CURRENT STATUS OF BIOMECHANICAL LASER MANUFACTURING. M.A. Sellés¹, E. Pérez-Bernabeu², S. Sánchez-Caballero³, H. Aromaa⁴

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Abstract: The aim of this work is to view different processes used for repair cartilage defect, and their suitability for laser based manufacturing. Many of human tissues can be equated to composite structure. Combination of a regular interconnected pore structure, materials' mechanical properties and hydrogel's lubrication characteristic can bring implant's structure closer to the form that can be founded in natural cartilage. Laser can be used for a wide variety of materials to manufacture complicated three dimensional structures. For this reason it was chosen for closer analysis. Research papers in official databases, medical science books and patents were used as research material.

1. INTRODUCTION

Three-dimensional objects can be constructed with finely focused laser beam. Wanted form of an object is designed with computer aided design (CAD), which automatically slices the readable data. These data slices are then fed to the fabricator, which builds the model. In year 2003 there were 25 different rapid prototyping methods available, of which 70% are based on different application of laser. Primary material can be either solid or liquid (Steen 2003).

Many of the rapid prototyping methods are used to create biomaterial implants. Laser is said to be nontoxic, fast, accurate and cheap manufacturing method for many medical appliances and instruments. When using a layer by layer manufacturing process some facts have to be considered. Each layer thickness can not be chosen individually and steps at the edge of a layer will affect the completed object. The shrinkage of different materials can vary (Steen 2003).

2. SELECTIVE LASER SINTERING

Selective laser sintering (SLS) produces three-dimensional parts from thermoplastic, ceramic or metallic powders. A thin layer of powder is placed on the top of the earlier solidified structure and fused together (Steen 2003).

The implant parts are fabricated immediately, directly and automatically. This allows the manufacture of the customized products in stead of mass production. A wide material range has opened the door for SLS in medical application field (Hao 2006).

Biomaterials, which have been used in selective laser sintering includepolyetheretherketone (PEEK), blend of PEEK/HA, titanium alloys (Ti6-Al4-V), HDPE and PCL. That is to say that any powder, which can be sintered or will bond without melting can be used (Steen 2003). Generally used polymer pulverulent for selective laser sintering to form 3D objects include polyester, polyvinyl chloride, polyacetal,

polypropylene, polyethylene, polystyrene, polycarbonate, polybutylene terephthalate, polyethylene terephthalate, polysulfone, polyarylene ether, polyurethane, polylactides, thermoplastic elastomers, polyoxyalkylenes, poly(N-methylmethacrylimides) (PMMI), polymethyl methacrylate (PMMA), ionomer, polyamide, copolyester, copolyamides, silicone polymers, terpolymers, and acrylonitrile-butadiene-styrene copolymers (ABS) (Patent 20070183918).

This wide material range makes SLS one of the most interesting RP methods in the medical sector. Other advantages of the selective laser sintering are solvent free fabrication, which lowers the risk of toxic residues or contamination, accuracy in the range +/-0.05-0.25 mm and good compressive strengths of the parts (Steen 2003).

Williams et al. (Williams 2005) have investigated polycaprolactone scaffold for bone or cartilage repair. Porous architecture was fabricated via selective laser sintering. Created scaffold with complex internal and external geometries was able to enhance tissue ingrowth and support in-vivo loads.

Selective laser sintering has been used to fabricate UHMWPE prosthetic devices. Rimell et al. in 1999 found that fully dense parts can not be achieved by direct fabrication. Powder caused shrinkage in the lasered material forming a gap between the lasered material and the powder bed. Also it was observed that polymer change from semicrystalline state to a more glassy state, as well as several chemical changes occurred. An increased number of end groups, double bonds and ketone groups in the gammairradiated material suggest physical breakdown of the UHMWPE chains.

Schmid et al. have investigated the use of PEEK in biomedical implants, when manufacturing with selective laser sintering. With SLS technique three-dimensional layer structured implants could be manufactured more precisely to fit into patient's damaged tissue. PEEK's crystallisation temperature is 300'C, so when processing it, powder have to be heated fast over this temperature to avoid the cooling of the previously sintered material. Cooling could cause shrinkage and deformation of the implant. Disadvantage was observed in homogeneity of the coated powder layer. This caused irregular geometry of the PEEK granules (Schmid 2007).

3. STEREOLITHOGRAPHY

The stereolithography process is based upon an ultraviolet laser beam. The accurate laser beam selectively polymerizes liquid photocurable monomer (Sachlos 2003).

The material selection has limited the wide use of stereolithography in medicine, but instead it is used for creating plastic or rubber forms, which are used for production of transitional wax models. These models can be then changed into implant and prosthetic appliances of titanium and its alloys with traditional casting or they can be used as presurgical models (Evseev 2004).

Materials used in stereolithography have thick consistency and they harden quickly. These materials are composed of a photoiniator and liquid monomers, normally with epoxy-, vinyl ether- or acrylate functional group (Steen 2003). The limitation of the usage of stereolithoraphy for biomaterial implants is the narrow material range. Only few acrylic

and epoxy-based monomers have been able to photopolymerized. These materials have not been optimized to be used in biomedical devices use in vivo (Popov 2004).

Objects of acrylic polymers are substantially contaminated by residual unreacted monomers, low molecular weight oligomers, initiators and binding agents. This can lead to different complications, in worst case to neuroses and rejection of implants. This fact has decelerated the development of stereolithography in health sector (Evseev 2004).

Grishenko et al. investigated the use of polyfunctional (meth)acrylic oligomers as an implant material already in 1985. The constructed object was three-dimensional spatial net. This material is insoluble in organic solvents and can be used to form polymer matrix for bioactive implants. Oligocarbonatedimethacrylate (OKM-2) combined with hydroxyapatite powder was investigated by Antonov 1998 for a bone substitute. The results were satisfactory for stimulation of new bone formation and integration with osteal tissue. Limitations of using laser stereolithography were formation of specific structure, which would be closer to the structure of osteal tissue.

Other investigation presented in the paper by Evseev et al. dealt with implants made from polyacrylates and polystearol. By using ultra-critical CO2 laser, better controlled pore size and concentration were achieved. Also use of the toxic admixtures was lowered and better biocompatibility was obtained (Evseev 2004).

Popov et al. (2004) have investigated mineral-polymer composite scaffold for bone regeneration and cranio-maxillofacial implants. Stereolithography was combined with supercritical fluid processing in this study. Latter process was used to effectively remove toxic residues from the polymer composite. In conventional methods, stereolithography is used to fabricate pure polymeric objects. Other similar kinds of investigations, where two fabrication methods are combined, have been performed in several papers. These methods use only indirectly laser based manufacturing, so they are left out from this review.

4. DIRECT LASER FORMING

DLF can be used in the field of orthopedical and trauma surgery, where individually shaped prosthesis and implants are required. Near net shape forms can be manufactured without waste (Wu 2003).

Not many biomaterials for direct laser forming have been investigated by now. In any case, single processing step, accuracy of $\pm 0,12$ mm within surface finishes and variation of metallic or intermetallic materials could provide the required features for implant fabrications (Lewis 2000).

With DLF tailored, porous parts are produced reasonably and effectively. Direct laser forming is mainly used to manufacture metallic biomaterial parts. Titanium and its alloys have been investigated as hard tissue replacements (Lewis 2000).

Alloys, which have very small processing window, the microstructure can be very sensitive to the laser processing parameters. For example Ti-6AI-4V alloy has a small processing window, so the chosen parameters have a large effect on the microstructure (Wu 2003).

Hollander et al. studied formation of the Ti-6Al-4V hard tissue implant with DLF. The process itself did not negatively alter either the chemical or biological properties of the material. The in vitro experiments demonstrated that DLF-fabricated Ti-6Al-4V allowed structure oriented growth of human osteoblasts on its surface. One disadvantage of using DLF was loosely bound small metal particles on the surface of the unfinished product. These particles could cause inflammation due to macrophage activation. Therefore some finishing treatment is inevitable (Hollander 2006).

5. LASER ENGINEERED NET SHAPING

Specific direct laser fabrication called the laser engineered net shaping (LENSTM) is a solid freeform fabrication system. LENSTM process is very similar to SLS process. Difference occurs when LENSTM powder is delivered in a gas jet through nozzles instead of lying in the powder bed.

LENSTM is a containerless melting system, which has a short manufacturing time. Other advantages using a LENSTM are fine, rapidly solidified specific microstructures (Weichang 2007).

Pure titanium, titanium alloys, nickel alloys, steel 316, cobalt, composites alloys and aluminum alloys are the main materials used for LENSTM (Schwender 2001). Also fine wires instead of material powder have been used. Material composition can be altered dynamically when fabricating a part, which is a mutually exclusive. LENSTM has said to have fever material limitations that SLS (World wide guide to RP reviewed 27.4.2008). LENSTM and Laser Engineered Net Shaping are trademarks of Sandia National Labs and they are used primary for nuclear weapon and aerospace applications. LENSTM method has been used since 1995 and its aim is to eliminate the need of secondary finishing. (Sandia National laboratories reviewed 27.4.2008) When manufacturing medical devices, pure titanium and titanium alloys have been given a special attention.

Like in other rapid prototyping techniques CAD design of three dimensional objects is created. Sliced information creates the object layer-by-layer. Highly focused laser creates a melt pool, where the powder feedstock is injected and melted. Powder flows through an inert gas multi-nozzle assembly, which can be seen in figure 11 as a material deposition head.

Computer controls three axis positioning system, which creates wanted layer characters. Substrate is controlled in X- and Y-directions. Four powder feeding nozzles are held at certain distance from the surface and they are raised in Z-direction after finishing the wanted layer. Successive layers create the wanted three dimensional forms (Krishna 2007).

Krishna et al. have produced porous pure titanium implant as bone substitute. With Laser Engineered Net Shaping LENSTM titanium implant's mechanical properties were customized to match the mechanical properties of human bone.

Metal powder surface was partially melted with low laser power beam and joint together due to presence of liquid metal in the wanted interfaces. The use of liquid phase sintering instead of solid state metal powders eliminated the brittleness. Density of 2,6-2,9

g/cm3 and porosity of 35-42 %, with open pore volume of 53-72 % was achieved. These values are close to human cortical bone.

This structure improves cell-implant interactions, adhesion and proliferation and long-term in vivo stability. Laser Engineered Net Shaping was able to produce lowmodulus tailored porosity implant, but still further in vivo investigations are needed (Krishna 2007).

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