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Additively manufactured custom load-bearing implantable devices: grounds for caution

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REVIEW

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ABSTRACT

Background
Additive manufacturing technologies are being enthusiastically adopted by the orthopaedic community since they are providing new perspectives and new possibilities. First applications were finalised for educational purposes, pre-operative planning, and design of surgical guides; recent applications also encompass the production of implantable devices where 3D printing can bring substantial benefits such as customization, optimization, and manufacturing of very complex geometries. The conceptual smoothness of the whole process may lead to the idea that any medical practitioner can use a 3D printer and her/his imagination to design and produce novel products for personal or commercial use.

Aims
Outlining how the whole process presents more than one critical aspects, still demanding further research in order to allow a safe application of this technology for fully-custom design, in particular confining attention to orthopaedic/orthodontic prostheses defined as components responding mainly to a structural function.

Methods
Current knowledge of mechanical properties of additively manufactured components has been examined along with reasons why the behaviour of these components might differ from traditionally manufactured components. The structural information still missing for mechanical design is outlined.

Results
Mechanical properties of additively manufactured components are not completely known, and especially fatigue limit needs to be examined further.

Conclusion
At the present stage, with reference to load-bearing implants subjected to many loading cycles, the indication of custom-made additively manufactured medical devices should be restricted to the cases with no viable alternative.

Key Words
Additive manufacturing, fast prototyping, orthopaedic implants, orthodontic implants, prostheses, fatigue resistance

What this review adds:

1. What is known about this subject?
Benefits coming from additive manufacturing of implantable devices are well known along with sparse information concerning mechanical properties of these devices.

2. What new information is offered in this review?
This review explores differences between mechanical properties of traditionally manufactured components and additively manufactured ones: it identifies causal factors for these differences, and outlines the need of further research

for load-bearing devices.

3. What are the implications for research, policy, or practice?

Standard implants are still to be preferred whenever they comply with requirements. Moreover, precise guidelines and regulations should be provided at the earliest.

Introduction

Benefits of additively manufactured components

The amount of interest towards additively manufactured components has originated from substantial improvements and benefits specific to this technology. With reference to medical applications, the most often cited benefits are customization and optimization.

Customization

Additive manufacturing can allow producing custom-made components at affordable prices[1] and in short times;[2,3] this aspect can become even more interesting considering recent advances in virtual prototyping i.e. the ability to build personalised 3D model from CT scans, laser or white light scans.[4,5] Customization is a mandatory issue when considering surgical interviews on very peculiar morphologies due to anatomic birth defects[6] or pathological outcomes as in the case of oncological surgery.[7] But also with reference to 'standard' morphologies, custom-made implants have recently come into the focus of renewed interest,[3] assuming they can provide biomechanical advantages such as improved fit and more even stress distribution, the only drawback being related to higher costs.[8]

Optimization

AM components can be optimized i.e. their mechanical performance can more closely replicate the former performance of substituted native bones or bone portions. Traditional implants are machined, forged or cast solid pieces of metal and usually result to in excessive stiffness, which can create problems because load sharing between bone and implant becomes unequal: the bone is 'bypassed' and is resorbed not having enough stress on it,[9–11] then it moves away, leading ultimately to implant failure. Hollow[12] and grooved[13] implants have been designed in the past, but meshed[14] and porous[15] structures are now receiving attention due to new possibilities offered by 3D printing. Modulating material porosity is an efficient way to replicate bone performance more closely,[16] being able to 'tune' the mechanical properties of the material;[17] another advantage is the allowed bone ingrowth, leading to excellent secondary stability.[18] Recommended pore size ranges from 400–600 µm with a volume porosity of 75–85 per cent.[19]

Applications of additive manufacturing for implantable devices

Scaffolds

Many applications of additive manufacturing techniques can be found in the field of tissue engineering where scaffolds for bone, cardiac tissues and other soft tissues are being fabricated with encouraging outcomes: on these scaffolds cells can infiltrate, they differentiate according to their origin[20] and environmental factors,[21] and in ideal conditions they are guided to form new, durable biological tissues. Dedicated composite materials are being developed to elicit a favourable biologic reaction: for example, they can be made of tetracalcium phosphate as a reactive component, and either calcium sulphate or tricalcium phosphate as biodegradable fillers.

Up to now, these techniques can allow filling small bone defects, the major obstacles being reaching good cell differentiation and providing optimal cells feeding.[22]

Load-bearing structures

Biological responses such as osteoblastic cell adhesion, growth and differentiation are related to surface properties such as roughness, pores size and accessibility, and grain size. Implanted component loosening is still one of the main causes of revision, and this is the reason why further research is being carried out. Additive manufacturing has received much interest since it can drastically widen possible surface topography; implants coated with this sort of surfaces are already being implanted with encouraging clinical results.[23,24] Structure topography and density can be easily modulated, therefore the continuity between the porous and solid parts can be guaranteed and risks of detachment and corrosion are minimised.[24]

However, medical practitioners and designers must be aware that building load-bearing structures means making one more step: having assessed the favourable bone tissue reaction in a 3D coated implant, another requirement must be fulfilled i.e. providing adequate structural strength. This is the goal of this paper where structural properties of additively manufactured implants are being examined.

Material properties: A basic input for structural design

Loads acting on prosthetic components can be classified according to their time behaviour: usually three main classes are identified i.e., static loads, fatigue loads, and impact loads.[25] Static loads are applied continuously and are almost constant; fatigue loads have an oscillating pattern (think for example of gait cycles or chewing cycles); finally, impact loads are applied abruptly, usually as a consequence of an accident (head impact, for example). Each of these loading conditions leads to defined component specification in terms of yield strength and ultimate strength that are respectively the ability to withstand forces without incurring in permanent deformation or failure, fatigue strength, and resilience or impact strength.

Determining upper load limits for each component can be a very time-consuming and expensive process, requiring the construction of many prototypes, and bringing them to failure. This is not a viable perspective dealing with custom-made components as it would completely nullify one of the main advantages of AM that is 'short time to implant'.

An alternative is establishing a lower load limit for components: tests are performed for a certain load level and component integrity is tested.[26] This conservative approach usually leads to components oversizing, nullifying another outstanding AM benefit that is component optimization.

The most classical engineering approach is identifying constitutive material properties rather than component properties: stress distributions on components are calculated, expected peak stress values are compared to material specifications, considering a reasonable safety factor.

Do we know material properties?

The final material is produced by the combination of source material and production process

Additive manufacturing technologies can differ even restricting this analysis to metal additive manufacturing metal being the constitutive material of most orthopaedic prostheses.[27] In spite of this, there are some common aspects: material is laid in layers which adhere to one another having been brought to a liquid state. Mechanical properties can differ greatly according to process parameters,[28,29] and, more precisely, according to the way solid-liquid-solid transition is managed: how fast temperature changes, which is the temperature distribution across one layer, and layer thickness. The mechanical properties of material are therefore significantly affected by process parameters and this relationship is still to be thoroughly explored.[30,31] Yield and ultimate strength of metals more commonly used for 3D printing (316L stainless steel and Ti6Al4V) have been measured, even if confidence intervals are very wide in some cases,[27] but little information can be found with reference to fatigue strength (i.e., the resistance to variable loads) and impact strength.[27] Fatigue strength has been proved to be extremely sensitive to localised flaws and to notch effect relative to a certain morphology or to constitutive material being partially melted/sintered.[26,32] At this moment it is possible to obtain data relative to specific process parameters,[33] while more general results are still lacking. An interesting work by Wycisk et al.[34] highlights the influence of surface treatment, mean stress to alternate stress ratio, and process parameters on high cycle fatigue of Ti6Al4V, and shows no conventional fatigue limit exists (i.e., a stress amplitude which can be tolerated for an indefinite number of cycles): the higher the stress amplitude the shorter the specimen life.

'Homogenized' material properties are needed'

As previously mentioned, modulating material porosity is an efficient way to replicate bone performance more closely; this can be accomplished with different geometry of the 'elementary material cell'.[18,35] Some authors use the term "meta-materials" that is halfway from "materials" to "structures." A meta-material can be studied as a structure as far as its small scale features and properties are concerned, but it behaves like a material when its homogenized properties are evaluated at the macro scale.[36] The mechanical behaviour of porous structures depends on pore volume fraction,[37] pore size and distribution,[17] meta-material ultrastructure and local flaws;[38] these properties can be modulated controlling laser energy,[29] or, more precisely specific enthalpy.[28] The homogenized mechanical properties have been assessed on the basis of analytical relationships,[37,39] numerical simulations taking into account manufacturing irregularities,[40] and experimental tests.[26,28] However most studies refer to Young's modulus[28,40] ultimate and yield strength,[28,38] and compression loads.[26] Significant findings have been reported such as the transition from fragile to ductile behaviour according to the main mode of failure.[38] Previous studies have already shown how both Ti–6Al–4V and Co–Cr alloys significantly degrade fatigue strength when employed as porous coatings on solid components.[41,42] Hrabe et al.[32] observed this behaviour on EBM (selective Electron Beam Melting) Ti–6Al–4V and identified possible causes: stress concentrations from surface topography, stress concentrations from closed porosity and local flaws within structures. Other authors have compared fatigue behaviour of pure titanium, alloyed titanium and tantalum with reference to dodecahedron structure.[43] These authors have found very useful comparative results, however, with reference to high cycle fatigue, 1 million cycle stress limits have been derived by extrapolation and further efforts are required since estimated loading cycles are about 300,000 cycles per year for orthodontic prostheses, and 1-2 million gait cycles per year[27,44] for lower limb prostheses. Further research is also required to understand the relationships between fatigue behaviour, cell structure, and material porosity.

The hardest property to be determined: fatigue strength

Fatigue strength is the hardest property to be determined due to multiple factors. First of all mechanical tests require long times since usual tests run at few hundred Hertz and at least 10 million cycles must be performed[25] when a fatigue limit is supposed to exist (this is not the case of laser additive manufactured massif Ti6Al4V according to the above cited article[34]), otherwise the number of cycles in dynamic tests should replicate the expected implant life, reaching 30–40 million cycles for a lower limb prosthesis lasting 20 years. Secondly, this property has a sensible statistical variability; therefore at least 15 specimens need to be tested.[25] Finally, meta-materials usually exhibit a marked anisotropic behaviour due to both the geometry of the unit cell and build orientation during the selective melting process; as a consequence, different combinations of multiaxial loads must be studied to fully characterize material behaviour.

In literature it is possible to find data concerning compression fatigue of Ti–6Al–4V meshes with rhombic dodecahedron structure obtained by EBM.[32] These authors[26,32] found that the respective fatigue endurance ratios of fatigue strength and compressive strength are in the range of 0.1 and 0.2;[26,32] therefore titanium leagues, differently from aluminium leagues, are subjected to a significant degradation of fatigue strength as a consequence of increased porosity, and the authors conclude that fatigue strength still remains a key issue to be addressed for a safe biomedical application of metallic foam. Amin Yavari et al.,[45] inquired the relationship between the geometrical design of porous structures including the type of unit cell and porosity and their fatigue behaviour, with reference to SLM (selective laser melting[46]) titanium structures. They clearly outlined the importance of cell structure since the most deleterious loads for fatigue resistance come from tensile internal stresses; secondly, the number and kind of notch and imperfections is different for different cell structures. Wauthle et al.[43] have compared fatigue SN (stress amplitude vs number of cycles before failure) curves of dodecahedron structures made in tantalum, titanium, and the commonly used Ti6Al4V league, reaching the conclusion that pure titanium has a mechanical behaviour similar to tantalum and it should be the material of choice for cyclically loaded porous implants. The explored stress values have allowed reaching up to few hundred thousand cycles.

Finally, the fatigue mechanism appears to be an interaction between cyclic ratcheting and fatigue crack initiation and growth;[26] fatigue failure usually takes place in correspondence with micro-defects due, for example to gaseous bubbles entrapped during the powder fusion process; the number and frequency of these flaws is likely to depend not only on process parameters (defining the 'material' in a wide sense), but also on printed component size, leading to a relevant 'scale effect', which depends on the printed component itself and its morphology rather than on material properties.

From material properties to component properties

Deriving the mechanical strength of a component from constitutive material properties is not immediate, especially if this is expected to be done on the basis of numerical calculations without any experimental test, as it happens with custom-made AM components since they have a unique geometry, having been created for a specific patient. In facts, the correct estimation of notch effects (coming from peculiar morphology or from porosity) is mandatory, but these effects may change in relation to process parameters and kind of porosity and yet need to be tabulated for specific morphology in relation to specific production process. Besides, component failure, and more specifically, fatigue failure takes place in correspondence with local material defects; the number and entity of these defects is likely to be strictly related to process parameters, and specimen's size; therefore it should be estimated for each specific component, but at the moment such an estimate cannot be performed.

The above outlined limitations could not be so severe in relation to static tests since a single 'lower load boundary' test could be sufficient to test the adequacy of the component. Also component resilience estimation could be overlooked considering low probability of high impact force on a determined region, and reviewing it as a fatality balanced due to the urgency to find a solution. The true problem remains fatigue resistance which cannot be estimated a priori at the moment. Experimental tests are currently performed for standard components, according to existing regulations (e.g., ISO 7206-4, ISO 7206-8, ASTM F1800-12, etc.); excellent clinical results are being reported for these standard components.[23,24] However experimental tests cannot be performed on fully custom components due to long times (in order to perform over 10 million cycles) and the minimum sample size required (at least 15 samples, as said above).

This means that these prostheses could fail in a few years, with a greater criticality for lower limb ones, according to the above cited estimates of number of cycles/year. This limit has been clearly outlined in a recent study regarding the feasibility of the production of customized hip stem prostheses through EBM.[47] Even with reference to traditionally made components, fatigue life has proved to be critical: consider for example recent findings on the influence of permanent laser markings,[48–50] or catastrophic exits of peculiar geometries,[51] fatigue failure due to microstructural changes in the material produced by high-frequency electrocautery[52] or fretting corrosion,[53,54] and premature failure due to overloads produced by an inadequate bone support.[55,56] As previously mentioned, additively produced materials have shown to have generally lower fatigue strength, therefore it is not surprising that this aspect is even more critical for these components. Fatigue failure of custom-made additively manufactured implants has already been reported in literature: for example, the mandibular implant used for tumour treatment of a patient failed several months after surgery and this outcome is explained by means sophisticated numerical simulations,[47] leading to emphasize the opportunity of using FE simulation to predict stress fields in complex patient-specific implants and to assist the design of such implants. Another methodology to gain insight into fatigue resistance of custom made components is using computed tomography to identify defects and FEM simulation to predict stress concentration[57] and fatigue life through models of crack growth.[33]

Conclusions

Caution should be exerted when thinking of additive manufacturing for custom-made medical applications. The reason is that constitutive material properties are not completely understood in relation to the high number of process parameters, and the final component performance is even more unknown and cannot be established ‘a priori’ at the moment, on a generic customized geometry, without specific tests. The most critical components are those fulfilling a substantial structural function (lower limb, upper limb, orthodontics) most of all if they are expected to be loaded by variable forces (‘cycles’).

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