Clinical and Economic Impact of Using Generic 7.3-mm Cannulated Screws at a Level II Trauma Center

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Abstract

We retrospectively studied the clinical and economic impact of a cost-containment program using high-quality generic 7.3-mm screws for fixation of femoral neck fractures and pelvic ring injuries at a level II trauma center. Included in the study were 174 patients with femoral neck fractures or posterior pelvic ring injuries. These injuries were managed with 203 conventional and 178 generic implants.

Study results showed no significant differences in age, sex, American Society of Anesthesiologists status, or fracture pattern; no differences in operative time, estimated blood loss, or complication rates; no increase in varus collapse, shortening, screw cutout, screw deformation, loosening, or conversion to arthroplasty; and no differences in hospital complications of deep venous thrombosis, pulmonary embolism, urinary tract infection, or pressure sores. Overall, our hospital realized a 70% reduction in implant costs, resulting in calendar-year savings of $50,531. At our institution, use of generic 7.3-mm cannulated screws has been a success.

Hospital implant costs decreased significantly without any associated increase in complication rate or change in radiographic outcome. Generic implants have the potential to markedly reduce operative costs as long as quality products are used.

In today's climate of cost containment and fiscal responsibility, generic implant alternatives represent an interesting area of untapped resources. Traditional implant companies develop their proprietary implants and are in direct competition with one another. Unlike the pharmaceutical industry, the implant industry has lacked the generic equivalents that could help lower costs to hospitals, insurance carriers, and patients. In 2009, the total US orthopedic trauma implant market was valued at more than $3 billion, and the large cannulated screw market was estimated to be $186 million annually.[1] As patents on many commonly used trauma implants have expired, generic alternatives have recently become available.

We retrospectively studied the costs, implementation, and outcomes of a cost-containment program using equivalent-quality generic 7.3-mm screws for fixation of femoral neck fractures and pelvic ring injuries.

Materials and Methods

In January 2011, after obtaining institutional review board approval, the orthopedic traumatologists at our institution began using generic 7.3-mm cannulated screws (Orthopaedic Implant Company, Reno, Nevada). Before this project was initiated, these much less expensive screws were biomechanically tested and were found to be equivalent to major implant company products. Reviewing our trauma database, we identified patients with minimally displaced femoral neck fractures and posterior pelvic ring injuries managed with generic 7.3-mm cannulated screws. We compared these patients with patients treated in a similar manner but with conventional implants in 2010. Charts were reviewed to obtain basic demographic data, such as age, sex, and American Society of Anesthesiologists (ASA) status. Operative records were analyzed to identify any intraoperative complications, operative time, and estimated blood loss (EBL).

For femoral neck closed reduction percutaneous pinning cases, hospital charts were examined to compare rates of deep venous thrombosis, pulmonary embolism, urinary tract infection, and pressure sores during the postoperative period. Clinic charts were assessed to identify cases of infection, nonunion, conversion to arthroplasty, and mortality. Four blinded authors reviewed radiographs for fracture type and occurrence of screw cutout, varus collapse, and shortening. Hospital financial records were examined to determine operative implant costs.

For sacroiliac screw cases, operative records were reviewed to identify additional pelvic fixation, any intraoperative complications, operative time, and EBL. Four blinded authors reviewed radiographs for injury type, healing time, and occur-

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Table I. Patient Demographics for Sacroiliac Screws

Demographic	Conventional (n = 44)	Generic (n = 35)	*P*
Mean (SD) age, y	47.4 (16.7)	43.4 (15.2)	.27
Sex, % male	63.6%	65.7%	.84
Mean (SD) ASA score	2.73 (0.83)	2.66 (1.08)	.77
Mechanism of injury			.44
Fall	11.9%	22.8%	
Motor vehicle accident	69.1%	60.5%	
Other	19.0%	16.7%	
Compression (Tile class)			.83
Anteroposterior	59.5%	47.1%	
Lateral	40.5%	52.9%	
Fracture type (OTA class)			.11
B.1	19.1%	37.1%	
B.2	30.9%	37.1%	
B.3	35.7%	22.8%	
C1/C2	14.3%	3.0%	

Abbreviations: ASA, American Society of Anesthesiologists; OTA, Orthopaedic Trauma Association.

Table II. Operative Data for Sacroiliac Screws

	Conventional (n = 44)	Generic (n = 35)	*P*
Bilateral fixation	45.2%	22.8%	.04
Anterior plate	35.7%	34.2%	.89
Anterior external fixation	11.9%	11.4%	.94
Mean (SD) operative time, min	89.3 (70.1)	58.9 (49.1)	.029
Mean (SD) estimated blood loss, mL	218.8 (382)	70.9 (144.7)	.026

rence of screw cutout, screw deformation, screw loosening, and fixation loss. Hospital financial records were examined to determine operative implant costs.

Data were analyzed using SAS version 9.2 for Windows (SAS Institute, Cary, North Carolina). Descriptive statistics were used to describe the data. Two-sample t tests were applied to detect the differences of means for continuous variables, and χ^2 and Fisher exact tests were used to test the differences of proportions for categorical variables between conventional and generic groups. Level of significance was set at $P < .05$.

Results

Sacroiliac Screws

Reviewing our institutional database, we identified 44 patients treated with conventional implants in 2010 and 35 patients treated with generic 7.3-mm cannulated screws in 2011. In the conventional group, 59 screws, 59 guide pins, and 50 washers were used. In the generic group, 45 screws, 45 guide pins, and 40 washers were used. Demographic information is presented in **Table I**. Mean (SD) age was 47.4 (16.7) years in the conventional group and 43.4 (15.2) years in the generic group ($P = .27$). The conventional group was 63.6% male, and the generic group was 65.7% male ($P = .84$). Mean (SD) ASA score was 2.73 (0.83) in the conventional group and 2.66 (1.08) in the generic group ($P = .77$). In the conventional group, 11.9% of the injuries were caused by falls, and 69.1% by motor vehicle accidents; the remaining 19% had other causes. In the generic group, 22.8% were caused by falls, and 60.5% by motor vehicle accidents; the remaining 16.7% had other causes ($P = .44$) The Tile classification breakdown for the conventional group was 59.5% anteroposterior compression and 50.5% lateral compression, and the breakdown for the generic group was 47.1% anteroposterior compression and 52.9% lateral compression ($P = .83$). The Orthopaedic Trauma Association (OTA) classification distribution for the conventional group was 19.1% B.1, 30.9% B.2, 35.7% B.3, and 14.3% C1/C2, and the distribution for the generic group was 37.1% B.1, 37.1% B.2, 22.8% B.3, and 3% C1/C2 ($P = .11$). There were no significant differences in age, sex, ASA status, or fracture pattern between the 2 groups.

Operative data are presented in **Table II**. Bilateral sacroiliac fixation was used in 45.2% of the patients in the conventional group and in 22.8% of those in the generic group ($P = .04$). Concomitant anterior plate fixation was used in 35.7% of the conventional group and 34.2% of the generic group ($P = .89$). Similarly, a supplemental anterior external fixator was placed in 11.9% of the conventional group and 11.4% of the generic group ($P = .94$). Mean (SD) operative time was 89.3 (70.1) minutes in the conventional group and 58.9 (49.1) minutes in the generic group ($P = .029$). Mean (SD) EBL was 218.8 (382) mL in the conventional group and 70.9 (144.7) mL in the generic group ($P = .026$). Neither group had any intraoperative complications. The groups were similar in their treatment types. There were no differences in operative time, EBL, or intraoperative complication rate, and there were no problems with instrumentation.

Postoperative data are presented in **Tables III** and **IV**. Postoperative infection occurred in 4.5% of the patients in the conventional group and in 8.5% of those in the generic group ($P = .63$). Nonunion was observed in 2.3% of the conventional group and 0% of the generic group ($P > .99$). Revision surgery was required in 4.5% of the conventional group and 0% of the generic group ($P = .51$). Radiographic review revealed no cases of screw cutout in either group. Bending was noted in 2.2% of the conventional screws and 0% of the generic implants ($P > .99$). Screw loosening, indicated by lucency, was found in 15.9% of conventional implants and 8.5% of generic implants ($P = .32$). Fixation loss, indicated by screw backout, was noted in 2.7% of the conventional group and 0% of the generic group. Mean healing time was 145 days in the conven-

tional group and 107 days in the generic group (P = .46). Thus, statistical analysis revealed no differences in screw bending, screw cutout, screw deformation, or screw loosening.

Cost analysis findings are presented in **Table V**. Mean cost of the 7.3-mm cannulated screw implants was $494 in the conventional group and $167 in the generic group (P < .0001). Mean savings per case was $327 in implants alone. Annual implant costs were $21,738 in 2010 and $5860 in 2011. Overall, our hospital realized a 73% reduction in implant costs, resulting in calendar-year savings of $15,878.

Hip Closed Reduction Percutaneous Pinning

Reviewing our institutional database, we identified 54 patients treated with conventional implants in 2010 and 45 patients treated with generic 7.3-mm cannulated screws in 2011. In the conventional group, 144 screws and 144 guide pins were used. In the generic group, 133 screws and 133 guide pins were used. Demographic data are presented in **Table VI**. Mean (SD) age was 76 (15.1) years in the conventional group and 76.6 (13.0) years in the generic group (P = .82). The conventional group was 29.6% male, and the generic group was 31.1% male (P = .91). Mean (SD) ASA score was 3.21 (0.69) in the conventional group and 2.81 (0.75) in the generic group (P = .14). The OTA classification distribution for the conventional group was 57.2% B1.1, 28.5% B1.2, and 14.3% B1.3, and the distribution for the generic group were 59.5% B1.1, 24.2% B1.2, and 16.3% B1.3 (P = .91). There were no significant differences in age, sex, ASA status, or fracture pattern between the 2 groups.

Operative data are presented in **Table VII**. Mean (SD) operative time was 14.4 (6.1) minutes in the conventional group and 16.1 (8.2) minutes in the generic group (P = .29). Mean (SD) EBL was 3.1 (10.6) mL in the conventional group and 2.4 (14.9) mL in the generic group (P = .79). There were no statistically significant differences between the 2 groups and no intraoperative complications or instrumentation problems in either group. Postoperative hospital data are presented in **Tables VIII** and **IX**. Neither group had any cases of deep venous thrombosis or pressure sores. One pulmonary embolism occurred in the conventional group, none in the generic group (P > .99). Six urinary tract infections (11.1%) occurred in the conventional group, 2 (4.4%) in the generic group. There were no differences in short-term hospital parameters. One postoperative infection occurred in the generic group, none in the conventional group (P = .45). Nonunion was observed in 2 conventional cases (3.7%) and 1 generic case (2.2%) (P > .99). Revision surgery was needed in 6 conventional cases (11.1%) and 4 generic cases (8.8%; P = .75).

Postoperative radiographic data are presented in **Table X**. Mean (SD) shortening was 2.35 (3.62) mm in the conventional group and 2.43 (3.31) mm in the generic group (P = .92). Screw cutout was observed in 1 generic (3.3%) and no conventional cases (P = .49). Varus collapse was discovered in 2 conventional (6.4%) and no generic cases (P = .49). Thus, there were no statistical differences in varus collapse, shortening, or screw cutout.

Cost analysis findings are presented in **Table XI**. Mean (SD) case implant cost was $955 ($170) for the conventional group

Table III. Postoperative Data for Sacroiliac Screws

	Conventional (n = 44)	Generic (n = 35)	*P*
Infection	4.5%	8.5%	.63
Nonunion	2.3%	0	> .99
Revision surgery	4.5%	0	.51
Mortality	0	0	N/A

Table IV. Postoperative Radiographic Data for Sacroiliac Screws

	Conventional (n = 44)	Generic (n = 35)	*P*
Cutout	0	0	N/A
Bending	2.2%	0	> .99
Loosening	15.9%	8.5%	.32
Loss of fixation	2.7%	0	> .99
Healing time, d	145	107	.46

Table V. Cost Data for Sacroiliac Screws

	Conventional (n = 44)	Generic (n = 35)	*P*
Case mean	$494	$167	< .0001
Annual cost	$21,738	$5860	—
Mean savings per case	$327	—	—
Total savings		$15,878	—

Table VI. Patient Demographics for Hip Closed Reduction Percutaneous Pinning

	Conventional (n = 54)	Generic (n = 45)	*P*
Mean (SD) age, y	76 (15.1)	76.6 (13)	.82
Sex, % male	29.6%	31.1%	.91
Mean (SD) ASA score	3.21 (0.69)	2.81 (0.75)	.14
Fracture type (OTA class)			.91
B1.1	57.2%	59.5%	—
B1.2	28.5%	24.2%	—
B1.3	14.3%	16.3%	—

Abbreviations: ASA, American Society of Anesthesiologists; OTA, Orthopaedic Trauma Association.

and $376 ($50) for the generic group ($P < .0001$). Mean savings per case was $579. Annual implant cost for closed reduction percutaneous pinning was $51,549 in the conventional group and $16,896 in the generic group. Overall, our hospital realized a 67% reduction in implant costs, resulting in calendar-year savings of $34,653.

Table VII. Operative Data for Closed Reduction Percutaneous Pinning

	Conventional (n = 54)	Generic (n = 45)	*P*
Mean (SD) operative time, min	14.4 (6.1)	16.1 (8.2)	.29
Mean (SD) estimated blood loss, mL	3.1 (10.6)	2.4 (14.9)	.79
Complications	0	0	N/A

Table VIII. Hospital Data for Closed Reduction Percutaneous Pinning

	Conventional (n = 54)	Generic (n = 45)	*P*
Deep venous thrombosis	0	0	N/A
Pulmonary embolism	1 (1.8%)	0	> .99
Urinary tract infection	6 (11.1%)	2 (4.4%)	.28
Pressure sore	0	0	N/A

Table IX. Postoperative Data for Closed Reduction Percutaneous Pinning

	Conventional (n = 54)	Generic (n = 45)	*P*
Infection	0	1 (2.2%)	.45
Nonunion	2 (3.7%)	1 (2.2%)	> .99
Revision surgery	6 (11.1%)	4 (8.8%)	.75
Mortality	4 (7.4%)	0	.12

Table X. Radiographic Data for Closed Reduction Percutaneous Pinning

	Conventional (n = 54)	Generic (n = 45)	*P*
Mean (SD) shortening, mm	2.35 (3.62)	2.43 (3.31)	.92
Cutout	0	1 (3.3%)	.49
Varus collapse	2 (6.4%)	0	.49

Table XI. Cost Data for Closed Reduction Percutaneous Pinning

	Conventional (n = 54)	Generic (n = 45)	*P*
Mean (SD) cost per case	$954.7 ($170.3)	$375.5 ($50.2)	< .0001
Annual cost	$51,549	$16,896	—
Mean savings per case	$579.2	—	—
Total savings		$34,653	—

Discussion

In 2009, the US orthopedic trauma implant market was valued at more than $3 billion, and the US cannulated screw market was estimated at $361 million (expected to increase to $435 million in 2016). The large cannulated screw market was estimated to be $186 million annually in 2009, increasing to $208.8 million in 2016.[1] Given that the patent for the modern cannulated screw has expired (US4537185, June 10, 1983, Denis P. Stednitz), the 7.3-mm cannulated screws used in this study have been off-patent for several years. In this industry, generic options have become available only recently. Although multiple publications have reported efficacy and cost savings in pharmaceutical research, the same information does not exist for generic trauma implants. An exhaustive literature search identified only 1 paper on generic orthopedic implant use in arthroplasty: Waddell and Morton[2] described a clinical trial in Canada of generic total hip implants in 150 patients followed for more than 2 years. Use of the generic implants resulted in no increase in complication rates and general improvement in hip scores. To our knowledge, the present study is the first US study documenting the economic benefit and similar clinical results of using generic trauma implants.

There are multiple barriers to generic implant use. Perhaps most important is the lack of surgeon confidence in generics. Inaccurate perceptions of these products are propagated by surgeons, implant companies, and hospitals. Although biomechanical equivalence is confirmed before surgery, and all implants approved for use in the United States must meet Food and Drug Administration (FDA) standards, clinical efficacy must be demonstrated. Because of the general reluctance to adopt any generic implants, we used a mechanically sound and conceptually simple product that does not require any sales representation for implantation. Intramedullary nailing systems and locked plates have more complex biomechanical features, and their generic forms may take longer to gain acceptance. The present study evaluated use of a very simple device that fracture surgeons have been using for years. Our data set compared patients treated by 3 orthopedic traumatologists over a 2-year period. One group received generic implants, the other conventional implants. Equivalence was demonstrated across all operative, postoperative, and radiographic parameters. The only difference was significant cost savings.

Another barrier to change is surgeon conflict of interest. At many institutions, orthopedic traumatologists are paid consultants or have royalty agreements with implant companies. These conflicts can make it difficult to effect change. At our institution, no surgeon

has a consulting agreement or royalty agreement with any of the major branded implant companies. This lack of conflicts may ease the adoption of generic implants at our institution. Certainly conflicts of interest arise in the presence of such relationships, and this has been a major factor in recent US Department of Justice investigations of total hip prosthetic use. For institutions that fear loss of research funding, we suggest that money saved from generic implant use can be appropriated toward research and service line reinvestment, which will free institutions of manufacturer bias or single vendor support. Our institutional trauma fellowship program and research projects are now funded by the hospital because of orthopedic cost savings from supply chain management and operating room efficiency programs.

Another concern is that conventional implant vendors and sales representatives might alter the level of service they provide or increase the prices on unique implants and instrumentation. At our institution, use of generic alternatives has stimulated better service from conventional companies wanting to preserve their market share. In addition, dramatic savings have given the hospital the ability to more effectively negotiate prices on conventional items, such as intramedullary nails and plate and screw constructs. As a result, use of generic alternatives has succeeded on many levels.

Patient perceptions are another theoretical barrier to generic implant use. Sewell and colleagues[3] described this barrier vis-à-vis generic medication. For underinsured populations, use of generic medications with efficacy similar to that of brand-name medications clearly has its advantages. However, 4 focus groups with 30 community members (one-fourth uninsured, more than half with a high school education or less) revealed many misconceptions about generic medicine: Generics are not "real" medicine, generics are only for "minor" illnesses, the medical system cannot be trusted, and so forth. Sewell and colleagues[3] concluded that, though education about generics could help overcome misinformation, "overcoming mistrust of the medical system and the sense of having to settle for generics because of poverty may be more challenging." According to the World Health Organization, strategies promoting generic substitution should be included in national medicine policies.[4]

One weakness of our study is that one of its authors is an Orthopaedic Implant Company stockholder. Dr. Althausen, however, believes strongly in the generic mission. There are many alternative generic companies, and our data support the clinical equivalence implied by FDA standards and companies themselves. In an effort to ensure the integrity of our clinical data, we had all chart reviews, data extraction, and radiographic analyses performed by 4 blinded authors with no clinical involvement and no financial interest in the generic implant company. Statistical analysis was performed by a clinical professor of biostatistics at our local state university. A follow-up clinical and economic study comparing multiple generic offerings from a variety of sources is certainly warranted.

Evaluations of cost-effectiveness and comparative effectiveness are increasingly being reported in the peer-reviewed orthopedic literature. Evaluation of the cost-effectiveness of generic large cannulated screws is simple. An implant or intervention that has equivalent effectiveness and costs 65% to 70% less is clearly cost-effective. Assuming biomechanical equivalence, generic products have a huge potential for cost savings. The credibility and viability of generic implants are directly tied to the capacity of the scientific community to properly vet generic implants and ensure that their quality and effectiveness are equivalent to "name brand" implants. The intramedullary nail market, estimated at $408 million in 2009, is expected to increase to $788 million by 2016. The 2009 estimate was $68 million for sliding hip screws and $255 million for cephalomedullary nails. In 2009, the external fixation market was estimated to be $500.5 million, and the plate and screw market $1529.2 million.[1] These numbers are staggering. If the 65% to 75% cost reduction found in this study can be applied to other implants, orthopedic trauma surgeons can have a massive effect on the economics of the health care crisis. Given that many of our patients are uninsured or underinsured, it is our duty to be cost-conscious as long as biomechanical equivalency and clinical performance remain equal.

With use of generic implants, surgeons can help reduce the escalating costs of health care without compromising patient safety or quality of outcomes.

Conclusions

Perhaps the most crucial result of using generic implants is the renewed focus on surgeons as end users of health care resources. With use of generic implants, surgeons can help reduce the escalating costs of health care without compromising patient safety or quality of outcomes. As health care resources become more limited if not scarce, innovative cost savings programs will become essential to physicians trying to preserve patient care standards within an evolving and increasingly complex health care delivery system.

Use of generic 7.3-mm cannulated screws in the management of femoral neck fractures at our institution has been very successful, saving more than $50,000. Hospital implant costs were reduced significantly and without any associated increases in complication rates or changes in radiographic outcomes. These results have profound implications for the treatment of trauma patients, as patents have expired on many other products, including intramedullary nails, locking plates,

and drill bits and other disposable items.

Generic implant use has the potential to markedly reduce operative costs, much as was done in the generic pharmaceutical industry. As long as quality products are being used, patient care is unaffected and cost savings can be realized. A portion of savings from such a change can be reinvested in the hospital trauma program to support OTA/American Academy of Orthopaedic Surgeons position statement guidelines and reduce fracture implant costs in the future.

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