PRODUCTION OF MEDICAL PRODUCTS FOR THE PURPOSES IN ORTHOPEDICS AND TRAUMATOLOGY IN NOVI SAD

PROIZVODNJA MEDICINSKIH SREDSTAVA ZA POTREBE ORTOPEDIJE I TRAUMATOLOGIJE U NOVOM SADU

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Introduction

Since the development of medical thought there has been a tendency not only to preserve the general health but also to improve human function of movement in order to achieve security, functionality, speed, esthetics, economy because moving means to live.

In case of the development of pathological changes which make movement difficult or impossible, the application of appropriate methods of rehabilitation, surgical methods or transplants, implants or prosthetic system makes it possible to re-establish normal functioning of the musculoskeletal system of a human body and thus enable movement. We have to know and believe that normal functioning of the musculoskeletal system can be reconstructed and reestablished by the application of appropriate measures and resources that are available, as well as by developing new ones. The hip joint is certainly one of the most important joints of the locomotor system as it allows ambulation, especially upright walk, which is one of the important characteristics that distinguish the human population from the rest of vertebrates.

Of all the joints in the body, the hip joint is most commonly affected by degenerative changes, injuries or illness, thus it undergoes the most numerous, most likely, and most successful surgical procedures in the world (Figure 1).

"Carry each other’s burdens, and so fulfill the law of Christ.” Galatians 6:2; Paul the Epistle to the Galatians, the Gospel of Christian Freedom and Obedient Holy Love and Charity.

Modern medicine faces increasing demands for re-establishment of the function of human organs...
that have been damaged by degenerative changes (Figure 2 a), diseases (Figure 2 b), or injuries (Figure 2 c). A complication on the skeletal system can be managed by applying implants, which presents a gold standard.

The application of the implant and prosthetic components fulfills an old medical aspiration to replace a damaged part of the human body both functionally and esthetically. Modern computer software allows modeling of implants and prosthetic components, performing calculations and verifications, preparation of codes and simulation of its functionality for production with computer-controlled machines. This software is known as CAD/CAM systems [1].

All this serves to enable normal life and work of the users of implants and prosthetic elements.

According to modern research [2] a half million hip replacements are done in 15 developed countries of Western Europe per year, which is statistically 131 surgeries per 100,000 people. If that could be converted for Serbia for approximately 6,000,000 residents, the expected number of surgically installed hip endoprostheses would be 60 x 131 = 7860. The reason for this upward trend of total number of implanted hip endoprostheses, as a result of improved communication between surgeon and patient, can be found in the following:

– Improved diagnostics
– Improved surgical conditions
– Improved surgical technique
– Improved training of surgeons-orthopedists
– Increased number of surgeon-orthopedist
– Extended life expectancy and the elderly must receive appropriate medical care

In Novi Sad, in the period from 1987 to 2005 year, 3,850 hip endoprostheses (total cemented endoprostheses) were produced, which were surgically installed in the Socialist Federal Republic of Yugoslavia (SFRJ) and Federal Republic of Yugoslavia (SRJ) [3].

Material and Methods

The idea to produce medical equipment, especially hip joint endoprostheses, which was then called an artificial hip or hip prosthesis or prosthesis of the hip, was promoted by Dr Branko Secerov, an orthopedist, at the beginning of the 1980s. He first worked at the Department of Orthopedics and Traumatology, Novi Sad and then moved to Germany in the mid-seventies, where he successfully performed orthopedic trauma surgeries. With the help of German company "Mec-
kron”, he designed a cemented hip joint endoprosthesis with centralizer. He easily convinced the former general director of “DES” company, Novi Sad, Uros Mandic, BSc in Economics (Figure 3) to start producing implants for purposes of dentistry, traumatology and orthopedics in Novi Sad.

The development and organization of production of the hip endoprosthesis was initiated in 1982. It took the leading position in the mid-term plans for period 1986-1990 of the company “DES”, Novi Sad, on the basis of the decision made by the work council No. 10844 on 14.10.1986 [4]. This decision was supported by all departments of “DES”, the Municipality of Novi Sad and Province of Vojvodina. It was accepted by all famous orthopedists who participated in JUOT in Novi Sad in 1986 and most of the clinics and hospitals from all over Yugoslavia. One could say it was a Yugoslavian program since many business entities from all over the country participated in its realization.

External fixator

Having specialized at the Department of Orthopedics and Traumatology in Novi Sad, Prof. Dr. Jovan Krajcinovic (Figure 4) went to Paris in 1972 to get sub-specialization with the scholarship granted by the French government. There he noted the importance of surgical treatment in orthopedics. He became aware of the need of multidisciplinary approach in orthopedics, including implant production and its installation. When he became Chief of the Department of Orthopedics and Traumatology 1981-1998, he tried to share his knowledge in Novi Sad. In partnership with Jelena Stankov, PhD, Faculty of Technical Sciences, Novi Sad, he initiated a project on the construction of external fixator according to the “Hoffman” within a graduation thesis to be done at the Institute for Mechanical Engineering. Production of the fixator was offered to the company “Jugodent”, Novi Sad, the manufacturer of medical devices and equipment for dentistry. Unfortunately, they were not interested in this program. Thanks to the initiative of directors of the company “DES”, Uros Mandic and Vladimir Krklec (Figure 5), and with the consent of the Chief of the Department of Orthopedics and Traumatology Prof. Dr. Jovan Krajcinovic, an agreement was made between the Institute of Surgery, Faculty of Medicine, Novi Sad and the company “DES”, Novi Sad in 1984. It

Figure 3. Uroš Mandić, Director
Slika 3. Uroš Mandić, Direktor

Figure 4. Prof. dr Jovan Krajčinović
Slika 4. Prof. Dr. Jovan Krajčinovič

Figure 5. Vladimir Krklec, Director of Metalac Company
Slika 5. Vladimir Krklec, direktor JUR Metalac
was based on mutual cooperation on production and clinical testing of medical devices.

Mr. Jovan Grujić, an engineer (Figure 6), was in charge of development of technical and technological documentation of production and control of medical devices for the company “DES” Novi Sad. During 1984 a complete technological documentation and samples of external fixator were made according to the system “Hoffman”. Manufacturing and clinical application began in 1985. In the meantime, the controls of biocompatibility of materials and technologies of the production of implants and needles for the external fixator were provided.

From the material intended for the production of implants, screw-like test tubes were made and embedded into the animal bone (Figure 7) at the Department of Experimental Surgery within the Ward for Orthopedics and Traumatology in Sremska Kamenica. This building used to be the Children’s Sanatorium for Bone Tuberculosis, and it was founded by Dr. Katherine Macphail Stuart, a Scottish physician, a great friend and benefactor of our people.

As a result of war conflicts in former Yugoslavia and the influx of refugees, this building was converted into a collective accommodation for the reception of refugees in 1993. Since then it has not been in use for the needs of orthopedics and traumatology and experimental surgery.

After three to four months the animals were sacrificed. The necessary pathological-histological analysis of the surrounding bone and soft tissue was made at the Department of Pathology and the Institute for Mechanical Engineering, Faculty of Technical Sciences, Novi Sad. Research of metallic material incorporated into the animal bone was conducted to identify any possible changes. Thanks to the positive results, the Institute for Surgery prepared a “report on testing physical and biological effects of metallic material implanted into the animal bone.”

As a result of this research Prof. Dr. Jovan Krajčinovic, Faculty of Medicine Novi Sad and Mr. Jovan Grujic, from the company “DES”, Novi Sad did a study about production of external fixator.

On the basis of this study, Prof. Dr. Jovan Krajčinovic, wrote the first book “External Fixation” in Serbian language.

The hip endoprosthesis

TYPE: KPD1

Production of external fixator per the “Hoffman” system took place according to the desired schedule. Prof Dr Jovan Krajcinovic proposed and developed the design for total cemented endoprosthesis of the hip joint (Figure 8 a). Mr. Jovan Grujic made the structure (Figure 8 b) and prepared technology for production of total cemented hip arthroplasty called KPD1 (hip prosthesis “DES” model 1). Casting in vacuum from super alloy CoCrMo was done in LPO Ada. Final processing of stem (body) of endoprosthesis, head and acetabular cup, as well as final verification and packaging were done by the company “DES”, Novi Sad. The production of the
total cemented endoprosthesis of the hip joint was carried out during 1986 and 1987 followed by appropriate marketing promotions. In September 1987, since the assessment had positive verification, the first cemented total hip endoprosthesis produced in Novi Sad was installed in human body. Implantation was done by Prof. Dr. Jovan Krajcinovic, at the Department of Orthopedics and Traumatology. Few days after the installation in Novi Sad, Prof. Dr. Zika Jovanovic installed the second cemented total hip endoprosthesis type KPD1 at the Military Medical Academy in Belgrade. Soon after, all clinics and hospitals in Yugoslavia began to install the total cemented hip endoprosthesis KPD 1 of domestic production. In order to promote marketing a film, whose synopsis was written by Grujic Jovan, was made about the production of total cemented endoprostheses. The film, directed by Prvoslav Maric, Radio Television of Vojvodina Novi Sad, was broadcast by Yugoslav Radio Television (JRT) on three occasions after the national news “Dnevnik” on Sunday. Several more models of total hip joint endoprosthesis were developed in cooperation with Prof. Dr. Jovan Krajcinovic, as well as partial “Austin Moore” endoprosthesis (Figure 9 a) which were successfully produced and incorporated all over SFRJ.

“Custom made” type endoprosthesis

Application of resection tumor endoprosthesis in reconstructive surgery after removal (extractions) of bone tumors, made according to “Custom Made” or modular “Ready Made” types, is a safe procedure and the “gold standard”. In 1989 Prof. Dr. Jovan Krajcinovic, designed a tumor endoprosthesis type “Custom Made” (Figure 9 b). Four endoprostheses of this type were produced that year and and installed by Dr. Mika Tubic, MD and Prof. Dr. Jovan Krajcinovic. One prosthesis was a revision due to loss of bone density of proximal part of the femur as a complication of previously installed endoprosthesis of the hip joint.

The knee joint endoprosthesis

Production of total cemented knee joint endoprostheses began in 1995 within the cooperation between the Department of Orthopedics and Traumatology, Novi Sad especially Prof. Dr. Goran Ercegan, and Dr. Aleksandar Lazetic, and the company “Grujic & Grujic”. Tools for precise casting of endoprosthesis of the knee joint were made in two sizes: 58 and 64. Precise vacuum casting was done in “LPO” Ada and the final processing and production of insole and patella made of polyethylene took place in the company “Grujic & Grujic”, Novi Sad. The production program also included the revision knee joint endoprosthesis with extended stem for femoral and tibia component (Figure 10). Most of the knee joint endoprostheses produced in Novi Sad were installed by Prof. Dr. Goran Ercegan. About 40 knee joint endoprostheses were produced and installed in the period from 1995 to 2005.

Implants for ligament

Screws for ligamentoplasty of the knee joint

Design, construction and production of screw for ligamentoplasty for the knee joint were performed in

![Figure 9 a. Partial endoprosthesis “Austin Moore,” produced by “DES”](image)

![Figure 9 b. Tumor endoprosthesis, type “Custom Made”, produced in Novi Sad from 1989 to1993 year.](image)

![Figure 10. Revision knee endoprosthesis with extended stem a) implant, b) indication and installed endoprosthesis of the knee joint](image)
the company “Grujic & Grujic” Novi Sad during 1998 in cooperation with the Department of Orthopedics and Traumatology in Novi Sad, at the request of Prof Dr Miroslav Milankov. It was intended for anterior cruciate ligament injuries. The first model was made according to the type “Kurosaki” with sharp peaks of the thread (Figure 11), with a specific screw profile in shape of olive for easier and more reliable application of bone-tendon-bone method during installation. The design was modified and the screw with rounded tops was made in order to increase reliability and decrease complications during installation. All instruments necessary for installation were produced, for both open and arthroscopic method of installation. Several instruments and devices were innovative and they were registered in Patent Office.

Screws for ligamentoplasty of the shoulder joint

Production of screws for ligamentoplasty of shoulder joint and instruments for their arthroscopic installation began in 1999 as the business and technical cooperation between IOHB “Banjica” (Dr Ivan Diklic was in charge) and the company “Grujic & Grujic” Novi Sad. Production of screws for ligamentoplasty of knee and shoulders joints, as well as the instrumentation required for their installation, which were designed at the Department of Orthopedics and Traumatology Novi Sad, and produced by companies “DES” and “Grujic & Grujic” Novi Sad, represent high technology products. Good clinical results, affordable price and expediency of production were not sufficient for its intensification and expansion. Thanks to the cooperation among the Department of Orthopedics and Traumatology, the company “Grujic & Grujic” Novi Sad, and the Faculty of Technical Sciences, Novi Sad several research projects and patent solutions were realized, scientific studies were published and master’s theses were defended (Grujic Jovan, Srdjan Ninkovic, Natasa Janjic), as well as doctoral theses (Natasa Miljkovic, Srdjan Ninkovic, Natasa Janjic, Vladimir Harhaji).

Results

As the consequences of the war that led to disintegration of Yugoslavia in the early 1990s, and especially in the presence of uncontrollable high inflation which resulted in high prices of imported materials and low-cost finished products, the company “DES” had to discontinue production of medical materials and implants thus ending the idea of directors Uros Mandic and Prof. Dr. Jovan Krajevic and the whole team that the company “DES” should become a major production system of medical materials, especially of endoprosthesis. The company “DES” ceased the production in 1993, in the time of economic sanctions in Yugoslavia. A few small companies emerged especially in Serbia and they had more or less successful production of medical devices for the needs of orthopedics and traumatology. Their production was based on the experience gained in the company “DES” Novi Sad and “LPO” Ada, and it might be said that “DES” was the school for manufacturing implants.

Discussion

The external fixator and implants, total cemented hip endoprosthesis, partial hip joint prostheses, total cemented knee joint endoprosthesis, screws for ligamentoplasty of knee and shoulders joints, as well as the instrumentation required for their installation, which were designed at the Department of Orthopedics and Traumatology Novi Sad, and produced by companies “DES” and “Grujic & Grujic” Novi Sad, represent high technology products. Good clinical results, affordable price and expediency of production were not sufficient for its intensification and expansion. Thanks to the cooperation among the Department of Orthopedics and Traumatology, the company “Grujic & Grujic” Novi Sad, and the Faculty of Technical Sciences, Novi Sad several research projects and patent solutions were realized, scientific studies were published and master’s theses were defended (Grujic Jovan, Srdjan Ninkovic, Natasa Janjic), as well as doctoral theses (Natasa Miljkovic, Srdjan Ninkovic, Natasa Janjic, Vladimir Harhaji).

Conclusion

The cooperation among the Department of Orthopedics and Traumatology, Novi Sad, the Faculty of Technical Sciences and companies engaged in the production, i.e. “DES”, Novi Sad and “Grujic & Grujic”, Novi Sad resulted in the realization of the idea of good manufacturing of implants on scientific principles.
References


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