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Abstract

In this study we report the results of thumb carpometacarpal (CMC) joint replacements in the Norwegian population over a 17-year period. In total, 479 primary replacements performed from 1994 to 2011 were identified in the Norwegian Arthroplasty Register. Implant survival and risk of revision were analyzed using Cox regression analyses. Four different implant designs were compared and time trends were analyzed. The overall 5 and 10 year survivals were 91% and 90%, respectively. The newer metal total arthroplasties did not outperform the older silicone and mono-block implants. At 5 years, the implant survival ranged from 90% to 94% for the different implant brands. Gender, age, and diagnosis did not influence the risk of revision. The incidence of thumb CMC joint replacement did not change during the study period. Despite relatively satisfactory implant survivorship in our register study, current evidence does not support widespread implementation of thumb CMC replacements.

Keywords

Thumb CMC joint replacement, register study, Swanson Silastic, Elektra, Swanson titanium basal thumb, Motec

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Introduction

Postmenopausal women commonly suffer symptomatic thumb CMC joint osteoarthritis (Raven et al., 2007). More than 10% of the female population between age 45 and 70 years have symptoms at the thumb CMC joint (Armstrong et al., 1994). Several studies have compared the results of different surgical treatment options using a variety of methods and implants (Hartigan et al., 2001; Lovell et al., 1999; Raven et al., 2007; Schroder et al., 2002; Tagil and Kopylov, 2002). Lovell et al. compared the results after Swanson Silastic and sling excision arthroplasties. They concluded that trapeziectomy combined with Swanson Silastic implant had better results in the short term if there were no peri-operative complications. Recently, many newer thumb CMC joint replacements have been reported to have high failure rates (Hernandez-Cortez et al., 2011; Klahn et al., 2012). The literature on the long-term outcome of

thumb CMC replacements is scarce. The Norwegian Arthroplasty Register (NAR) has registered replacements in the thumb CMC since 1994. The aim of this study was to report on the results of total thumb CMC replacements in the NAR.

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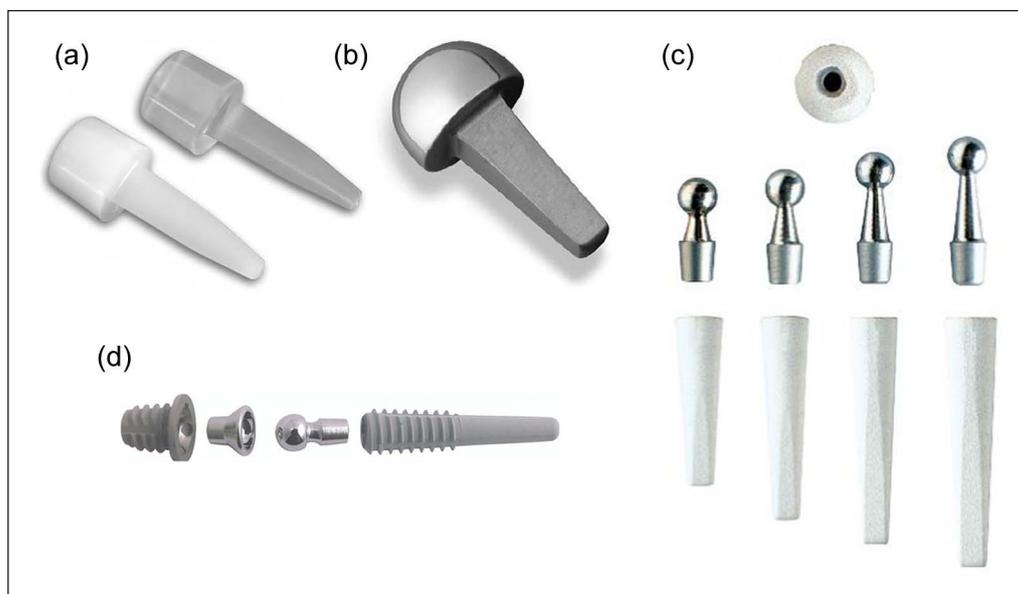


Figure 1. The implants (a) Silastic Trapezium. (b) Swanson Titanium Basal Thumb. (c) Elektra. (d) Motec.

Methods

Data for the present study were obtained from the NAR. The NAR was established in 1987 as a nationwide hip arthroplasty register. In 1994, the register was expanded to include all other joint replacements (Havelin, 1999). The NAR receives information on primary operations and any revisions directly from orthopaedic and hand surgeons. Patient-related outcome measures and radiographic findings are not reported to the register.

From 1994 to 2011, 515 primary thumb CMC arthroplasties were registered in 432 patients. Thirty-six cases were excluded from the analysis: 12 because they had been operated on with rare implants (five were custom made and seven were Avanta arthroplasties); 16 due to missing information about the brand of implant; and eight due to missing (five) or rare diagnoses (three).

Four different brands of CMC implants were included in the analysis: Silastic Trapezium (Swanson Silastic) hemiarthroplasty; Swanson Titanium Basal Thumb (Swanson Titanium) hemiarthroplasty; Elektra total arthroplasty; and Motec total arthroplasty (Figure 1).

The Swanson Silastic (Wright Medical Group Company, Arlington, Virginia, USA) hemiarthroplasty is a flexible, one-piece intramedullary stemmed implant. It is made of silicone elastomer and is available in five sizes. The stem of the implant fits into the intramedullary canal of the first metacarpal and has a triangular cross-section. The head of the implant has a slightly concave surface (Figure 1a).

The Swanson Titanium (Wright Medical Group Company) hemiarthroplasty is a one-piece intramedullary stemmed implant made of pure titanium (ASTM F67). The implant stem fits in the intramedullary canal of the first metacarpal and the convex head into a concave surface made by the surgeon on the distal surface of the trapezium (Figure 1b).

The Elektra (Fixano, Peronnas, France) is a modular unconstrained uncemented ball-and-socket total arthroplasty. The metacarpal implant is a hydroxyapatite-coated titanium stem available in four sizes. The chrome-cobalt head and neck component is available in four sizes. The trapezium component is a chrome-cobalt cone-shaped cup with a threaded hydroxyapatite coated surface, available in one size only (Figure 1c).

The Motec (Swemac AB, Linköping, Sweden) is an unconstrained uncemented ball-and-socket total arthroplasty. The metacarpal implant is modular with a threaded, slightly conical intramedullary component and four head sizes. The trapezium component is also modular, threaded, and comes with one socket size only. The articulation is metal-on-metal cobalt chrome-molybdenum alloy treated with chromium nitride, and the stems are made of titanium alloy, blasted and coated with Bonit (Figure 1d).

Patient diagnoses were stratified in two groups: inflammatory arthritis (IA) (108, 22.5%) and osteoarthritis (OA) (371, 77.5%). In the IA group, 99 cases had rheumatoid arthritis, eight had psoriatic arthritis, and one had lupus.

Data analysis

Data from each surgery were filled in at the completion of the operation. The data from primary and revision surgeries were linked through each patient's unique identification number. The register is not compulsory, but completeness of data from primary and revision operations are regularly checked against compulsory registers (see Discussion).

Observation time was the time from the primary operation until revision, until the end of study or patient death. Date of death for deceased patients was obtained from Statistics Norway (<http://www.ssb.no/english/>). Revision was defined as the exchange or removal of the whole or part of the prosthesis. Median follow-up (observation) time was calculated using the reverse Kaplan-Meier method.

Statistics

We used the Student's *t*-test and analysis of variance (ANOVA) to compare continuous variables. For comparison of categorical variables, Chi-square tests were used. All *p* values were two-tailed, and significance was set to 0.05. In the Kaplan-Meier survival curves, the endpoint was revision for any reason. Survival curves were presented with log-transformed 95% confidence intervals (CIs) and a lower limit adjustment for the number of patients at risk. Survival curves were stopped at 10 years or when only five cases remained, whichever came first.

Differences in revision rates between groups were tested using the log-rank test. Cox multiple regression analyses were used to study relative risks (RR, hazard rate ratios) of revision according to prosthesis type, diagnosis, age, and sex. Poisson regression analysis was used to analyze trends in the incidence of wrist replacement procedures. These analyses were performed based on yearly population rates for the Norwegian population, obtained from Statistics Norway. The *p* values given in the text were derived from these Poisson analyses. Analyses were done using IBM SPSS version 19 and program R (version 2.13.0), a free software and official part of the GNU project (<http://www.R-project.org>).

Results

The rate of implanting the thumb CMC joint arthroplasties did not change during the study period ($p = 0.55$) (Figure 2). The number of arthroplasties performed for IA decreased ($p = 0.003$), whereas operations for OA increased ($p < 0.001$).

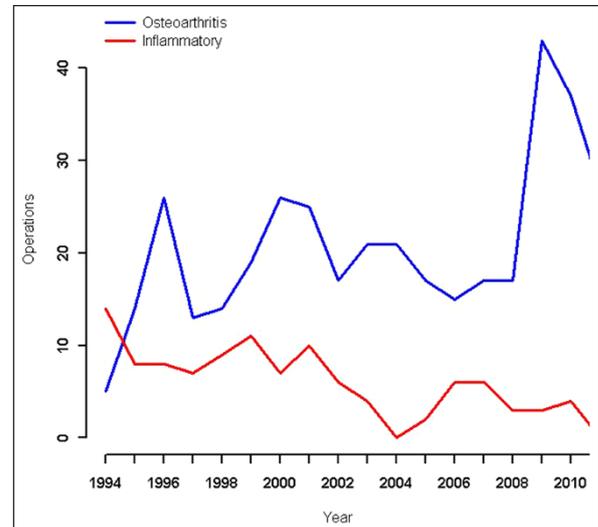


Figure 2. Operations/year per diagnosis.

Types of prostheses

The Swanson Silastic and Titanium were used in both diagnosis groups. The Motec and Elektra implants were used in OA patients only (Table 1). Median follow-up time was longer for the Swanson Silastic (7.9 year) and Swanson Titanium (11.7 years) than for the Elektra (2.0 years) and Motec (1.9 years) implants ($p < 0.001$). Median follow-up for all prostheses was 7.4 years.

Revision and survival

Forty-two (8.8%) of the 479 CMC implants were revised (Table 1). Mean time until first revision was 7.0 (95% CI 6.6–7.5) years. Sixteen hospitals in Norway performed thumb CMC arthroplasty surgery during the study period. The number of arthroplasties performed at each hospital during the observation period ranged from one to 70 prostheses.

When interposition implants (Swanson Silastic and Titanium) were compared with the total arthroplasties (Elektra and Motec), no statistically significant difference in prosthesis survival was found at 5 years ($p = 0.70$) (Table 2). There were no differences in survival between patients with IA and OA ($p = 0.55$). The overall 5 and 10 year survival rates were 91% (95% CI 88–93) and 90% (95% CI 87–93), respectively. There were no statistically significant differences in survivorship between the implant brands ($p = 0.60$) (Table 2, Figure 3). The implant with the highest number of cases and longest follow-up time (Swanson Silastic) had 5 and 10 year survival rates of 90% and 89%, respectively.

Table 1. Demographic characteristics.

Prosthesis	Number of primary prostheses	Females, %	Mean age (range), years	OA	IA	Number of hospitals	Average operations per hospital (range)	Number of revisions	Median follow-up, years
Silastic trapezium	326	89	64 [21-86]	239	97	14	23 [2-185]	33	7.9
Swanson titanium basal	71	82	63 [38-82]	60	11	4	18 [1-52]	4	11.7
Elektra	29	72	62 [50-72]	29	0	1	29 [29-29]	2	2.0
Motec	53	60	63 [51-85]	53	0	3	18 [4-38]	3	1.9
Total	479	84	64 [21-86]	371	108	16	30 [1-202]	42	7.4

Table 2. Five and 10 year survival and RRs from an unadjusted Cox-regression model on CMC 1 arthroplasties reported to the NAR (1994-2011).

Prosthesis brand (number of implants)	5 year survival (95% CI), %	10 year survival (95% CI), %	RR (95% CI)	p value
Swanson Silastic (326)	90 [86-93]	89 [85-93]	1**	0.60
Swanson Titanium (71)	94 [89-100]	94 [89-100]	0.50 [0.18-1.42]	0.20
Elektra (29)	90 [75-100]	-	0.80 [0.19-3.35]	0.76
Motec (53)	91 [81-100]*	-	0.73 [0.22-2.38]	0.60
All prostheses (479)	91 [88-93]	90 [87-93]		

* Number represents 3 year survival because of insufficient follow-up.

** The Swanson Silastic was used as the reference prostheses with which the others were compared.

Dislocation of the implants ($n = 20$) and pain ($n = 23$) (more than one reason for revision was possible in each case) were the most frequent reasons for revision (Table 3). Among the 42 patients who underwent revision, implants were removed in 19 cases. In the remaining cases, the whole or parts of the implant were exchanged.

Risk factors for revision

Gender (RR females vs males: 1.0 [95% CI 0.4-2.5]), age (RR for each 10 years' increase: 1.0 [95% CI 0.7-1.3]), and diagnosis (RR IA vs OA: 0.6 [95% CI 0.3-1.4]) did not influence the rate of revision. The revision rate in the five hospitals performing more than 30 procedures was not statistically different to the revision rate in the 11 hospitals that had performed fewer than 30 procedures ($p = 0.32$).

Discussion

Prosthesis type and survival

In this study, the 5 year survival for all implants was 91%, and the 10 year survival was 90%. The 5 year survival for Swanson Silastic was 90%, and the 10 year survival was 89%. Several papers have

described high rates of dislocation, wear, and osteolysis. However, radiological complications did not directly correspond to poor clinical results and reoperation rates [Carter et al., 1986; Gudmundsson et al., 1985; Sollerman et al., 1988]. The Swanson Silastic implant may act merely as a spacer and mould for the formation of fibrous tissue and not as a joint prosthesis, as emphasized by Swanson [1973].

In a study of the Swanson Silastic by van Cappelle et al. (2001), the subjective clinical result was good in only 60% of cases after a mean follow-up of 13.8 years, but only 27% had been revised. The survival rates in our study do not necessarily reflect the clinical outcome, as a significant proportion of patients that were not revised probably had poor results of the surgery.

Hay et al. (1988) found that failure of the Swanson Silastic implant (implant fracture and dislocation) occurred with increasing frequency at increasing follow-up. These findings were asymptomatic in the majority of cases.

Creighton et al. (1991) evaluated 151 Swanson Silastic prosthesis at an average of 51 months after surgery. Patient satisfaction reporting good results in 84% did not correlate with the scaphoid or metacarpal radiographic changes.

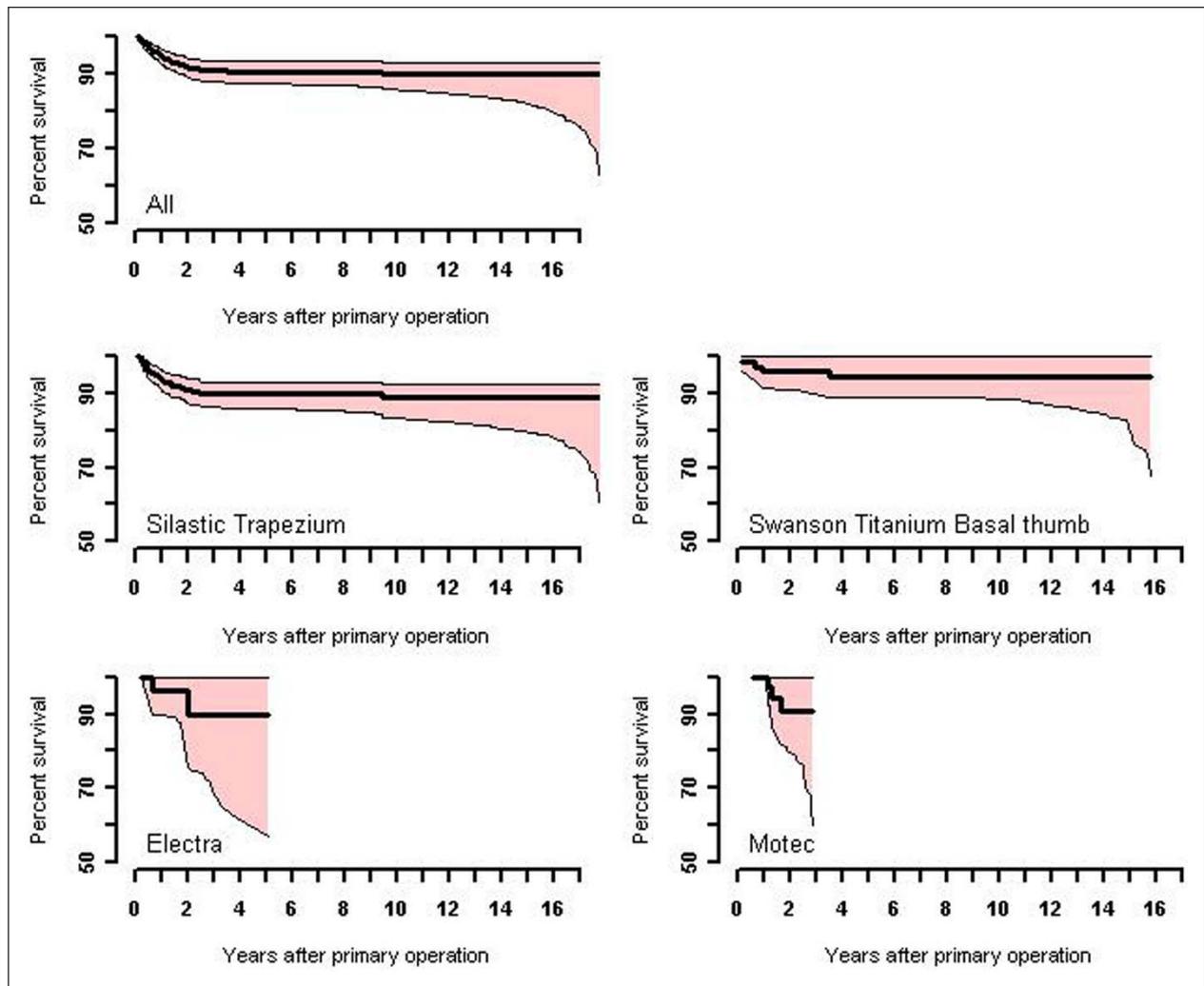


Figure 3. Kaplan-Meier Survival.

Table 3. Reasons for revisions (more than one reason for each case is possible).

Reason for revision operation	Swanson Silastic	Swanson Titanium	Elektra	Motec	Total
Loosening	1	1	1	3	6
Dislocation	18	1	1		20
Instability	5		1		6
Pain	19	3		1	23
Total number of revisions	33	4	2	3	42

In the present study, the Swanson Titanium had a survival of 94% after 5 and 10 years. In a study by Pritchett and Habryl (2012), the survival of the implant was 94% at a mean follow-up of 6 years. Condamine et al. (2007) reported no revisions after a mean follow-up of 4.4 years.

In our study, the 5 year survival for the Elektra was 90% and the 3 year survival for the Motec was

91%. These results are encouraging compared with other reports on uncemented ball-and-socket designs (Hernandez-Cortez et al., 2011; Klahn et al., 2012). Wachtl et al. (1998) reported a 59% survival rate with the Ledoux implant in 45 patients after only 16 months. Regnard (the inventor of the prosthesis) reported significantly better results with the Elektra prosthesis (Regnard, 2006). He

found 15% implant failure of the press-fit screw-in trapezium component in the first 100 patients after 54 months. The results of these studies cannot be compared directly with our results because failure in our study is equivalent to implant revision, whereas failure in Wachtl and Regard's papers also included clinical and radiological failure. Not surprisingly, the failure rate in the latter papers were therefore higher.

Risk factors for revision

Gender, age, or diagnosis did not significantly affect the outcome in this study. This is in accordance with the results of studies on ankle prostheses (Doets et al., 2006). In a study on survivorship of wrist prostheses, we found that women had a 3 fold risk for revision (Krukhaug et al., 2011). The inability to show differences due to factors other than gender in the present study may be caused by a lack of power (type 2 error). As far as we know, there are no reports on risk factors for revision of thumb CMC prostheses in the literature.

The findings of the present study must be interpreted with caution due to a relatively low number of cases, hospitals, and surgeons. Factors such as surgeon, follow-up routines, and revision traditions may influence the results. Data on the Silastic implant are quite robust with 326 cases, long follow-up, and 14 different hospitals represented. The external validity of the results of the Silastic is therefore probably high.

There were major differences in patient demographics and inclusion periods among the different implants. In the Elektra and Motec groups the patients only had OA, whereas in the Swanson Silastic and Titanium groups, patients had both IA and OA. Follow-up was longer in the Swanson Silastic and Titanium groups. Mean ages and number of women were significantly different between the hemi- and total-arthroplasty groups (Table 1). For these reasons, our results on differences between prosthesis types should be interpreted with caution.

Time trends

The reduction in patients treated for IA and concomitant increase in patients with OA are consistent with a trend in recent years also found for other joint replacements (da Silva et al., 2003; Fevang et al., 2007).

Completeness of data

The reporting of arthroplasty procedures to the NAR is not compulsory, but all hospitals and surgeons

participate in the data collection. The completeness of registration in the NAR was recently evaluated comparing it to the mandatory reporting of administrative data to the Norwegian Patient Register (NPR). In total, 97% of hip replacements and 99% of knee replacements were included (Espehaug et al., 2006). The coding system in the NPR does not separate thumb CMC joint prostheses from other radiocarpal or carpal arthroplasties. Thus, the NPR data cannot be used to measure NAR coverage of specific carpal procedures. The completeness for thumb CMC replacements in the NAR is therefore unknown. Under-reporting would severely affect the results only if it is unevenly distributed among the different prostheses brands or if revisions were reported less than primary procedures. This may be more likely for implants that are removed with no implant replaced, as there would be no new arthroplasty.

The results of thumb CMC arthroplasty may not be substantially better than with arthrodesis, trapeziectomy, or trapeziectomy with tendon interposition (Vermeulen et al., 2011). Vermeulen also found that total joint prosthesis might have better short-term results compared to trapeziectomy with ligament reconstruction and tendon interposition. In the study by Tagil et al. (2002), patients were randomized to receive a Swanson Silastic implant or tendon interposition arthroplasty using a strip of the abductor pollicis longus tendon after excision of the trapezium. They concluded that both methods gave good, but not complete, pain relief and neither produced better results than the other in the short term. Raven et al. (2007) compared three surgical procedures: resection arthroplasty (the joint surfaces of the metacarpal and trapezium were resected); trapeziectomy with tendon interposition; and trapezio-metacarpal arthrodesis. They found no differences among the groups.

In conclusion, thumb CMC replacements probably do not require revision very often, although there is an appreciable risk that implant removal with no re-implantation would not be reported in the NAR, which may significantly reduce the reported revision rates. It is widely reported that many patients may have poor outcomes without revision. The data cannot resolve the debate on whether or not to use thumb CMC joint replacements and does not provide data to support their use.

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Conflict of interests

The author declares that there is no conflict of interest.

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