The innovation trap: modular neck in total hip arthroplasty

Samo K. Fokter,[1] Vesna Levašič,[2] Simon Kovač[2]

[1] *Department of Orthopaedics, Division of Surgery, University Medical Centre Maribor*

[2] *Valdoltra Orthopaedic Hospital, Ankaran, Slovenia*

Correspondence:
Samo K. Fokter,
e: samo.fokter@guest.arnes.si

Key words:
hip arthroplasty; modular neck fracture; titanium-alloy; complications of arthroplasty; arthroplasty registries

Cite as:
Zdrav Vestn. 2017; 86: 115–26.

Received: 1. 9. 2016
Accepted: 16. 2. 2017

Abstract

Background: Innovations play a key role in the success of orthopeadic surgery. However, even minor modifications in the established concepts and designs may result in disasters. We face an endemic of modular femoral neck failures occurring in fully modular total hip arthroplasty (24 of approx.4000 implanted), which has been popular in Slovenia for the last 20 years. Its most unfortunate consequences challenge us to seriously address this problem. The aim of this report was to analyse the volume, and the causes of the problem, on the one hand, and to propose possible solutions, on the other.

Methods: The literature was searched for problems associated with Profemur Z fully-modular femoral stem, made of titanium alloy (Ti6Al4V)or earlier versions with the same taper-cone design.The available hip arthroplasty registries were used to determine failure rates associated with the above mentioned design. The mechanisms of failure were studied in order to get in-depth understanding of this hip reconstruction device.

Results: Since 2010, several case reports on catastrophic modular femoral neck fractures of Profemur Z have been published. In Slovenia the first case was described in 2012. The first two large series with modular femoral neck fractures were reported in 2016. The Australian Joint Replacement Registry was the first to discover elevated revision rates due to fractures of this hip reconstruction system. In 2010, the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP) received the first 2 reports on Profemur Z modular neck complications, submitted by foreign institutions. The first Slovenian report dates back to 2012, and altogether 7 reports from Slovene hospitals had been received by December 2016. Corrosion at the neck-taper interface, where two equal or different materials are subject to constant wear in the presence of body fluids, was assumed to be responsible for the unacceptably high failure rates.

Conclusions: Manufacturers are responsible for producing and marketing safe devices. However, orthopaedic surgeons should carefully monitor all innovations for any adverse effects. JAZMP took appropriate measures only after receiving urgent field safety corrective notice from the manufacturer in 2015, stating that all lots of long modular necks made from cobalt-chromium alloy should be withdrawn. It should be noted here that the regulatory agency of the Republic of Slovenia was not receiving vigilance reports as appropriate, and was thus unaware of the dimension of this problem. A national arthroplasty registry would have most probably alerted the orthopaedic community to this questionable innovation earlier. Regulatory bodies should set up such a registry for the benefit of our patients as soon as possible.

Cite as: Zdrav Vestn. 2017; 86: 115–26.

Introduction

The primary goals of total hip arthroplasty (THA) include: pain reduction, range of motion improvement, and stability provision. Currently, we also aim to reach equal limb length and to restore the center of rotation. This goal is technically easier to achieve by using endoprostheses with modular necks, where the femoral component is comprised of two parts: the stem and the neck. The advantage of this design is that it allows the orthopaedic surgeon to choose intraoperatively the most suitable neck for the patient, independently of his or her stem size. In this manner, femoral offset and neck orientation can be adjusted more precisely. Important gender-specific anatomic differences exist regarding the femoral diameter, neck length and angle between the diaphysis and the neck (CCD angle) (1,2). Improper biomechanical restoration after total hip arthroplasty could lead to limping and faster wear of the artificial joint. It has been shown that primary anatomic hip conditions could be restored in 50 % of patients using 8 versions of modular femoral necks (3).

Thanks to the above described benefits, the popularity of modular femoral stems increased substantially over the last 30 years and they can now be found in the portfolio of practically all global producers of hip implants.

In the nineties, early modular femoral stems GSP and later on, Anca-Fit (Cremascoli Ortho Company, Milan, Italy) with an oval Morse cone, which requires no additional screwing at coupling, were increasingly used by the orthopaedic surgeons in Slovenia. The effective design provides good torsional stability and simple intraoperative use (4). The US Wright Medical Technology, Arlington, Tennessee, bought the Italian company in 2000. The company changed the design of the femoral stem but kept the original taper-cone and the material the GSP was made of, i.e. the titanium alloy (Ti6Al4V). The new product Profemur Z, was placed on the market in 2002. The longer variant (Profemur Z Revision), suitable for revision surgery with metaphyseal-diaphyseal femoral bone fixation, was introduced later on. Unlike some other models (Profemur E and Profemur L), both aforementioned models were available on the Slovenian market.

The taper-cone coupling between the femoral stem and modular neck is not ailment-free. It is subject to mechanically supported crevice corrosion, which is a combination of fretting corrosion and crevice corrosion, and may lead to failure of the modular neck (5). The first case report on the Profemur Z modular femoral neck failure was published in 2010, and the first case of the GSP modular femoral neck failure in Slovenia was reported in 2012 (6,7). A doubled revision rate of fully modular THA due to dislocation and aseptic loosening was documented by the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) in 2010. After a 10-year follow-up, the rate of revisions due to prosthesis fracture was higher with modular designs than with conventional models (1.3 % vs. 0.8 %) (8). Such sudden fracture of the modular femoral neck represents a catastrophic failure of the previously normally functioning THA. Also, it represents a most stressful experience for the patient, as it usually necessitates a complete exchange of the femoral component of the prosthesis (Figs. 1 and 2).

The aim of this paper was to search the literature for information on prob-

Figure 1: A Profemur Z implant femoral stem after explantation at the revision total hip arthroplasty. The fractured modular neck with a ceramic femoral head still attached.

lems arising from the use of Profemur Z, both in Slovenia and worldwide, in the period 2010–2016, and to propose solutions for earlier detection of similar complications associated with the use of "innovative" orthopaedic devices .

Methods

Using the keywords »modular neck failure«, »GSP«, »Anca Fit« and »Profemur Z«, the PubMed, Scopus and Google Schoolar databases were searched for cases reported in the literature. From the collected articles, common characteristics of patients were retrieved, focusing on the causes of this treatment complication. We obtained information on potential complications of this fully modular primary total hip arthroplasty from all Slovenian hospitals.

We also reviewed the published reports of national arthroplasty registries with emphasis on the fully modular prosthesis design. We examined the data provided by the Valdoltra Orthopaedic Hospital Arthroplasty Registry and the Library of Implants of Valdoltra (9), as well as by the Public Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP). We collected data related to incidents with medical devices of the manufacturer Wright Medical (from 2014 MicroPort Orthopedics Inc., USA) in Slovenia.

In addition, we reviewed The Manufacturer and User Facility Device Experience (MAUDE) database of the Food and Drug Administration (FDA), U.S.A., for the period 2000–2016 using the keywords »Profemur« and »fracture« (10).

Results

Literature search

A total of 9 articles reporting modular neck fractures were found (6,7,11-17). In the first 8 articles, 13 patients (11 patients with Profemur Z and 2 patients with GSP,) with modular femoral neck fracture were described (Table 1). All the patients were males who experienced modular femoral neck fracture 4.4 years after the primary THA (mean range 2–12 years). Their average body mass index (BMI) was 31.6 kg/m^2 (range, 26–39.3 kg/m^2). In all the patients, a long modular neck was implanted.

Pour et al. described fracture of 7 necks in the group of 242 patients (277 hips) treated with fully modular Profemur E (170 endoprostheses) and Profemur Z (107 endoprostheses) THA in the period 2003–2009 with the average follow-up of 50 months (17). In the Profemur E group, revision surgery was necessary in 15 (9 %) hips because of aseptic loosening. In the Profemur Z group, revision was required in 6 (6 %) hips because of fracture of the modular neck. Interestingly, only one (0.6 %) hip was revised because of modular neck fracture in the Profemur E group.

Figure 2: A fractured modular femoral neck. The distal part is still in the female part of the Morse taper of the femoral stem.

All fractures occurred in long modular necks (17).

Registry reports

According to the 2013 annual report of the Australian arthroplasty registry (AOANJRR) the proportion of revisions of modular prostheses with the exchangeable neck compared to those with a single-piece (monoblock) femoral stem had been on a continuous increase over the previous 4 years. The cumulative percentage of revisions during the 10-year follow-up period was 6.4 % with monoblock stems and 10.8 % with modular stems. The Australian registry also found that the combination of a titanium-alloy stem and a cobalt-chromium alloy modular neck was associated with a higher revision rate than the combination of titanium-alloy femoral stem and a titanium-alloy modular neck (8).

In Europe, reports on fully modular stems are found in the arthroplasty registries of Italy, where they were initially manufactured by Cremascoli Ortho (Registries of Lombardy and Emilia Romagna), as well as in Great Britain, Finland, Lithuania, the Netherlands, Slovakia, France and Spain. On the initiative of Prof. Labek, the then Head of the European arthroplasty registry, the Croatian Institute for Public Health launched the project PARENT (PAtient REgistries iNiTiative) involving a statistical analysis of the data retrieved from the registries ROLP (Registro Ortopedico Protesico Lombardo) from Lombardy, Italy, Great Britain, Finland, Lithuania, Slovakia, France and Slovenia (Valdoltra). A total of 41,694 femoral stems with modular necks were analyzed. The results of the analysis were presented at the congress of the European Association of Orthopedics and Traumatology (EFORT) in Prague in 2015. The analysis did not confirm the conclusions of the Australian registry, except in Finland, which had the highest rate of revisions of modular femoral stems (i.e. 7.18 % at 12 years) and 8 implant fractures in 543 primary THAs.

In registry analyses it is particularly difficult to determine which part of the implant was broken, because most registries do not distinguish between these entities. The heading »implant fracture« therefore also encompasses breaks of the ceramic head of the older generation, which is a more frequent cause of the incident than a modular neck fracture.

The Valdoltra survey was presented at the Valdoltra Orthopaedic Hospital Research Day in 2014. In a total of 1,057 primary THAs using the Profemur Z modular femoral stems, 3 fractures of the modular neck occurred; all necks were made of a titanium alloy. The overall survival at 11.5 years, irrespective of the cause of the revision, was 94.5 % (± 3.1 % C.I.), which did not stand out compared with other types of primary THAs (18).

In 2010, JAZMP received 2 reports on the incident with the medical device Profemur long varus / valgus modular neck from abroad, whereas the first na-

tional report on the modular neck fracture was submitted in 2012. In 2013, two Slovenian hospitals reported on 3 modular neck fractures, in 2014, a report was received on the fracture of one modular neck, and in 2016, fractures of 2 modular necks made of cobalt-chromium alloy were reported. In August 2015, the authorized representative of the manufacturer (MicroPort Orthopedics BV, Netherlands) informed JAZMP of the initiation of the recall for the long modular neck made of cobalt-chromium alloy because of fracture risk. In 2015, JAZMP was notified that the medical device had been recalled. The fact that 2 vigilance cases were reported in 2016, clearly indicates that in 2015 the Slovenian distributor Mark Medical d.o.o., Sežana did not send the emergency recall notification issued by the manufacturer of the device to all hospitals in Slovenia, but only to those having the incriminated medical devices still in stock. At the request of JAZMP, in 2016, the distributor informed about the recall the rest of Slovenian hospitals.

Tabela 1: Objavljeni prikazi primerov zlomov izmenljivih vratov.

Author (year of publication)	Age (years)	Body mass index (kg/m^2)	Time to failure (years)	Size of femoral component	Neck length and orientation	Articulation
Wright et al. (2010)	49	39.3	4	4	Long, varus anteverted	MoM
Atwood et al. (2010)	30	29	2	NA	Long, straight	CoC
Wilson et al. (2010)	62	25.6	2	5	Long, retroverted	CoC
Dangles and Altstetter (2010)	63	NA (127,6 kg)	3.5	NA	Long, retroverted	MoM
Skendzel et al. (2010)	55	31.2	3,7	NA	Long, varus	NP
	67	34.6	3,4	NA	Long, varus	NP
Ellman and Levine (2013)	59	29.6	5	3	Long, varus	MoM
Vučajnk and Fokter (2012)	56	32	12	5 (GSP)	Long, straight	CoC
Fokter et al. (2016)	42	30	3.1	6 (GSP)	Long, straight	MoP
	54	33	2.3	6	Long, straight	CoC
	57	35	5.2	5	Long, straight	MoP
	37	34	6	8	Long, straight	CoC
	51	26	4.8	5	Long, straight	CoC

NA – not available; CoC – ceramic-on-ceramic; MoM – metal-on-metal; MoP – metal-on-polyethylene

Table 2: Patients with modular femoral neck fractures treated in Slovenia

Case	Gender	BMI (kg/m^2)	Time to revision years)	Acetabular component: manufacturer; model, diameter (mm), inlay	Femoral part: manufacturer; model, size	Neck: length, orientation, material	Head: diameter (mm), material, length in mm, (description)
1	M	30	3.1	CO; RCM 56, Poly	CO; GSP #6	Long, straight, Ti	28, CoCr, +3.5 (L)
2	M	33	2.3	WMT; EHS 54, Cer	WMT; Profemur Z #6	Long, varus, Ti	28, Cer, 0 (M)
3	M	35	5.2	WMT; EHS 54, Poly	WMT; Profemur Z #5	Long, varus, Ti	28, CoCr, 0 (M)
4	M	34	6	WMT, EHS 52, Cer	WMT; Profemur Z #8	Long, straight; Ti	28, Cer, 0 (M)
5	M	26	4.8	WMT; Procotyl L 52, Cer	WMT; Profemur Z #5	Long, straight, Ti	36, Cer, 0 (M)
6	F	39.4	7.8	WMT; EHS 50, Cer	WMT; Profemur Z #6	Long, straight; Ti	28, Cer, +3.5 (L)
7	M	30.3	4.5	Biomet; Eternity 54, Cer	WMT; Profemur Z-R #6	Short, straight, Ti	36, Cer, +3.5 (L)
8	M	33.8	2.8	ZIM; Allofit 52, X-Poly	WMT; Profemur Z #5	Long, varus, Ti	36, CoCr, 0 (M)
9	M	25.2	3.9	WMT; EHS 52, Cer	WMT; Profemur Z #6	Long, varus, Ti	28, Cer, -3.5 (S)
10	F	31.9	8.8	WMT; EHS 52, Cer	WMT; Profemur Z #3	Long, straight, Ti	28, Cer, +3.5 (L)
11	M	32	12	CO; AnCA Fit 56, Cer	CO; GSP #5	Long, straight, Ti	28, Cer, +3.5 (L)
12	F	29.3	3.3	WMT; Procotyl L 48, Cer	WMT Profemur Z #3	Long, straight, Ti	32, Cer, -3.5 (S)
13	M	32.1	6.0	WMT; EHS 56, Poly	WMT Profemur Z #4	Long, varus, Ti	28, Cer 0(M)
14	M	25.1	3.9	WMT Procotyl L 56, Poly	WMT Profemur Z #6	Long, varus, Ti	36, Cer +3.5(L)
15	M	29.2	5.9	WMT; EHS 56, Cer	WMT Profemur Z #3	Long, varus, Ti	28, Cer +3.5 (L)
16	M	33.2	4.8	WMT; EHS 56, Poly	WMT Profemur Z #7	Long, retroverted, Ti	28, Cer -3.5 (S)
17	M	30.7	3.1	WMT; Procotyl L 48, Cer	WMT Profemur Z #3	Long, varus CoCr	32, Cer 0 (M)
18	M	35.6	3.2	WMT; Procotyl L 58, Poly	WMT Profemur Z #4	Long, varus CoCr	36, Cer -3,5 (S)
19	M	26	2.0	WMT; Procotyl L 52, Poly	WMT Profemur Z #5	Long, varus, CoCr	32, Cer 0 (M)
20	M	31	5.1	WMT, Procotyl L 60, Cer	WMT Profemur Z #7	Dolgi, retroverted, Ti	36, Cer 0 (M)

Case	Gender	BMI (kg/m^2)	Time to revision years)	Acetabular component: manufacturer; model, diameter (mm), inlay	Femoral part: manufacturer; model, size	Neck: length, orientation, material	Head: diameter (mm), material, length in mm, (description)
21	M	31	6.9	WMT, Procotyl L 56, Poly	WMT Profemur Z #8	Long, varus, Ti	36, Cer +3.5 (L)
22	M	NA	NA	WMT, NA	WMT Profemur Z #NP	Long, NA, Ti	NA
23	M	NA	NA	WMT, NA	WMT Profemur Z #NP	Long, NA, Ti	NA
24	M	NA	NA	WMT, NA	WMT Profemur Z #NP	Long, NA, Ti	NA

BMI–body mass index; CO–Cremascoli Ortho; WMT–Wright Medical Technology; ZIM – Zimmer; CoCr – cobalt-chrome alloy; Cer – Ceramic; Poly – polyethylene; X-Poly – cross-linked polyethylene; Ti–titanium alloy; NA – not available.

FDA MAUDE base

The FDA MAUDE database for the voluntary reporting of adverse events by the U.S.A. professionals, received at least 41 reports on fractured THA modular necks during the period 2010–2016 (10).

Modular neck fractures in Slovenia

By the end of July 2016, a total of 24 modular femoral neck fractures occurring after THA had been reported in Slovenia: 9 were revised in the Celje General Hospital, 7 in the Maribor University Medical Center, 4 at the Ljubljana Department of Orthopedic Surgery, 3 in the Valdoltra Orthopaedic Hospital, and one in the Murska Sobota General Hospital. According to the representative who marketed modular femoral stems in Slovenia, 3,244 Profemur Z modular necks were delivered from 2006 to the end of marketing, in 2015; for the older versions (GSP and Anca Fit) data were no longer available. Assuming that all those Profemur Z modular necks have actually been implanted, the percentage of modular neck fractures is 0.68 % (22 fractures of the 3244 implanted prostheses). The figure is likely to represent the real rate of these events, because fractures of the Profemur Z modular neck, which had been on the Slovenian market since 2003, never occurred later than 9 years after the primary THA. According to the literature data, the majority of fractures occurred in males (21 out of 24 cases). Most patients were overweight, with the average BMI 31.1 (25.1 to 39.4) kg/m^2. In 23 cases, a long neck has been used; a short neck has been implanted only in one case. Most necks were made of the titanium alloy (21 modular necks) and only 3 necks were made of cobalt-chromium (CoCr) alloy. Detailed data on patients and implants are summarized in Table 2.

Discussion

The concept of interchangeable necks represents a useful solution for total hip arthroplasty in cases where anatomical conditions are not ideal, e.g in dysplastic arthritis. Understandably, it was first used in revision arthroplasty and then also in younger arthroplasty patients with greater expectations for an active lifestyle after primary THA.

Modern uncemented hip endoprostheses are mainly made of titanium al-

loys. Titanium alloys are slightly less strong than cobalt alloys, but the modulus of elasticity of the former is closer to the bone than the modulus of elasticity of cobalt alloy. Moreover, they are distinguished by a high level of bio-compatibility, and good corrosion resistance provided by the passive layer of titanium oxide on their surface. Endoprosthesis may be subject to various forms of corrosion, such as crevice corrosion, and fretting, pitting and galvanic corrosion. The use of titanium alloys for the manufacture of modular femoral necks was therefore a logical choice of many manufacturers. Unfortunately, it soon became clear that at the site of the contact between the femoral stem and the modular neck, an unexpected and rapid onset of corrosion may occur, resulting in fracture of the neck despite the same material used. Grupp et al. reported on 68 modular titanium-alloy neck fractures in 5,000 necks implanted (1.4 %) occurring on average 2 years after the implantation of the Metha hip stem (Aesculap AG, Tuttlingen, Germany). The device was therefore removed from the market (19). The analysis of the fractured necks revealed micro cracks due to stress corrosion on the surface. At the modular neck-stem junction, fretting corrosion is followed by crevice and pitting corrosion: the modular neck is load-deflected and rubbed at the taper interface. This type of corrosion leads to continuous removal of the passive protective layer on the surface of titanium alloy. The authors, therefore, recommended, that in patients with a high BMI, modular necks made of cobalt alloys should be used, because they are distiguished by better resistance to fretting corrosion, greater strength, higher modulus of elasticity, greater abrasion resistance and lower rate of crack propagation. Unfortunately, the combination of cobalt-chromium modular necks and titanium-alloy stems proved to be problematic. Femoral calcar erosion, pseudotumour formation and accelerated fretting corrosion have been reported (20,21). In addition, local toxicity of cobalt ions released by the additional galvanic corrosion at the modular neck-stem junction of the Rejuvenate prosthesis (Stryker, USA) was responsible for 86 % of revision operations required on average 4 years after primary THA (22). Accelerated corrosion at the trunnion of a titanium-alloy stem and a modular neck made of cobalt-chromium alloy may cause an even faster collapse of otherwise stronger cobalt-chromium necks. Menciere et al. reported on a collapse of modular cobalt-chromium neck, which occurred only 22 months after a THA with a Profemur L prosthesis, performed in a women with a low level of physical activity and a BMI of 28.7 kg/m^2 (23). Our first patient who sustained fracture of cobalt-chromium modular neck only 2 years after the implantation had only a minimally elevated BMI (26 kg/m^2). The manufacturer's recommendation to implant long modular necks made of cobalt-chromium alloy instead of titanium alloy was therefore completely inappropriate.

The analysis of modular neck fractures pointed out that the complication was due to similar factors: corrosion at the modular neck-stem junction and overload of the modular neck, that undoubtedly accelerated the corrosion processes, causing larger bending of the neck in the taper. Thus it is not surprising that our patients who sustained modular neck fracture had increased BMI. In addition, a higher torque is known to accelerate fracture, so the majority of the fractures occurred in THA using a long neck component. The bending moment with a long neck is 32 % higher than with a short neck (14). A study published in

2017 found that in the patient with an implanted long modular neck a 30 % increase in body weight resulted in 2.45 times greater load upon the site where the neck is locked on the femoral stem, as compared to the patient with an implanted short femoral stem (24). In our group of patients, fracture of the short modular neck occurred in one patient only, which is to some extent attributable to the use of a large femoral head (36 mm in diameter). Larger femoral heads exert greater stress on the implanted neck and may cause fractures of monobloc stems made of cobalt-chromium alloy (25).

The first to set up arthroplasty registries in Europe were the Nordic countries (Sweden, Finland, Norway, Denmark), in the eighties, followed by Hungary (1988), the Czech Republic (2001), Romania, Slovakia (2002), Austria, England and Wales (2003). Italy has two good regional registries i.e. ROLP (Lombardy) and RIPO (Registro dell'implantologia Protesica Ortopedica, Emilia-Romagna), a national registry is still in the project phase. In Poland, Luxembourg and Croatia national registries did not go beyond the project stage (26). Slovenia belongs to a small group of European countries, including Bulgaria, Cyprus, Greece, Estonia and Latvia, in which a functioning arthroplasty registry has not yet been established.

The Arthroplasty Register of Slovenia (RES) is still in the deployment phase. It is aimed to monitor survival of implanted hip and knee joint prostheses. It will thereby ensure quality control of arthroplasty and allow for earlier identification of poor-quality products and processes. This will reduce the cost of primary and, in particular, of revision hip and knee arthroplasties. The collected registry data will enable us to determine which implants are successful in the long term. A comparison with equal implants used in the countries with the established arthroplasty registries will thus be possible. By selecting better implants we will be able reduce the number of revision hip and knee arthtoplasties .

In order to standardize the data collection process in the European Commission PARENT project, coordinated by the Slovenian National Institute of Public Health (NIJZ), a »Questionnaire for device registries« was created. Under the PARENT project and in cooperation with the Valdoltra Hospital and NIJZ a hip arthroplasty RES database application was developed. The largest proportion of costs of the new database creation has already been covered. For the operation, the RES application will run on a server maintained by NJIZ; and data will be sent over the established secure connections to all Slovenian hospitals. It is foreseen that database management will take place in the Valdoltra Hospital, an institution known for its 14-year experience in managing their hospital arthroplasty registry and for its active participation in designing the RES application. RES will be run by the Registry Committee and all the participant representatives of the major orthopedic institutions, the Valdoltra Hospital, NIJZ, the Ministry of Health of the Republic of Slovenia, the Health Insurance Institute and the Slovenian Orthopaedic Association involved in orthopaedic implantology in Slovenia.

Until now, we have been dependent on the notifications received from foreign registries. The following is an example we can learn from: in the U.S.A. the Articular Surface Replacement (ASR, DePuy) THA was implanted long after its use had been stopped in Sweden based on the first 329 registry reports . The registry detected an unacceptably high rate of early prosthesis loosening due to the ineffective design and inad-

equate material used. The revision hip arthroplasty rate in Sweden is one-half lower than in the U.S.A (3.2 % vs. 7.0 % in 7 years) thanks to the data provided by the registry (27). In the States, a national register was created in 2010, but it does not yet include all hospitals in the country. In addition to the national registry, the Kaiser Permanente Implant Register and the local East Health Implant Register have been established in the U.S.A., but they are owned by major health care companies.

The data of the Swedish registry can be translated into the Slovenian numbers as follows: for primary THAs a valid projection is from the current 3,500 cases a year to 4,500 cases a year in 2050 and the estimated increase in the rate of revision operations (10–15 %) is from the currrent 440 to 560 in 2050. (28) Assuming that each THA revision costs approx. 10,000 euros, excluding the costs of treatment-related social burden, let alone the patient's suffering, one can easily calculate that a reduction in the number of THA revisions by 200 interventions per year, as expected with the introduction of the national registry, would save 2,000,000 EUR per year. This sum significantly exceeds the costs of maintaining the registry.

Conclusions

The Profemur endoprosthesis was designed as an innovative device, but because of the reported unanticipated fractures of modular femoral necks, it did not prove to be sufficiently safe. Unfortunately, shifting from titanium-alloy modular necks to those made of cobalt-chrome alloy soon turned out to be a bad solution. The responsibility for producing and marketing safe products lies with the manufacturers or relevant institutions awarding certificates to producers. Doctors, however, must pay particular attention to potential adverse effects of newly introduced materials and designs of orthopedic implants. The history of orthopedics is criss-crossed with bad innovations. In order to pinpoint them as soon as possible, arthroplasty registries were established in developed countries, and they are now being set up also in other areas of orthopedics.

The fact is that the Slovenian orthopedic community would have been much earlier alerted to the bad results of this problematic innovation, if a national arthroplasty registry had been established in Slovenia. Orthopaedic surgeons, who have been striving for this registry for many years, therefore request the responsible authorities to give full support to the establishment of a national arthroplasty register for the benefit of orthopedic patients in Slovenia.

Acknowledgements

The authors would like to thank Marko Kotnik, M.D., orthopaedic surgeon, Head of the Department of Orthopedics and Sports Injuries at the Celje General Hospital, primarius Slavko Kramberger, M.D., orthopaedic surgeon, Head of the Department of Orthopaedics at the Murska Sobota General Hospital, and Drago Dolinar, M.D., orthopaedic surgeon, Section A, the Department of Orthopaedic Surgery, Ljubljana, for the supplied data on modular neck fractures. Many thanks also go to Urška Ocvirk from the JAZMP Sector for medical devices for the data on vigilance cases relating to the Profemur Z endoprosthesis, and to the distributor of the THA models considered, for providing the number of the supplied modular necks.

References

1. Traina F, De Clerico M, Biondi F, Pilla F, Tassinari E, Toni A. Sex differences in hip morphology: is stem modularity effective for total hip replacement? J Bone Joint Surg Am. 2009;91 Suppl 6:121–8.
2. Archibeck MJ, CumminsT, Carothers J, Junick DW, White RE Jr. A comparison of two implant systems in restoration of hip geometry in arthroplasty. Clin Orthop Relat Res. 2011;469(2):443–6.
3. Massin P, Geais L, Astoin E, Simondi M, Lavaste F. The anatomic basis for the concept of lateralized femoral stems: a frontal plane radiographic study of the proximal femur. J Arthroplasty. 2000;15(1):93–101.
4. Antonietti B, Paderni S, Sama D, Comitini V, Sudanese A. Anatomic cementless total hip arthroplasty with ceramic bearings and modular necks: 3 to 5 years follow-up. Chir Organi Mov. 2003;88(3):259–265.
5. Collier JP, Mayor MB, Williams IR, Surprenant VA, Surprenant HP, Currier BH. The tradeoffs associated with modular hip prostheses. Clin Orthop Relat Res. 1995;(311):91–101.
6. Wright G, Sporer S, Urban R, Jacobs J. Fracture of a modular femoral neck after total hip arthroplasty: a case report. J Bone Joint Surg Am. 2010;92(6):1518–1521.
7. Vučajnik I, Fokter SK. Modular Femoral Neck Fracture after Total Hip Arthroplasty. In: Fokter SK, ed. Recent Advances in Hip and Knee Arthroplasty. Rijeka: InTech; 2012;11:169–80 [cited 2016 aug 20]. Available from: http://www.intechopen.com/books/recent-advances-in-hip-and-knee-arthroplasty/modular-femoral-neck-fracture-after-total-hip-arthroplasty.
8. Australian Orthopaedic Association National Joint Replacement Registry. Annual Report 2013 [cited 2016 aug 29]. Available from: https://aoanjrr.sahmri.com/annual-reports-2013.
9. Levašič V, Milošev I. Register artroplastike Ortopedske bolnišnice Valdoltra. [cited 2016 aug 27]. Available from: http://www.ob-valdoltra.si/sl/raziskovalna-dejavnost/register-artroplastike-ob-valdoltra.
10. Manufacturer and user facility device experience database (MAUDE). United States Food and Drug Administration [cited 2016 aug 29]. Available from: http://www.fda.gov/cdrh/maude.html.
11. Atwood SA, Patten EW, Bozic KJ, Pruitt LA, Ries MD. Corrosion-induced fracture of a double-modular hip prosthesis: a case report. J Bone Joint Surg Am. 2010;92(6):1522–1525.
12. Wilson DAJ, Dunbar MJ, Amirault JD, Farhat Z. Early failure of a modular femoral neck total hip arthroplasty component: a case report. J Bone Joint Surg Am. 2010;92(6):1514–1517.
13. Dangles CJ, Altstetter CJ. Failure of the modular neck in a total hip arthroplasty. J Arthroplasty. 2010;25(7):1169.e5-e7.
14. Skendzel JG, Blaha JD, Urquhart AG. Total hip arthroplasty modular neck failure. J Arthroplasty. 2011;26(2):338.e1-e4.
15. Ellman MB, Levine BR. Fracture of the modular femoral neck component in total hip arthroplasty. J Arthroplasty. 2013;28(1):196.e1-e5.
16. Fokter SK, Rudolf R, Molicnik A. Titanium alloy femoral neck fracture-clinical and metallurgical analysis in 6 cases. Acta Orthop. 2016;87(2):197–202.
17. Pour AE, Borden R, Murayama T, Groll-Brown M, Blaha JD. High risk of failure with bimodular femoral components in THA. Clin Orthop Relat Res. 2016;474(1):146–53.
18. Levašič V, Kovač S. Naše izkušnje s Profemur Z modularnim femoralnim deblom deblom. In: 4. raziskovalni dan Ortopedske bolnišnice Valdoltra; 30.maja 2014; Ankaran, Slovenija. Ankaran: Ortopedska bolnišnica Valdoltra; 2014.
19. Grupp TM, Weik T, Bloemer W, Knaebel H-P. Modular titanium alloy neck adapter failures in hip replacement-failure mode analysis and influence of implant material. BMC Musculoskelet Disord. 2010;11:3.
20. Sotereanos NG, Sauber TJ, Tupis TT. Modular femoral neck fracture after total hip arthroplasty. J Arthroplasty. 2013;28(1):196.e7-e9.
21. Molloy DO, Munir S, Jack CM, Cross MB, Walter WL, Walter WK Sr. Fretting and corrosion in modular-neck total hip arthroplasty femoral stems. J Bone Joint Surg Am. 2014;96(6):488–93.
22. Bernstein DT, Meftah M, Paranilam J, Incavo SJ. Eighty-six percent failure rate of a modular-neck femoral stem design at 3 to 5 years. J Bone Joint Surg Am. 2016;98:e49(1–7).
23. Mencière ML, Amouyel T, Taviaux J, Bayle M, Laterza C, Mertl P. Fracture of the cobalt-chromium modular femoral neck component in total hip arthroplasty. Orthop Traumatol Surg Res. 2014;100(5):565–8.
24. Fokter SK, Moličnik A, Kavalar R, Pelicon P, Rudolf R, Gubeljak N. Why do some titanium-alloy total hip arthroplasty modular necks fail? J Mech Behav Biomed Mater. 2016;69:107–114.
25. Reito A, Eskelinen A, Pajamäki J, Puolakka T. Neck fracture of the Exeter stem in 3 patients: A cause for concern? Acta Orthop. 2016;87(2):193–196.
26. Labek G. EAR Handbook for Register Development. Efort.org. 2009 [cited 26. 1 2016]. Available from: http://www.ear.efort.org/downloads/HandbookRegisterdevelopmentfinal.pdf.
27. Gray BH, et al. Registries as a Knowledge-Development Tool: The Experience of Sweden and England 2013 [cited 30. 8. 2016]. Available from: http://www.urban.org/research/publication/registries-knowledge-development-tool.
28. Mavčič B. Potrebe po endoprotezah kolka in kolena v Sloveniji do leta 2050. Med Razgl. 2016;55(1):5–12.