Journal of Long-Term Effects of Medical Implants, 12(4), 211–229 (2002)

An Innovative Surgical Suture and Needle Evaluation and Selection Program

Robin R. Szarmach, C.S.T./C.F.A.,[1] Jean Livingston, R.N., Ph.D.,[1] George T. Rodeheaver, Ph.D.,[2] John G. Thacker, Ph.D.,[3] & Richard F. Edlich, M.D., Ph.D.[2]*

[1]Consorta, Inc., Catholic Resource Partners, 3701 Algonquin Road, Suite 550, Rolling Meadows, IL 60008, rszarmach@consorta.com; [2]Plastic Surgery Research Program, University of Virginia Health System, Charlottesville, Virginia; [3]Department of Mechanical and Aerospace Engineering, University of Virginia, Charlottesville, Virginia

*To whom all correspondence should be addressed.

ABSTRACT: This report describes an innovative suture and needle clinical evaluation program jointly designed by hospital representatives of Consorta, Inc., a healthcare resource management and group purchasing organization, and United States Surgical/Davis & Geck Sutures (USS/D&G), manufacturer of surgical biomaterials. Nineteen Consorta shareholder hospitals enrolled 699 surgeons to participate in Phase I of this nonexperimental observational study of the clinical performance of surgical needles and sutures. Performance characteristics of the sutures and needles produced by USS/D&G, which were evaluated in 3407 surgical procedures, included packaging and ease of opening, needle strength and sharpness, tissue drag, knot security, tensile strength, and clinically acceptable and unacceptable determinations. In these 30-day studies, the surgeons concluded that the needles and sutures were clinically acceptable in 98.1% of the evaluations. The general, cardiothoracic, and orthopedic surgeons, who performed 73.8% of the product evaluations, reported that the suture and needle products were clinically acceptable in 97.2% of the evaluations. More than half (50.1%) of the evaluations involved the POLYSORB* braided synthetic sutures, which received a clinically acceptable rating in 98.4% of the evaluation. The next most frequently used sutures were the SOFSILK*, followed by the monofilament nylon suture. SOFSILK* was found to be clinically acceptable in 98.7% of the evaluations, whereas the monofilament nylon was noted to be clinically acceptable in 96.3% of the evaluations. Surgical needles made by USS/D&G had a 97.9% clinical acceptability rating.

KEYWORDS: surgical suture, surgical needle, group purchasing, surgical specialties, clinical acceptability, surgeon, nurse, hospital administrator

Document#JLT1204-211-229 (175)

I. INTRODUCTION

The scientific basis for suture selection depends on the ability of the surgeon to construct a secure knot that will not slip or untie. It is unfortunate that many surgeons perceive surgical sutures and needles more as an art form than a science. In the past, the use of sutures and needles by surgeons has often been a matter of habit, guesswork, or tradition.[1] This approach to selecting sutures and needles has contributed to a growing concern that the selection of sutures and needles by many surgeons is not optimal. In fact, it has been reported that surgeons use faulty techniques in tying knots, which is the weakest link in a tied surgical suture. When the recommended configuration of a knot, determined by mechanical performance tests, was compared to configurations used by board-certified general surgeons, only 25% of the surgeons correctly used appropriate knot construction.[2] Of 25 gynecologists, mostly department heads, who were polled about their knot-tying techniques, many believed that they constructed square knots even though their tying techniques produced slip knots, which became untied.[3] When a knotted suture is unable to perform its function, the complications may be disastrous—for instance, massive bleeding may occur when the suture loop compressing a vessel breaks or becomes untied, and wound dehiscence or incisional hernia may develop after knot disruption.

Because many surgeons determine suture selection based on testimonials and anecdotal experiences, a continuing education program, "Scientific Basis for Selection of Surgical Sutures and Needles," was developed for surgeons; this program is credited by the Dannemiller Memorial Foundation for 4 Category 1 continuing education credits.[4] This educational program was designed to teach surgeons the scientific basis for suture and needle selection and to examine the appropriate surgical techniques involved in the wound repair of skin and abdominal incisions and femoral arteriotomies. The teaching program also allowed surgeons to compare the performance of needles and sutures made by different manufacturers. Because the course was conducted in an experimental laboratory environment, it had limited application for the hospital setting in which sutures and needles are used for wound closure in patients.

Consequently, a group comprising Consorta, Inc. (Consorta) (Rolling Meadows, Illinois), a resource management group purchasing organization; United States Surgical/Davis & Geck Sutures (USS/D&G) (a division of United States Surgical, Norwalk, Connecticut), manufacturers of surgical biomaterials; and a clinician task force designed a reproducible surgical evaluation program for needles and sutures in a large cooperative of healthcare systems. Because of the subjective nature of the more commonly used suture selection techniques, a nonexperimental observational study approach was designed to replace perception of performance characteristics with actual clinical experience.

This unique program allows surgeons to evaluate the performance of a supplier's needles and sutures to ensure that the best needles and sutures are selected for patient care in the hospital setting. The selection process can easily be replicated in other hospital settings, which affords the purchasing division scientific evidence regarding the performance of competitive needle and suture products. This evaluation model for suture and needle selection is now being used for the selection of other surgical biomaterials employed in the hospital setting. The evaluation model is carefully outlined in a proprietary manual that illustrates a preevaluation process as well as the evaluation process.

II. MATERIALS AND METHODS

Consorta is a healthcare resource management and group purchasing organization whose shareholders are Catholic-sponsored, nonprofit health systems. As a cooperative, Consorta's shareholders participate fully in the organization's performance and receive competitive prices through scale-purchasing economies. Consorta provides the opportunity for improving hospital care by including its outcome comparisons for wound closure that, in turn, provide benchmark data for performance improvement. Consorta's data-driven contracting process facilitates administrative and surgeon participation in the selection of optimal products for wound closure. Nineteen shareholder hospitals participated in the study, which involved 3407 surgical patients.

II.A. Suture and Needle Product Evaluation

The suture and needle product evaluation was divided into two distinct steps: the preevaluation process and the evaluation. The overall objectives of the suture and needle evaluation were to (1) establish clinical acceptance through an unbiased method that measured the willingness of surgeons and staff to use suture and needle products from whatever supplier was awarded a Consorta agreement, and (2) achieve the best competitive price for suture and needle products. Consorta and USS/D&G prepared a proprietary manual that provides a clear understanding of their goals and objectives, as well as the evaluation process.

A.1. Preevaluation Process

As a first step, the hospitals were asked to review and sign an evaluation plan outlining suppliers' and hospitals' responsibilities in creating an unbiased environment for the evaluation. An evaluation team was formed, which consisted of the executive administrator, materials manager, operating room directors, nurse managers, and all surgeons. The group selected a project leader to coordinate all aspects of the evaluation process with the supplier whose products were being evaluated and to meet daily with the supplier's team members. A nurse leadership seminar and a site visit to the supplier's manufacturing facilities was undertaken to ensure the thorough education of key personnel on the products and quality assurance standards that those products must meet. In addition, the supplier had to designate a supplier evaluation team with representation determined by location and hospital requirements. The supplier team had to be on site at each hospital for the 30-day evaluation period. The supplier had to provide onsite nursing and surgeon inservice training programs to ensure proper communication and education on the process and products being evaluated. The supplier and evaluation teams developed a suture and needle evaluation form that included the following minimum evaluation criteria: packaging/ease of opening, needle strength and sharpness, tissue drag, knot security, tensile strength, and clinically acceptable and unacceptable determinations.

The evaluation team developed plans to prohibit access to the representatives from the incumbent suture product supplier(s) to the hospital site during the 30-day evaluation pro-

cess. Competitive products were removed from the operating room area to assure adequate opportunity for a fair trial of the new product. At the end of the 30-day evaluation, the incumbent products replaced the inventory of new products provided by the supplier.

A.2. Evaluation Process

All surgeons and staff participated in the evaluation of the suture and needle products of USS/D&G (any surgeon choosing not to participate would not have a role in the decision-making process). Uniform evaluation tools were provided to collect clinical feedback. All participants were asked to sign the evaluation forms after adequate experience with the products. Copies of the completed evaluation forms were available to both the project leader and the supplier on a daily basis. Surgeon feedback on nonacceptable products was pursued immediately to determine clinical justification as well as to propose solutions to meet the surgeons' needs.

The core measure of the criteria on which the suture and needle products were evaluated was clinical acceptability. Feedback on the products' clinical acceptability was provided on the evaluation forms. The evaluation results from all 19 hospitals were aggregated and summarized by Consorta for each shareholder. The final summary was reported to Consorta, Contracts and Programs, the Surgical Advisory Subcommittee, and the Suture Product Task Force.

III. SUTURES

Important considerations in wound closure are type of suture and mechanical performance, in vivo and in vitro. Measurements of the in vivo degradation of sutures separate them into two general classes, *absorbable* and *nonabsorbable.* Sutures that undergo rapid degradation in tissues, losing their tensile strength within 60 days, are considered absorbable. Those that maintain their tensile strength for longer than 60 days are considered nonabsorbable. This terminology is somewhat misleading, because even some nonabsorbable sutures (i.e., silk and nylon) lose a degree of tensile strength during this 60-day interval. Postlethwait[5] measured the tensile strength of implanted nonabsorbable sutures during a period of 2 years. Silk lost approximately 50% of its tensile strength in 1 year and had no strength at the end of the 2 years. Nylon lost approximately 25% of its original strength throughout the 2-year observation period.

III.A. Nonabsorbable Sutures

The nonabsorbable sutures of USS/D&G can be classified according to their origin. Nonabsorbable sutures made from natural fibers are *silk* sutures. *Metallic* sutures are derived from stainless steel. Modern chemistry has developed a variety of synthetic fibers including polyamides (nylon), polyesters (Dacron), polyolefins (polyethylene, polypropylene), polytetrafluoroethylene, and polybutester.

Polypropylene is a linear hydrocarbon polymer that consists of a strand of polypropylene, a synthetic linear polyolefin. All polypropylenes begin with a base resin and then go through

the following steps: extrusion, drawing, relaxation, and annealing. Each step in the process will influence the ultimate biomechanical performance of the suture. Biomechanical studies demonstrate that the manufacturing process (i.e., annealing, relaxation) can dramatically influence the surface characteristics without altering strength. Changes in the surface characteristics can facilitate knot construction of the suture. The polypropylene suture SURGIPRO* has a low coefficient of friction that facilitates knot rundown and suture passage through the tissue. A new polypropylene suture, SURGIPRO* II, has increased resistance to fraying during knot rundown, especially with smaller diameter sutures. Polypropylene sutures are extremely inert in tissue and have been found to retain tensile strength in tissues for as long as 2 years. Polypropylene sutures are widely used in plastic, cardiovascular, general, and orthopedic surgery. They exhibit a lower drag coefficient in tissue than nylon sutures, making them ideal for use in continuous suture closure.

Nylon is a polyamide polymer that is extruded into a monofilament suture (MONOSOF*, DERMALON*). Although it has high tensile strength and low tissue reactivity, it degrades by hydrolysis in vivo at a rate of about 12.5% per year. The pliability characteristics of nylon sutures permit good handling. Because they are more pliable and easier to handle than polypropylene sutures, they are favored for the construction of interrupted percutaneous suture closures. However, polypropylene sutures encounter lower drag forces in tissue, which accounts for their frequent use in continuous dermal and percutaneous suture closure. Nylon sutures are also available in a braided construction (SURGILON*), which are relatively inert in tissue and possess the same handling and knot construction characteristics as natural fiber, silk sutures (SOFSILK*).

Polyester sutures (SURGIDAC*, TI-CRON*) are composed of fibers of polyester or poly(ethylene terephthalate), a synthetic linear polyester derived from the reaction of a glycol and a dibasic acid. Polyester sutures were the first synthetic braided sutures shown to last indefinitely in tissues. Their acceptance in surgery was initially limited because the suture had a high coefficient of friction, which interfered with passage through tissue and with knot construction. However, when the sutures were coated with a lubricant, they gained wide acceptance in surgery. This coating markedly reduced the sutures' coefficient of friction, thereby facilitating knot construction and passage through tissue. The surface lubricants vary from polybutylene adipate (SURGIDAC*) to silicone (TI-CRON*).

The polybutester suture (NOVAFIL*) is a block copolymer that contains butylene terephthalate and polytetramethylene ether glycol. Polybutester sutures have unique performance characteristics that may be advantageous for wound closure.[6] This monofilament synthetic nonabsorbable suture exhibits distinct differences in elongation compared with other sutures. With the polybutester suture, low forces yield significantly greater elongation than that found with the other sutures. In addition, its elasticity is superior to other sutures, allowing the suture to return to its original length once the load is removed. The clinical performance of polybutester sutures has been enhanced by coating its surface with a unique absorbable polymer (VASCUFIL*).[7] This coating is a polytribolate polymer composed of three compounds: gylcolide, ε-caprolactone, and poloxamer 188. Coating the polybutester suture markedly reduces its drag forces in musculoaponeurotic, colonic, and vascular tissue.

The nonabsorbable sutures also may be characterized by their physical configurations. Sutures constructed from one filament (nylon, propropylene, polybutester, polytetrafluoroethylene, and stainless steel) are called *monofilament* sutures. Sutures containing multiple fibers (nylon, polyester, stainless steel, and silk) are called *multifilament* sutures.

Only nylon and stainless steel sutures are available as both a monofilament and a mul-

tifilament suture. Monofilament stainless steel (SURGISTEEL*) is manufactured as varying-diameter single strands of stainless steel. Multifilament stainless steel sutures (FLEXON*) are formed by winding one filament around another, forming a twisted suture. Long, continuous strands of stainless steel are twisted together to form sutures of various gauges.

The other multifilament sutures are formed by intertwining three or more filaments. For instance, several very fine silk fibers are twisted together to form yarns, which are then braided. The number of silk fibers used regulates the suture gauge; a large gauge suture can be made with braids of synthetic filaments by increasing either the number or the size of the filaments.

III.B. Absorbable Sutures

The absorbable sutures of USS/D&G are made from either collagen or synthetic polymers. The collagen sutures are derived from the submucosal layer of ovine small intestine or the serosal layer of bovine small intestine (gut). This collagenous tissue is treated with an aldehyde solution, which cross-links and strengthens the suture and makes it more resistant to enzymatic degradation. Suture materials treated in this way are called *plain gut.* If the suture is also treated with chromium trioxide, it becomes *chromic gut,* which is more highly cross-linked and more resistant to absorption than plain gut. When this treatment of collagen sutures is limited, the result is a special form of chromic gut, MILD CHROMIC GUT*, which is more susceptible to tissue absorption. Plain gut and chromic gut sutures comprise several plies that have been twisted slightly, machine ground, and polished, yielding a relatively smooth surface that is monofilament-like in appearance. Salthouse et al.[8] demonstrated that the mechanism by which gut reabsorbs is the result of sequential attacks by lysosomal enzymes. In most locations, this degradation is started by acid phosphatase, with leucine aminopeptidase playing a more important role later in the absorption period. Collagenase is also thought to contribute to the enzymatic degradation of these collagen sutures.

The type of gut being used determines the rate of absorption of surgical gut. Plain gut is rapidly absorbed. Its tensile strength is maintained for only 7–10 days postimplantation, and absorption is complete within 70 days. A limited exposure to chromium trioxide accelerates tensile strength loss and absorption of MILD CHROMIC GUT*. This fast-absorbing surgical gut is used primarily for ophthalmic and cuticular applications in which sutures are required for only 5–7 days. The tensile strength of MILD CHROMIC GUT* may be retained 10–14 days.

Natural fiber absorbable sutures have several distinct disadvantages. First, they have a tendency to fray during knot construction. Second, there is considerably more variability in their retention of tensile strength than is found with the synthetic absorbable sutures. A search for a synthetic substitute for collagen sutures began in the 1960s. Soon procedures were perfected for the synthesis of high molecular weight polyglycolic acid, which led to the development of the polyglycolic acid sutures (DEXON* II).[9] These sutures are produced from the homopolymer, polyglycolic acid. Because of the inherent rigidity of this homopolymer, monofilament sutures produced from polyglycolic acid sutures are too stiff for surgical use except in the finest size. Consequently, this high molecular weight homopolymer is extruded into thin filaments, braided, and coated with POLYCAPROLATE*.[9] The polyglycolic acid sutures degrade in an aqueous environment through hydrolysis of the ester linkage.

Copolymers of glycolide and lactide were then synthesized to produce a new braided absorbable suture (POLYSORB*). The glycolide and lactide behaved differently when exposed to tissue hydrolysis. Glycolide provides for high initial tensile strength but hydrolyzes rapidly. Lactide has a slower and controlled rate of hydrolysis, or tensile strength loss, and provides for prolonged tensile strength in tissue. Lactomer™ is a polymer consisting of glycolide and lactide in a 9:1 ratio.

The handling characteristics of POLYSORB* sutures were found to be superior to those of the Polyglactin 910™ suture.[10] Using comparable knot construction and suture sizes, the knot breaking strength for POLYSORB* sutures was significantly greater than that encountered by Polyglactin 910 sutures. In addition, the mean maximum knot rundown force encountered with the POLYSORB* sutures was significantly lower than that noted with the Polyglactin 910 sutures, facilitating knot construction.

The surfaces of these synthetic sutures have been coated to decrease their coefficient of friction.[10] The coating on the polygolic acid suture was an absorbable surface lubricant, poloxamer 188, that has now been changed. POLYSORB* sutures are coated with an absorbable mixture of caprolactone/glycolide copolymer and calcium stearoyl lactylate. At 14 days postimplantation, approximately 65% of the tensile strength of these braided sutures remains. Approximately 40% of their tensile strength is retained at 21 days. Absorption is minimal until day 40, and essentially complete between days 56 and 70.

A monofilament absorbable suture (MAXON*) has been developed using trimethylene carbonate.[11] Glycolide trimethylene carbonate is a linear copolymer made by reacting trimethylene carbonate and glycolide with diethylene glycol as an initiator and stannous chloride dihydrate as the catalyst. The latest innovation in the development of monofilament synthetic absorbable sutures has been the production of Glycomer 631™, a terpolymer composed of glycolide, trimethylene carbonate, and dioxanone (BIOSYN*), which has several distinct advantages over braided synthetic absorbable sutures.[12] First, it is significantly stronger than the braided synthetic absorbable suture over 4 weeks of implantation. Absorption is complete between 90 and 110 days. In addition, it potentiates less bacterial infection than does the braided suture. The handling characteristic of this monofilament suture is superior to the braided suture because it encounters lower drag forces in the tissue.

The strength of the MAXON* suture is maintained in vivo much longer than that of the braided synthetic absorbable suture. The MAXON* retained approximately 70% of its breaking strength after implantation for 28 days and still retained 13% of its original strength at 56 days. In contrast, braided absorbable sutures retained only 1–5% of their strength at 28 days.[12] Absorption of the MAXON* suture is minimal until about day 90 postimplantation and is essentially complete within 6 months. The direct correlation of molecular weight and breaking strength of the synthetic absorbable sutures with both in vivo and in vitro incubation implies a similar mechanism of degradation. Because in vitro incubation provides only a buffered aqueous environment, the chemical degradation of these sutures appears to be by nonenzymatic hydrolysis of the ester bonds. Hydrolysis would be expected to proceed until small, soluble products are formed, then dissolved and removed from the implant site. In contrast, the gut or collagen suture, being a proteinaceous substance, is degraded primarily by the action of proteolytic enzymes.

A distinction must be made between the rate of absorption and the rate of tensile strength loss of the suture material. The terms *rate of absorption* and *rate of tensile strength loss* are not interchangeable. Although the rate of absorption is of some importance with regard to late

suture complications, such as sinus tracts and granulomas, the rate of tensile strength loss is of much greater importance to the surgeon, considering the primary function of the suture: maintaining tissue approximation during healing.

When considering an absorbable suture's tensile strength in vivo, we recommend that the manufacturer provide specific measurements of its holding capacity, rather than the percentage retained of its initial tensile strength. The United States Pharmacopoeia (USP) has set tensile strength standards for synthetic absorbable suture material. If the manufacturers were to use these standards to describe maintenance of tensile strength, the surgeon would have a valid clinical perspective with which to judge suture performance. Some manufacturers persist in reporting maintenance of the tensile strength of their suture in tissue by referring only to the percentage retained of its initial tensile strength, making comparisons among sutures difficult. Using USP standards in reporting is particularly important when there are marked differences in the initial tensile strengths of synthetic sutures. For example, the initial tensile strength of BIOSYN* is 43% greater than that of polydioxanone. At 2 weeks, the BIOSYN* suture is approximately 30% stronger.

IV. SURGICAL NEEDLES

The surgical needles of USS/D&G are produced from stainless steel alloys, which have excellent resistance to corrosion.[13] All true stainless steels contain a minimum of about 12% chromium, which allows a thin, protective surface layer of chromium oxide to form when the steel is exposed to oxygen. Since their development during the early 1960s, high-nickel maraging stainless steels have found extensive use in structural materials in many applications requiring a combination of high strength and toughness. The basic principle of maraging consists of strengthening FeNi martensitic matrices by the precipitation of fine intermetallic phases, such as Ni_3Ti. These precipitates are so small that they are only evident on transmission electron microscopy. They strengthen the metal by preventing the planes of atoms in the stainless steel from sliding over each other. A high-nickel maraging stainless steel, such as S45500, comprises 7.5–9.5% nickel, 0.8–1.4% titanium, and 11–12.5% chromium. In contrast, S42000 stainless steel comprises 12–14% chromium without nickel or titanium. Scientists have successfully employed the concept of high-nickel maraging stainless steels (S45500) to develop stainless steel wires with superior strength and ductility for use as surgical needles. Surgical needles made of high-nickel maraging stainless steel have a greater resistance to bending and breaking than stainless steels without nickel.

A new high-nickel stainless steel, SURGALLOY*, has been used recently to manufacture surgical needles.[14] Biomechanical performance studies of cutting edge needles made of S45500 stainless steel alloy and SURGALLOY* stainless steel demonstrated that needles made of SURGALLOY* had superior performance characteristics over those made of S45500. The SURGALLOY* needles had considerably greater resistance to bending than the needle produced from the S45500 alloy. In addition, SURGALLOY* stainless steel had almost a 2-fold greater resistance to fracture than the S45500 stainless steel alloy.

IV.A. Components of the Needle

Every surgical needle has three basic components: *swage, body,* and *point.*

A.1. Swage

The swage is the site of attachment of the suture. Since 1914, an eyeless needle, in which the suture is attached to a drilled hole in the needle, has been used. The swaging process provides a smooth juncture between the needle and suture; needles produced by this swaging process created smaller holes in tissue than did threaded eye needles. However, this swaging process was only possible for larger diameter needles (>0.36 mm) because the mechanical drill could not reliably cut uniform holes in the ends of small needles. Consequently, a forming tool was used to create a channel one half of the diameter of smaller-diameter needles with an underlying receptacle for the attachment of the suture. However, the linear splits in the walls of these smaller diameter needles increased the drag force encountered by tissues during needle passage. With the advent of the laser (yttrium-aluminum-garnet [YAG]), uniform holes are reliably produced in the ends of small needles, resulting in a smooth swage that encounters lower drag forces than channel needles.[15] These low-drag forces caused by laser-drilled needles are associated with minimal mechanical trauma to tissues.

The laser-drilled needles have other unique advantages over the channel needles related to the length of the swage ends. The length of the channel in channel swage needles is 4 times longer than that of the laser-drilled hole. Because swages are more susceptible than is the body of the needle to being bent or broken by the needle-holder jaws, surgeons are warned to grasp the needle with the needle holder at a site beyond the swage. In the case of 18-mm-long needles with laser-drilled and channel swages, the depths of the laser-drilled holes and channel swages are 1.5 mm and 6.0 mm, respectively. The laser-drilled needle can be held by the needle-holder jaws 3 mm from the needle end, whereas the channel swage needle is grasped 7.5 mm from the needle end. By grasping the needle close to its end, the surgeon can more easily manipulate the passage of the needle through tissue. This benefit of laser-drilled needles is accomplished without altering the needle suture attachment strength. These distinct advantages of swages produced by lasers indicate that they should eventually replace all channel swage needles.

The needle is attached to the suture by uniformly compressing the walls of the swage against the suture, creating a strong attachment force that prevents the surgeon from detaching the suture from the needle without exerting considerable force on the swage. This suture attachment force is so great that separation of the needle from the suture is accomplished more easily by cutting the suture rather than by applying sufficient force to the suture to separate it from the swage. A special swage has been created by using lower compression forces around the circumference of the swage than conventionally used, allowing the surgeon to detach the suture from the needle using relatively low detachment forces, which obviates cutting of the suture. The swage requiring lower uniform forces to detach its suture is called by a variety of names (e.g., *pop-off control release*). It was originally developed for abdominal wound closure, bolus dressings for skin grafts, and hysterectomies, in which large numbers of interrupted sutures are used.

A.2 Body

The body of the needle is that portion grasped by the needle holder. The security with which needle-holder jaws grasp the needle is influenced by the presence of teeth in the needle-holder jaws, the ratchet setting of the needle-holder handle, and the shape of the cross-sectional area of the needle body. Although the shape of the cross-sectional area of the body has a significant effect on needle-holding security, the presence of teeth in the needle-holder jaws and the ratchet setting of the needle-holder handle are much greater determinants of needle-holding security than is needle body shape.[16]

The shape of the cross-sectional area and the geometric configuration of the length of the needle can categorize the geometry of the needle body. The shape of its cross-sectional area will influence the security with which the needle holder jaws grasp the needle, as well as its resistance to bending.

The cross-sectional areas of the bodies of different needles can be circular, triangular, rectangular, or trapezoidal. Needles with rectangular cross-sectional areas are created by flattening either the sides of or the top and bottom of the circular wire. When the top and bottom portions of the needle body are flattened, the long axis of its rectangular cross-sectional area will gain intimate contact with the faces of the needle-holder jaw. This position of the needle body between the needle-holder jaws is similar to that of the needle body with a trapezoidal shape. In both cases, the needle-holding security against twisting and rotation is greater than with side-flattening rectangular, triangular, and circular needle bodies. The benefit of enhanced needle-holding security must be weighed against an associated reduced resistance to bending compared to that of the other needle bodies. Because we can increase the needle-holding security of all needles by advancing the ratchet setting of the needle holder, we prefer side-flattened needle bodies because they exhibit greater resistance to bending than any other needle body.

Longitudinal ribbing or grooves on the inside and outside curvature of curved needles do not enhance needle-holding security. However, the geometry of the length of the needle will have considerable influence on the surgeon's use of a surgical needle. The curvature of the needle is described in degrees of the subtended arc. The radius of the needle is the distance from the center of the needle to the body of the needle if the curvature of the needle was continued to make a full circle. The curvature of the needle with one radius of curvature may vary from 90° (¼), 135° (⅜), 180° (½), to 225° (⅝). A compound curved needle has two distinct radii of curvature. The curvature of its tip extends 35° before it assumes a regular, uniform curvature in the remaining portion of the needle body (100°).

The surgeon uses needles with a curvature of 135° to approximate divided edges of thin planar structures that are readily accessible (e.g., skin), requiring a limited arc of wrist rotation to pass the needle through the tissue. It is difficult to use the 135° needle in deep body cavities because the limited arc of wrist rotation in passing this needle is usually not sufficient to expose the needle point, so that it will remain buried in the tissue and pose a challenge for the surgeon to retrieve. The 180° needle is ideally suited for use in deep body cavities because a limited arc of wrist rotation will successfully pass the entire needle through the tissue, allowing adequate exposure of the needle point for easy retrieval. The surgeon uses needles with a 90° angle of curvature in microsurgery.

The compound curved needle has been primarily used to alter the geometry of 135° needles.[17] The tight needle curvature at the point permits rapid, accurate needle passage at a selected depth and controlled exiting. Its design also offers a mechanical advantage over the

standard needle with a single radius of curvature. Although originally designed for anterior segment ophthalmic surgery, the compound curved needle now has broader clinical applications, including vascular and microvascular surgery and dermal and skin closure.

In addition to its curvature and radius, a surgical needle can be characterized by three other measurements: *chord length, needle diameter,* and *needle length.* Chord length is the linear distance measured from the central point of the needle swage to the point of the needle. Needle diameter is the width of the original circular wire used in the manufacturing process for the production of the needle. Needle length is the arc length of the needle measured at the center of the wire's cross-section.

A.3. Point

The point of the needle extends from its tip to the maximum cross-section of its body. Each type of needle point is designed to penetrate specific types of tissue. In general, there are needles with cutting edges, taper points, or a combination of both. *Cutting edge* needles have at least two opposing edges designed to penetrate tough tissue. When cutting edge needles have three cutting edges, the position of the third cutting edge categorizes the needle as either a *conventional* or a *reverse* cutting edge needle. Use of the conventional cutting edge needle leaves a hole that is susceptible to tissue cut-through. Because its third cutting edge is on the inside, concave curvature of the needle, the inside cutting edge causes a linear cut that is perpendicular and close to the incision, against which the suture will exert a wound closure force that may ultimately cut through the tissue. In contrast, the third cutting edge of the reverse cutting edge needle is located on the outer, convex curvature of the needle. When the reverse cutting edge needle cuts through skin, it leaves a wide wall of tissue, rather than an incision, against which the suture exerts its wound closure force. This wall of tissue resists suture cut-through.

Specifically designed cutting edge needles have been developed for anterior segment surgery in ophthalmology. These needles received a modification that converted the triangular geometry to a trapezoidal or spatulated configuration by flattening the outer convex surface. The flattening process also produces a lateral widening (*cobra head*) of the needle body. In addition to ophthalmic surgery, these spatulated needles have been used successfully to repair lacerations of the nail matrix. Referred to as *spatula needles,* they are flat on their concave and convex surfaces, with long side-cutting edges. The needle's side cutting edges separate or split through the thin lamellar plane of corneal and scleral tissue with minimal damage.

The sharpness of cutting edge needles can be increased by electrohoning, narrowing the needle point configuration, narrowing the cutting edge angles, and providing a silicone coating. When the needle is electrohoned, its surface is polished and its edges sharpened.

Narrowing the point configuration of the cutting edge needle to a taper point spreads the tissue without cutting it. The point geometry of this needle can be measured by its taper ratio, which is the length of the tapered portion of the needle divided by its diameter. The taper ratio of these needles varies from 12:1 to 8:1. They are used in soft tissues that do not resist needle penetration, such as vessels, abdominal viscera, and fascia. They are preferred when the surgeon wants to make the smallest hole possible in tissue without cutting.

Tapercut needles combine the unique features of taper point and cutting edge needles. The cutting edges of the tapercut needle extend only a short distance from the needle tip and blend into a round, taper body. In vascular surgery, tapercut needles are used frequently

for the anastomosis of calcified and fibrotic blood vessels to prosthetic grafts. Its cutting tip penetrates the calcified portion of the artery without the cutting edges of the needle body tearing the friable vessel, thereby minimizing the risk of leakage around the needle puncture. Tapercut needles have also been advocated for closure of wounds in oral mucosa. Their short cutting edges produce a tiny hole in oral mucosa that is considerably smaller than that encountered with cutting edge needles.

The biomechanical performance of surgical needles and needle holders is determined by the following parameters: (1) needle sharpness, (2) needle resistance to bending, (3) needle ductility, and (4) needle-holder clamping moment.[18] A sharpness tester measures the force needed to pass a needle through a membrane that simulates the density of human tissue. Manufacturers measure needle resistance to bending in the laboratory by recording the force required to bend the needle 60° or 90°, to determine the needle's ultimate bending moment. The more critical measurement to the surgeon is the needle's yield moment, the force required to irreversibly deform the needle. Ductility is a measurement of the needle's resistance to breakage. The needle-holder clamping moment is a measure of the force exerted by the needle-holder jaws on a curved surgical needle.

V. PACKAGING SYSTEM FOR SURGICAL NEEDLES AND SUTURES

Packages for surgical needles swaged to sutures have been designed and constructed to achieve several specific objectives.[19] First, the package and its contents must be susceptible to sterilization. Second, the package must afford convenient and sterile transfer of the surgical needles swaged to sutures to the sterile field. Third, the needle must be protected to prevent dulling of its cutting edges and point. Finally, the suture must be kept as straight as possible until knot construction.

In the USS/D&G products investigated in this study, the sutures swaged to their needles are contained within at least two layers of packaging. These layers allow sterile transfer to the sterile field. The "breather" or outer pouch is made of a laminate of Tyvek™ on one side and heat sealed to plastic film on the other. The exterior surfaces of this overwrap are not considered sterile. The inside surfaces of the overwrap and primary packet within it are sterile as long as the overwrap remains intact and undamaged. The Tyvek backing is permeable to ethylene oxide, which permits reliable gas sterilization of the inside of the overwrap as well as the inner packet containing the suture swaged to the needle. The outer wrap has two flaps that are peeled apart to allow transfer of the inner packet to the sterile field. The outer wraps for the packages containing absorbable or nonabsorbable sutures swaged to needles have identical dimensions and construction.

The braided sutures are packaged in a retainer of rigid film having a spiral labyrinth specially designed for delivering a kink-free suture. The suture exits from this labyrinth in a manner that maintains the suture's straight, uniform configuration. The braided absorbable suture is packaged in a sterile inner packet of hermetically sealed aluminum foil.

Because the physical and chemical properties of the monofilament sutures are different from those of the braided sutures, an inner packet has been designed for these sutures. The plastic memory of these monofilament sutures is so great that the shape of the suture conforms to the shape of the packet. The monofilament suture is wrapped around four fixation pins in figure-8-shaped loops. These multiple loops are secured in medical-grade paper

TABLE 1. Hospital Suture and Needle Evaluation*

Shareholder hospital	Patients	Suture/needle products clinically acceptable	Suture/needle products clinically not acceptable	Total	% Clinically acceptable
Shareholder A					
Hospital 1	611	1,742	6	1,748	99.7
Shareholder B					
Hospital 1	12	12	0	12	100
Hospital 2	66	182	0	82	100
Hospital 3	161	437	8	445	98.2
Hospital 4	192	453	10	463	97.8
Hospital 5	286	588	19	607	96.9
Shareholder C					
Hospital 1	59	140	0	140	100
Shareholder D					
Hospital 1	26	50	0	50	100
Hospital 2	363	1,384	38	1,422	97.3
Hospital 3	98	202	10	212	95.3
Shareholder E					
Hospital 1	167	354	0	354	100
Shareholder F					
Hospital 1	202	471	8	479	98.3
Shareholder G					
Hospital 1	356	686	17	703	97.6
Hospital 2	213	563	3	566	99.5
Shareholder H					
Hospital 1	132	446	7	453	98.5
Hospital 2	78	269	2	271	99.3
Shareholder I					
Hospital 1	57	208	0	208	100
Hospital 2	270	729	45	774	94.2
Hospital 3	58	176	1	177	99.4
TOTALS	3,407	9,092	174	9,266	98.1

* 699 surgeons and partnerships participated in the evaluation.

boards. All braided and monofilament sutures are swaged to needles, which are cradled in foam to protect their delicate cutting edges and points.

VI. RESULTS

Nine shareholder partners, represented by their 19 hospitals, participated in the Phase I suture and needle evaluation (Table 1, see previous page). This 30-day study involved surgery performed on 3407 patients, in which 9266 suture and needle products were evaluated. The surgeons determined that the suture and needle products were clinically acceptable in 98.1% of the evaluations. This high level of clinical acceptability of the surgical needle and suture products was encountered in all hospitals participating in the evaluation; the lowest rate of clinical product acceptability reported was 94.2%.

A wide range of surgical specialists participated in the study (Table 2); 13 surgical specialties, involving 699 surgeons, were included. General surgeons performed more product evaluations (2857) than any other specialty, followed by cardiothoracic surgeons (2070), then orthopedic surgeons (1914). Together, these three specialties performed 73.8% of the product evaluations. The general, cardiothoracic, and orthopedic surgeons reported a uniformly high rate of suture and needle product acceptability, which was, respectively, 97.6%, 99.6%, and 98.2%. Of all the surgical specialists, only plastic surgeons gave the suture and needle products a lower acceptability rating of 77.7%, involving 121 product evaluations, 1.3% of the sample size.

TABLE 2. Surgical Specialist Evaluation of Suture and Needle Performance

Surgical specialty	Clinically acceptable	Clinically not acceptable	Total	% Acceptable
Cardiothoracic	2,062	8	2,070	99.6%
General	2,789	68	2,857	97.6%
Neurosurgery	308	9	317	97.2%
Obstetrics & Gynecology	943	7	950	99.3%
Ophthalmology	51	3	54	99.4%
Orthopedics	1,879	35	1,914	98.2%
Otolaryngology/Head & Neck	122	1	123	99.2%
Pediatric	15	0	15	100%
Plastic	94	27	121	77.7%
Podiatric	79	0	79	100%
Transplant	44	0	44	100%
Urologic	201	5	206	97.6%
Vascular	505	11	516	97.9%
TOTALS	9,092	174	9,266	98.1%

TABLE 3. Clinically Not Acceptable Ratings by Surgical Specialist

Surgical specialty	Clinically not acceptable	Needle	Suture	Not specified	Both
Cardiothoracic	8	2	6	0	0
General	68	18	28	14	8
Neurosurgery	9	3	6	0	0
Obstetrics & Gynecology	7	2	5	0	0
Ophthalmology	3	1	2	0	0
Orthopedics	35	9	18	7	1
Otolaryngology/Head & Neck	1	0	1	0	0
Pediatric	0	0	0	0	0
Plastic	27	5	10	9	3
Podiatric	0	0	0	0	0
Transplant	0	0	0	0	0
Urologic	5	1	4	0	0
Vascular	11	6	0	5	0
TOTALS	174	47	79	35	12
Percent not acceptable		(27%)	(5.4%)	(0.1%)	(7%)

The suture and needle products received a nonacceptable rating in 174 evaluations (Table 3). The frequency of this rating was greatest in general surgery (68 evaluations), orthopedics (35 evaluations), and plastic surgery (27 evaluations). The nonacceptable ratings for sutures (79 evaluations) was almost 2-fold greater than the nonacceptable needle ratings (47 evaluations).

The performance of the surgical sutures was determined to be clinically acceptable in 9092 evaluations, or 98.1% (Table 4). More than half (50.1%) the evaluations of surgical sutures involved the POLYSORB* braided synthetic absorbable suture, which received a clinically acceptable rating in 98.4% of the evaluations. The second most frequently evaluated suture was SOFSILK*, which was determined to be clinically acceptable in 98.7% of the evaluations. The new monofilament polypropylene suture SURGIPRO* II, followed by the monofilament nylon sutures MONOSOF* and DERMALON*, were the next most frequently used sutures. SURGIPRO* II was found to be clinically acceptable in 99.2% of the evaluations, whereas MONOSOF* and DERMALON* were clinically acceptable in 96.3% of the evaluations. Even the less frequently used sutures had a very high clinically acceptable rating. Although the monofilament polybutester (NOVAFIL*) suture had the lowest clinical acceptable rating, its performance was determined to be clinically acceptable in 93.3% of the evaluations.

The surgical needles evaluated also had a high rating of clinical acceptability (97.9%) in the 8211 evaluations (Table 5). The most frequently used needle in this study was the taper-point needle, which accounted for 5281 evaluations, or 64.3% of the total needle

TABLE 4. Evaluation of Performance of Surgical Sutures

Suture trademark	Clinically acceptable	Not acceptable	Total uses	% Acceptable
POLYSORB*	4,569	76	4,645	98.4
SOFSILK*	996	13	1,009	98.7
SURGIPRO*II	627	5	632	99.2
MONOSOF*	618	24	642	96.3
SURGIDAC*	567	13	580	97.8
SURGIPRO*	423	8	431	98.1
MILD CHROMIC GUT* and chromic gut	385	10	395	97.5
BIOSYN*	351	9	360	97.5
MAXON*	197	8	205	96.1
SURGISTEEL*	129	1	130	99.2
SURGILON*	136	3	139	97.8
Plain gut	50	3	53	94.3
NOVAFIL*	14	1	15	93.3
VASCUFIL*	12	0	12	100
FLEXON*	10	0	10	100
DERMALON*	4	0	4	100
DEXON* II	4	0	4	100
TOTALS	9,092	174	9,266	98.1

evaluations. This needle received a clinically acceptable rating in 98.3% of the evaluations. The next most frequently used needle was the premium reverse cutting needle, which was rated in 1738 evaluations, or 21.1% of the total needle evaluations, and received a clinically acceptable rating in 97.3% of the evaluations.

VII. DISCUSSION

In two previous studies performed in the biomechanical research laboratory at the University of Virginia, the biomechanical performance of polypropylene sutures and braided synthetic absorbable sutures made by Ethicon, Inc. (Somerville, New Jersey) and USS/D&G were compared.[10,20] However, the biomechanical performance tests were not complemented by a subjective clinical evaluation by surgeons. Consequently, these biomechanical performance studies were expanded to include a subjective clinical evaluation of suture materials by skilled surgeons.[21] In the biomechanical performance tests of monofilament polypropylene sutures, there was no significant difference in their biomechanical performance as measured by knot security, knot rundown, and tissue drag. In the case of synthetic absorbable sutures, there

TABLE 5. Evaluation of Performance of Surgical Needles*

Needles	Clinically acceptable	Clinically not acceptable	Uses	Total % acceptable
Blunt Point	7	0	7	100
Conventional Cutting (SCC, SCC1, GCC90 Series)	128	1	129	99.2
Premium Conventional Cutting	191	6	197	97.0
Premium Reverse Cutting (HE Series)	10	1	11	91.0
Premium Reverse Cutting P Series)	1,691	47	1,738	97.3
Premium Spatula (SE Series)	19	3	22	86.4
Reverse Cutting (C, GS, HOS Series)	574	9	583	98.5
Spatula (SS Series)	4	0	4	100
Straight Cutting	23	0	23	100
Taper Point (CV, V, MV Series)	5,192	89	5,281	98.3
Penetrating Point (DT Series)	1	0	1	100
Taper Cutting (MVK Series)	17	0	17	100
Taper Cutting (KV Series)	188	10	198	95.0
TOTALS	8,045	166	8,211	97.9

* 110 reel were also included in the evaluation in which surgical needles were not evaluated; 109 of the reel were determined to be clinically acceptable. 945 tie were included in the evaluation in which needles were not evaluated; 938 of the tie were determined to be clinically acceptable.

were notable differences in their biomechanical performance. First, the POLYSORB* sutures displayed a greater knot-breaking force than the VICRYL* sutures. Second, the POLYSORB* sutures exhibited a greater knot rundown force than VICRYL* sutures. In addition, the VICRYL* sutures experienced higher tissue drag forces than POLYSORB* sutures.

Our clinical subjective evaluation of the monofilament polypropylene sutures used in the experimental research laboratory correlated with the results of the biomechanical performance studies. In the comprehensive clinical subjective evaluation as well as the biomechanical performance studies of the polypropylene sutures, there were no significant differences in the handling properties of the two sutures. In contrast, the biomechanical evaluation of the two synthetic absorbable sutures demonstrated the superiority of the POLYSORB* suture. However, these distinct differences in biomechanical performance of the absorbable sutures did not alter their performance in the subjective clinical evaluation. Because clinical evaluation still remains the gold standard for evaluating the performance of surgical sutures, it was

concluded that the two polypropylene sutures and two synthetic absorbable sutures were equally acceptable for clinical use in surgery. A shortcoming in this clinical study was that the investigation was performed by clinical surgeons using experimental animals in a laboratory setting, rather than being conducted on patients in a hospital operating room.

Consorta and USS/D&G designed and developed an intricate product evaluation plan that involves hospital administrators, surgeons, and suppliers. This investigation attempted to improve the efficacy of product selection by establishing a protocol for determining the clinical acceptability of a product in a hospital environment by using surgeons' evaluations of products in the operating room. The evaluation of sutures and needles described in this article rated 9266 evaluations of suture and needle products used by 699 surgeons from 13 specialties on 3407 patients. The products studied had an extremely high acceptability rating (98.1%). We believe the study provides important guidelines for judging the clinical acceptability of suture and needle products in a hospital setting, and this rigorous performance evaluation should provide the framework for evaluating the acceptability of a wide range of other biomaterials used in hospitals.

VIII. CONCLUSION

The purpose of this report is to describe an innovative suture and needle evaluation program devised by Consorta and USS/D&G. Consorta, a healthcare resource and management group purchasing organization, coordinated this evaluation in its shareholder hospitals, reporting the results of their comprehensive performance evaluations of the suture and needle products made by USS/D&G. A manual was prepared outlining the process by which the surgeons determined the performance of needles and sutures. The evaluation involves hospital executive administrators, materials managers, operating room directors, nurse managers, and surgeons from 13 specialties.

This present evaluation involved 19 hospitals in which the supplier's suture and needle products were used in 3407 patients by 699 surgeons. During this 30-day trial, there were 9266 evaluations of the supplier's sutures and needles. The surgeons determined the performance of the needles and sutures to be acceptable in 98.1% of the evaluations. The surgeons, in their assessment of the individual suture and needle products, expressed a similar, extremely high level of satisfaction. The surgeons found that the needles were clinically acceptable in 97.9% of the evaluations, and the sutures were determined to be clinically acceptable in 98.1% of the evaluations. On the basis of its successful evaluations of suture and needle products, Consorta will be expanding its evaluation programs to assess the clinical performance of other biomaterials commonly used in hospital settings.

REFERENCES

(1) Haxton H. The influence of suture materials and methods on the healing of abdominal wounds. Br J Surg 1965; 372–375.
(2) Thacker JG, Rodeheaver G, Kurtz L, Edgerton MT, Edlich RF. Mechanical performance of sutures in surgery. Am J Surg 1977; 133:713–715.

(3) Trimbos JB. Security of various knots commonly used in surgical practice. Obstet Gynecol 1984; 64:274–280.
(4) Lin KY, Frost-Arner L, Rodeheaver GT, Williams FM, Edlich RF. Scientific Basis for the Selection of Surgical Needles and Sutures. San Antonio, TX: Dannemiller Memorial Educational Foundation, 1999.
(5) Postlethwait RW. Long-term comparative study of non-absorbable sutures. Ann Surg 1970; 171:892–898.
(6) Rodeheaver GT, Nesbit WS, Edlich RF. NOVAFIL*, a dynamic suture for wound closure. Ann Surg 1986; 204:193–199.
(7) Rodeheaver GT, Shimer AL, Boyd LM, Drake DB, Edlich RF. An innovative absorbable coating for the polybutester suture. J Long-Term Eff Med Implants 2001; 11(1&2):41–54.
(8) Salthouse TN, Williams JA, Willigan DA. Relationship of cellular enzyme activity to catgut and collagen suture absorption. Surg Gynecol Obstet 1981; 129:691–696.
(9) Rodeheaver GT, Thacker JG, Edlich RF. Mechanical performance of polyglycolic acid and polyglactin 910 synthetic absorbable sutures. Surg Gynecol Obstet 1981; 153:835–841.
(10) Faulkner BC, Gear AG, Hellewell TB, Mazzarese PM, Watkins FH, Edlich RF. Biomechanical performance of a braided absorbable suture. Surg Gynecol Obstet 1981; 153:497–507.
(11) Katz AR, Mukherjee DP, Kaganov AL, Gordon S. A new synthetic monofilament absorbable suture made from polytrimethylene carbonate. Surg Gynecol Obstet 1985; 161:213–222.
(12) Rodeheaver GT, Beltran KA, Green CW, Faulkner BC, Stiles BM, Stanimir GW, Traeland H, Fried GM, Brown HC, Edlich RF. Biomechanical and clinical performance of a new synthetic monofilament suture. J Long-Term Eff Med Implants 1996; 6:181–196.
(13) Edlich RF, Thacker JG, McGregor W, Rodeheaver GT. Past, present and future for surgical needles and needle holders. Ann J Surg 1993; 166:522–532.
(14) Watkins FH, London SD, Neal JG, Thacker JG, Edlich RF. Biomechanical performance of cutting edge surgical needles. J Emerg Med 1997; 15:679–685.
(15) Ahn LC, Towler MA, McGregor W, Thacker JG, Morgan RF, Edlich RF. Biomechanical performance of laser-drilled and channel taper point needles. J Emerg Med 1992; 10:601–606.
(16) Thacker JG, Borzelleca DC, Hunter JC, McGregor W, Rodeheaver GT, Edlich RF. Biomechanical analysis of needle holding security. J Biomed Mat Res 1986; 20:903–917.
(17) Abidin MR, Becker DG, Paley RD, Doctor A, Westwater JJ, McGregor W, Edlich RF. A new compound curved needle for intradermal suture closure. J Emerg Med 1989; 7:441–444.
(18) Bond RF, McGregor W, Cutler PV, Becker DG, Thacker JG, Edlich RF. Influence of needle holder jaw configuration on the biomechanics of curved surgical needle bending. J Appl Biomat Res 1990; 1:39–47.
(19) Noriega LK, Rodeheaver GT, Thacker JG, Edlich RF. Modern concepts of packaging surgical needles and suture. Med Prog Tech 1994; 271–279.
(20) Faulkner BC, Tribble CG, Thacker JG, Rodeheaver GT, Edlich RF. Knot performance of polypropylene suture. J Biomed Mater Res 1996; 33:187–192.
(21) Lin KY, Farinholt H-MA, Reddy BR, Edlich RF, Rodeheaver GT. The scientific basis for selecting surgical sutures. J Long-Term Eff Med Implants 2001; 11(1&2):29–40.