THE GEOMETRICAL ACCURACY OF A CUSTOM ARTIFICIAL INTERVERTEBRAL DISC IMPLANT MANUFACTURED USING COMPUTED TOMOGRAPHY AND DIRECT METAL LASER SINTERING

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Abstract

Rapid Manufacturing (RM) has emerged over the past few years as a potential technology to successfully produce patient-specific implants for maxilla/facial and cranial reconstructive surgeries. However, in the area of spinal implants, customization has not yet come to the forefront and with growing capabilities in both software and manufacturing technologies, these opportunities need to be investigated and developed wherever possible.

The possibility of using Computed Tomography (CT) and Rapid Manufacturing (RM) technologies to design and manufacture a customized, patient-specific intervertebral implant, is investigated. Customized implants could aid in the efforts to reduce the risk of implant subsidence, which is a concern with existing standard implants. This article investigates how accurately the geometry of a customized artificial intervertebral disc (CAID) can represent the inverse geometry of a patient's vertebral endplates. The results indicate that the endplates of a customized disc implant can be manufactured to a calculated average error of 0.01mm within a confidence interval of 0.022mm, with 95% confidence, when using Direct Metal Laser Sintering.

Keywords: Rapid Manufacturing, Direct Metal Laser Sintering, Total Disc Replacement, Artificial Disc, Computed Tomography

1. INTRODUCTION

Whether through direct or indirect means, intervertebral disc degeneration is a leading cause of back pain and disability in adults. Seventy to eighty percent of the population of the Western world experiences low-back pain at one time or another (Bertagnoli & Kumar, 2002), (Viscogliosi et. al., 2004). This could be caused by repeated injury to the back, or because of ageing (Spine Health, 2010).It can induce pain as a worn disc becomes thin, narrowing the space between the vertebrae. Pieces of the damaged disc may also break off and cause irritation of the nerves. As the disc loses its ability to absorb stress and provide support, other parts of the spine become overloaded, thus leading to irritation, inflammation, fatigue, muscle spasms and back pain. This gradual deterioration of the discs between the vertebrae is referred to as degenerative disc disease (DDD), and typically involves a rupture of the annulus fibrosis and subsequent herniation of the nucleus pulposus (Spine Health, 2010).

Treatments for DDD vary according to a patient's condition and usually start with conservative, non-invasive to minimally invasive techniques. In other cases surgical procedures may however be prescribed where non-invasive methods have been ineffective. For severe cases, where the intervertebral disc has degenerated significantly, disc fusion or a total disc replacement (TDR) procedure may be considered. The choice in treatment is however still controversial, and two philosophies of support have emerged – namely those who “refuse to fuse” and the “I don't believe in disc replacement” groups. For a long time, disc fusion has been considered the “gold standard” for treating DDD. In many cases, surgeons are unable to identify the exact location of the pain generator prior to surgery, and fusion is effective in eliminating the source(s) of pain by stabilizing the entire joint. Concerns about how disc fusion affects degeneration in the adjacent discs (so-called adjacent disc disease or adjacent level degeneration) has led a growing trend towards the use of motion preserving devices, such as intervertebral disc implants, to treat DDD (Park et. al., 2004), (Cheh et. al., 2007), (Harrop et. al., 2008), (Matsumoto et. al., 2009), (Higashino et. al., 2010). These intervertebral disc implants are however, not without their own set of concerns which could influence the success of a TDR operation, with difficulties such as disc subsidence, incorrect disc selection and incorrect positioning of the implant, having been reported (Punt et. al., 2008).

Most existing disc implants consist of endplates that are designed relatively flat in comparison to the concave bony endplate geometry of the vertebra. In order to accommodate the implant, the vertebrae's endplates are often surgically reduced to a flat plane and a slot is cut to receive the implant keel (a fin-like protrusion to secure the implant). This action compromises the strength of the vertebral shell and reduces its ability to withstand pressure, which can lead to implant subsidence or vertebral fracture (Auerbach et. al., 2010), (Lowe et. al., 2004). A more elegant solution would be to leave the endplates as intact as possible and rather adapt the shape of the implant to match the geometry of the vertebra.

One approach may be to design the implant endplates with some measure of generic concavity to match that of the vertebra, based on morphometric studies of different population groups. However, Van der Houwen contends that data on the prevalent shapes of the vertebral surfaces are scarce, citing 10 studies that have investigated the morphometry of vertebral bodies and their endplates, using a variety of methods (cadaver, CT, MRI, and X-Ray). Van der Houwen instead suggests that a solution may lie with customized disc implants, based on CT data (Van der Houwen et. al., 2010).

Rapid Manufacturing (RM) has emerged over the past few years as a potential technology to successfully produce patient-specific implants for maxilla/facial and cranial reconstructive surgeries (De Beer et. al., 2008).

However in the area of spinal implants, customization has not yet come to the forefront and with growing capabilities in both software and manufacturing technologies, these opportunities need to be investigated and developed wherever possible.

This article investigates how accurately the geometry of a customized artificial intervertebral disc (CAID) can represent the inverse geometry of the patient's vertebral endplate.

2 MATERIALS & METHODS

A specific methodology was used to design the CAID using CT data and a combined software solution to semi-automate parametric features based on selected anatomical landmarks. A simple ball-and-socket disc design was used to illustrate the design process, with an emphasis on customizing the interface surface that comes in contact with the vertebral bone endplate. It must be noted that this study did not attempt to design a new disc implant, and was therefore not as concerned with the clinical functionality of the ball-and-socket aspect of the design. Benefits of using Rapid Manufacturing may in future indeed prove useful in this area of the design. However, this did not fall within the scope of our study, as there are indeed several design alternatives to the typical ball-and-socket configuration.

The process-flow shown in Figure 1, gives an overview of the steps followed to design and manufacture the CAID, which was used to do the accuracy test.

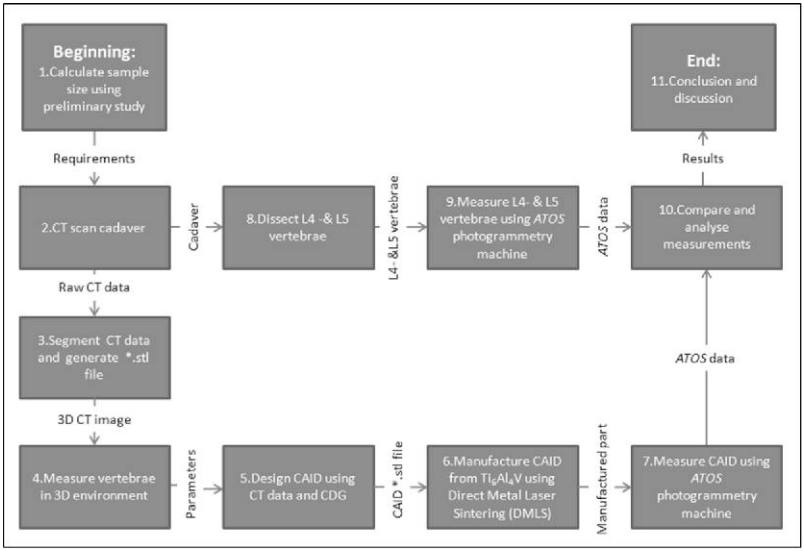


Figure 1 – The process-flow diagram to determine the accuracy of the CAID.

A preliminary study, which involved the accuracy assessment of a benchmark part with several geometric features using CT scanning, was used to determine the sample size. Statistically it was calculated that approximately 300 points were necessary to determine the true population average error with a confidence interval of 50 µm.

2.1 Sourcing of cadavers and data acquisition

One male cadaver (age 48 years), was acquired under approved institutional protocol from the Division of Anatomy and Histology, Department of Biomedical Sciences, at the University of Stellenbosch. Detailed geometrical information of the vertebrae for customizing implant designs was acquired by means of CT scanning. The scan was performed at the Radiology department of Stellenbosch Medi-Clinic (Van Wageningen & Partners) using a calibrated Siemens Somatom Emotion 16-slice CT scanner.

The dicom files (standard output files from CT scanners) were segmented using software called Mimics (Materialise, Belgium) at a threshold window between 226 HU and 2011 HU. This process involves the isolation of specific CT information (in this case bone material) from other anatomy in the digital environment, based on Hounsfield density values. Subsequently, 3D STL files (a mesh file type containing 3D coordinates of vertices and surface normals) of the vertebrae were generated from the 2D CT scan slices (see Figure 2).

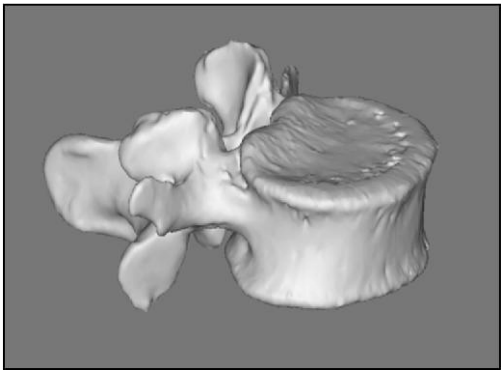


Figure 2 – STL file of the L4 vertebra generated from CT scan data

2.2 Identifying anatomical landmarks

The next step involved identifying specific anatomical landmarks that served as input parameters to the Custom Disc Generator (CDG) (a parametric design platform). The STL files for the L4- and L5 vertebrae were exported to ATOS Professional software (GOM GmbH, Germany), where a coordinate system was configured and seven anatomical landmarks identified and subsequent parameters measured from these coordinate points.

Six of these points were then used to define a spline curve which formed the footprint profile for the endplate of the intervertebral disc prosthesis. The seventh landmark on each vertebra was used to construct the centre line on which the centre point of the spherical ball-and-socket joint connection was defined. Figure 3 shows the approximate positions for each anatomical landmark, as well as angle- and distance parameters that are calculated from these landmarks. Feature limits which are calculated from the selected landmarks include the following:

- Angle between L4- and L5 vertebral contact surfaces (defined as α)
- Position of the centre point of the ball-and-socket joint mechanism
- Radius of the spherical ball
- Gap between the superior and inferior endplates of the prosthesis
- Allowable size of feature rounds

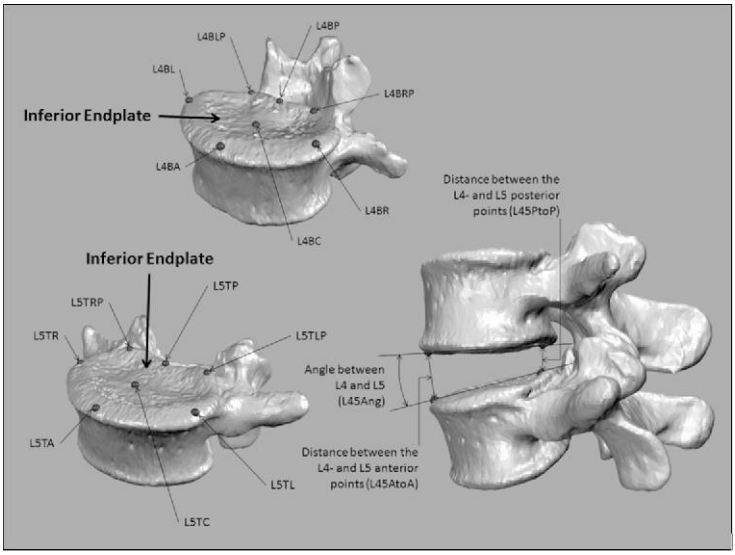


Figure 3 – Anatomical landmarks for design of patient-specific disc implant endplates

2.3 Automated parametric disc design (custom disc generator)

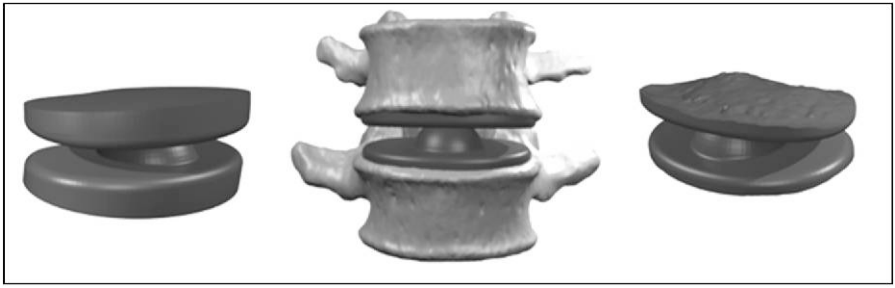
Once the fourteen landmarks were identified, their coordinates were exported to MS Excel (Microsoft Corporation, Washington). The MS Excel file was linked to a 3D parametric CAD model that was designed using Autodesk Inventor Professional 2009 (Autodesk, California). Each feature in the CAD model was carefully designed with linked constraints and relationships, with their dimensions driven by the set of coordinates of the MS Excel file.

Changing values in the MS Excel file caused changes to the profile, angle between the vertebrae or the centre of rotation in the CAD program.

This interaction used trigonometric and other calculations to update feature dimensions in the CAD model automatically.

2.4 Endplate design customization

Once the basic geometry for the intervertebral disc implant had been defined, the final step in the design process was to modify the implant endplates to match the geometry of the vertebrae endplate surfaces. This was done by performing a simple Boolean subtraction between the implant and the vertebrae. STL files of the implant, along with the vertebrae, were exported from the CDG to software called 3-Matic (Materialise, Belgium) where the subtraction was performed directly on the STL files. The subtraction step was then followed by an undercut removal function, to ensure that the implant could potentially be inserted without obstructions caused by undercuts. Figure 4 shows the resulting steps of (a) the implant, with (b) overlapping geometries and (c) the final implant model.



(a) CDG Implant **(b) Overlapping geometries** **(c) Final implant**

Figure 4 - Boolean subtraction of implant and vertebrae to create bone-matching endplate geometries

2.5 Rapid Manufacture of the patient-specific implant

Over the last decade several Additive Manufacturing (AM) technologies have emerged that have shown notable promise in their ability to directly manufacture customized implants in final, end-use materials. Direct metal fabrication processes can be grouped into three categories (Wohlers, 2010). The first group describes systems that use a laser to heat powder to form metal parts. All of the systems in this group produce parts in a powder bed, such as for example, Direct Metal Laser Sintering (DMLS), Electron Beam Melting (EBM) and LaserCusing. The second group includes systems that use a powder deposition head to deposit the metal powder, such as Direct Metal Deposition. The third group consists of systems that use special approaches to produce metal parts and do not fit into the first two groups, e.g. Direct Metal Printing (from ProMetal) and Laser Engineering Net-Shaping (LENS).

In the case of this project, due to its availability, DMLS was the RM technology chosen and parts were produced an EOSINT M270 machine, using Ti6Al4V powder as suitable material at the Centre for Rapid Prototyping and Manufacturing (CRPM) of the Central University of Technology (Bloemfontein, South Africa). Three implants (each with two endplates) were manufactured simultaneously and on the same building platform. Figure 5 shows an example of one of the implants that was manufactured. Post processing involved the part removal from the manufacturing base plate by means of wire cutting and surface treatment with mild bead blasting to ensure a smooth and uniform surface finish. No surface treatment material allowance was included in the original CAD design so as to assess the accuracy of the process as a whole. The spherical ball and mating socket was not surface treated any further during this project. However, since these are articulating surfaces, polishing is recommended for future functional implant designs. Dimensions in the CAD design will subsequently need to compensate for such material removal.

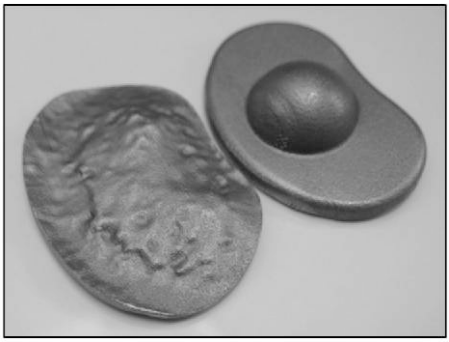


Figure 5 – An example of a patient-specific intervertebral implant manufactured from Ti6Al4V using Direct Metal Laser Sintering

2.6 Accuracy assessment

After the CT scanning of the cadaver, the L4- and L5 vertebrae were dissected from the rest of the spine and all soft tissue was removed through a standard procedure of boiling and air drying each vertebra. Although this does not represent what would typically be encountered in practice during surgical discectomy, at this stage, an accuracy comparison was sought purely between the vertebra geometry and implant manufactured, without the presence and possible influence of soft tissue cartilage. A grid of 50 points were plotted digitally on the 3D CAD model's superior endplate of the L5 vertebra and inferior endplate of the L4-vertebra, as shown in Figure 6. With three sets of implants, a total of 300 points were identified. Both the manufactured implants and dissected vertebrae were then measured for accuracy at each of the 300 points using an ATOS I photogrammetry machine (GOM GmbH, Germany). The measurements were overlayed and compared statistically.

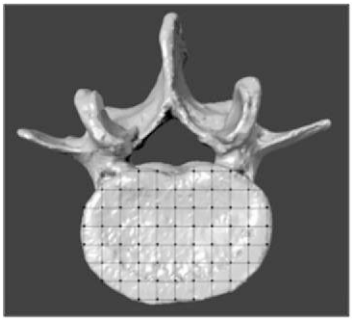


Figure 6 - The vertebra endplate of the L4 vertebra is measured according to a grid

3. RESULTS & DISCUSSION

An average vector error ($\bar{d}$) of 0.01 mm and a standard deviation ($\bar{s}$) of 0.1883 mm were observed when the vertebrae and implant measurements were compared. A typical example of the analysis of the measured errors is shown in Figure 7 below for the L4 vertebra endplate surface using the ATOS Professional software (GOM GmbH, Germany). Most of the surface area is shaded in green indicating a small error. It is interesting to note that positive errors were observed on exposed bony ridges, while negative errors were observed at pockets and indentations to the vertebra geometry.

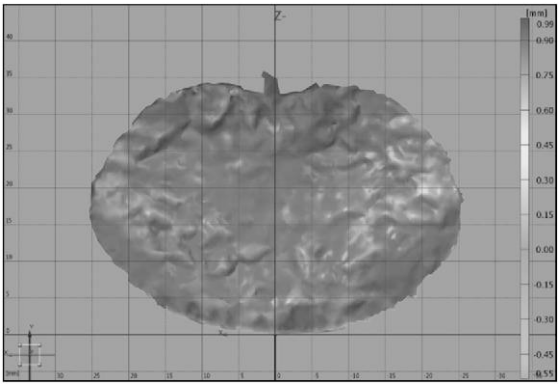


Figure 7 – Error analysis of L4 vertebra endplate with ATOS software

The results were also plotted on a histogram to visually compare the measured error with the theoretical error (see Figure 8). The x-axis on the graph indicates the error interval, whilst the y-axis indicates the probability of the error interval. The dark grey shows the measured error and the lighter grey the calculated error according to the theoretical normal distribution.

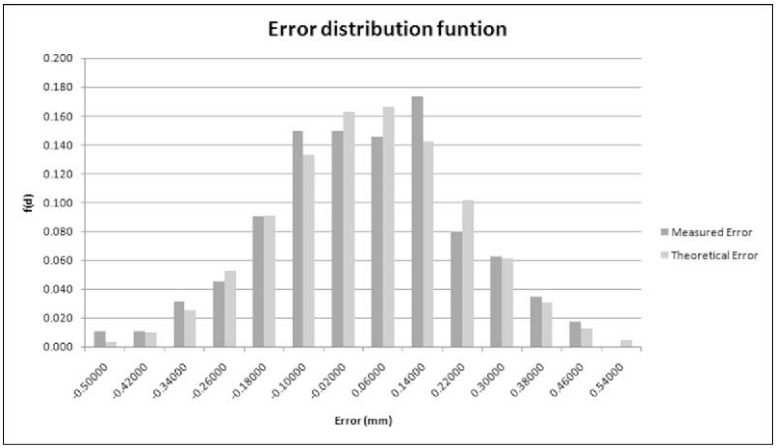


Figure 8 - The error distribution function observed when the vertebrae and implant measurements were compared

A hypothesis was set that the vector error has a normal distribution with above mentioned parameters ($\bar{d}$ and $\bar{s}$). A chi-square test was done to determine if the hypothesis should be rejected. The chi-square value (X^2) was calculated according to:

$$\chi^2 = \sum_{i=1}^{k} \frac{(O_i - E_i)^2}{E_i}$$

where O_i is the observed frequency in the *i*th number of *k* class intervals, and E_i the expected frequency in the *i*th class interval computed from the hypothesized probability distribution.

For the measured errors, x^2 was calculated as x^2=7.1 and compared to the critical chi-value x^2_{crit}=14.07. Since $x^2 < x^2_{crit}$ there is no reason to reject the hypothesis. Thus the measured errors mimic a normal distribution sufficiently and the confidence interval can be calculated.

Conclusively, with 95% confidence, the true population average error falls in a confidence interval of 0.022 mm of the calculated sample average. This means that there is a 95% chance that the true population average falls between -0.012 mm and 0.032 mm.

The absolute cumulative error was calculated and plotted on a histogram, as seen in Figure 9. According to the histogram, 95% of the measured errors are smaller than 0.37 mm and was calculated (using the bootstrap method) as follows:

95% of the absolute errors are smaller than= *0.333+(0.950-0.923)×(0.375-0.333)/(0.953-0.923) =0.37 mm*

Thus, *P(F(d)=0.37)=0.95*

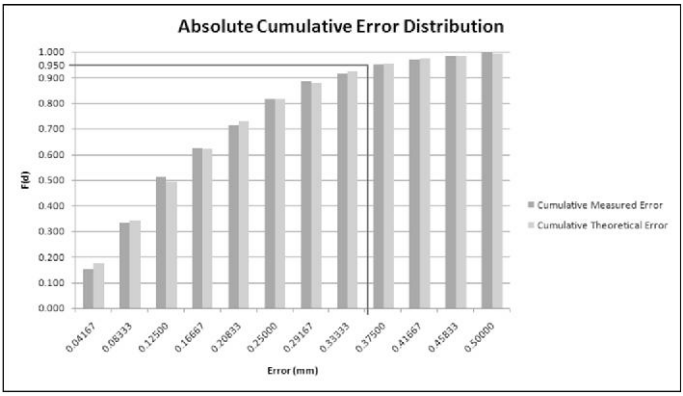


Figure 9 – The absolute cumulative error function measured by the ATOS

4. CONCLUSIONS

This study indicates that a patient-specific intervertebral disc implant can be designed and manufactured by means of Direct Metal Laser Sintering, with a calculated average vector error of 0.01mm. By making use of combined software packages, the design process can be semi-automated, which drastically decreases design time and facilitates instant dimensional adjustments based on selected individual patient anatomical landmarks.

The results of this study show that there are indeed significant potential benefits that can be achieved through the use of customization during the design and manufacture of intervertebral disc implants. With the design and manufacturing process that has been proposed, these and other potential benefits can and should be developed for the improvement of existing disc implant designs.

In order to utilize opportunities for growth in this field of research, the following recommendations for further work are suggested:

- The establishment of biomechanical simulation models during the design phase of the process chain needs to be incorporated. Specific motion capturing techniques, as well as the automation thereof, need to be defined. The link between the data captured and the simulation model must also be established.

Work in this field has already begun and literature has shown a trend towards the use of open-source software (OpenSim, https://simtk.org/home/opensim) for the design and dissemination of simulation models that can be shared between research groups. An added advantage in using open-source software, apart from the obvious cost savings, is the fact that shared research is done on a common platform by which results can be readily compared.

- Regulatory approval is a key (and necessary) issue for medical implant devices. Yet it poses a logistical challenge when customizing implants for individual patients, as it will not be feasible to apply existing approval procedures for each case. This still remains a significant area that will need to be addressed to achieve a longer term solution than the current patient/surgeon consent process. A comprehensive study of the FDA approval system and how customization can be accommodated should be investigated. A strong emphasis on simulation as a tool for testing and design verification needs to be considered as well.

- Design of surgical tools for implantation of a customized intervertebral disc implant was not addressed comprehensively during this study, since was deemed to be an iterative design improvement problem. The importance of implantation and the role that customization can play in the creation of custom jigs and fixtures is still a significant topic for further study. This should be investigated further, especially since placement of spinal implants has been identified as such a crucial success factor with intervertebral disc replacement surgeries.

- Along with surgical tools, fixation of the disc to the vertebral endplate was also considered to be a design improvement problem. Existing disc designs incorporate a keel or a number of spikes to improve fixture and osteo-integration of the implant device. If endplates are customized and still make use of the keel mechanism, any incorrect keel alignment will result in a mismatching of the endplate surfaces and defeat the original purpose of customization. Several possible alternatives to the standard keel design should therefore be considered. The use of Rapid Manufacturing further enables the design of endplate features such as honeycomb structures (which can prove to be good for ingrowth and fixation) that can otherwise not be manufactured due to its complexity.

- Finally, this study investigated the use of customization during implant design for the spine and used the intervertebral disc implant as a demonstrator for this process chain. Other medical devices can also benefit from this same process chain, though slightly modified.

Two obvious additional product applications that may be considered for further study are the customization of the endplates of intervertebral cage devices, as well as vertebral body replacement devices.

5. REFERENCES

Auerbach, JD; Ballester, CM; Hammond, F; Carine, ET; Balderston, RA; Elliott, DM, 2010, The effect of implant size and device keel on vertebral compression properties in lumbar total disc replacement, The Spine Journal, Vol. 10, pp. 333-340.

Bertagnoli, R; Kumar, S, 2002, Indications for full prosthetic disc arthroplasty: a correlation of clinical outcome against a variety of indications, European Spine Journal, 11 (Suppl. 2), pp. S131-S136.

Cheh, G; Bridwell, KH; Lenke, LG; Buchowski, JM; Daubs, MD; Kim, Y; Baldus, C, 2007, Adjacent Segment Disease Following Lumbar/Thoracolumbar Fusion With Pedicle Screw Instrumentation - A Minimum 5-Year Follow-up, Spine, Vol. 32 (20).

De Beer, N; Dimitrov, D; Van der Merwe, AF, 2008, Manufacturing of Custom-Made Medical Implants for Cranio/Maxillofacial and Orthopaedic Surgery - An Overview of the Current State of the Industry, Journal of New Generation Sciences, Vol. 6 (2), pp. 1-15.

Harrop, JS; Youssef, JA; Maltenfort, M; Vorwald, P; Jabbour, P; Bono, CM; Goldfarb, N; Vaccaro, AR; Hilibrand, AS, 2008, Lumbar Adjacent Segment Degeneration and Disease After Arthrodesis and Total Disc Arthroplasty, Spine, Vol 33 (15).

Higashino, K; Hamasaki, T; Kim, JH; Okada, M; Yoon, ST; Boden, SD; Hutton, WC, 2010, Do the Adjacent Level Intervertebral Discs Degenerate After a Lumbar Spinal Fusion? An Experimental Study Using a Rabbit Model, Spine, Vol 35 (22).

Lowe, TG; Hashim, S; Wilson, LA; O'Brien, MF; Smith, DAB; Diekmann, MJ; Trommeter, J, 2004, A Biomechanical Study of Regional Endplate Strength and Cage Morphology as It Relates to Structural Interbody Support, Spine, Vol. 29 (21), pp. 2389-94.

Matsumoto, M; Okada, E; Ichihara, D; Watanabe, K; Chiba, K; Toyama, Y; Fujiwara, H; Momoshima, S; Nishiwaki, Y; Iwanami, A; Ikegami, T; Takahata, T; Hashimoto, T, 2009, Anterior Cervical Decompression and Fusion Accelerates Adjacent Segment Degeneration - Comparison With Asymptomatic Volunteers in a Ten-Year Magnetic Resonance Imaging Follow-up Study, Spine, Vol. 35 (1), pp. 36-43.

Park, P; Garton, HJ; Gala, VC; Hoff, JT; McGillicuddy, JE, 2004, Adjacent Segment Disease after Lumbar or Lumbosacral Fusion: Review of the Literature, Spine, Vol. 29 (17).

Punt, IM; Visser, VM; Van Rhijn, LW; Kurtz, SM; Antonis, J; Schurink, GWH; Van Ooij, A, 2008. Complications and reoperations of the SB Charité lumbar disc prosthesis: experience in 75 patients. European Spine Journal, 17(1): pp. 36-43.

Spine Health. Back Pain Health Center. [Online].; 2010 [cited 21 March 21 2010]. Available from: http://www.spine-health.com/conditions/back-pain.

Van der Houwen; EB, Baron, P; Veldhuizen, AG; Burgerhof, JG; Van Ooijen PM; Verkerke, GJ, 2010. Geometry of the Intervertebral Volume and Vertebral Endplates of the Human Spine. Annals of Biomedical Engineering, 38(1): p. 33–40.

Viscogliosi, A.G; Viscogliosi, J.J; Viscogliosi, M.R, 2004, Spine Industry Analysis Series - Beyond Total Disc, The Future of Spine Surgery, Viscogliosi Bros, LLC.

Wohlers, T, 2010, Wohlers Report - Rapid Prototyping, Tooling & Manufacturing: State of teh Iindustry Annual Worldwide Progress Report, Wohlers Associates Inc., Fort Collins, USA