NanoHive™ with Soft Titanium® is Preferred 3D Printed Interbody Device on Radiographic Inspection

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Abstract

Interbody fusion devices produced through subtractive manufacturing offer many historical benefits and some drawbacks. Surgeons desire the ability to visualize interbody fusion devices intraoperatively and to evaluate fusion success and prefer devices that provide those benefits. 22 Surgeons were surveyed to determine the importance of key factors of visualization of interbody fusion devices, each selecting their most preferred device, radiographically, from a set of 4 commercially available options. HD LifeSciences™ NanoHive™ device with Soft Titanium® was ranked the most preferred with regard to visualization on radiograph.

Keywords: Visualization, Radiolucency, Fusion Assessment, 3D Printing, Titanium, Spine Implant, Bone Growth

Intro

The last 20 years have seen a significant change in material and design used in interbody fusion procedures. During that time surgeons have used products of a variety of sizes, shapes and materials. There are benefits and drawbacks to the use of each device type, however manufacturers have made advances in design and approach in an attempt to overcome some of the common issues. In particular, titanium and titanium alloys are considered to possess appropriate biologic conditions to encourage bony growth and solid fusions. However, the radiopaque nature of conventionally designed implants comprised of titanium makes it challenging to adequately evaluate device placement and the presence of bridging bone via radiograph.

Utilizing advanced 3D printing technology in combination with implant grade titanium offers unique advantages in creating structures to maximize the strength, bioactive surface characteristics and benefits of titanium, but at the same time allow for improved visualization over titanium implants made through subtraction manufacturing.

In the following, we discuss the importance of visualization for interbody device placement and fusion assessments and demonstrate surgeon preference for the HD LifeSciences™ NanoHive™ interbody comprised of Soft Titanium® compared to several 3D printed commercially available options.

Background

Advocates for 3D printed devices highlight the benefits of surface technology improvements in titanium implants which promote device stability and resistance to subsidence, influence osteogenic and angiogenic growth factors and contribute to nature BMP production and support multiaxial new bone growth [1-3].

With these improvements in surface topography, however, the presence of titanium in the disc space risks a reduction in visualization and ability to evaluate a solid fusion following the interbody procedure due to the inherent radiopacity of titanium. Users of titanium interbody fusion devices have historically accommodated the less than ideal imaging properties of these devices in order to take advantage of other beneficial properties such as device fit, stiffness, porosity and surface topography. With the recent use of 3D printing technologies, interbody fusion device manufacturers have looked to not only leverage these benefits but have looked to maximize visualization through product design.

At HD LifeSciences, our goal was to design a device which once implanted in the disc space prepared for fusion, offers a powerful feature set, including:

- a supporting scaffold for bone growth,
- ideal pore characteristics for ingrowth,
- maximal surface for bone to attach,
- mechanical compatibility,
- and intraoperative visibility.

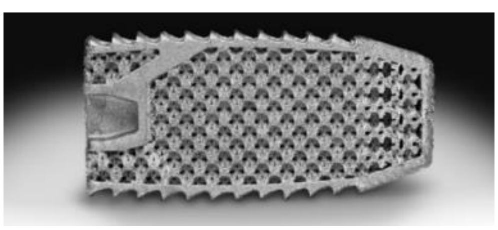

Figure 1 - Example HD LifeSciences™ NanoHive™ interbody comprised of Soft Titanium®.

The essential visibility allows the evaluation of device placement intraoperatively as well as improved ability to evaluate the fusion mass on subsequent imaging studies.

Implant Design

Utilizing advanced 3D printing technology in combination with implant grade titanium offers unique advantages. Such methods enable porous volumes to allow permeability to bone for tissue ingrowth, surface modification, better mechanical compatibility and enhanced radiographic properties as compared with subtractively manufactured titanium implants.

Research Approach

To better understand current perspectives on visualization and radiolucency in clinical practice, a set of spine surgeons were surveyed to provide their feedback on 4 commercially available 3D-printed interbody fusion devices.

Objectives

This research was designed to understand the importance of variables associated with device visuzalization, to compare radiographs of devices in clinically relevent situations, and to highlight the factors important to them during and after the procedure.

Methodology

An online survey of 22 questions was created to gather input from United States based spine surgeons experienced with interbody fusion procedures. Respondents were screened for spine surgery experience and were provided a fair market value honorarium for completing the research. Research was double blinded for the respondents and the sponsor company. A broad distribution of typical device usage and geographic location was obtained.

Surgeons were asked to rate a list of visualization factors which could impact preference of an interbody fusion device. A set of four commercially available 3D printed interbody fusion devices were presented via clinically relevant radiographs for evaluation. A color-coded scheme was used to simplify survey mechanics. As a baseline comparator, a PEEK device was used as a "control" image. The products included and images presented are show in Figure 2 and were as follows:

- Stryker Tritanium®: Red
- Titan ENDOSKELETON®: Orange
- HD LifeSciences™ NanoHive™: Green
- 4Web Truss System™: Blue

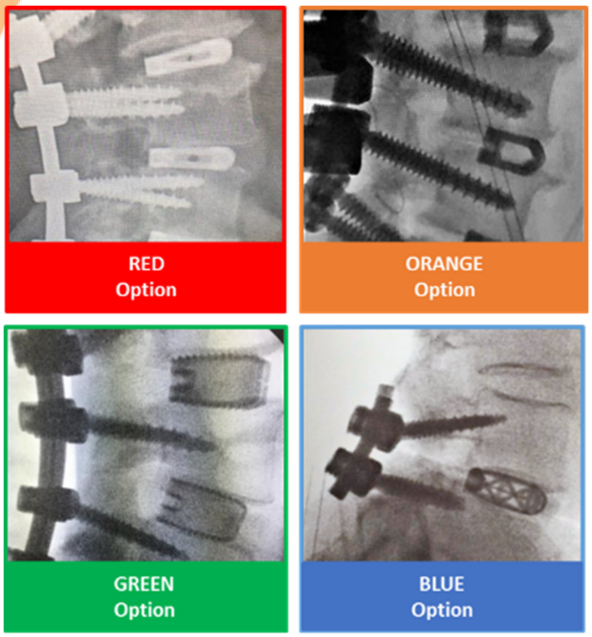

Figure 2 – Radiographic images provided for surgeon ranking.

All images were taken by the same surgeon at the same facility with minimal post-processing to ensure comparable color quality and size across the test group.

Of the 22 respondents participating in the research, only 6 had personal experience with 3D printed interbody fusion devices. Of those surgeons, they had used devices from NuVasive, Medicrea, Stryker, K2M and 4WEB. Surgeons were generally unfamiliar with the 3D printed products presented and only 3 surgeons were able to correctly identify 2 of the options presented.

Statistical Analysis

Where appropriate, statistical analysis was run to justify the conclusions found. While challenges do exist with a small sample size, research completed by Rockette et.al. indicates that responses from 20 or more respondents given 4 discrete choices on a rank order is sufficient to run certain statistical analyses.[1]

To better compare and run statistical analysis of ranked factors ad devices an Importance Score and a Preference Score was created. The Importance Score is an average of the rank for each factor surveyed.

For the Preference Score, Preference Points were assigned to each device by the following methodology. The devices preferred first were assigned 3 points, second were assigned 2 points, third were assigned 1 point and fourth were assigned 0 points for a maximum of 72 points (first preferred choice of 3 points multiplied by 24 respondents). The resulting points were converted to a percentage to compare to the other device preference points and a statistical analysis was run to confirm the rankings of the devices.

A Friedman statistical analysis was run to confirm the rankings of the devices. The same Friedman statistical test of ranks is performed to compare surgeon preferences between factors impacting visualization. This experimental design is consistent with prior work demonstrating power in ranked choice image comparisons [4].

It is worth noting that the ranking, regression, and statistical evaluation performed in this study assume a regular and even spacing between ranks. It is unlikely that this is true, as any one device may be considered slightly different or dramatically different than a neighboring ranked device, but only the exact number of evenly spaced bins are offered for ranking.

However, the forced-choice scenario is important because it causes a discrete choice of the highest rank or most preferred device which lends itself to the real-world choice of devices for use in surgery. A follow—up study may investigate the additional comparison points between factors and devices.

Results

Importance of Visualization

Imaging is an important factor in choosing an interbody device as indicated by 21 of 22 respondents agreeing. One outlier indicated that size and shape of the device was a more important consideration.

Surgeons were asked to rank the importance of several factors and key visualization aspects to be taking into consideration for this study. Specifically, respondents were asked to rank the importance of their ability to:

- Visualize and position the device intraoperatively
- Visualize the graft material in and around the device intraoperatively
- See a ‘good fit’ and endplate contact
- Visualize solid bone in the center of the device
- Visualize continuous bridging bone to verify fusion

We found that the two factors related to implanting and placing the device were ranked the highest. The “Ability to visualize and position the device intraoperatively” and the “Ability to see a ‘good fit’ and endplate contact” were ranked as the top two and therefore important to take into consideration when choosing appropriate interbody fusion devices to use.

Importance Score of the Evaluation Criteria

In assessing the importance of factors impacting visualization, we find a significant ($p<0.001$; Table 1) ranking by surgeon users.

Table 1a,b – Ranking of Factors Impacting Visualization and Friedman Test Statistic indicating significant ranking ($p<0.001$) and Test Statistics.

Aspects of Visualization	Mean Rank
Visualize Intraoperatively	2.08
Visualize In and Around Device	4.08
See “good fit”	2.67
Visualize Bone in Center	3.21
Visualize Bridging Bone for Fusion	2.96

Test Statistics	Value
Chi-Square	*20.833*
Asymp. Sig.	*0.000*

Device Preference

After ranking visualization preferences, respondents were asked to review the radiographs from the set 3D printed options and choose their most preferred device based on visualization.

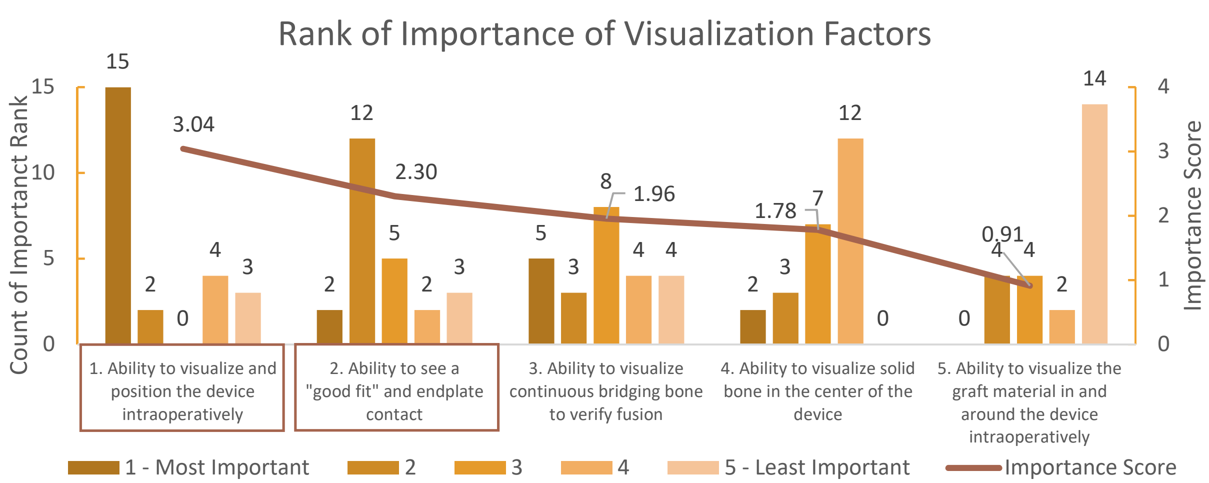

Figure 3 – Rank of Importance of Visualization Factors.

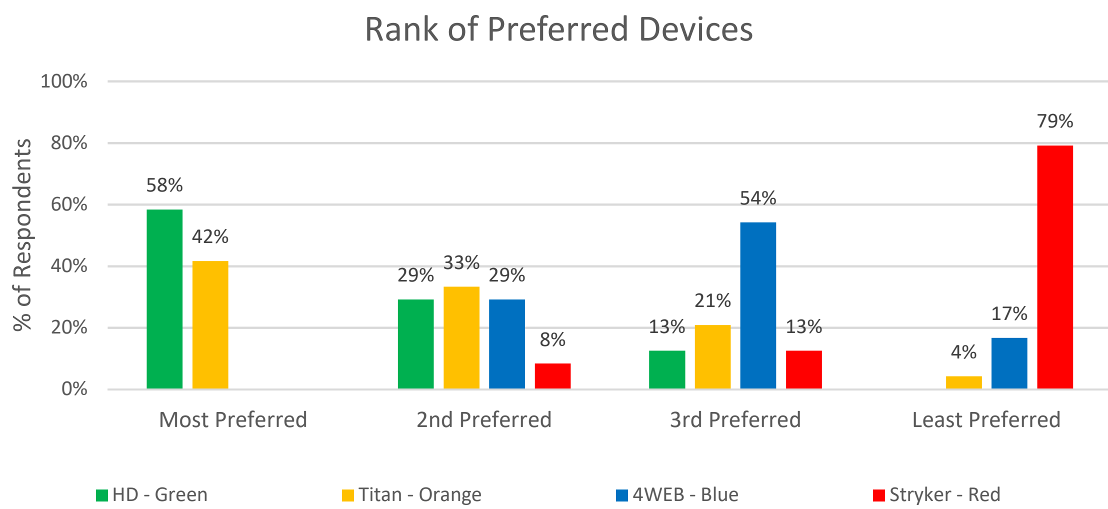

Figure 4 – Rank of 3D printed device (numbers may not add due to rounding).

The most preferred device was the HD LifeSciences™ NanoHive™ device with 58% indicating that it was the most preferred device presented and 88% ranking it as first or second choice. Of the four devices presented, the NanoHive device was the only one not chosen as last by any of the surgeons.

The HD LifeSciences NanoHive device was the most preferred option with 88% of respondents ranking it as first or second.

Respondents indicated that of the four options, the HD device had the best visualization overall and was the "easiest to see through." When asked to provide the material or brand/manufacturer of the HD LifeSciences device, one respondent indicated that it looked like a device made from PEEK which further demonstrates the radiolucent qualities of the NanoHive structure.

Other reasons for choosing the HD LifeSciences device included visualization of bony healing, assumed best evaluation of a solid interbody fusion by CT scan, most open space within the implant and other preferred design related factors.

The second most preferred device was the Titan ENDOSKELETON with the 4Web Truss System and the Stryker Tritanium to follow.

With 58% of respondents picking the HD LifeSciences device as most preferred and 42% choosing the Titan device, a Preference Score was used to perform additional analysis. The HD NanoHive 3D printed device was the most preferred on radiographic evaluation and captured 82% of "preference points."

Device	Mean	Std. Deviation	Min	Max
Red – Stryker	2.13	0.900	0	3
Blue – 4WEB	1.13	0.680	0	2
Green – HD	2.46	0.721	1	3
Orange – Titan	0.33	0.637	0	2

Test Statistics	Value
Chi-Square	*40.782*
Asymp. Sig.	*0.000*

Table 2a,b – Ranking of Images and Friedman Test Statistic indicating significant ranking (p<0.001) and Test Statistics.

Comparison between device Preference Scores are significant ($p<0.001$; Table 2), indicating a measurable difference in surgeon preference between devices.

The HD device performed better or equal to other offerings on the most important factors related to imaging: intraoperative visualization and fit in the disc space.

Of the larger manufacturers, higher percentages from NuVasive (67%) and K2M (57%) users preferred Titan as did Titan (100%) and 4WEB (100%) users.

Niche users also preferred HD LifeSciences, with all three users who have experience with Alphatec, Medicrea and Precision Spine choosing NanoHive over the other options.

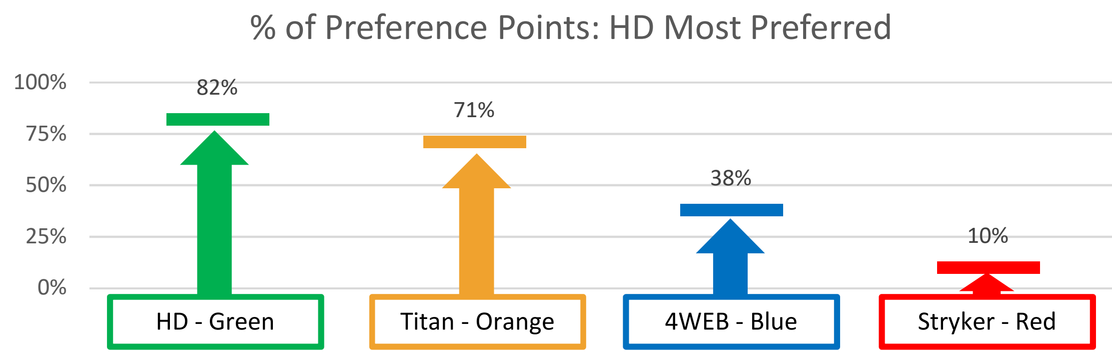

Figure 5 – Percent of Preference Points: HD Lifesciences Most Preferred.

Additionally, more often than not, respondents that used leading manufacturer interbody products today preferred the radiographic properties of the HD LifeSciences device over other options.

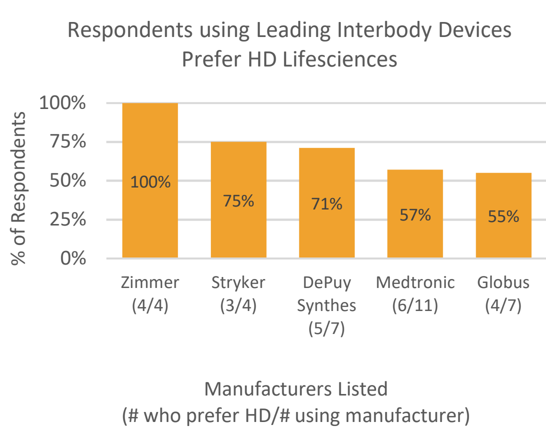

Figure 6 – Respondent Using Leading Interbody Devices Prefer HD LifeSciences

Discussion and Conclusion

While titanium and titanium alloys offer biologically superior characteristics for use in an interbody fusion procedure, one of the biggest clinical issues relates to their imaging characteristics. Due primarily to their density, titanium interbodies make it very difficult to assess fusion either radiographically or with a CT scan. [5-6] Unfortunately, poor imaging qualities force many surgeons to switch to biologically inferior materials – a compromise which no longer needs to be made. By designing a structurally efficient Soft Titanium lattice, HD LifeSciences minimized the density and total mass of the NanoHive interbodies. In practice, this means switching from PEEK to NanoHive titanium interbodies will not require a change in fusion assessment techniques and patient follow up.

Competitive titanium products, with solid support structures cause significantly more radiographic opacity and CT scatter.

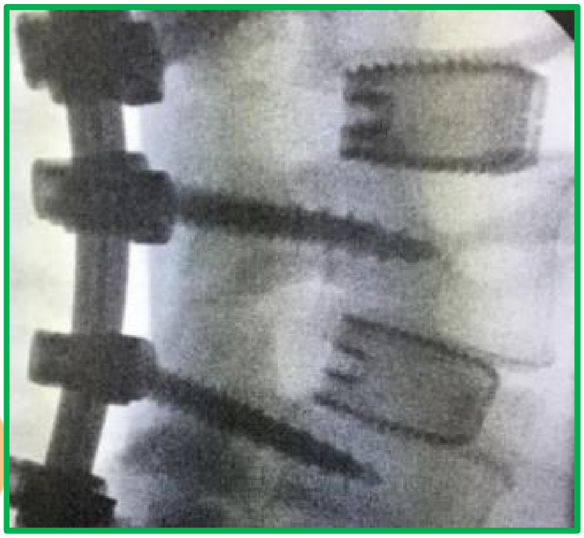

Figure 7 – Image of HD LifeSciences NanoHive Interbody Device with Soft Titanium.

Device Choice

Modern manufacturing techniques have now made the compromise between biologically active materials and visualization a thing of the past. Using a 3D printed device with an appropriate surface topography, surgeons do not need to sacrifice key aspects of an ideal interbody fusion device:

- Supporting scaffold for bone growth
- Ideal pore characteristics for ingrowth
- Maximal surface for bone to attach
- Mechanical compatibility
- Intraoperative visibility

Current users of 3D printed devices, who appreciate the features possible on these new devices realize the improvement to radiolucency that can be obtained. Of the 6 survey respondents who are current users, 4 choose the HD LifeSciences due to the nature of the visualization of the device.

"[The HD Device is] the most radiolucent while offering the best height restoration." – Spine Surgeon

While this research specifically evaluated the radiolucency of 3D printed devices, speculation as to the applicability of the findings to the conventional devices is natural. One may consider the tradeoffs made with regard to device design and radiolucency when using conventional devices. Consider the potential for an improvement in clinical outcomes and radiographic evaluation with the use of a 3D printed device such as the HD LifeSciences NanoHive with Soft Titanium that offers both the biologic and intraoperative benefits desired.

AUTHOR CONTRIBUTIONS

This work was conducted, analyzed, and authored independently by IW, with blinded statistical analysis provided by CJ. JT provided input on the study design as well as selected and submitted clinical images for use. Patient consent was obtained for use of all images.

FOLLOW-UP

For further information on Soft Titanium® and HD LifeSciences™ NanoHive™ interbody devices, please visit HDLifeSciences.com or contact info@HDLifeSciences.com.

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