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REVIEW OF EXISTING CLINICAL SOLUTIONS FOR ARTIFICIAL JOINTS

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Abstract: *This paper presents short review of existing clinical solutions for artificial joints (knee joints, hip joints, shoulder joints, elbow joints, and spine segments). One of the main objectives in design of these implants is to minimise and eliminate friction and wear in moving elements and to provide full adhesion and cell proliferation for stable parts, such as for hip stem. Knee joint surgeries are important for young people, especially in sport, and they can be total or partial replacements. Hip joint surgeries are among the most performed procedures today, with increased number of young people undergoing it. Trabecular Metal technology, with porous structure, has emerged as the efficient approach to provide cell proliferation and adhesion of the hip stem. CoCr, Ti and stainless steel, together with polymers and ceramics are used for production of elements in hip replacement solutions. Shoulder joint replacements are very complex and require careful planning. Replacements of elbow joints are less present in comparison with other types of artificial joints. Solutions for vertebra, segments composing the spine, are the most important area of orthopedic trauma since it directly influences the quality of life in all the ways. This is important area of research that impact lives of millions humans. Beside standard production technologies and application of advanced CNC machines, 3D printing has emerged as efficient production technology offering custom design of personalised implants, very fast production with excellent quality, without significant post-processing as required in standard technologies, such as casting or forging.*

Keywords: *artificial joints, clinical solutions, trabecular metal, production technologies*

1. INTRODUCTION

Reducing friction and wear prolongs the work life of the tribomechanical system. According to [1] the laser sintered materials leads to improvement of elastic structure of the hip joint. Some authors [2] explain that spinal implants obtained by 3D printing of PEEK (Polyether ether ketone) have many advantages compared to metal, including friction and wear. Material of which implants are made has a significant impact on tribomechanical characteristics of hip joints. Hip joints have been made with three hard-on-hard prostheses: PCD (polycrystalline diamond)-on-PCD, ceramic-on-ceramic and metal-on-metal couples. They have been experimentally tested. The results confirmed that PCD on PCD have the best tribomechanical characteristics [3]. The proper selection of materials, the manufacturing technology and application of appropriate coating on implants reduce the possibility of pseudotumor formation, apoptosis, inflammation, and allergic reactions of the body [4]. Application of anti-frictional coatings on hip implants reduces the frictional heating in hip implants and therefore, there is no degradation of the material, which leads to better stability and longer work life of the implant [5]. Hip and knee joints produced by additive manufacturing are the new direction in their development, and resulting joints are lighter, and can be custom made per individual patient [6].

There are many orthopedic device companies nowadays offering numerous clinical solutions for artificial joints. Selection of the best solution is complex task, related to many factors, among which biomaterials of the implant and complexity of the surgical procedure are only some of them. Ten largest orthopedic device companies, according to sales reported for fiscal year 2017 are [21]:

1. Stryker, $12.4B
2. DePuy Synthes, $9.3B
3. Zimmer Biomet, $7.8B
4. Smith & Nephew, $4.8B
5. Medtronic (Spine Division), $2.6B
6. DJO Global, $1.2B
7. NuVasive, $1.0B
8. Wright Medical, $745M
9. Globus Medical, $636M
10. Össur, $569M

Comparison with that same report, 2 years ago, in 2016, shows that this market is rapidly growing and changing:

1. Stryker Corp, $9.9 billion
2. DePuy Synthes, $9.3 billion
3. Zimmer Biomet, $6.0 billion
4. Smith & Nephew, $4.7 billion
5. Medtronic Spinal, $2.9 billion
6. DJO Global, $1.1 billion
7. Integra Lifesciences, $883 million
8. NuVasive Inc., $811 million
9. Globus Medical, $545 million
10. Wright Medical, $415 million

It is clear that biomaterials market in orthopedics has extremely significant role in economy, beside its relation to health. Many new companies are emerging dealing with novel advanced biomaterials in this sector and improvements of existing solutions is ongoing process, aiming at ideal artificial joints.

2. BIOMATERIAL SOLUTIONS FOR KNEE JOINT

There are many commercially available solutions for knee joints that are already used in clinical practice:

- *Natural knee system* Zimmer - These tibial base plates have incorporated asymmetrical shape, thus resulting in optimal overlapping of the tibial plateau. They exhibit the best possible stability while at the same time minimizing the risk of impingement [7].
- *The NexGen Complete Knee Solution Legacy Posterior Stabilized (LPS) Flex Fixed Bearing Knee System* Zimmer – The system have been designed for patients with significant knee flexion [8].
- *NexGen CR Knee System* Zimmer and Triathlon Total Knee, Stryker - These systems provide secure flexion capability of up to 155° while maintaining the kinematic function for natural femoral rollback
- *NexGen LPS-Flex Mobile and LPS-Mobile Bearing Knee Systems* Zimmer – They have anteriorly positioned pivot point near the entry point of the anterior cruciate ligament.
- *NexGen CR Knee System* Zimmer – It provides secure flexion capability of up to 155° while maintaining the kinematic function for natural femoral rollback [9].
- *Innex System 2001* Zimmer – This system has mobile sliding surface platform and support the treatment of degenerative diseases of the knee joint [9].
- Scorpio Single Axis, Stryker has been implanted more than 500,000 worldwide, during the last 10 years.
- AOX Antioxidant Polyethylene, DePuy is made of advanced antioxidant polyethylene, thus promoting new biomaterials.
- Legion TKS, Smith & Nephew, comprising modular elements for total and partial

knee replacements. It can contain oxidized zirconium

The largest manufacturers of artificial joints today, are Zimmer (with approx 25% of all replacements today), Biomet (recently merged with Zimmer to Zimmer Biomet), DePuy, Stryker, Smith&Nephew and many smaller companies. There are also many solutions for partial knee joint replacement, such as Zimmer Gender Solutions Patello-Femoral Joint (for reduction of patellofemoral pain) and Persona Partial Knee with different gradual sizes available according to specific person [10, 11].

2.1 Revision knee system solution

Total knee replacement is one of the most successful procedures, especially important for sports injuries. However, over time, the replacement may fail for a variety of reasons and revision surgery is needed in such cases, usually total knee replacement.

Although both procedures have the same goal, to relieve pain and improve function, revision surgery is different than primary total knee replacement. It is a longer, more complex procedure that requires extensive planning, and specialized implants and tools to achieve a good result. There are currently several clinical options for revision knee systems.

The NexGen LCCK has been designed to provide stabilization related to medio-lateral, anteroposterior, or varus / valgus ligament function. This system is used when both basic ligaments have been removed and is used with shaft extensions [9].

The Zimmer Segmental System is a revision knee prosthesis to replace the distal femur, mid-femur, proximal femur, and / or entire knee in cases where extensive resection and recovery is required. This system enables complete replacement of the lower extremity, from mid-calf to hip. It is a modular system composed of leg extensions, segments, intercalar segments, sliding surfaces and distal femoral components [12].

The NexGen RH Knee has a modular joint mechanism that ensures that 95% of the load is on the femoral condyle. The femoral condyles remain centered on the tibia over the range of motion. Complex arthroplasty can involve more than one replacement solutions in one surgery, depending on the bone defects.

2.2 Manufacturing technology

Standard manufacturing technologies have been used, to produce implants with gradual changes in sizes, to fit specific patients. However, there is often a misfit of the implant in some degree. New 3D printing technologies have offered unique possibility to produce custom made implants with perfect fit to each patient, based on scan images of their own bone anatomy. Another important aspect of 3D printing is lower material loss, in comparison with standard production technologies, such as casting with subsequent processing technologies, such as cutting, polishing, drilling etc. 3D printing also enables small production batches with low cost of production and significantly less time needed for the final product.

A key element in this manufacturing process involves advanced digital imaging technology and 3D printing. The production process can start with computer tomography (CT) scan of the hip, affected knee, or ankle to ensure close resemblance of the patient anatomy. Engineers use specifi software solutions to convert CT scan images to 3D model of the implant, that is further processed by 3D printer and custom made implant produced. 3D printing can produce exact mold to cast the implant (e.g. femoral component of the knee). Post-processing usually requires polishing of the frictional surfaces to reduce wear [13]. Recently, 3D printing of metal and polymer parts has significantly advanced, enabling direct printing of the implant.

3. BIOMATERIAL SOLUTIONS FOR HIP JOINT

The hip is the second most agile joint in the human body. For that reason there are many injuries and natural defects. There are many existing clinical solutions for the complete or partial hip replacements, and some of the most used today are:

- *Fitmore stem,* Zimmer - The shape of this system is the result of close observation of individual anatomy in a large European and US patient sample. Three different medial shaft curvatures were designed. In the light of today's younger and more active patients, consideration has also been directed towards maintaining muscle tone and bone in the greater trochanter and compatibility with minimally invasive surgical procedures.
- *Alloclassic Zweymüller Shaft,* Zimmer - Since 1979, more than 500,000 hip joints have been replaced with this hip stem, making this cementless prosthesis one of the most widely used implants in the world [9].
- *CLS Spotorno hip stem* - Since 1984, this hip stem system, developed by Prof. Lorenzo Spotorno, has become one of the most successful implants in the Swedish national hip arthroplasty registry, with more than 560,000 replaced hip stems [14].
- *Zimmer M/L Taper hip prosthesis*, made of Ti-6Al-4V requires adequate bone tissue to be able to position it and provide secure mediolateral stability. This hip stem is available in 14 sizes from 4 *mm* to 22.5 *mm,* as well as standard and extended offsets.
- *CLS Brevius shaft with Kinectiv technology* enables adjustment of leg length, offset and antetorsion (Figure 1). The stem design is based on the original CLS Spotorno Hip Stem, which showed excellent survival rate of 95% in clinical use after 20 years [15]. The optimized shaft length also helps the surgeon maintain more bone and make the procedure less invasive.
- *Original M.E. Müller straight shaft* - Since its development in 1977, this system is essentially unchanged, with very good results over 20 years period. During first 26 years (1977-2003) this system was implanted more than one million times worldwide. The small proximal collar serves to compress the cement and prevent the stem from sinking into the cement. Together with the fine radiated surface of the straight shaft, a very stable anchoring of the implant was achieved.

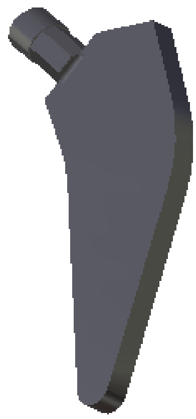

Figure 1. Hip joint in orthopedic surgery

3.1 Revision hip system solution

Revision surgeries are often needed, in case when hip replacement fails. The procedure may involve complete replacement of the previous implant, or some part of it. Clinical solutions for revision surgeries are often rather different than those used at the first surgery. Some existing solutions are described further.

The *Zimmer Trabecular Metal Acetabulum Revision System* combines Trabecular Metal technology with individualized solutions for different patients via modular design. This system is well adjusted for allogeneic bone graft without the risk of resorption or disease transmission. Important properties of the trabecular metal material include similarity to the bone in design and behaviour, close resemblance to natural bone structure, since it is three-dimensional porous material. It exhibits the highest biocompatibility among the endoprosthetic components and promotes the ingrowth of bones and soft tissue like no other material. Trabecular metal implants exhibits the following:

- 75-80% porosity: similar permeability as the bone,
- similar elasticity as bone with high strength and ductility,
- high levels of friction and stability,
- enables osteoconductivity and fixation,
- 10 years of clinical success [16, 17].

Revitan revision hip system has been designed with conical slope of 2 degrees to achieve rotational stability over 8 longitudinal ribs, which goes into the cortical bone. Its shape resembles anatomical shape for the natural antecurvation of the femur, in order to allow longer prosthesis stems without femur osteotomy to be implanted [9].

The *Wagner SL revision hip stem* has been designed to bridge the proximal bone defect for distal fixation and rotational stability. It has a proven blasted surface and a biocompatible titanium alloy. A tapered implant body and eight longitudinal ribs provide rotational stability. Different implant diameters and lengths are available to suit different patients.

3.2 Manufacturing technology

The process selection for fabricating a total hip prosthesis depends very much on the materials to use. Materials such as cobalt chrome, titanium and stainless steel are usually shaped by forging or investment casting, followed by rough machining, polishing and coating. For materials such as ultra-high molecular weight polyethylene, moulding and machining are essential. Ceramic biomaterials elements, such as alumina and zirconia femoral balls, are normally produced by sintering followed by grinding and polishing or lapping. The schematic is given in Figure 2. Polishing is one of the most efficient methods to achieve shape accuracy, surface roughness, and surface integrity of the prostheses. All of these characteristics are very important for longevity. Some elaborates that polishing has the key role in the good functioning of hip joint prostheses [18].

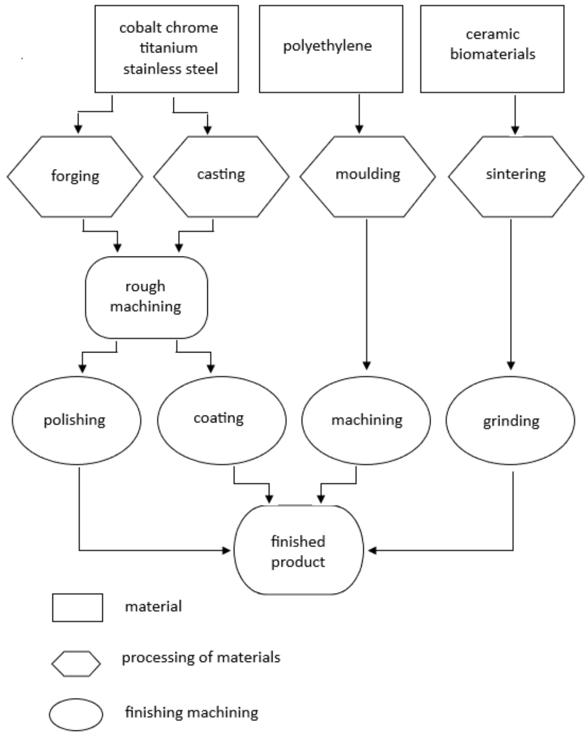

Figure 2. Manufacturing process of hip joint

4. BIOMATERIAL SOLUTIONS FOR SHOULDER JOINT

Shoulder is the most agile joint in human body. It has tremendous range of motion thus making the shoulder extremely unstable, far more prone to dislocation and injury than other joints. Surgical procedures for joint replacements are very complex and not so present as in case of other joints. There are clinical solutions for shoulder joint replacement, as the following:

- *Anatomical Shoulder Domelock System, Zimmer* - has modular design to provide accurate and reproducible reconstruction of the glenohumeral joint [9].
- *Anatomical Shoulder System, Zimmer*, has inverse / reverse system.
- The *Anatomical Shoulder Fracture, Zimmer* has been designed to treat complex fractures of the proximal humerus.

The coefficient of friction of the trabecular metal material, combined with its strength and flexibility, provides optimal initial stability. The osteoconductive properties of the trabecular structures promote vascularization and enable better bone formation and maintenance. Biomechanical tests have demonstrated higher initial, medium term and long term stability than polyethylene cemented glenoid.

4.1 Manufacturing technology

The process selection for fabricating the total shoulder prosthesis is similar to fabricating a hip joint. The mostly used materials are cobalt chrome, titanium and stainless steel and they are usually shaped by forging, followed by rough machining, polishing and coating. For materials such as ultra-high molecular weight polyethylene, moulding and machining are essential.

5. BIOMATERIAL SOLUTIONS FOR ELBOW JOINT

The elbow joint is located between the humerus in the upper arm and the radius and ulna in the forearm which allows the forearm and hand to be moved towards and away from the body. One of the existing clinical solutions is *Coonrad / Morrey elbow,* Zimmer and it has been used for a long time, also for treatment of rheumatoid and degenerative arthritis, beside fractures [19].

5.1 Manufacturing technology

The process selection for fabricating a total elbow prosthesis is consisted of ulnar, radial and humeral parts. The most used materials are titanium alloy Ti-6Al-4V for durable, lightweight construction shaped by forging, followed by rough machining, polishing and coating. Plasma spray coating provides enhanced cement fixation; implant intended to be used with bone cement for both immediate and long-term fixation. Special Poly Bushings constructed by Zimmer, with ultra-high molecular weight polyethylene, prevents metal-to metal contact, and for this materials moulding and machining are essential.

6. BIOMATERIAL SOLUTIONS FOR VERTEBRA - SEGMENTS COMPOSING THE SPINE

Each vertebra represents irregular bone. The size of the vertebrae varies according to placement in the vertebral column, spinal loading, posture and pathology. Along the length of the spine the vertebrae change to accommodate different needs related to stress and mobility. Vertebras are divided into: cervical, thoracic and lumbar. They have many functions. The main is the protection of the spine, along with mobility of the upper body, and carrying the weight of the body. They are often prone to injuries and during life vertebras goes through the pathologic changes. There are different clinical solutions related to main three areas: cervical, thoracic and lumbar vertebras. Some cervical vertebras are:

- *InViZia Anteriores Cervical Plate System* Zimmer, was developed for the anterior vertebral screw fixation of the cervical spine.
- *Trinica and Trinica Select Anterior Cervical Plate System* Zimmer are versatile implant systems that offer a wide range of plate and screw sizes to ensure better anatomical fit. These anterior cervical plate systems are designed for anterior vertebral screw fixation on the cervical spine. Secure-Twist anti-migration system secures up to three screws with a single turn of the wrist. It also provides common guidance for drilling, puncturing and screw placement.
- *TMS cervical fusion system* Zimmer is cervical spine implant made of trabecular metal. It provides a high coefficient of friction to prevent implant migration and expulsion, and has a low modulus of elasticity thus minimizing the stress shielding effect. With an average porosity of up to 80% and a uniform open-pored structure, the material closely replicates the architecture and mechanical properties of cancellous bone, and provide excellent environment for bone ingrowth and vascularization [9].

Some artificial thoraco lumbal implants are:

- *Ardis vertebral body system* Zimmer is self-distending posterior vertebral body fusion system.
- *Product Family Dynesys Dynamic Stabilizatio* Zimmer is non-fusion system for the spine, also used for degenerative diseases treatments.
- *TM-Ardis vertebral body system* Zimmer is made of trabecular metal, with an automatically-distracting implant tip, convex geometry and a wide range of sizes [9].
- *Universal Clamp spinal fusion system* Zimmer is a spinal implant system that provides segmental stability and provides compression, distraction, derotation, and transmission while maintaining pedicles and reducing contact stress on the implant and bone.

6.1 Manufacturing technology

3D printing manufacturing technology showed its benefits especially in this complex area of designing and fabricating spinal implants. The process starts from 3D scanning, as shown in Figure 3.

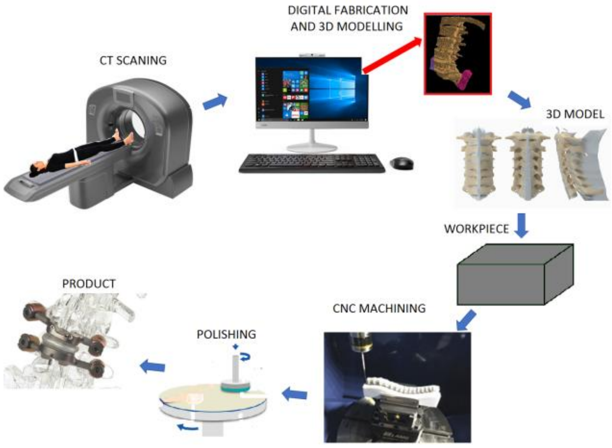

Figure 3. Vertebra manufacturing process based on CT scan images

Generated image slices are further imported into the 3D modelling software. Once all the images have been imported, appropriate image processing and meshing is done to eliminate errors due to different organic matter images, along with segmentation [20]. After all parameters have been set, the 3D model of the cervical spine can be generated and optimised prior to 3D printing or some other production route. Elements can be processed at CNC machines, with machining and polishing as final steps.

7. CONCLUSION

The main objective of this paper was to present different existing solutions of implants related to artificial joints that are clinically used: knee joints, hip joints, shoulder joints, elbow joints, and spine segments. There are many existing clinical solutions, depending on health issues that they address. Selection of specific solution depends on several factors, whereas health condition, type of trauma, implant material and complexity of surgical procedure are some of them.

The most beneficial materials for joints are novel titanium alloys and trabecular metals, together with new approaches in their processing and fabrication. New 3D printing technologies have emerged and enabled custom design and fabrication of joints' elements, according to specific patient needs. New technologies have shortened the production time and offered better fit of the implant to the human environment. However, even with many exisiting artificial joints solutions, and good results in clinical practice, they all have some drawbacks at certain percentage of patients, or developing over functional time. Research is still needed, related to the development of new materials and improvement of existing ones, as well as production technologies which governs the majority of functional properties of the implant.

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