Journal of Surgical Research **141,** 220–233 (2007)
doi:10.1016/j.jss.2006.11.023

Surgeon Evaluation of Suture and Endo-Mechanical Products

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Submitted for publication June 28, 2006

Background. **Surgeons select medical instruments without comparative performance data. This analysis seeks to determine if suture and endo-mechanical products made by different vendors have equivalent performance profiles or are clearly distinguished by physicians on different dimensions.**

Materials and methods. **A sample of 45 surgeons evaluated eight vendors of five categories of suture and endo-mechanical products: clip appliers, staplers, trocars, needles and sutures, and endoscopic specimen retrieval devices. Surgeons rated each vendor's products in each category on multiple performance dimensions at six animal laboratories at academic medical centers around the U.S. between April and September 2005. Performance dimensions included the product's clinical acceptability, ergonomics, functionality, overall performance, and relative rank-order preference.**

Results. **Physician evaluations of vendor performance vary widely. Vendors rated as clinically equivalent on a given product received different performance ratings by physicians. Ethicon's products (Somerville, NJ) were rated consistently high by physicians across product categories. This suggests the presence of some superior brand performance. Nevertheless, within some categories, there were alternative vendors (U.S. Surgical [Mansfield, MA], Applied Medical [Rancho Margarita, CA]) whose products are rated similar to the brand leader. This suggests there are often multiple vendors from which to choose. There was also evidence of idiosyncratic physician preference, especially due to the physician's gender, height, and glove size.**

Conclusions. **Suture and endo-mechanical products made by different vendors do not have equivalent performance profiles. Specific brand seems to be the most important determinant of physician evaluations of the different vendors' products. These results suggest the value and importance of conducting head-to-head comparisons of multiple vendors of the same product.**

Key Words: **endo-mechanical; suture; product performance; surgeon evaluation.**

INTRODUCTION

Evaluations of suture and endo-mechanical products have typically been conducted by group purchasing organizations (GPOs) and vendors. GPOs commission market research to survey surgeons, materials managers, and operating room (OR) supervisors at member hospitals regarding their vendor preferences and their rating of products' clinical acceptability. One recent GPO-sponsored evaluation of suture and endo-mechanical products made by U.S. Surgical (USS) reported high rates of clinical acceptability (97% or more) across surgical specialties and products. The study could not differentiate between USS's various products and did not compare USS to any other vendor [1–3]. Vendors likewise commission market studies to compare how their products fare against their competitors, or conduct evaluations of their products in individual hospitals that trial their products.

A recent review by ECRI, a technology assessment firm, uncovered few peer-reviewed studies and no head-to-head comparisons of products and vendors across eight product categories [4]. ECRI researchers concluded there was insufficient evidence to conclude whether competing vendors' products are interchangeable (substitutable) or differentiated in most product categories. The ECRI review found that extant studies

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0022-4804/07 $32.00

were more likely to compare different products (e.g., absorbable *versus* nonabsorbable sutures) than to compare the same product from different vendors. As a result, ECRI recommended that hospitals conduct their own product evaluations and consult physicians regarding their product and vendor preferences.

A small number of surgeons at specific hospitals with minimally invasive surgery training centers have conducted their own evaluations of endo-mechanical products. One unpublished study conducted at Legacy Health System in Portland (OR) by Hong *et al.* compared five different types of trocars. The findings suggest there was greater variation in performance between different types of trocars (e.g., cutting *versus* non-cutting) than among similar types of trocars made by different vendors. Another unpublished study conducted at Montefiore Hospital by Antonacci compared the two dominant stapler vendors. In both studies, the number of clinicians involved, the number of product categories, and the number of vendors compared were small.

Overall, there is not much evidence regarding the relative performance of vendors and their products as evaluated by surgeons. Extant studies are typically not published in peer-reviewed journals, include only one or a small number of vendors, encompass few product categories, and do not control for potential statistical confounds in their analyses. Such factors as the surgeon's current preferred vendor, the number of years the surgeon has had a relationship with a specific vendor, the presence of financial retainer relationships, anatomical differences among surgeons that might influence how the product "feels", and differences in clinician skill level, which may be associated with use of and proficiency with endo-mechanical devices, might all be expected to influence the surgeon's preference among competing products [5].

This study seeks to avoid these shortcomings in posing its two research questions. First, do physicians rate all vendors of the same product as clinically acceptable? Clinical equivalence has been frequently analyzed as an outcome of such product evaluations. Evidence of perceptual and stated equivalence would suggest that products are commodities and, thus, may be interchangeable. What has not been addressed in prior research is whether perceived clinical equivalence (i.e., willingness to use any vendor's product) translates into vendor indifference (i.e., willingness to switch vendors, equal preference among vendors). This study thus measures vendor products on multiple performance dimensions (such as clinical acceptability, ergonomic performance, and rank-order of preference), and looks at the interrelationships among these different measures of performance. Second, if physicians do not rate all vendors of the same product as equivalent, which performance dimensions appear to distinguish vendors and which vendors offer the superior product?

MATERIALS AND METHODS

Vendor and Product Description

A large national GPO invited vendors of suture and endo-mechanical products to submit their products for comparative evaluation prior to the GPO's awarding of national contracts for its member hospitals. Nine different vendors participated: Applied Medical (Rancho Santa Margarita, CA), Conmed (Utica, NY), Ethicon (Johnson and Johnson, Somerville, NJ), Genicon (Winter Park, FL), Neosurg (Houston, TX), Taut (Geneva, IL), U.S. Surgical (Tyco, Mansfield, MA), Aesculap (Center Valley, PA), and Teleflex (Research Triangle Park, NC). Eight of the nine vendors (all but Neosurg) submitted products in overlapping categories that could be compared with one another. To ensure comparability of the products made by different vendors within a given category, the GPO requested products by matched, cross-referenced catalog numbers. Vendors shipped only those products and product numbers designated by the GPO for evaluation to six evaluation sites as sterile "patient ready" products.

The GPO then asked its member hospitals to nominate surgeons to evaluate the competing products in animal laboratories associated with six academic medical centers (AMCs) across the country: Columbia University, University of Cincinnati, University of Texas, San Antonio, University of Southern California, University of Washington, and Emory University. None of the AMCs or their animal laboratories had any affiliation with the GPO. Review Boards at each of the animal laboratories reviewed and authorized the study protocol. Medical Directors at the AMCs that housed the laboratories served as advisors to the GPO on the design and implementation of the study, and also validated the categories and types of products to be included in the analysis.

Surgeons attended the animal laboratories during April–September 2005 and evaluated five categories of products. These included: clip appliers, internal mechanical and endoscopic-mechanical staplers, trocars (10 mm, bladed and non-bladed), sutures and needles, and endoscopic specimen retrieval devices (4 in. × 6 in.). The products evaluated were selected by a surgeon advisory panel convened by the GPO in February 2005. For clip appliers, the panel selected one standard model across all vendors (10 mm diameter, rotating, multiclip instrument with medium/large clips). For staplers, the panel selected several commonly-used models in both open procedures (linear cutters–straight and articulating, circular

TABLE 1

Suture Products Evaluated – by Vendor

Suture type	Ethicon	US Surgical	Aesculap	Teleflex
Silk	Perma-Hand	Sofsilk	Silkam	Silk
Chromic	Surgical Gut Chromic	Surgigut Chromic	Softcat Chrom	
Absorbable poly	Coated Vicryl	Dexon	Safil	
Nylon	Ethilon	Monosof		
PDS II type	PDS II	Maxon	Monoplus	
Plain	Surgical Gut Plain	Surgigut Plain	Softcat Plain	
Monofilament	Monocryl	Caprosyn	Monosyn	

curved intraluminal staplers) and endoscopic procedures (articulating linear cutters). For sutures, the panel selected several varieties listed in Table 1.

Not all vendors offered a product in each of the five categories or contributed products in each category for evaluation. Some product categories (e.g., staplers, trocars, sutures) had more than one type of product. As a result, the study considered a total of 51 unique vendor products for evaluation (see Tables below).

Participating Surgeons

Forty-five surgeons (primarily general surgeons) attended the animal laboratories and completed the product evaluations. Using the AMA's Masterfile, we compared the general surgeons in our sample with the population of general surgeons. There were no statistically significant differences by age decile groups ($X^2 = 6.28$, 4 df, $P < 0.18$), gender ($X^2 = 1.85$, 1 df, $P < 0.17$), secondary specialty of urological surgery ($X^2 = 0.06$, 1 df, $P < 0.81$), U.S.-trained *versus* IMG ($X^2 = 0.92$, 1 df, $P < 0.34$), hours of hospital practice decile groups ($X^2 = 10.92$, 10 df, $P < 0.36$), or primary type of practice—resident, direct patient care, administration ($X^2 = 3.12$, 2 df, $P < 0.21$). There were two significant differences: our sample contained a greater proportion of surgeons in large metropolitan statistical areas or MSAs ($X^2 = 8.15$, 3 df, $P < 0.04$) and fewer surgeons in the New England, South Atlantic, and Mountain census divisions ($X^2 = 21.97$, 8 df, $P < 0.01$). To deal with the lack of geographic representativeness among our general surgeons, we computed the inverse mills ratio and included it as an additional covariate in supplemental models.

Wharton researchers collected background data from each physician prior to the evaluation, using a short questionnaire as well as the AMA's Masterfile. These data were used in the multivariate analyses to control for factors that might influence the surgeon's evaluation of specific products: surgeon age, gender, height, glove size, specialty, subspecialty, hand preference, trocar preference (bladed *versus* nonbladed), animal laboratory site, and proclivity for video games (surrogate for hand dexterity, laparoscopic skills, and suturing capability) [6]. Interitem correlations revealed the three variables of gender, height, and glove size were strongly related (average correlation = 0.55). We used principal components analysis to generate a factor-based score that summarized the three highly correlated variables. The factor had an eigenvalue of 2.09 and explained 70% of the variation. These data were also used to control for specific factors that might influence the surgeon's evaluation of specific *vendors*: retainer relationship with vendor (past or present), current preferred vendor for staplers, and the number of years the surgeon has used the preferred vendor. Univariate statistics on these measures are reported in Table 2.

The data reveal that 78% of the participating physicians expressed a prior preference for the market-leading vendor (Ethicon), while an additional 9% favored the other leading vendor (USS). The high Ethicon penetration in our sample exceeds the 53% to 72% national market share enjoyed by Ethicon for trocars, staplers, clip appliers, and disposable specimen retrieval devices, as reported by IMS Health. This higher share constitutes an important, potential source of bias in the study. We handle this bias in two ways. First, we initially analyze the relationship between preferred vendor and each of the performance dimensions. Second, we then employ multivariate models that control for any effects of retainer relationships, preferred vendor, and tenure with the current endo-mechanical vendor on the product performance evaluations. Our results suggest that the surgeon's preferred vendor does not bear any strong or consistent relationship with the evaluation of any vendor's products.

Data Collection

Surgeons rotated through four stations in the animal laboratory. Study physicians did not start out at the same station for two reasons. First, GPO staff wanted to minimize any possible influence of station and station sequence on the evaluations. Second, because more than one physician might be scheduled to be in the laboratory at the same time, GPO staff sought to physically separate them and isolate their product evaluations from one another. While surgeons were not randomly assigned to stations, laboratory staff recorded the particular station at which surgeons began; empirical analysis revealed no impact of station order on the subsequent evaluations and thus no learning effects.

Each station contained a different set of products to be tested using slightly different procedures. Due to surgeon time constraints, surgeons who rotated through all four stations evaluated roughly 40 of the 51 products. Surgeons did not choose which products they evaluated; products were assigned based on the study's experimental design. As a result, any missing data are both missing by being ignored and missing completely at random [7].

At each station, a qualified surgical scrub technician assisted the surgeon with the tasks that were to be completed. Because variation in surgical technique might influence the performance evaluations, GPO staff sought to standardize the task technique and sequence at each station visited by the physician. Prior to the laboratory evaluations, the advisory panel of consulting surgeons debated and ultimately defined the set of tasks that the surgeon should perform. The standardized protocol physicians were asked to follow is briefly summarized below (and wholly available from the lead author).

TABLE 2

Physician and Site Characteristics

Categorical measures	N	%
Animal lab location		
Site #1	18	40
Site #2	13	29
Site #3-6	14	31
Surgical specialty		
General surgeon	39	87
Other	6	13
Surgical subspecialty		
Urological surgery	35	78
Other	10	22
Hand preference		
Right	41	91
Left	4	9
Trocar preference		
Bladed	16	35
Non-bladed	29	65
Retainer relationship with vendor		
Yes	8	18
No	37	82
Prefer market leader (Ethicon, USS) for internal and endoscopic staplers		
Yes	39	87
No	6	13
Play video games		
Yes	20	44
No	25	56
Gender		
Male	40	89
Female	5	11
Continuous measures	**Mean**	**St. dev.**
Height (inches)	69.84	3.62
Glove size	7.32	0.59
Years with current preferred vendor	5.9	3.9
Age	45.04	9.76

Station 1

The surgeons performed a small bowel resection with side-to-end anastomosis on a euthanized pig. Surgeons evaluated the silk, chromic, absorbable polyester and nylon suture types, as well as internal mechanical stapler products (internal staplers, circular staplers, internal cutters) at this station.

Station 2

The surgeons performed another small bowel resection with side-to-end anastomosis on a euthanized pig. Here, surgeons evaluated the PDS II and plain suture types as well as the internal mechanical staplers examined in Station 1. However, the latter products came from different vendor(s) than those evaluated in Station 1.

Station 3

The surgeons performed a laparoscopic small bowel resection on a live pig. Surgeons evaluated the monofilament 4.0 type suture, internal endoscopic mechanical stapler products (endo-cutters), endoscopic clip appliers from one group of vendors, a specimen retrieval device from one vendor, and disposable bladed trocars while completing the tasks at this station.

Station 4

The surgeons performed another laparoscopic small bowel resection on a live pig. Here, surgeons evaluated a monofilament 5.0 suture, internal endoscopic mechanical stapler products, endoscopic clip appliers from another group of vendors, a specimen retrieval device from a different vendor, and disposable nonbladed trocars.

The technician sought to obscure the identity of the vendor of the product being evaluated at each station. No sales representatives or employees from any of the vendors were present at the laboratory evaluations, or played any role in the data collection and analysis. The technician also sought to mask any vendor identification on the products evaluated by physicians. There were limits to this, since the researchers did not want to introduce additional "drag" on the instruments that might influence ratings of ergonomics and functionality. To be sure, surgeons who have used a particular vendor's products for years might easily recognize the vendor of a given product. However, feedback from the laboratory technicians revealed that surgeons became quickly immersed in the laboratory evaluation process and the surgical task at hand, rather than to be focused on the vendor of the product(s) used at teach station. Moreover, in several instances, a surgeon expressed interest in knowing the vendor of a product just used without recognizing that he/she had used that vendor in the past. Finally, to counter the heavy preference toward one or both of the market leading vendors, the technician asked surgeons to evaluate alternative vendors of the same product in random order, rather than allow them to evaluate a given vendor's product first.

In the process of completing the tasks, the scrub technician also read aloud product evaluation questions and recorded the surgeon's responses immediately after a given product had been used by the surgeon. The clinical evaluation coordinator for the laboratory ensured that the surgeon evaluated the appropriate set of products at each station. At the end of the evaluation, the physician's responses were sealed inside an express mail packet and sent to the Wharton School for analysis.

The physician evaluations are thus based on direct product trial, not on previous recall of product usage and impression. The evaluation design also permits head-to-head comparisons of different vendors of the same product across five product categories. To ensure accuracy, the evaluations were also videotaped and sent to the Wharton researchers for review and confirmation of both the procedure and data.

Data Array, Predictors, and Outcome Measures

The database for the study has three components: (1) surgeon background and personal information, (2) product and vendor information, and (3) surgeon evaluations of each vendor's product performance on multiple dimensions (2–5 dimensions, depending on the product). Given that we study 45 physicians, each of whom evaluates roughly 40 different vendor products on 2–5 performance dimensions per product, the study design affords thousands of data observations.

While we control for physician characteristics, the main predictors of product performance in the model are the specific vendors of the evaluated products. We developed eight binary variables (1 = yes, 0 = no) denoting each vendor in the study. Because all analyses are conducted separately for each of the five product categories, there are no variables denoting product category. We also created binary variables for each of the laboratory stations (station 1–station 4) at which the surgeons evaluated the product; however, they were excluded from most of the analyses since most products were evaluated by physicians at the same station.

The third component of the database is each surgeon's evaluation of the 51 unique vendor products on multiple dimensions of performance. These evaluations serve as the dependent variables in the analyses below. Physicians were first asked to evaluate competing vendors' products in terms of their ergonomics, functionality, and overall performance. Multiple items were used to assess each of these performance dimensions to ensure consistency in the physician evaluations. The specific items used were developed by the surgeon advisory panel and several of the study authors.

Physicians answered the evaluation items in uniform fashion across the five product categories using Likert-type scales that rated products on a 1–7 scale: (7 = extremely satisfactory, 4 = neutral, 1 = extremely unsatisfactory). For all five categories, physicians also answered whether they felt the products were clinically acceptable ("Would you use this product routinely?") in a yes *versus* no fashion. Finally, for clip appliers, trocars, and sutures, surgeons rank-ordered the products tested in the same product category and at the same station against each other: 1 is ranked highest, 2 is ranked second highest, etc.

Table 3 lists the performance dimensions for each product category and the items that comprise each dimension that physicians evaluated. In the interest of parsimony, we developed summary scales of the items to capture the overall dimension. The table provides the Cronbach's alpha coefficient, (which measures the internal consistency and scalability of the items), as well as the scale's mean and standard deviation [8, 9]. In all cases, the high alpha coefficients suggest high interdependence among the items and little loss of information by combining the item measures into scales.

Analytic Approach and Multivariate Models

The evaluation of each vendor product is conducted at the physician level of analysis. We first present the correlations among the different performance dimensions. We next address the important issue of whether a surgeon's expressed prior preference for the market leaders' endo-mechanical products is related to the surgeon's subsequent evaluation of any vendor's product. To conduct this analysis, we present results from analysis of variance (ANOVA) models showing whether mean scores on the performance dimensions are significantly different based on the surgeon's expressed prior vendor preference. We next present the mean levels of each performance dimension by vendor and by product, adjusting for the physician background characteristics.

The specific analytic technique used here to derive the least-square means is a hierarchical random effects regression analysis. Random effects models are required because we make repeated observations over the same physician, which can lead to correlated error terms across ratings within a physician. Two sets of mixed linear models (incorporating both fixed and random effects) are used here: the first are estimated using Proc Mixed in SAS for continuous

TABLE 3

Performance Dimensions and Constituent Survey Items – by Product Category

Product category	Performance dimension	Items	Cronbach's alpha	Scale mean (1–7)	Standard deviation
Clip appliers	Ergonomics	Adequately fits in hand Ease of firing Ability to use only one hand when firing Ease of arming reloads (if applicable) Sturdiness of instrument	.97	5.76	1.18
	Functionality	Clip closure adequate Shape of clip effectiveness Hemostasis obtained (per observation)	.93	5.77	1.48
	Clinical acceptability	Would you use the clip applier routinely?	NA	0.68	0.47
Internal and endoscopic staplers	Ergonomics	Adequately fits in hand Ease of firing Ability to use only one hand when firing Sturdiness of instrument	.89	5.54	1.30
	Functionality	Staple line complete and intact Instrument produced desired result Safety locks and mechanism function Complete circular ring of tissue visible (circular stapler only)	.83	6.17	1.14
	Reload functionality	Ease of arming reloads Staple line complete and intact Consistency of reload firing Blade remained sharp (cutter stapler only)	.83	5.85	1.15
	Clinical acceptability	Would you use this stapler and reloads routinely?	NA	0.75	0.43
	Overall performance	Stapler overall performance	NA	5.45	1.54
Trocars	Trocar functionality	Feel of the trocar in hand before insertion (heavy, light, bulky, comfortable) Ease of instrument introduction through peritoneum Functional effectiveness of safety tip device (if applicable) Ease of instrument introduction through check valve and/or seal (instrument drag) Effectiveness of check valve and/or seal around instrument (air-leakage) Ease of instrument movement thru check valve and/or seal (instrument drag)	.88	5.20	1.17
	Trocar sleeve functionality	Effectiveness of sleeve in maintaining pneumoperitoneum throughout procedure Grip quality between sleeve and peritoneum Ease of removal from peritoneum Peritoneal closure after removal (typical, excessive)	.79	5.63	1.12
	Clinical acceptability	Would you use this trocar routinely?	NA	0.52	0.50
Suture and needle	Needle functionality	Ease of tissue penetration (sharpness) Needle stays attached to suture Ease of detachment (pop-offs only) Durability of needle (does needle seem to dull with usage?) Bends appropriately or inappropriately (surgeon to bend needle to measure)	.85	6.14	0.80
	Overall needle performance	Overall needle performance	NA	6.00	1.00
	Suture functionality	Ease of handling (memory release) Ease of tying Knot holds appropriately during tying Tensile strength during suturing and tying	.86	6.09	0.84
	Clinical acceptability	Would you use this suture routinely?	NA	0.85	0.36

TABLE 3—*Continued*

Product category	Performance dimension	Items	Cronbach's alpha	Scale mean (1–7)	Standard deviation
Disposable endoscopic specimen retrieval device	Device functionality	Handle size fits hand Ease of introduction through trocar valve and sleeve Ease of bag deployment Stays open during specimen introduction Stays closed during extraction Pulls through trocar or peritoneum without breaking	.90	6.04	0.89
	Clinical acceptability	Would you use this disposable specimen retrieval device routinely?	NA	.85	.36

dependent variables (ergonomics, functionality, overall performance, rank order); the second are estimated using Proc Glimmix in SAS for dichotomous dependent variables (e.g., clinical acceptability). We note that this is not a fully-crossed design, since each of the eight vendors does not offer a product in each of the five categories. We also investigated the impact of different covariance structures by using a fixed effects model. The model results were the same.

There is, of course, the concern that the three measures of prior vendor relationship (retainer, preferred vendor, and years with vendor) are endogenous. To deal with this issue, we sought to develop instrumental variables (IVs) for all three. We were successful in developing an IV for years with vendor using AMC affiliation, MSA size, and hours of hospital practice as the instruments which, along with our other equation right-hand side variables, served as significant predictors (F value = 16.09, $P < 0.001$). Subsequent analyses that used the Hausman test suggested limited evidence of endogeneity: the residuals from the IV model were significant predictors ($P < 0.05$) of the dependent measures in only 7 of 70 regression models [10, 11]. Nevertheless, we conducted some supplemental analyses that incorporated the IV for vendor tenure rather than the original variable. Its inclusion did not alter our findings.

There is also the concern that our analysis estimates a large number of models on multiple dependent variables that are interrelated. To address this concern, we estimated models using averages of the interrelated dependent variables as well as MANOVA models. Our results were the same regardless of the model specification.

RESULTS

Relationship Among the Performance Dimensions

Table 4 presents the correlations among the different performance dimensions, computed separately for each of the five product categories. The table reveals several interesting findings. First, the dimensions of ergonomics, functionality, overall performance, and clinical acceptability are all strongly correlated. Coefficients range from 0.36 to 0.91, with an average inter-item correlation of 0.62.

Second, clinical acceptability is more weakly correlated with these measures (average inter-item correlation = 0.50). This may reflect the fact that the definition of clinical acceptability used here taps the surgeon's expressed willingness to routinely use the product rather than the product's attributes.

Third, the rank-order of the vendor's product is more weakly correlated with all of these other performance dimensions. The coefficients here range from only 0.14 to 0.61, with an average inter-item correlation of only 0.34. Physicians' rank-ordering of products is only moderately associated with clinical acceptability (average correlation = 0.46).

Fourth, the pattern of inter-item correlations varies across product categories. For example, the relationship between clinical acceptability and vendor rank varies considerably from 0.35 among clip appliers to 0.61 among trocars.

Relationship of Prior Vendor Preference and Retainers with Vendor Evaluation

The first two columns of Table 5 present summary data on the relationship between the surgeon's expressed prior preference for one of the two market leading vendors (Ethicon) and his/her rating of the performance of each of the two top vendors' products (Ethicon, USS). Of particular interest here is whether those with an expressed prior preference for Ethicon evaluate Ethicon's products *more* favorably, and evaluate USS's products *less* favorably, than those without such a preference. The middle two columns in Table 5 present the same summary data for surgeons with an expressed preference for the other market leading vendor (USS). Thus, for any given performance dimension, there are four interesting contrasts to inspect. The results are broken out by each of the five product categories.

For clip appliers, there were four performance dimensions on which to evaluate Ethicon and USS, rendering a total of sixteen possible contrasts. In only one of those contrasts (functionality) do physicians with a prior USS preference evaluate Ethicon's product significantly lower. In another contrast, surgeons with a preference for Ethicon actually ranked USS's product higher than those without a preference for Ethicon.

For staplers, there were five performance dimensions on which to compare Ethicon and USS, rendering a total of twenty possible contrasts. In only two of those contrasts (reloads, clinical acceptability) did surgeons who prefer Ethicon rate its products significantly higher.

TABLE 4

Correlations Among Performance Dimensions – by Product

Product	Performance dimension										
	Ergonomics	Functionality	Clinical acceptability	Reloads	Trocar	Trocar sleeve	Clinical acceptability	Needle	Overall needle performance	Suture	Clinical acceptability
Clip appliers (N = 195)											
Ergonomics											
Functionality	.77										
Clinical acceptability	.56	.52									
Rank	.21	.14	.35								
Staplers (N = 352)											
Ergonomics											
Functionality	.66										
Clinical acceptability	.64	.42									
Reloads	.72	.79	.61								
Overall performance	.79	.67	.75	.76							
Trocars (N = 276)											
Trocar											
Trocar sleeve					.71						
Clinical acceptability					.44	.36					
Rank					.37	.28	.61				
Sutures and needles (N = 725)											
Needle											
Overall needle performance								.91			
Suture								.66	.54		
Clinical acceptability								.46	.49	.49	
Rank								.36	.39	.28	.42
Disposable endoscopic specimen retrieval devices (N = 75)											
Device											
Clinical acceptability											.53

Note. Rank is reverse-coded.

TABLE 5

Impact of Vendor Preference on Performance Ratings

Product category	Performance dimension	Prior preference for Ethicon		Prior preference for USS		Impact of retainer relationship	
		Rating of Ethicon	Rating of USS	Rating of Ethicon	Rating of USS	Rating of Ethicon	Rating of USS
Clip appliers	Ergonomics	NS	NS	NS	NS	NS	NS
	Functionality	NS	NS	Lower[a]	NS	NS	NS
	Clinical acceptability	NS	NS	NS	NS	NS	NS
	Rank	NS	Higher[a]	NS	NS	NS	NS
Staplers	Ergonomics	NS	NS	Lower[c]	NS	NS	NS
	Functionality	NS	NS	Lower[c]	NS	NS	Lower[a]
	Reloads	Higher[b]	NS	Lower[c]	NS	NS	NS
	Clinical acceptability	Higher[c]	NS	Lower[c]	NS	NS	NS
	Overall performance	NS	NS	NS	NS	Lower[a]	Lower[b]
Trocars	Trocar	NS	NS	NS	NS	NS	Lower[a]
	Trocar sleeve	NS	NS	NS	NS	Lower[a]	NS
	Clinical acceptability	NS	NS	NS	NS	NS	NS
	Rank	NS	Higher[a]	NS	NS	Higher[b]	NS
Suture and needle	Needle	Higher[c]	Higher[b]	Lower[c]	NS	NS	NS
	Overall needle performance	Higher[c]	Higher[b]	Lower[c]	NS	NS	NS
	Suture	Higher[c]	NS	Lower[c]	NS	NS	Lower[c]
	Clinical acceptability	NS	NS	NS	NS	Higher[b]	NS
	Rank	NS	Lower[b]	NS	Higher[b]	Higher[b]	Lower[c]
Disposable endoscopic specimen retrieval dev.	Device	NS	NS	NS	NS	NS	Lower[b]
	Clinical acceptability	—	NS	—	NS	—	NS

NS, not significant, $P > 0.10$.
[a] Significant, $P < 0.10$.
[b] Significant, $P < 0.05$.
[c] Significant, $P < 0.01$.

In four additional contrasts, surgeons who preferred USS rated Ethicon's products significantly lower.

For trocars, there were four performance dimensions on which to compare Ethicon and USS, rendering sixteen possible contrasts. Only one of them was statistically significant. Physicians who expressed a prior Ethicon preference ranked USS's trocars more highly than physicians who did not express an Ethicon preference.

For sutures and needles, there were five performance dimensions on which to compare Ethicon and USS, yielding twenty possible contrasts. In four contrasts (needle, overall needle performance), surgeons with a prior Ethicon preference rated both Ethicon's and USS's products higher than surgeons without a preference for Ethicon (three of ten and one of ten contrasts, respectively). Consistent with an expectation of bias, surgeons preferring Ethicon rated its suture higher and ranked USS lower, while surgeons preferring USS rated Ethicon lower on both needle and suture dimensions.

Finally, for endoscopic disposable specimen retrieval devices, there were two performance dimensions, yielding a total of eight possible contrasts. There were no significant differences in vendor evaluations between physicians who do *versus* physicians who do not express a preference for Ethicon or USS.

The last two columns of Table 5 repeat the analysis for physicians who have retainer relationships with a market leading vendor (primarily Ethicon). Once again, we find significant differences in only one-quarter of the possible contrasts, most of which (but not all) are consistent with bias.

Overall, there is limited evidence for prior vendor bias effects in the performance evaluation data. Across the five product categories, the majority of contrasts between physicians who do *versus* physicians who do not express a prior preference for Ethicon or USS, or do *versus* do not have retainer relationships, reveal insignificant relationships between prior vendor relationships and product evaluations. Moreover, the limited evidence for vendor bias in product evaluations is inconsistent. Nevertheless, prior preferences and retainer relationships are statistically controlled in the subsequent analyses.

Physician Rating of Vendors: Adjusted Means

Table 6 compares the surgeon rating of each vendor's product on each performance dimension, by product category, adjusted for all of the physician covariates.

TABLE 6

Adjusted Mean Rating of Vendors – by Product Category

Product category	Rating measure	Vendor: Applied Medical 1	ConMed 2	Ethicon 3	Genicon 4	Taut 5	US Surgical 6	Aesculap 7	Teleflex 8	Significant pairwise differences*	Model significance level**
I. Clip appliers											
	Ergonomics (1-7)	6.11	5.58	6.36			5.77		4.80	1 > 8; 3 > 2, 8; 6 > 8	.01
	Functionality (1-7)	6.13	5.84	6.32			6.09		4.19	1 > 8; 2 > 8; 3 > 8; 6 > 8	.01
	Clinical acceptability (%)	81.1	55.6	95.0			80.3		18.0	1 > 8; 3 > 2, 8; 6 > 8	.01
	Rank (1 = Highest)	1.73	2.79	1.47			1.04		1.95	1 < 2; 3 < 2; 6 < 2, 8	.01
II. Internal and endoscopic staplers											
A. EndoCutter											
	Ergonomics (1-7)		3.20	6.01			5.34			6 > 2; 3 > 2	.01
	Functionality (1-7)		4.62	6.48			6.07			3 > 2 6 > 2	.01
	Reloads (1-7)		4.58	6.29			5.73			3 > 2 6 > 2	.01
	Clinical acceptability (%)		7.68	88.3			80.4			3 > 2 6 > 2	.03
	Overall performance (1-7)		2.77	6.12			5.27			6 > 2 3 > 2	
B. Internal cutter											
	Ergonomics (1-7)			6.02			5.02			3 > 6	.01
	Functionality (1-7)			6.64			6.09			3 > 6	
	Reloads (1-7)			6.19			5.51			3 > 6	
	Clinical acceptability (%)			93.5			47.9			3 > 6	
	Overall performance (1-7)			6.08			4.72			3 > 6	
C. Internal stapler											
	Ergonomics (1-7)			6.19			5.64			3 > 6	.01
	Functionality (1-7)			6.38			5.98			3 > 6	.01
	Reloads (1-7)			NA			NA				
	Clinical acceptability (%)			92.2			72.0				
	Overall performance (1-7)			6.18			5.47			3 > 6	.01
D. Circular stapler											
	Ergonomics (1-7)			6.01			5.11			3 > 6	.01
	Functionality (1-7)			6.07			6.31				
	Reloads (1-7)			NA			NA				
	Clinical acceptability (%)			88.0			69.3				
	Overall performance (1-7)			5.61			5.68				.01
III. Trocars											
A. Disposable bladed											
	Trocar (1-7)	5.24	5.18	5.77	3.95		5.41			1 > 4; 2 > 4; 3 > 4; 6 > 4	.01
	Trocar sleeve (1-7)	5.64	5.34	6.10	5.15		5.78				.01
	Clinical acceptability (%)	62.1	30.6	83.6	18.4		75.5			1 > 4; 6 > 2, 4; 3 > 2, 4	
	Rank (1 = Highest)	2.32	3.15	1.48	2.90		2.14			3 < 2, 4	.01
B. Disposable nonbladed											
	Trocar (1-7)	5.28	4.66	6.34	4.57	5.26	5.31			1 > 2; 3 > 1, 2, 4, 5	.01
	Trocar sleeve (1-7)	5.73	5.42	6.27	5.12	5.53	5.51			3 > 1, 2, 4, 5	
	Clinical acceptability (%)	72.9	12.8	97.7	28.6	36.3	100.0			1 > 2; 6 > 2; 3 > 2, 4, 5	.02
	Rank (1 = Highest)	2.12	3.23	1.43	2.94	2.32	2.39			1 < 2; 3 < 2, 4	.01
IV. Suture and needle											
A. Silk											
	Needle (1-7)			6.33			6.09	5.61	5.86	3 > 7, 8; 6 > 7	.01

TABLE 6—*Continued*

Product category	Rating measure	Vendor: Applied Medical 1	ConMed 2	Ethicon 3	Genicon 4	Taut 5	US Surgical 6	Aesculap 7	Teleflex 8	Significant pairwise differences*	Model significance level**
	Overall needle performance (1-7)			6.30			6.01	5.25	5.58	3 > 7, 8; 6 > 7	.01
	Suture (1-7)			6.33			6.32	6.17	5.98	3 > 8; 6 > 8	.01
	Clinical acceptability (%)			97.6			90.5	64.3	67.7	3 > 7, 8; 6 > 7	
	Rank (1 = Highest)			1.72			2.04	3.10	3.11	3 < 7, 8; 6 < 7, 8	.01
B. Chromic											
	Needle (1-7)			6.38			6.23	5.85		3 > 7	.05
	Overall needle performance (1-7)			6.30			6.29	5.63		3 > 7; 6 > 7	.01
	Suture (1-7)			6.20			5.69	5.88		3 > 6	.05
	Clinical acceptability (%)			96.9			69.4	87.2		3 > 6	
	Rank (1 = Highest)			1.64			2.32	1.93			
C. Absorbable poly											
	Needle (1-7)			6.34				6.24			.01
	Overall needle performance (1-7)			6.22				6.12			.05
	Suture (1-7)			6.46				6.21			
	Clinical acceptability (%)			95.1				90.1			
	Rank (1 = Highest)			1.29				1.71			
D. Nylon											
	Needle (1-7)			6.22			6.27	6.00			.01
	Overall needle performance (1-7)			6.06			6.14	5.75			
	Suture (1-7)			6.24			6.07	5.91			.01
	Clinical acceptability (%)			97.3			87.2	75.0		3 > 7	
	Rank (1 = Highest)			1.75			2.00	2.18			
E. PDS II type											
	Needle (1-7)			6.38			6.18	6.16			.05
	Overall needle performance (1-7)			6.30			6.12	5.92			
	Suture (1-7)			6.23			5.85	5.84			.01
	Clinical acceptability (%)			94.9			81.0	87.5			
	Rank (1 = Highest)			1.67			2.03	1.93			
F. Plain											
	Needle (1-7)			6.06			6.17	5.45		3 > 7; 6 > 7	.01
	Overall needle performance (1-7)			5.90			6.05	5.11		3 > 7; 6 > 7	.01
	Suture (1-7)			5.95			5.65	5.75			.01
	Clinical acceptability (%)			77.2			75.9	66.4			
	Rank (1 = Highest)			1.46			2.03	2.43		3 < 6, 7	
G. Monofilament 4.0											
	Needle (1-7)			6.34			6.10	6.28			.01
	Overall needle performance (1-7)			6.21			5.89	6.18			.02
	Suture (1-7)			6.43			6.07	6.25			.01

TABLE 6—*Continued*

Product category	Rating measure	Vendor: Applied Medical 1	ConMed 2	Ethicon 3	Genicon 4	Taut 5	US Surgical 6	Aesculap 7	Teleflex 8	Significant pairwise differences*	Model significance level**
	Clinical acceptability (%)			89.1			89.5	89.5			
	Rank (1 = Highest)			1.75			2.21	2.04			
H. Monofilament 5.0											
	Needle (1-7)			6.28			6.13	6.17			.01
	Overall needle performance (1-7)			6.21			6.04	6.09			.01
	Suture (1-7)			6.08			5.96	6.15			.01
	Clinical acceptability (%)			91.1			82.3	85.0			
	Rank (1 = Highest)			1.63			2.29	2.04			
V. Disposable endoscopic specimen retrieval devices											
	Device (1-7)			6.25			5.78			3 > 6	
	Clinical acceptability (%)			100.0			68.6			3 > 6	

Note. Model covariates: Site #1, Site #2, lab station, general surgeon, urological subspecialty, right hand preference, retainer relationship, market leader preference, age, years with current vender, gender/height/glove size (principal component).

* $P < 0.01$.

** Improvement in -2 log likelihood over intercept-only model.

The last two columns indicate which pairs of vendors are rated significantly different ($P < 0.01$, with Bonferroni correction) and the level of significance of the regression model.

Two findings are immediately evident from Table 6. First, surgeons do evaluate vendors of the same product differently; second, they evaluate these vendors differently on most dimensions. The latter finding is not surprising, given the strong correlations among the performance dimensions. The former finding is significant, however, because it contradicts ECRI's supposition that vendors make substitutable products (supported here only for several types of sutures).

Another remarkable finding is the huge variation in clinical acceptability ratings across vendors. The percentage of physicians rating products as clinically acceptable ranges from a high in the 90s to a low in the single digits. This likely reflects the presence here of multiple vendors (as opposed to a single vendor in many studies) and the definition of clinical acceptability used here.

In addition, the data in Table 6 reveal that clinical equivalence between products does not necessarily mean equivalent performance on other dimensions. For example, when one compares the clip appliers of Applied Medical and USS, or the plain sutures of Ethicon and USS, nearly identical percentages of physicians rate these vendors' products as clinically equivalent. However, these same physicians express significantly higher ratings of USS for clip appliers, and Ethicon for plain sutures.

Table 6 also reveals that certain vendors are consistently rated lowest or highest across product categories. For example, on the negative side, ConMed and Teleflex are rated lowest for clip appliers, ConMed is rated lowest for staplers/endocutter and for trocars (along with Genicon), and Aesculap and Teleflex are rated lowest for several types of sutures. On the positive side, Ethicon, USS, and Applied Medical are rated highest for clip appliers and trocars, while Ethicon is rated more highly than USS for staplers and endoscopic specimen retrieval devices.

Supplemental Analyses

We re-estimated our models several different ways as sensitivity analyses. First, we included the inverse mills-ratio in the models to correct for any sampling bias. Second, we substituted the IV for the original measure of the surgeon's tenure with the preferred vendor to handle any possible endogeneity. Third, we used a fixed effects rather than a random effects model. The pattern and significance level of the results presented in Table 6 remained the same.

Effects of Physician Background and Site Characteristics

While not presented in Table 6, the regression models also revealed which of the surgeon background

characteristics—expressed prior preference for a particular vendor, length of tenure with this vendor, and the presence of retainer relationships—influence the product evaluations. Consistent with Table 5, there were few relationships. The surgeon's expressed prior preference for the market leading vendors exerted a significant impact ($P < 0.05$) on the evaluations in only seven of the 70 models. Similarly, the tenure of the surgeon with the preferred vendor exerted a significant impact in only one model, while retainer relationships exerted significant impacts in only three regression models.

The only other physician characteristics that exert consistent effects across a number of models are the factor-based score capturing the surgeon's gender, height, and glove size, and whether or not the physician is right-handed. In all models where these effects are significant, the effects are positive. That is, male surgeons who are tall and have large glove sizes express more favorable evaluations of the products, as do surgeons who are right-handed. Thus, physical and anatomical differences may play a major role in the physician's comfort with the product and ease of product use.

We also conducted supplemental analyses that partitioned the variation in the performance dimensions explained by the vendor dummy variables *versus* the set of surgeon background characteristics. Across the vast majority of our models, the vendor variables accounted for the largest share of the explained variation.

DISCUSSION

This study answers two research questions. First, surgeons do not rate all vendors of a given product as equivalent. There is widespread variation in evaluating products as clinically acceptable, defined here as willingness to routinely use a product (not necessarily prefer it). Most types of sutures and endo-mechanical products appear to be physician preference items rather than commodities that are interchangeable in the eyes of clinicians. Moreover, even when it exists, clinical equivalence does not translate into vendor indifference. Surgeons distinguish vendors of the same product on several dimensions of performance (ergonomics and functionality). While most of these performance dimensions are positively and strongly correlated (and thus tap an overarching measure of product performance), they are less strongly correlated with the rank-order a physician assigns to a given vendor's product. Product evaluations are thus not identical to product choice. The most consistent physician-level predictors of a product's evaluation are the anatomical differences among surgeons.

Second, the results also show that many of the products of one vendor (Ethicon) are evaluated more favorably than the others, and enjoy brand preference. Such high evaluations are mostly distinct from any prior relationship the physician has had with the vendor and any retainer relationships. The analyses also suggest that product brand is typically more powerful in explaining the variation in physician evaluations than are individual physician preferences (e.g., due to anatomical differences).

Limitations of Study

There are several limitations to our study. First, we have a small sample of physicians that was not randomly drawn from the larger population of general surgeons. However, χ^2 analyses reveal few systematic differences between our sample and the population, and sensitivity analyses reveal no differences in the results when including the inverse mills ratio in our models.

Second, we have not studied physician evaluations of products as they are actually used in patient settings. Our animal laboratory study is still an improvement over the majority of studies that are based on physician recall or perception. The study also benefits from surgeons' ability to use multiple vendors' products one after the other in a short time period and then compare and rank their performance, which is practically unfeasible in patient settings.

Third, our sample of vendors does not include every vendor in each of the five product categories. Nor is the sample of vendors studied here randomly drawn. With one exception, all of the vendors in this study volunteered to participate in the evaluation. We have not conducted any analysis of the representativeness of the vendors in each of the five product categories. The study does, however, include the two market leading vendors in these categories, as well as newer entrants with growing shares of the endo-mechanical market.

Fourth, the database on physician characteristics does not include other possible covariates of interest that might influence the evaluations (e.g., prior training and experience with each of the vendors, and preferred vendor for each product type). Similarly, there is no information on the physician's general skill level with laparoscopic procedures. Skill levels have been found to influence the use of endo-mechanical devices, as well as the efficiency and quality of surgery [12–15]. We did include one measure (video game experience) that is correlated with surgeon skill, and found no significant effects on the evaluations.

Fifth, we use subjective data on product performance (i.e., physician evaluations), rather than objective data on product performance. In our defense, we cite ECRI's conclusion that variations in patient anatomical differences and physician product use are more important than product defects and malfunctions. To ECRI's point, we would also add that variations in physician anatomical differences also seem to be important. Finally, our data collection instrument was not subjected to well-defined validation phases and tests.

CONCLUSIONS

This study makes several contributions to the limited literature on physician product evaluation. First, it conducts head-to-head comparisons of multiple vendors of a given product, replicates this across five categories of suture and endo-mechanical products that hospitals purchase, and utilizes multiple dimensions of product performance in actual trials. By contrast, prior studies have typically examined only one vendor's products or one category of products, and used physician recall and perception of product performance. In such an information vacuum, hospitals and their buying agents (GPOs) have historically been forced to rely on the vendors' own product information and physician requests in deciding which products to purchase.

Second, such head-to-head evaluation data may help hospitals to purchase surgical products in a more cost-effective fashion. A critical issue is whether the product under consideration is a commodity item or a "physician preference item" (PPI). For commodity items, clinicians perceive competing products as clinically equivalent, thereby allowing hospitals and GPOs to minimize vendor claims of product differentiation and to pit one vendor against another on the basis of price. Conversely, for PPIs, clinicians view competing products as different or differentially suited to their needs/tastes. In such instances, hospitals and GPOs deal either with one preferred vendor (brand leader), a small number of preferred vendors, or a range of vendors that match differing physician tastes. In the case of one market leading vendor, historical experience suggests there is likely to be no GPO contract with the vendor, and hospitals are price-takers. In the case of several preferred vendors, there may be a dual- or multi-source contract. Here, GPOs pursue a "targeted savings" approach, e.g., achieve a certain percentage savings on the contract by limiting the number of vendors under contract and trying to induce some price competition among them in exchange for increases in market share. While there may be greater justification for pricing differences between vendors, the evaluation data presented here enable the hospital and GPO to empirically distinguish which products and which vendors of those products are more subject to physician preference and which are not. Such information can clarify the buyer's contracting decision and negotiating position.

Third, sutures and endo-mechanical products account for a large dollar volume of hospital supply spending. The suture market is estimated at roughly $1 billion annually in sales. Hospital-level data from IMS Health for 2004 indicate total sales of endo-mechanical products of roughly $1.5 billion ($1 billion endoscopy, $0.5 billion mechanical). The majority of endoscopy spending (roughly 60%) is in two product categories considered here: endo-cutter and rigid trocars. The majority of mechanical spending (nearly 60%) is on internal staplers, another category considered here. Moreover, both the suture and endo-mechanical markets are mature, low-growth markets, with an estimated 2% to 3% cumulative average growth rate (CAGR) in laparoscopic procedures [16]. With such low growth rates, suture and endo-mechanical vendors compete not only for market share but also for GPO contracts. Such competition potentially heightens vendor as well as hospital interest in the outcome of product evaluations by a major clinical customer (the physician). Such competition should increase the salience and impact of evaluations such as the one conducted here.

Fourth, technology is frequently cited as the number one determinant of rising healthcare costs in the U.S. Government data reveal that, on average, 35% of the increase in national healthcare spending over each of the past 40 years is accounted for by the introduction and use of expensive technology [17]. The Medical Payment Advisory Commission (MedPAC) estimates that 30% of hospital costs are dedicated to supplies (medical-surgical, pharmaceutical, device) and their procurement and handling. Such costs have not been systematically addressed and controlled in the past [18]. To begin controlling such outlays, hospitals need to recognize that the ordering process is heavily influenced by physicians, and that vendors enjoy a much closer relationship with physicians than do hospitals. Hospitals will thus need to understand how their clinicians view vendors and their products, and whether or not clinicians view competing vendors' products as unique or substitutable.

ACKNOWLEDGMENTS

The authors thank the Associate Editor and two anonymous reviewers for their very helpful comments and suggestions on an earlier draft of this paper. The authors also thank Kelly Chang for her econometric advice.

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