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Time of cochlear implant surgery in academic settings

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Abstract

OBJECTIVE—Establish time required to perform cochlear implantation (CI) in academic settings.

STUDY DESIGN—Historical cohort study.

SETTING—German and American academic centers.

PATIENTS—2,639 patients underwent CI (1997–2007), excluding patients receiving experimental device or technique with abnormal cochlear anatomy or incomplete charts, leaving 2,253 for analysis.

INTERVENTION—Unilateral, bilateral and revision CI with devices approved in USA and Europe.

MAIN OUTCOME MEASURES—Mean surgical time (ST) and total OR time (TORT).

RESULTS—Mixed model analysis was employed; estimated marginal means given in minutes after adjusting for random effect of individual surgeon. No differences between unilateral (ST=171, TORT=245) and revision CI (ST=160, TORT=232), but bilateral procedures were longer than (ST=295, TORT=377, $p=0.000$). Unilateral surgeries - Cochlear Limited (CL) devices were

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implanted faster (ST=165, TORT=225) than Advanced Bionics (ABC) (ST=183, $p=0.001$, TORT=240, $p=0.023$) or MedEl (ST=193, $p=0.000$, TORT=253, $p=0.002$). No differences for unilateral CI between ABC and MedEl. For revision CI, ABC (ST=141, TORT=219) was faster than CL (ST=181, $p=0.001$, TORT=266, $p=0.000$). No differences by age group or between Germany and the USA. ST and TORT were shorter for 575 CI performed in the final two years of the study (unilateral CI: ST=145, TORT=209; bilateral CI: ST=259, TORT=330; revision CI: ST=138, TORT=205). For unilateral CI, ST and TORT decreased yearly (linear regression, $p<0.001$) and inversely correlated with surgeon experience (linear regression, $p<0.01$).

CONCLUSIONS—We report time required to perform CI in academic settings, data vital for cost-benefit analyses and assessing new CI techniques.

Introduction

Since its clinical inception over two decades ago, cochlear implantation (CI) has evolved to become an effective and widely-performed procedure for the restoration of hearing in profoundly deafened individuals. Over 112,000 cochlear implantations have been performed worldwide; in the United States, estimates place these numbers at 23,000 adults and 15,500 children.¹ The problem of hearing loss is significant: 2 to 3 per 1000 children are born yearly in the United States with deafness or significant hearing loss, and more develop this pathology with age.² Despite the increasingly standardized technique of CI surgery, sparse literature exists analyzing surgical time. A study published in 2000 reported operative time of 192–206 minutes and total anesthesia time of 249–269 minutes for unilateral CI.³

An accurate estimation of the length of time required to perform CI would be valuable for cost-benefit analysis, determining appropriate 3rd party reimbursement, and determining if newer, less invasive techniques for CI, such as endaural,⁴ suprameatal,^{5,6} minimal access,^{7–10} or percutaneous¹¹ approaches will provide a tangible benefit in terms of decreased operative time. Shorter surgical times translate into decreased duration of general anesthesia and decreased fees, critical factors in determining the overall cost-benefit analysis for a given procedure.

The purpose of this study is to analyze the operative time required to perform cochlear implantation in both American and German academic settings. While there can be differences among cases, e.g. congenital malformations or extensive medical comorbidities that dictate an unusual approach, most surgeries proceed in a predictable, standardized manner. There are important workflow differences in cochlear implantation between the United States and Europe that warrant performing this analysis in both settings. For example, in German academic centers, the chairperson or professor may run multiple operating rooms simultaneously with attending physicians (*uberarzt*) performing large portions but not the entirety of the surgery. In America, most academic centers abide by the Centers for Medicare and Medicaid (CMM) rules, which prevent one attending physician from running multiple rooms.

Materials and Methods

IRB approval was obtained to perform a retrospective review of electronic and paper charts at two academic centers – Vanderbilt University (Nashville, TN) and Medical University of Hannover (Hannover, Germany). Implanted devices were manufactured by Cochlear Limited (Sydney, Australia), Advanced Bionics (Sylmar, California, USA), and MedEl (Innsbruck, Austria). Patients and surgeons were anonymized and data sorted by hospital, gender, date of birth, date of procedure, type of procedure (unilateral, bilateral, or revision unilateral surgery) device manufacturer, and side of implantation. The times of patients entering the room or initiation of blocked operating room (OR) time, incision, completion of surgery, and patient exiting room or completion of total blocked OR time were identified in the charts and used to

calculate surgical and total OR time. Where date of birth was available, the age of the patient at time of procedure was calculated.

Surgical time (ST) was defined as the period between incision and completion of procedure. With regard to total OR time (TORT), charts in the USA noted the exact times at which the patients entered and left the operating room, and TORT was calculated as the period between these points. In Germany, however, charts did not indicate the times of entry and exit from the OR, but instead recorded blocks of pre- and post-procedure time (*forarbeit* and *nacharbeit*, respectively), that included anesthetic time but also pre-surgical room setup and post-surgical room cleaning. As a result, it is impossible to deduce from the German charts at exactly what moment within these blocks the patient entered and left the room, and thus exact total OR duration is unobtainable. In Germany, mean blocked OR periods averaged 31 ± 4 minutes prior to incision and 30.3 ± 3 minutes post-operatively. TORT for German procedures was calculated with this caveat in mind.

For the time period June 1997 to September 2007, a total of 2639 CI patients were identified. Patients involved in ongoing studies of new or unfamiliar devices or modification in technique were excluded. Also excluded were individuals with grossly abnormal cochlear anatomy identified on preoperative imaging. Finally, a number of patients had incomplete charts regarding operating room times, location of procedure, or device manufacturer, and were thus removed, leaving 2,253 eligible patients.

SPSS Software (Chicago, Illinois, USA) was used to perform statistical analysis in consultation with a statistician (author M.D.). Mixed model analysis was used to calculate estimated marginal means for surgical and total OR times with 95% confidence intervals after controlling for the random effect of individual surgeon. Next, unilateral and bilateral surgeries were examined separately for fixed effects of implant manufacturer and hospital. Pair-wise comparisons were carried out using the Bonferroni modification. Linear regressions were utilized to assess the relationship between individual data points for year of surgery or surgeon experience and operative times. The effect of surgeon experience was estimated by listing unilateral CI in the order they were performed for each surgeon and then performing a linear regression between this rank order and the corresponding operative time. Nine cases were excluded from this calculation because the primary surgeon had performed only one or two total CI, leaving 2,016 cases to be analyzed for the effect of experience.

Results

Two-thousand twenty-five unilateral and 97 bilateral implants were included in the study. Additionally, revision surgery, consisting of explantation of an existing implant with insertion of a new device, was performed in 131 individuals. Two-thousand twenty-one CI were performed at Medical University of Hannover and 232 were performed at Vanderbilt University Medical Center.

The mean age of patients receiving unilateral implantation was 29.5 ± 26.6 years, whereas the mean age for bilateral implantation was 12.2 ± 20.8 years. The average age of those undergoing reimplantation was 26.0 ± 23.8 years. Twenty-nine surgeons were included in the study; the number of surgeries performed by each ranged from 1 to 407, with a mean of 78 ± 110 . Excluding the eight surgeons who performed one implant and one surgeon who performed two implants yielded a range of 5 to 407 and mean of 113 ± 118 cases per physician.

The estimated marginal mean surgical and total OR times for unilateral, bilateral, and revision cochlear implantation are listed in Table 1. All results are given in minutes. The ST required to perform a unilateral CI was 171 (95% CI 157–185), with a TORT of 245 (95% CI 228–262). The ST to perform a bilateral CI was 295 (95% CI 277–313), with a TORT of 377 (95% CI

357–398). For patients undergoing revision unilateral CI, the ST was 160 (95% CI 143–177) and TORT was 232 (95% CI 212–252). Bilateral implants had significantly longer surgical ($p=0.000$) and total OR times ($p=0.000$) than unilateral or revision procedures, but there was no difference in ST ($p=0.115$) or TORT ($p=0.106$) between the latter two groups.

Statistical analysis failed to demonstrate a difference in ST by hospital, although significance was approached for TORT ($p=0.112$) between Hannover (257, 95% CI 240–274) and Vanderbilt (221, 95% CI 179–263) for unilateral procedures. (See Table 2)

The breakdown of procedure by manufacturer was as follows: Cochlear Limited – 1099 unilateral, 64 bilateral, 37 revision; Advanced Bionics – 825 unilateral, 26 bilateral, 93 revision; MedEl – 101 unilateral, 7 bilateral, 1 revision. Table 3 depicts surgical and total OR times stratified by manufacturer. For unilateral procedures, Cochlear Limited implants were significantly faster in terms of ST ($p=0.001$, $p=0.000$) and TORT ($p=0.023$, $p=0.002$) than both Advanced Bionics and MedEl, respectively, but there was no difference in ST between the latter two devices. When manufacturers were compared for unilateral procedures within each hospital, the differences in ST and TORT were no longer significant (data not shown).

For revision surgery, Advanced Bionics had significantly shorter ST ($p=0.001$) and TORT ($p=0.000$) than Cochlear Limited devices. No difference in either ST or TORT was found between Advanced Bionics and Cochlear Limited products for bilateral procedures. For statistical reasons, MedEl devices were not included in the analyses of bilateral and revision surgeries by manufacturer due to the small number of non-unilateral CI patients in whom these implants were used.

Surgical time for unilateral CI was analyzed as a function of patient age, but no correlation was found (data not shown). Figure 1 depicts the ST and TORT for unilateral cochlear implantation by year performed. Of note, 1997 and 2007 include only partial year data. Overall, there was a substantial increase in number of CI performed annually over the course of the study. Linear regression analysis revealed a statistically significant inverse relationship between year of surgery and ST (correlation coefficient -0.39 , R-squared 0.15, and $p<0.01$) as well as year of surgery and TORT (correlation coefficient -0.44 , R-squared 0.19, $p<0.01$). Accordingly, ST and TORT for the 575 cases in the final two years of the study (2006–2007) are shorter (unilateral CI: ST=145, TORT=209; bilateral CI: ST=259, TORT=330; revision CI: ST=138, TORT=205), reflecting this trend toward faster operative times (Table 4).

Figure 2 shows ST for unilateral cochlear implantation when correlated with surgical experience. Linear regression analysis revealed a statistically significant relationship between increasing surgeon experience and decreased ST (correlation coefficient -0.25 , R-squared 0.06, $p<0.01$).

Discussion

This study reports the surgical and total OR times required for unilateral, bilateral, and revision cochlear implantation (CI) in American and German academic settings. Bilateral CI was significantly more time-consuming than unilateral and revision surgeries, and among unilateral procedures, Cochlear Limited implantations were significantly faster than those of Advanced Bionics or MedEl. There was no difference in ST or TORT among manufacturers for bilateral CI, but Advanced Bionics devices were significantly faster than Cochlear Limited implants for revision cases. There was no difference in ST between Hannover and Vanderbilt, although a significantly longer TORT was approached at Hannover. ST and TORT decreased yearly over the study period. ST was also inversely correlated with surgeon experience.

Bilateral CI took an additional 124 minutes of ST and 132 minutes of TORT when compared to unilateral CI, which is not surprising given the additional work involved. Revision surgery with removal of an existing implant and insertion of a new device was also faster than bilateral but no different than primary unilateral implantation.

Unilateral Cochlear Limited implants required 18 and 28 fewer minutes to perform than Advanced Bionics and MedEl devices, respectively. This statistically significant difference may be attributable to a familiarity effect, as most of the devices used were made by Cochlear Limited (1,099, versus 825 Advanced Bionics and 101 MedEl), but one cannot rule out the possibility that certain devices were inherently more efficient to place. The data failed to reveal significant time differences by manufacturer for bilateral implantation, but the study's power was greatly reduced in this area due to the smaller number of bilateral CI performed (97 bilateral versus 2,028 unilateral procedures). With regard to revision surgery, Advanced Bionics devices were 40 and 47 minutes faster than Cochlear Limited implants for ST and TORT, respectively. Again, this may have been due to a familiarity effect, as more Advanced Bionics implants were used in revision surgery (93 versus 37 Cochlear Limited and 1 MedEl).

There was no difference in ST between Hannover and Vanderbilt. There was, however, a trend toward faster TORT in the USA ($p=0.112$), with a difference of 36 minutes between locations. As alluded to previously, it is difficult to make conclusions based upon this finding, due to the differences in the manner in which TORT was recorded in each hospital. The average blocked periprocedure time in Hannover was 61 minutes (31 minutes prior to and 30 minutes following surgery); if we estimate that the patient was present in the room for approximately half of this period (30 minutes), then the corrected total OR time for Germany would be essentially the same as in the USA (only 5 minutes longer). Alternatively, it is possible that the German patients did indeed spend more time in the operating room pre- and post-procedure, due to a difference in anesthetic technique or perioperative protocol.

The ST and TORT decreased yearly over the course of this study. This may have been due to increased surgeon and staff familiarity with the procedure, resulting in increased overall efficiency. Additionally, refinements in surgical technique are made as experience grows. For example, a smaller postauricular incision was introduced circa 2000/2001 that decreased the amount of time required to expose and later close the surgical site. Another new trend in cochlear implantation surgery, the temporalis pocket technique, which obviates the need for drilling a bony recess for device placement, was not used in any study patients. In addition to surgical advancements, electrode design refinements introduced by manufacturers during the study period may have contributed to this trend of decreasing operative time. The data given for 2006–2007 provide a current snapshot of the time requirements for CI in academic settings.

There was a significant correlation between surgeon experience and surgical duration. This finding is consistent with studies of stapedectomy which demonstrated that approximately 60–100 cases were necessary for surgeons to reach full skill and comfort with this otologic procedure,^{11–13} except that in our study the trend toward increased efficiency continued beyond 100 procedures. In the current study there was a substantial population of cases that did not fit this inverse correlation of surgeon experience and surgical time; instead, there were numerous instances of long surgical duration despite considerable surgeon volume. There are several possible explanations for this observation. First, as surgeons are developing comfort with a procedure, they go through a period of learning and increased efficiency. During this period, they are likely performing the majority of the surgery themselves in an effort to become fully facile. Subsequently, with increased experience comes an obligation for academic surgeons to teach residents, fellows, and other trainees. As a result, much of the work of many cochlear implantations is actually performed by junior physicians under close observation from experienced faculty, likely contributing to increased surgical time. Furthermore, particularly

in Germany, it is not unusual for multiple patients to be anesthetized under the care of junior attendings (*oberarzt*) whom are in turn supervised by the department or division chief. As a result, short procedural delays are inevitable as junior faculty await clinical validation and approval before proceeding to the next step of the procedure. Surgeons in large academic centers may also be more likely to work with various operating teams of nurses, scrub technicians, and ancillary staff, whose unfamiliarity with the procedure and instrumentation can induce further operative delays. Finally, with greater experience comes referral of more complex cases, which may add to surgical time for higher volume surgeons and tertiary care centers.

Prior to this study, few data existed regarding the length of time required to perform a typical cochlear implantation in an academic setting. Such a data set is useful since operative time relates to patient morbidity and overall cost. Studies, now six to eight years old, have estimated the cost of a standard CI in a child at \$46,000 to \$57,000 in Germany¹⁴ and \$44,000 in the United Kingdom.¹⁵ Direct surgical costs of \$24,475 for pediatric CI have been reported in the United States.¹⁶ At Vanderbilt, the facility fee for the first 30 minutes of surgery is \$1,581, with each subsequent ½ hour costing \$1,265. Using our data from 2006–2007, the facility fee alone for a typical unilateral CI (144 minutes) would be \$6,641, which, combined with the list price of the implant (\$28,900),¹⁷ yields a bill of \$35,541, not including recovery room, anesthesia, laboratory, pharmacy, surgeon, anesthesiologist, clinic, or other fees. The 2008 Center for Medicare & Medicaid reimbursement for a unilateral CI is \$25,046,¹⁸ not including professional fees, clearly insufficient to cover the true cost of the procedure. These results are thus useful for justifying more realistic reimbursements for CI.

This study was successful in establishing a baseline operative time requirement for performing standard cochlear implantation. Safely reducing operative time can clearly have cost-saving implications for patients. Decreasing surgical duration may also decrease patient morbidity associated with longer anesthetic times, such as post-operative nausea and vomiting.¹⁹ Any decrease in operative time, however, must not come at the expense of procedure effectiveness or safety. The results of this study can be used to compare the cost-benefit profile of traditional CI to novel, minimally invasive techniques for device placement. In performing this comparison, however, it is necessary to consider that our data were obtained from academic centers, and thus the operative time for a standard CI could be shorter in other settings.

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Figure 1.
Mean operative and total OR time for unilateral C year performed.

Figure 2.
Mean operative time for unilateral CI by surgeon experience.

Table 1

Mean surgical and total OR times for unilateral, bilateral, and revision CI

Procedure	# Patients	Surgical Time (min)	Total OR time (min)
Unilateral	2025	171 (95% CI 157–185)	245 (95% CI 228–262)
Bilateral	97	295 (95% CI 277–313)	377 (95% CI 357–398)
Revision	131	160 (95% CI 143–177)	232 (95% CI 212–252)

Bilateral procedures had significantly longer surgical and total OR times than unilateral or revision CI ($p=0.000$). Statistical significance was approached but not reached between unilateral and revision groups for surgical ($p=0.115$) and total OR times ($p=0.106$).

Table 2

Mean surgical and total OR times by location for unilateral CI

	# Patients	Surgical Time (min)	Total OR time (min)
Hannover	1812	179 (95% CI 164–194)	257 (95% CI 240–274)
Vanderbilt	213	183 (95% CI 146–220)	221 (95% CI 179–263)

There were no differences in surgical or total OR times by location, although significance was approached for total OR time ($p=0.112$).

Table 3

Mean surgical and total OR times by manufacturer

Procedure	Manufacturer	# Patients	Surgical Time (min)	Total OR Time (min)
Unilateral *	CL	1099	165 * (95% CI 146–186)	225 * (95% CI 203–248)
	ABC	825	183 * (95% CI 162–204)	240 * (95% CI 216–263)
	MedEl	101	193 * (95% CI 170–217)	253 * (95% CI 227–280)
Bilateral	CL	64	291 (95% CI 251–331)	369 (95% CI 332–406)
	ABC	26	284 (95% CI 241–326)	365 (95% CI 326–405)
	MedEl	7	N/A	N/A
Revision *	CL	37	181 * (95% CI 154–208)	266 * (95% CI 236–296)
	ABC	93	141 * (95% CI 118–163)	219 * (95% CI 194–244)
	MedEl	1	N/A	N/A

CL = Cochlear Limited, ABC=Advanced Bionics N/A = Insufficient number of samples to calculate estimated marginal mean.

* = Statistically significant difference among means within procedure type.

For unilateral procedures, CL had significantly shorter surgical times than ABC ($p=0.001$) and MedEl ($p=0.000$) devices. Total OR times were also shorter for CL than ABC ($p=0.023$) or MedEl ($p=0.002$). For revision surgery, ABC had significantly shorter surgical ($p=0.001$) and total OR times ($p=0.000$) than CL.

Table 4

Mean surgical and total OR times for years 2006–2007

Procedure	# Patients	Surgical Time (min)	Total OR Time (min)
Unilateral	504	145 (95% CI 121–169)	209 (95% CI 183–234)
Bilateral	37	259 (95% CI 232–286)	330 (95% CI 302–359)
Revision	34	138 (95% CI 111–166)	205 (95% CI 176–235)