The economic impact of failures in total hip replacement surgery

28,997 cases from the Norwegian Arthroplasty Register, 1987–1993

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The Norwegian Arthroplasty Register was established in 1987. Until January 1994, approximately 200 different implant combinations had been used in total hip replacements (THR) in Norway. About 5,500 THR were performed each year in this period with a total cost of 70 million USD per year. We analyzed the economic consequences related to the use of some inferior primary hip arthroplasties in this period.

As the reference arthroplasty, we chose the most commonly used prosthesis in Norway, i.e., the Charnley prosthesis fixed with high viscosity cement containing antibiotic and with systemic antibiotic prophylaxis (n 4,970). We compared this reference group to all other primary THR registered in the same time period (n 24,027), and to the following sub-groups of primary THR: 1) uncemented Ti-Fit/Bio-Fit (acetabulum/femur) combination (n 173), 2) uncemented Coxa/Femora combination (n 153), 3) THR with low-viscosity cement (n 1,807) and 4) THR with Boneloc cement (n 1,250).

We estimated the number of additional revisions compared to the reference arthroplasty after a follow-up of 3–5 years in the different groups, with adjustment for age, sex and diagnosis. The direct extra revision costs were calculated.

Compared to the reference arthroplasty, the group of all other primary THR gave an extra revision cost estimated at about 1.7 million USD per year. About 1,000 uncemented Bio-Fit femoral prostheses have been applied in Norway, including those implanted before the registration started (1985–1987). The extra revision costs the first postoperative years for these 1,000 prostheses amount to about 0.7 million USD per year. Corresponding figures in the Coxa/Femora group were 0.08 million USD, in the group with low-viscosity cement, 0.3 million USD and in the Boneloc group, 0.4 million USD per year.

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Though the economic benefits of total hip replacements (THR) have been documented (Cushner and Friedman 1988, Kristiansen 1990, Boettcher 1992), the costs are posing a formidable challenge to the health care system. In Norway, the annual cost of hip arthroplasty amounts to about 70 million USD, and the revision costs account for about 18% of this figure.

We analyzed data on close to 30,000 primary THR collected in the Norwegian Arthroplasty Register from September 1987 until January 1994 to address the economic consequences of implants and cement types, used in Norway, that have been found to be inferior (Havelin et al. 1991, 1995).

Patients and methods

Primary THR and revisions from September 1987 until January 1994 in Norway, with 4.3 million inhabitants (1993), were registered in the Norwegian Arthroplasty Register. All 64 hospitals where THR are performed in Norway participated, and both primary operations and revisions were reported individually. The patients were identified by their unique 11-digit social security number assigned to all Norwegians, and the revisions were linked to the primary arthroplasty by this number (Havelin et al. 1993).

The prostheses were grouped by their trade names. The trade names of the prosthesis used in the acetabulum and in the femur respectively together constitute one THR combination. Thus the Spectron/ITH combination denotes an arthroplasty using a Spectron prosthesis in the acetabulum and an ITH prosthesis in the femur. The Charnley arthroplasty—i.e., the Charnley/Charnley combination (DePuy, UK) with high-viscosity antibiotic-containing cement in patients also given systemic antibiotic prophylaxis—is the commonest combination in primary THR in Norway and has a good outcome (Espehaug et al. 1995, Havelin et al. 1995). This arthroplasty was therefore chosen as a reference group (n 4,970), to which all

other results were compared.

The reference group was first compared with all other primary THR registered in the same time period (n 24,027). The survival curves were constructed by the Kaplan-Meier method. Survival time was defined as the time from the primary THR to the first revision, irrespective of the reason. The subgroups were followed until less than 50 hips were at risk. Survival times of prostheses in patients who died without being revised were censored. Confidence intervals (95%) were calculated using Greenwood's variance estimator (Dixon et al. 1990). The number of revisions during the first 5 years was calculated for the reference group and for the other arthroplasties separately. Adjustment for differences in age, sex and diagnosis was carried out by stratification. 5-year survival probabilities were estimated for the two groups in 8 strata defined by age (< 70, > 70 years), sex and diagnosis (arthrosis vs. other). Thus the adjusted number of additional revisions of implant A over a 5-year period compared to the reference was:

$$\text{Extra rev}_{(A)} = \sum_{j=1}^{8} [P_{j\,(A)} - P_{j\,(\text{Reference})}] \times N_{j\,(A)}$$

where j = 1, 2, ..., 8 denotes the eight age-sex-diagnosis strata; Pj (A) the 5-year survival probability of implant A in stratum j; Pj (Reference) the 5-year survival probability of the reference group in stratum j and Nj (A) the number of type A implants in stratum j registered. We note that the adjusted number of extra revisions is the sum of all strata of the stratum-specific differences between type A and the reference. Thus if a prosthesis performs better than the reference, the number of additional revisions will be negative.

The survival data of the uncemented Ti-Fit/Bio-Fit (Richards, TN) (n 173) and Coxa/Femora (Thackray, England) (n 153) combinations, the cemented prostheses with low-viscosity cement, i.e., CMW 3 with and without gentamicin (CMW Laboratories Dentsply, UK) and Palacos E-Flow (Schering-Plough International Inc., New Jersey, NJ, USA) (n 1,807) and the THR cemented with the Boneloc cement (Polymers Reconstructive A/S, Farum, Denmark) (n 1,250) were in the same way compared with the reference arthroplasty. The additional revisions were estimated in each group. For the Boneloc group and the Coxa/Femora group, however, maximums of 3- and 4-year follow-up data, respectively, were available.

The analyses were performed with the BMDP statistical package (Dixon et al. 1990) and custom-written FORTRAN programs.

Based on the Norwegian diagnosis-related groups (DRG), an uncomplicated primary THR was allocated a cost of 12,500 USD in 1994 (Sosialdepartementet 1993). In an economic appraisal in 1990 (Daellenbach et al. 1990), the extra costs associated with reoperations were estimated at 3,000 USD (the base case). At an annual discount rate of 3%, which has been the discount rate used in health care budgeting in Norway during the last 4 years, the figure today is approximately 3,500 USD.

On the basis of these figures, we have estimated the direct cost of all kinds of re-arthroplasties to be, on the average, about 16,000 USD (1 USD = 6.50 NOK). The direct costs include the cost of the intervention and the treatment of postoperative complications.

Results

During the years 1987–1993, 199 combinations of cemented and uncemented prostheses with different trade names were used. Only 48 of them had been used in more than 30 hips each (Table 1), and only 12 of the combinations that had been implanted in more than 100 hips each had been in use throughout the whole registration period (Table 1). In 1993, 29 acetabular components and 26 femoral components with different trade names were used, compared to 32 and 30 different trade names, respectively, in 1988. However, the number of different designs and sizes among these implant trade names has increased from 398 in 1988 to 487 in 1993.

Uncemented arthroplasties are most commonly applied in younger patients and the preoperative diagnosis is less often primary coxarthrosis (Table 2).

The estimated cumulative probability of revision at 5 years was 4.4% in the group of all other primary THR, compared to 2.2% in the reference group (Table 3, Figure 1). Using an estimated revision cost of 16,000 USD, the direct costs of these 533 additional revisions (adjusted) in a 5-year period thus came to 8.5 million USD (95% confidence interval: 5.4–12 million USD) (Table 4).

The estimated revision percentages at 5 years for the Ti-Fit/Bio-Fit combination and at 4 years for the Coxa/Femora combination were 26% and 17%, respectively (Table 3, Figure 2). If the nearly 800 Bio-Fit prostheses implanted before the registration period were included, the extra costs have been 0.7 million USD per year in the first 5 years postoperatively compared to 0.08 million USD per year in the Coxa/Femora group (Table 4).

The cumulative probability of revision at 5 years for the group of THR with low-viscosity cement and

Table 1. Total hip replacements in Norway, Sept 1987–Jan 1994 (n 28,997). Observed frequency of different combinations used in primary arthroplasties

Acetabulum–Femur	No.	%	Period used
1. Cemented			
Charnley/Charnley	13409	57.7	1987–
Exeter/Exeter	2992	12.9	1987–
Titan/Titan	2053	8.8	1987–
Spectron/ITH	1467	6.3	1987–
Elite/Charnley	860	3.7	1988–
Spectron/SP II Lubinus	277	1.2	1987–
Spectron/Bio-Fit	226	1.0	1987–1992
Spectron/Titan	209	0.9	1987–
SP Hip (Lubinus)/SP Hip (Lubinus)	207	0.9	1987–
LMT Biomet/LMT Biomet	197	0.9	1987–1991
SP Hip (Lubinus)/Lubinus	171	0.8	1987–
Müller Type/Müller Type	165	0.7	1987–
Spectron/SP Hip (Lubinus)	162	0.7	1987–
Modular Hip System/Bio-Fit	143	0.6	1992–
Biomet Watson Farrar/LMT Biomet	113	0.5	1989–1991
European cup system/LMT Biomet	73	0.3	1987–1991
Müller THP/Müller Type V	65	0.3	1988–1989
Scan-Hip/Scan-Hip	57	0.3	1987–1992
Müller Type/Müller Type V	51	0.2	1987–1988
Spectron/Spectron	41	0.2	1988–
Müller Style/Müller Style	30	0.1	1987–1989
Spectron/Müller Type	30	0.1	1987–1992
Original M.E. Müller/Original M.E. Müller	30	0.1	1987–1990
Others: 65 different combinations (1–27)	188	0.8	
All cemented combinations	23250	100	
2. Uncemented			
Corail/Corail-Atoll	1459	38.9	1988–
Gemini/Profile	328	8.8	1991–
European Cup System/LMT Biomet	243	6.5	1988–1991
Endler/Zweimüller	242	6.5	1987–1991
LMT Biomet/LMT Biomet	238	6.4	1987–1991
Ti-Fit/Bio-Fit	173	4.6	1987–1991
Harris-Galante/Harris-Galante	155	4.1	1987–
Coxa/Femora	153	4.1	1988–1992
Aesculap Parhofer/Aesculap Parhofer	150	4.0	1987–
Tri-lock Plus/Profile	79	2.1	1988–1992
Landos/Zweimüller	79	2.1	1989–
PCA/PCA	52	1.4	1987–
Opti-Fix/Ti-Fit	52	1.4	1990–
Endler/Landos	49	1.3	1987–1989
Ti-Fit/Ti-Fit	46	1.2	1989–1992
ABG/ABG	39	1.0	1992–
LINK Cementless screw in cup/ LINK Rippensystem	37	1.0	1988–1992
Ceraver/Bio-Fit	32	0.9	1987–1989
Others: 36 different combinations (1–24)	140	3.7	
All uncemented combinations	3746	100	
3. Hybrids			
Titan/Corail-Atoll	421	32.8	1988–
Endler/Landos	335	26.1	1987–1992
SP Hip (Lubinus)/SP Hip (Lubinus)	98	7.6	1987–1992
Gemini/Charnley	73	5.7	1991–
Ti-Fit/Bio-Fit	51	4.0	1987–1992
Coxa/Charnley	39	3.0	1988–1991
LMT Biomet/LMT Biomet	35	2.7	1987–1990
Others: 50 different combinations (1–20)	233	18.1	
All hybrid combinations	1285	100	

at 3 years for the Boneloc group, were 7% and 8%, respectively (Figure 2, Table 3). Thus 83 additional revisions would be necessary in 5 years in the low-viscosity cement group and 82 additional revisions in 3 years in the Boneloc group (Table 4). The total extra costs of these revisions during a 5- and 3-year period, respectively, amount to 1.3 million USD in each group (Table 4).

Discussion

In view of the number of hip arthroplasties performed, many different types of implants have been used. Moreover, most of them have been applied in only a few cases for a short time. This precludes proper evaluation of their survivorship and the economic consequences of this practice. The costs of orthopedic implants and of the equipment related to their use represent a major contribution to the increase in the average hospital cost for THR (Barber and Healy 1993, Clark 1994). Thus the practice of introducing a new implant system in Norway has been expensive. The surgeons now seem to be aware of the problem and fewer implants (trade names) are currently applied. Nevertheless, more consideration should be given to the cost/benefit relationship during the development and assessment of any new technology, compared to the established one. To make economic evaluations, it is essential that valid statistical data on the survivorship of the different types of implants are collected. In the absence of prospective randomized studies of the various implant systems, prospective multi-center registration of these operations might function as a continuous quality control. The analyses made in this article confirm the additional economic benefits of this registration.

The survival time was defined as the time until the first revision, irrespective of the reason for the revision. As our article addresses the economic consequences of the differences observed, the reasons for

Table 2. Age, sex and preoperative diagnosis in percentage in the 6 groups

	n	Age < 70 yr	Men	Coxarthrosis
Charnley/Charnley, reference	4970	45.4	26.0	55.8
All other primary THR	24027	54.1	31.6	70.1
1) Ti-Fit/Bio-Fit, uncemented	173	99.4	36.4	30.1
2) Coxa/Femora, uncemented	153	97.4	35.3	38.6
3) THR with low-viscosity cement	1807	39.2	30.8	80.4
4) THR with Boneloc cement	1250	38.6	27.8	79.6

Table 3. Estimated probability of revisions at 3, 4 and 5 years

		Remain at risk (n)			Revi-	Cumulative probability of revision (%)		
Acetabulum– Femur	n	3 yrs	4 yrs	5 yrs	sions	3 yrs	4 yrs	5 yrs
Charnley/Charnley, reference	4970	2357	1504	710	72	1.5 (1.1–1.8)	1.9 (1.4–2.4)	2.2 (1.7–2.8)
All other primary THR	24027	11813	7951	3998	656	2.6 (2.3–2.8)	3.6 (3.3–3.9)	4.4 (4.1–4.8)
1) Ti-Fit/Bio-Fit, uncemented	173	143	134	81	53	16.2 (10.7–21.7)	20.9 (14.8–27.0)	26.2 (19.5–32.8)
2) Coxa/Femora, uncemented	153	105	78	39	26	14.6 (9.0–20.2)	16.5 (10.4–22.6)	–
3) THR, low-viscosity cement	1807	856	535	292	64	3.0 (2.1–3.9)	5.5 (4.1–7.0)	6.7 (4.9–8.4)
4) THR, Boneloc cement	1250	12	0	0	45	7.6 (5.0–10.3)	–	–

All revisions included.

Table 4. The difference in the estimated number of additional revisions compared to the reference arthroplasty and the extra costs related to arthroplasties with inferior results

	n	Estimated revisions per 1000 primary THR [a] Unadjusted	Adjusted [b]	Additionalrevisions compared to the reference [a]	Extra costs a year USD (million)
Reference group	4970	22.4	22.4	–	–
All other primary THR	24027	44.5	44.6	533	1.71
1) Ti-Fit/Bio-Fit, uncemented	173	261.8	247.4	39	0.12
2) Coxa/Femora, uncemented	153	164.7 [a]	159.1 [a]	21 [a]	0.08
3) THR with low-viscosity cement	1807	66.5	68.4	83	0.27
4) THR with Boneloc cement	1250	76.5 [a]	80.1 [a]	82 [a]	0.44
Historical data					
Christiansen	6500	150 [c]		829	2.65
Wagner	2200	360 [c]		743	2.38

[a] In 5 years except for the Coxa/Femora combination (4 years) and the cemented THR with Boneloc cement (3 years).
[b] Adjusted for differences in age, gender and diagnosis compared to the reference group.
[c] Survival data from Sweden and Australia (Ahnfelt et al. 1990, Howie et al. 1990).

these revisions are of less importance here, but are given in other publications (Espehaug et al. 1995, Havelin et al. 1995).

In estimating the economic impact of the revisions, we chose to focus on the expected direct costs for reasons of simplicity, i.e., the actual cost of the intervention. The Norwegian DRG-data fail to register complications and comorbidity, and they do not account for longer operation time or larger expenses in terms of consumable items used as compared to a primary THR (Dreghorn and Hamblen 1989). Neither the evaluations preoperatively nor the postoperative follow-up are included. Thus they refer to the average hospital cost of an uncomplicated primary THR. According to Lavernia et al. (1995), revision hip surgery is not comparable to other arthroplasty cases. They estimated the average total charges for a revision total hip replacement in their hospital in Miami to be 30,000 USD or 1.5 times that for the primary case. An average direct revision-cost of 16,000 USD in Norway therefore seems to be a usable although conservative approximation. The exact cost in each case depends on the revision procedure and the revision implants chosen.

Based on the survival data presented, a total of 107 additional revisions had to be made each year in Nor-

Figure 1 (Right). Cumulative revision rates (percent; all indications) and 95 percent confidence intervals, according to Kaplan-Meier, for the reference group (Charnley with high-viscosity antibiotic-containing cement) vs. all other primary THR.

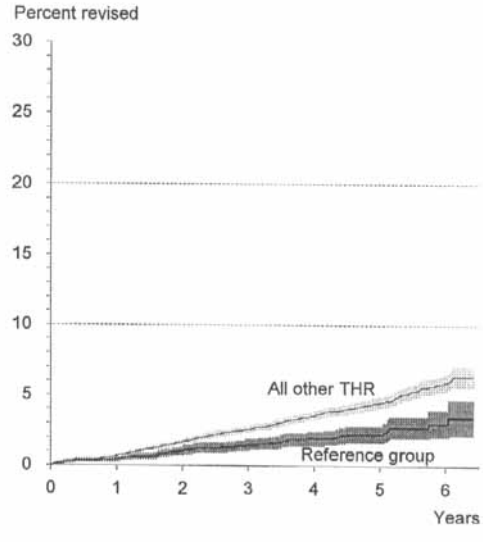
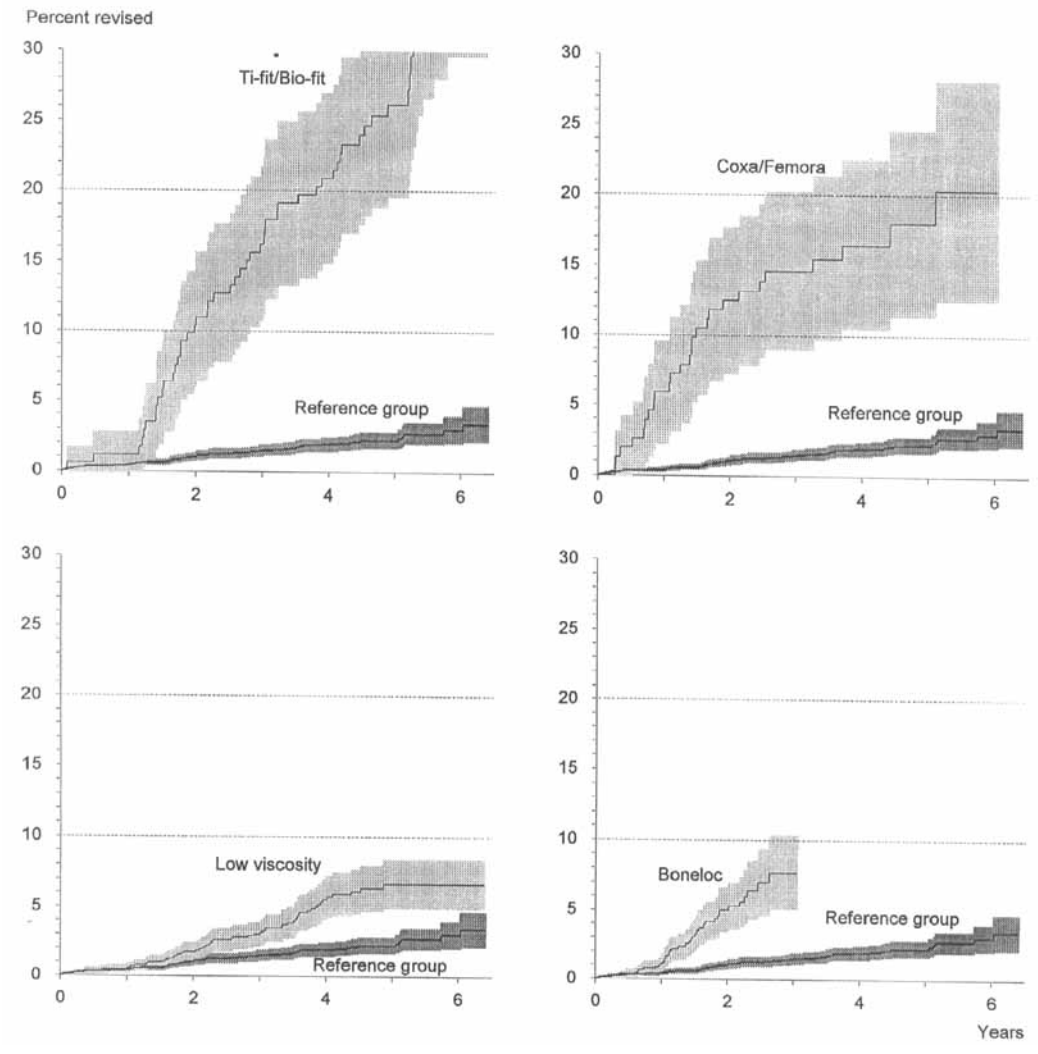


Figure 2 (Below). Cumulative revision rates (percent; all indications) and 95 percent confidence intervals, according to Kaplan-Meier for the reference group (Charnley with high-viscosity antibiotic-containing cement) vs. the uncemented Ti-Fit/Bio-Fit combination, the uncemented Coxa/Femora combination, THR with low-viscosity cement and THR with Boneloc cement, respectively.



way because of implant combinations used with results inferior to the reference arthroplasty. Thus the extra costs related to these revisions have been 1.7 million USD a year. It should be emphasized, however, that this group with inferior overall results also contains implants with results equal to and even superior to the chosen reference arthroplasty (Espehaug et al. 1995, Havelin et al. 1995). If these had not been included in the analyzed group, obviously the differences would have been even larger. We considered the Charnley arthroplasty to be an appropriate reference as this is the most commonly applied prosthesis in primary THR in Norway, with wide applicability, and it has documented good, although not the best, short- and long-term results.

In the quality control of prostheses there is no substitute for long-term observational or—preferably—randomized studies. The first Christiansen total hip arthroplasties (Francobal, France) in Norway were performed in 1970 and the preliminary clinical results (median 6 to 12 months follow-up) were considered good (Sundal et al. 1974). Despite poor documentation of clinical results, at least 6,500 primary THR with the Christiansen prosthesis were performed in Norway before its high rate of aseptic loosening was recognized in the early eighties (Josefsson et al. 1981, Sudmann et al. 1983). Based on this number and an observed revision rate of about 15% at 5 years (Ahnfelt et al. 1990), the direct extra costs for the Norwegian health care system were at least 2.7 million USD per year (Table 4). The total direct revision costs of the Christiansen prosthesis in a 10-year period with an observed revision rate of 37% (Ahnfelt et al. 1990) have been close to 40 million USD.

Moreover, the early results of cemented and uncemented double-cup resurfacing THR were encouraging (Steinberg 1982, Amstutz et al. 1986). This arthroplasty was introduced in Norway in the late seventies, but because of still poorer results Freeman and Bradley (1983) abandoned it 4–5 years later. An estimated number of 2,200 Wagner double-cup prostheses (Aesculap-Werke, Germany) had then been implanted in Norway, and from September 1987 to January 1994, 304 of these prostheses were revised. With an observed revision rate of about 34% at 5 years (Ahnfelt et al. 1990, Howie et al. 1990), the direct extra costs have been about 2.4 million USD annually, compared to the reference arthroplasty (Table 4). The total revision costs with an observed revision rate of 72% (Ahnfelt et al. 1990) have been about 25 million USD in the first 10 years postoperatively.

The inferior results of the uncemented Ti-Fit/Bio-Fit combination have been published earlier (Havelin et al. 1995). The Bio-Fit component was introduced in Norway before the Register was established, was freely available and was applied in about 1,000 THR all together (Havelin et al. 1995). Compared to these 3 examples, the production of the Femora prosthesis was stopped after a report from the Norwegian Arthroplasty Register in 1991 (Havelin et al. 1991). Only 153 of the Coxa/Femora combination had then been reported to have been used in Norway.

The effect of cement type on prosthesis survival in Norway has been reported by Havelin et al. (1995). After only 3 years of prospective registering, the inferior results of the Boneloc cement have been documented and its use has been abandoned in Norway.

Although hip-replacement surgery has a significant economic impact on the health care system, the benefits of THR offset the direct and indirect costs of this treatment (Cushner and Friedman 1988, Kristiansen 1990, Boettcher 1992). Valid economic evaluations of new technology, nevertheless, ought to be performed in order to justify decisions in allocating scarce resources. The former Christiansen and Wagner arthroplasties and the examples chosen here confirm that prospective registration and follow-up are necessary, and superior results must be documented before full-scale adoption of new implant technology can be recommended. The numbers of implants and implant combinations should be reduced and the clinical superiority in randomized trials should be a requirement before the marketing of new implants.

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