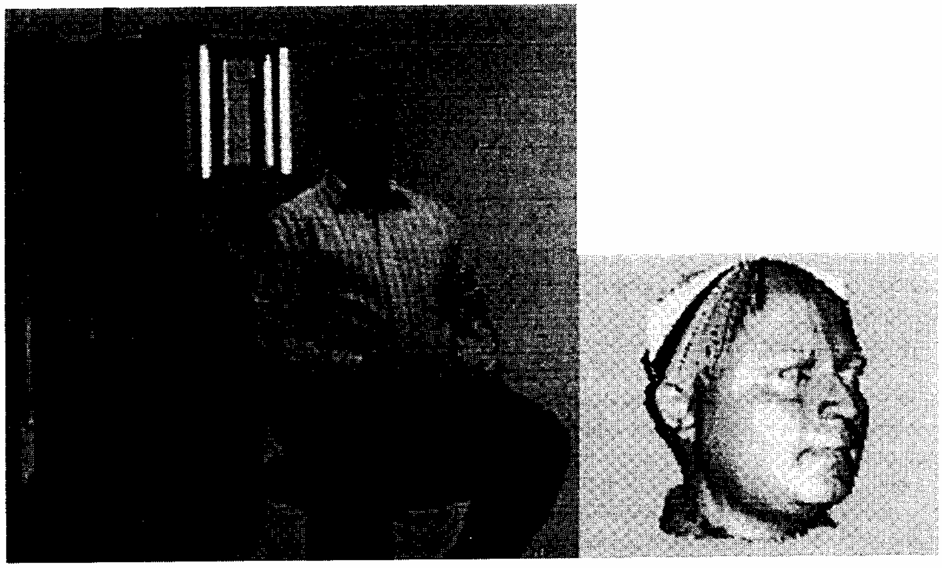

FIGURE 4. *Geometric information of a human head obtained by a Cyberware 3030PS scanner. The information is obtained by scanning the head from different angles and registering the different images. The information of the chin is used to make the customized prototype in Fig. 5.*

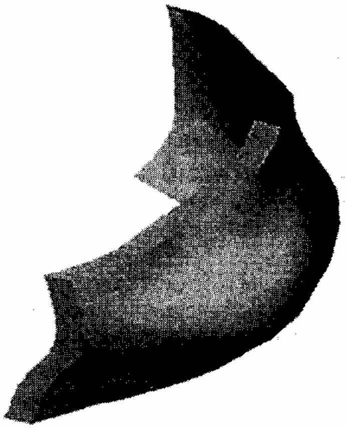

FIGURE 5. *A customized chin strap designed for the subject shown in Fig. 4.*

- *Geometric measurements*: The typical input will be surface geometry data from a given human part (shoulder, arm, wrist, neck, head) obtained through the use of two monocular cameras and/or from range-finding scanners. Figure 4 illustrates the kind of geometric information that can be obtained from a commercially available scanner. In addition to modeling the human body part, such measurements can also provide information for the design of products that are worn by the user. For example, a helmet or a rigid headband worn on the head, or (as shown in Fig. 5) a customized chin strap can be automatically prototyped with such geometric information. Geometric models for such components can be created automatically, and from these models, CAD/CAM models can be easily generated (*5*). These models can be used either for prototyping (and manufacturing), as shown in Fig. 5, or for inspection and quality control. The main challenges in obtaining the required measurements turn out to be important research problems in computer vision. In particular, robust techniques are needed for concurrently segmenting and fitting geometric models to each segment from data obtained from multiple viewpoints (*6*). Furthermore, there is a need for methods for representing geometric models at various levels of granularity depending on the desired tolerance and the complexity of the part.

- *Kinematic measurements*: The basic need is to accurately measure three-dimensional motion of moving body parts (e.g., the head and neck) without interfering with the dynamics of the moving bodies and to develop algorithms for estimating the three-dimensional movements. The available measurement systems include optical (accurate to 1–2 mm) and electromagnetic (accurate to 0.3–0.8 mm) sensors (*7*). Another possibility is a mechanical manipulandum (an articulated, low-inertia linkage with high-resolution position sensors, one end of which is attached to or moved by the individual) which is accurate to within 0.01 mm (*8*). Regardless of the measurement device, it is necessary to automatically determine kinematic models for articulated human limbs with minimal sensing. (See, e.g., Ref. *1*.) This problem is similar to the kinematic calibration problem encountered in robotics (*9*). Finally, methods for measuring the deformations, such as those caused by stretching of the tissue, in addition to the gross motion, are also important (e.g., for the design of soft orthotic braces). Although the medical community has developed sophisticated techniques for such measurements, many of these techniques are time-consuming and require clinically trained professionals and expensive equipment. Also, in this community, the kinematic models for limb movements are generally limited to ranges of motion at different joints. In contrast, we need fast, noninvasive measurement systems and methods for developing analytical models of limb movements. Frequently, we are not interested in the anatomy of internal features (such as the cervical vertebrae in head/neck movements), but we are only interested in capturing the kinematics of the gross motion. One approach involves the analysis of the deforming silhouette of moving limbs in a controlled studiolike environment (*10*). Our current research in this direction is the development of algorithms that will perform the data reduction and provide analytical models that can be used for designing the appropriate products.
- *Physical measures of performance*: To measure the performance of an individual, it is often necessary to measure the kinematics of three-dimensional motion while measuring the forces and movements that can be exerted at the end segment. The motion and force measurements, when appropriately transformed to joint coordinates, reflect joint motion ranges and strength characteristics. There are very few general-purpose instruments or general techniques to obtain such information. Our approach has been to use a manipulandum (*8*) or a robot (*11*) to measure forces and moments that can be exerted by a hand during manipulation. The application of such methods to model the head/neck movements of quadriplegics and able-bodied subjects in order to design head-controlled feeding aids is described in Ref. *7*. The major goals for future research in this area are a framework for modeling and representing information on human performance and algorithms for data reduction and representation.

Virtual Prototyping

Virtual prototyping is the process of design, analysis, simulation, and testing of a product within the computer, and using the results to refine the concept and redesign the product before making a physical prototype. Over the last decade, high-speed computer graphics workstations have proven to be very effective in allowing visualization of three-dimensional complex systems (*12*). With advances in robotics technol-

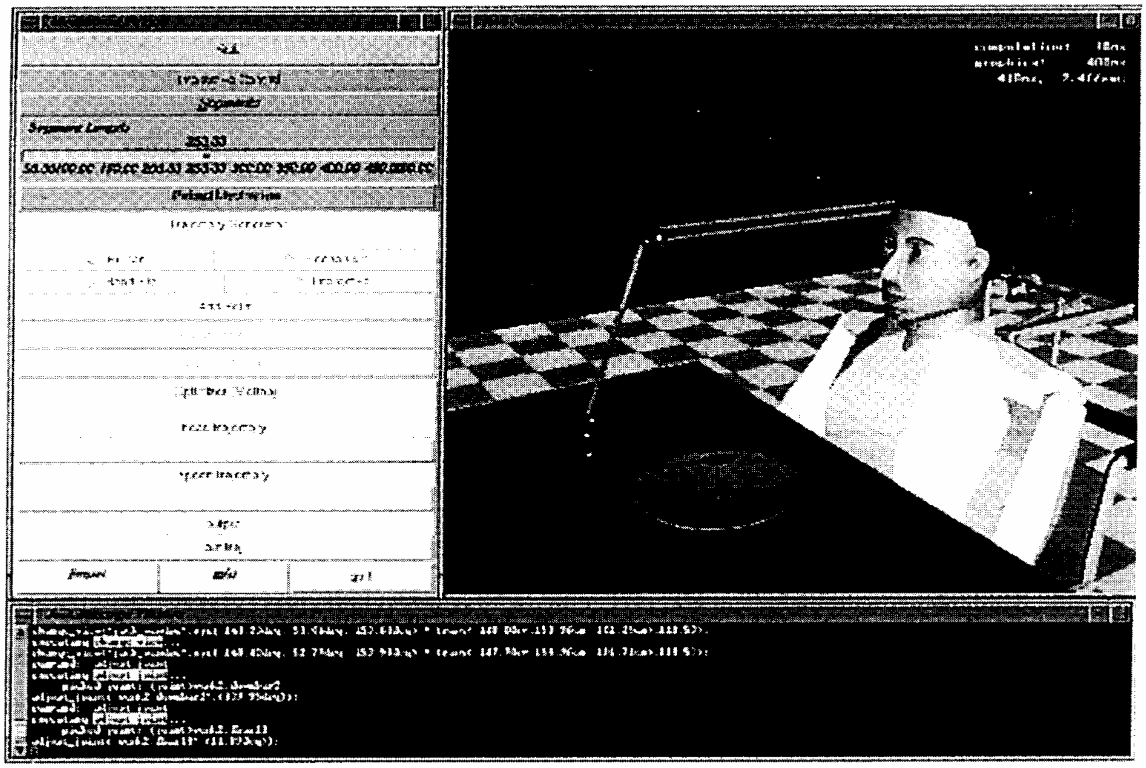

FIGURE 6. *A virtual prototype of a feeding device and the design interface.*

ogy, the potential for developing haptic interfaces that allow the user to feel forces exerted by the virtual environment (in addition to seeing the environment) has been successfully demonstrated (*13*). As computers become faster and as more sophisticated actuators and sensors are developed, computer interfaces will enable the user to feel, touch, and see the virtual product in a virtual environment.

For customized design and prototyping, it is essential to integrate VP with data acquisition. With the measurement of the user, the task, and the environment, we can create accurate dynamic models (specific to the user, the task, and the environment) and investigate the virtual creation and installation of a customized virtual product on a virtual human user as an integral part of the engineering process. Consider again the example of a feeding device. To evaluate candidate designs, it is useful to create a simulation of the user and the mechanical system, as shown in Fig. 6. The mechanism that links the human head to the feeding device is not shown in the figure. The designer can experiment with different kinematic coupling mechanisms and see how the movements of the user are translated into the movement of the end effector or the spoon. Three-dimensional graphics provides visual information about the design, whereas a real-time dynamics simulation package elicits information about the forces and the velocities that are required of the human head and neck to effectively

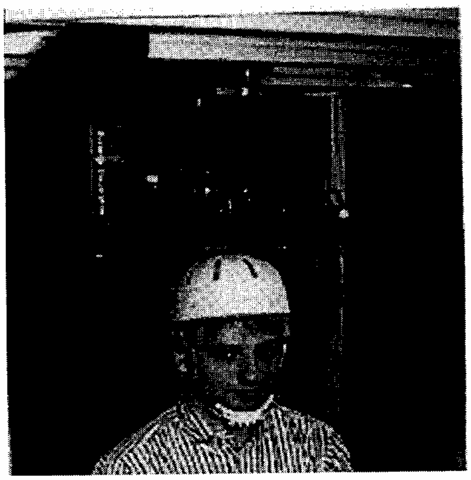

FIGURE 7. *A head-controlled haptic interface for a virtual environment. The user's helmet is attached to the PerForce, a six-degree-of-freedom manipulator (Cybernet Systems, Ann Arbor MI). The manipulator can be controlled to simulate the dynamics of a virtual prototype.*

accomplish feeding. By linking to an appropriate physiological database, one can verify the feasibility of the required head and neck motions and also investigate possible sources of discomfort or trauma with the virtual prototype before clinical tests are performed. Being able to develop a virtual prototype of the product also allows the consumer to use and evaluate the virtual product in an appropriate virtual environment before the designer commits to the expense of creating the physical prototype. In the rehabilitation engineering domain, the designer may miss important constraints due to a lack of affinity with the consumer (*14*).

Consumer feedback (and evaluation by experts such as therapists) during the VP phase and the redesign of the product in response to this feedback at a very early stage can ensure the success of the product and possibly avoid building multiple physical prototypes and incurring the resulting expenses.

To this end, in addition to allowing consumers to test the product by testing the virtual prototype, it is beneficial to provide haptic feedback so that a user can feel the dynamics of the product. An example of such a haptic interface (*15*) is shown in Fig. 7, in which the user wears a helmet that is attached to a six-degree-of-freedom manipulator. The manipulator can then be controlled to simulate the dynamics of the feeding device. It should be noted that the virtual prototype might include some physical models of the products, such as a prototype obtained from a stereolithography system (*16*). For example, a stereolithography prototype of a chin strap or a headband for the feeding device (possibly including metallic tabs to simulate the actual weight) may be worn by the user or designer to test the virtual prototype.

Rapid Design and Prototyping

The design process can be divided into a concept development and system-level design phase and a detail design phase (*3*). By rapid design we refer mainly to speeding up the detail design phase, which includes the specification of the geometry, materials, and the manufacturing process for each component. In customized production especially, it is essential to adopt a computer-integrated approach to rapid design where the designer can access and manipulate various heterogeneous pieces of information pertaining to geometry, kinematics, and dynamics.

At the heart of our design package is a graphical user interface (see Fig. 6) which also acts as a server to support the interactive design and analysis processes. The front end is developed using JACK, a package for human body simulation (*12*). The key is to have a generic request procedure that enables any of the component design/analysis packages or modules to call another package to obtain relevant information. Thus, information from any data acquisition, VP, or simulation module can be easily displayed on the visualization package. Finally, because the modules operate on different machines/architectures, efficient communication protocols between separate processes (relying on UNIX TCP/IP calls) are employed. This graphical server allows a modular approach to software development and enables the designer to interact with each module at different levels. Currently, the modules consist of the two data-acquisition modules for geometry (*6*) and kinematics (*7, 10*) and the VP module described earlier.

The user interface allows the designer to create a personalized simulation of a particular individual with the relevant geometric and kinematic characteristics. The designer can prescribe a desired trajectory (positions and orientations) for the simulated human agent using a mouse or a joystick. It is possible to see the simulated human execute the motions while conforming to the kinematic, dynamic, and physiological constraints that are characteristic of the individual and while being subject to the dynamics of the environment (the feeding linkage, in this example).

Rapid prototyping is the process of quickly making a physical prototype of a product from a design in order to evaluate or test the product. If our virtual prototype is guaranteed to be completely faithful, this stage is not necessary. However, because the virtual design environment might not incorporate accurate models of the environment and the tools, it is often necessary to go through this stage. Generally, this will be followed by redesign and possibly new prototypes. Sometimes, the result of rapid prototyping may not be the complete product. For example, the initial prototype of a new head-control interface may be limited to a stereolithography prototype of the headband or the chin strap. In such cases, this would be followed by a more refined prototype.

Again, it is important to emphasize the integration, in this case between VP and rapid physical prototyping, that is required to let the designer "kick the tires of the product" before committing to manufacture.

When a product is made by such free-form fabrication processes as selective laser sintering (*16*), it is easy to take a CAD design and quickly build a prototype. This is because the representation that is used for manufacturing a part relies on geometric descriptions of parallel slices of the part, and this is easily obtained from the CAD model. However, with other manufacturing processes, the procedure of going from a design and a virtual prototype to a physical prototype is very time-consuming because the representations used in CAD and CAM can be very different. Automating this procedure is a major challenge.

Even for customized design and manufacture, from an economic viewpoint it is beneficial to use off-the-shelf components whenever possible. However, this may not always be possible. First, because low weight and/or a high stiffness-to-weight ratio are important for many products used by people, we may have to redesign available components using lightweight materials such as carbon-fiber composites and plastics. Second, the possibly high cost or lower reliability of many off-the-shelf components may require the development of a simpler design with fewer custom-made components. Finally, there will be parts that must be custom designed for specific consumers. An important research problem is to determine when using multiple standard components with adjustments is superior to using simpler but custom-made components.

Such decisions in engineering design require an approach that combines such diverse methods as reliability analysis, models for costing (*3*), optimization (*17*), knowledge engineering (*18*), and models of imprecision (*19*). The cycle of virtual and rapid prototyping, with product testing and evaluation followed by redesign, will result in a detailed design. However, for producing the final usable product, it may be necessary to outsource the manufacture of many components. There will also be off-the-shelf components that must be acquired from vendors.

When low-volume customized products are being manufactured, it is likely that the "factory" will be a virtual production center, in which the manufacturers and vendors, as well as retailers, service providers, and consumers, are geographically distributed but integrated via an information network. Such a virtual production facility will require electronic linkages with remote facilities to allow for information flow. The information flow may include real-time audio and video for videoconferencing and VP, three-dimensional CAD drawings, and even force/touch information for and product evaluation by consumers. Such an information network requires (1) a high-speed electronic linkage (e.g., 80–100 Mb/s) that is capable of transmitting large amounts of data and (2) the capability of combining different types of data with different requirements on reliability and transmission rates.

Thus, one important area of research is software models and implementations for support-reliable real-time data transport, as is necessary for sensory feedback and kinesthetic data used for teleoperation of machines (*20*).

Concluding Remarks

In summary, we outlined the essential components necessary for the computer-integrated manufacture of low-volume customized products such as rehabilitation aids for people with motor disabilities. The basic concepts of customized production and the computer-integrated approach to design and prototyping outlined in this article are applicable to a wide range of products, from clothing, sports, and recreational equipment to computer workstations and machine interfaces.

Recent research in virtual fashion and customization of clothing (*21*) highlights another application involving components similar to the ones discussed in this article—the customization of an articulated human model and interactive simulation of the product with a model of the user in a virtual environment. Many of the same fundamental research issues arise and need to be addressed in both applications. These include identifying the significant variation in the population, empirically quantifying the individual users, automatically extracting measurements from empirical data, customizing a virtual model of the user, designing the product using this virtual model, and rapidly fabricating the product. The role of VP in aiding the visualization of the three-dimensional (clothing) design process, combined interactive simulation of the product (clothes) with (customized) models of the user, and refinement on the basis of functional simulations (dynamic drape) closely parallels its role in this article. We also briefly described some of the open research problems in the areas of data acquisition, virtual and physical prototyping, and systems integration. Many of these problems are not very different from problems encountered in robotics, computer vision, and databases.

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RISK COMMUNICATION

Introduction

Do cellular telephones cause brain tumors? What level of atrazine is safe in drinking water? Does sunscreen protect from skin cancer or increase the chances? Risk. One might say that we have become obsessed with the potential dangers of the world. One might also say that we have plenty to be concerned about. Some have made the argument—many have agreed—that the defining characteristic of modernity is risk: we now live in the "risk society," in which the identification and assignment of risk is woven into all aspects of life (*1*). Regardless of whether one takes an alarmist or Pollyannaish stance on the risks we face (and it is often reduced to that polemic), all must agree that the identification of, reaction to, and consequences of risk are strongly a function of communication—risk communication.

Risk communication is chimeric. As an area of professional practice, risk communication has been around quite a while (typically subsumed under the umbrella of industry public relations, public interest communication, or risk management). As an area of scholarship, risk communication is a rapidly emerging emphasis, and one that has arisen from a strongly interdisciplinary base (ranging from engineering to religion to psychology). As an endeavor of the social sciences, risk communication is especially a newcomer. Distinct tensions exist between the applied and theoretical worlds of risk communication. Other tensions exist among various scholarly perspectives that have sought to address risk communication. For example, risk communication is related to, but quite distinct from, the area of scholarship labeled risk perception. Because of these and other factors, the literature on risk communication is an unusually slippery one to get into the net. But let us try.

This treatment of risk communication will begin with a look at a definition of the term from several perspectives. With that accomplished, an examination of a few of the more long-standing theoretical or paradigmatic approaches to the study of risk