Abstract

Thousands of cases of spinal cord injuries occur annually. There is a constant threat of extremities surrounding the spinal cord being damaged, from the fracturing of vertebrae to the slipping of spinal discs, all potentially leading to paralysis. ProTHOR is a prosthetic for the vertebrae and discs in the thoracic region of the spine, providing support and structure for those who have suffered major, often irreparable damage to the region. The vertebral disc component consists of a protective outer layer of collagen mimetic peptides and an amidic alginate hydrogel interior. In addition, the vertebrae are composed of sturdy Grade-5 titanium alloy. With the development of the ProTHOR, individuals with major trauma in the thoracic region of the spine have the ability to replace the damaged area with a sturdy, functional prosthetic: the ProTHOR.
Present Technology

Spinal fusion surgery is routinely performed on patients with vertebral discs in need of replacement. In this procedure, the new spinal disc is welded into two adjacent vertebrae. The surgeon accesses the region for the spinal disc replacement by removing a small section of the vertebrae, allowing for improved access and the ability to remove a damaged section. The disc is fused into place, and the missing section of the vertebra is replaced. Pedicle screws are then inserted into the two vertebrae in order to keep them in place. This set of procedures, a surgery in the vein of arthroplasty, is typically performed on patients in need of a new L5-S1 disc, which is the most commonly damaged disc.

3D printing is another primary technology that is used in the creation of ProTHOR--more specifically, titanium 3D printing. Also known as direct metal laser sintering (DMLS), titanium 3D printing differs from traditional 3D printing in ways that benefit ProTHOR. Titanium allows the ability to print more complex features of the vertebrae from the 3D image. It incorporates a laser beam that fuses the titanium powder in the printer and melts it into a solid form. This allows for physically stronger structures to be printed, as DMLS creates structures with a 30 micron layer thickness. This makes implants 0.3-0.4 mm thick. Titanium 3D printing allows for absolute precision in construction.

Today, doctors are able to convert Magnetic Resonance Imaging (MRI) scans into Stereolithography (STL) format, which is compatible with 3-dimensional printers. The 3D printers are able to print an identical copy of the original scan, which is then used for various medical purposes. When referencing the MRI scans, multiple scans must be taken to capture
every single facet of the original source. The header and footer scans are then compressed into each other to create the image through Digital Imaging and Communications in Medicine (DICOM). From there, the newly created DICOM files are converted into Nearly Raw Raster Data (NRRD) to remove all patient-sensitive information. These NRRD files are finally converted into STL files, which are able to be printed. We currently have access to all of these different technologies, and the conversion process described is commonly used in similar procedures.

As the annulus fibrosus is composed of many layers of collagen, ProTHOR will use Collagen Mimetic Peptides (CMPs), specifically Proline-Hydroxyproline-Glycine (Pro-Hyp-Gly), to mimic the annulus fibrosus. The annulus fibrosus prevents the nucleus pulposus from leaking and causing herniation or irritation of nerves. Stiff, yet pliable, the nucleus pulposus allows for adjustment as it absorbs the shock of daily wear and tear. In order for the CMPs to work, the peptide chains have to assemble into a triple helix, which then would assemble into fibrous strands, and ultimately assembling into the collagenous material that will make up the synthetic annulus fibrosus. Multiple studies show that Pro-Hyp-Gly CMPs possess fibrous qualities that complement the amidic alginate hydrogel and aid it in carrying out the functions of the intervertebral disc and also the most efficient self-assembly process that will allow effective execution of the functions of the annulus fibrosus.

Amidic alginate hydrogel will be used to emulate the nucleus pulposus, which is the center of vertebral discs. Fabricated with seaweed extract, an alginate hydrogel would be ideal for ProTHOR as it has proven to work well under stress and absorbs shock effectively, which is
one of the main functions of the nucleus pulposus. In a study analyzed in Hydrogels: Biological Properties and Applications, it was found AAA hydrogel can swell to 250% of its original volume compared to the 200% of the original nucleus pulposus. Effective swelling of the material is crucial, as the swelling reduces shock to the body and disc degenerative disease that can develop when a spinal disc is lacking sufficient moisture to absorb shocks to the spine. The viscosity of AAA hydrogel is also beneficial, as it needs to be able to be inserted a syringe during application. While viscous, it worked well under stress tests, which ensures that the material would not allow flexibility that the body is not capable of.

Titanium is a material commonly used in various biotechnologies. Endorsed for its sturdy yet surprisingly lightweight qualities, it is more widely used in dental implants. Titanium is one of the few materials that allow for osseointegration, the phenomenon where the implant is a scaffold for bone material to grow naturally, due to its biocompatible abilities. Osseointegration reduces the risk of rejection greatly, which is beneficial for a technology where the risk of rejection is incredibly high due to amount of tissue being replaced. Titanium’s durability also prolongs continual usage of the prosthetic. Grade-5 ASTM Titanium alloy, which would be the specific alloy used in ProTHOR, is commonly used for biomedical purposes due to its superior Ultimate Tensile Strength (UTS) and Yield Strength (YS) compared to the other grades available.

Hyaline cartilage is a smooth, pliable cartilage between the vertebrae and intervertebral discs that prevents friction between the two tissues, preventing irritation and inflammation. Hyaline cartilage is different than fibrocartilage, the cartilage that makes up the annulus fibrosis, as fibrocartilage has interwoven fibrous sections that make the annulus fibrosus have the stiff,
yet pliable qualities that keeps the nucleus pulposus from causing herniation. The RGD
Arg-Gly-Asp Arginine-Glycine-Aspartic) conjugated chitosan hydrogel will be used to grow the
hyaline cartilage allograft. Many studies have shown that the prolific properties of this type of
hydrogels compared to other hydrogels is effective in producing an allograft that will fit the
needs and function of ProTHOR. It will provide the same function of cartilage as an original
spine; placed in between a vertebra and spinal disc to ensure minimal friction.

History

3D printing plays a large part in ProTHOR, with the first 3D printing technology has
been traced back to the 1980s. It was first known as Rapid Prototyping, due to its usefulness for
creating prototypes within the product development industry. The first 3D printing machine,
known as the Stereolithography Apparatus (SLA) machine, was patented by Charles Hull.
During the late 1980s and into the 1990s, other 3D printing technologies and processes were
emerging. These included Ballistic Particle Manufacturing, Laminated Object Manufacturing,
and Solid Ground Curing. These technologies advanced over time, eventually leading to the 3D
printing that we know of today. A popular theme that emerged in 2001 was Selective Laser
Sintering. This differed from the standard 3D printing at the time because it incorporated a laser
beam to sinter together the nylon particles for each individual layer. This allowed for very
complex geometric figures to be printed.

Thirty years ago, the first artificial vertebral disc replacement was reported. Metallic
spheres were used to act as “joints” and replace damaged vertebral discs. Although some doctors
reported good results, the devices were considered controversial. Later, this new technology
spread to the United States, Canada, and Sweden. Metallic discs were constructed to replace discs in the lumbar section of the spine.

Raymond Damadian, a doctor from New York, was struck with pain while in graduate school. Doctors detected nothing wrong using traditional methods, but the pain persisted, giving Damadian the idea to utilize less often used methods to diagnose himself. He considered using a machine that harnessed magnetic resonance on a larger scale in order to examine larger regions of the body. In 1970, Damadian tested tumors in afflicted rats, assuming that due to the amount of water in cancerous tumors, a disparity between the hydrogen atoms present in healthy regions of the body and cancers would appear. He was correct. The NMR scan showed that the radio waves emanating from the tumors lasted longer than those coming from healthy regions of the rats’ bodies. The experiment worked, and a precedent was set for using NMR to diagnose and locate cancers. Damadian began looking into the idea of producing a larger, human-sized scanner.

Paul Lauterbur, a scientist at the State University of New York, Stony Brook, researched NMR technologies. He determined that there was a way to produce a solid image using the NMR technology that had been established before, and, in a restaurant of all places, conceived of using magnetic gradients to show the disparity in strength of the nuclei emitting radio waves. He made this technology into a reality, and produced images of water in a test tube and a clam using this. Damadian ultimately designed the “indomitable,” rushing to patent before Lauterbur. He was too large to get a good reading off the machine, so his assistant Larry Minkoff volunteered his own thin body. Eventually, a reading of Minkoff’s chest was produced and the machine was a success.
Future Technology

Donald Blake is an average human male--147 pounds and 5’10’’. While driving on the interstate, Mr. Blake is struck by another oncoming car and sustains major injuries to his spine. The intervertebral discs in the midsection of his spine shifted, crushing and compressing nerves in the process. Additionally, the majority of his thoracic vertebrae (ranging from T1 to T6) are fractured, leaving him with incredible back pain. The injuries are major, and have the potential to cause lasting trauma to Mr. Blake’s spine. He is brought to the hospital in an urgent state.

In the hospital, Mr. Blake is put under anesthesia and transported to the MRI facilities. There, he is placed in a high-end MRI scanner, which was remotely turned on immediately as Blake was loaded into the ambulance. Mr. Blake is put on a moving platform under the scanner, and slides quickly through the machine, with the MRI scanner quickly recording its results. The MRI techs receive a digitally produced reading of Blake’s spine and back in under four minutes, and Mr. Blake is rushed to another wing to receive further treatment. From there, the DICOM (Digital Imaging and Communications in Medicine) file of Mr. Blake is sent to construction technicians in the hospital’s 3D printing lab. They review and digitally highlight the scan, analyzing the vertebrae of the spine that have been severely struck, the discs that have shifted, and the ways in which the other regions of the spine have been affected. The technologists take the data gathered from this scan and modify a 3D model of the spine to create a replacement. This preexisting 3D model is made larger to fit Mr. Blake’s profile, and the spacing of the spine pre-accident as determined by the techs is also added to the model. Finally, other modifications are made to provide support for structures of the spine indirectly affected by the crash.
This model is exported into a STL (stereolithography) file and sent to the 3D printer. Loaded with titanium dust, the 3D printer utilizes a laser to fuse the titanium into a single solid layer, creating the pieces of Mr. Blake’s thoracic region of the spine. These titanium pieces, with a thickness of about .4 mm and formed in a matter of seconds, are then taken out of the machine and snapped into place with interlocking artificial discs, which use the CMP (collagen mimetic peptide) Proline-Hydroxyproline-Glycine as the material that constructs the exterior and flexible alginate gel that forms the interior. An allograft is also placed between disc and vertebrae. The spine is formed and sent to the operating room to replace the damaged portion of Mr. Blake’s spine.

An open back surgery procedure commences, with an incision being made along the spine. The team of surgeons at the hospital cuts through the extensive amount of tissue and push through other obstacles to reach the spine. The thoracic region of the spine is then cut away and removed from the remainder of the rest of the spine, with the ProTHOR replacement being brought in for installation. The replacement fits in naturally, due to the accurate spinal scan taken earlier in the process, and the ProTHOR is fused with the contact points of the spine with artificial bone material and sublaminar wiring. The large cut is then stitched together, and Mr. Blake is sent into recovery.

**Breakthroughs**

Twenty years from now, MRI technology will have to make monumental leaps if it is to be properly used in cooperation with ProTHOR. Speed is everything, and design and production of the replica needs to have a quick turn-around. If we do utilize MRI technology, the rate at which the device scans will be an issue. The technology in current MRI scanners has to speed up.
and be processed in minutes. This will allow a faster setup time for the ProTHOR to target problem areas. A more detailed image produced by the MRI technology is also a foreseeable advancement in the future. A more detailed image will help the ProTHOR more accurately replicate the damaged portion of the spine, with more detail providing more to build off from and utilize. The ProTHOR can only get more accurate with more detailed spinal imagery.

With access to higher quality scanners and tools, the vertebrae and spinal discs will be 3D-printed to replicate the original spinal region. Depending on the source of pain, Computed Tomography (CT) scans or Magnetic Resonance Imaging (MRI) scans show the exact shape and size of the damaged vertebrae and adjacent discs. Current technology limits what we can do, both in terms of price and practicality, but the idea and implementation of laser-cut, perfectly measured spinal parts and discs is a likelihood. As of now, the spine is limited in that it must be professionally manufactured with certain materials and criteria. 3D printing material will become stronger and more durable, as well as more precise, and so can be used in countless applications with the spine.

Because 3D printing is such a time consuming task, the ProTHOR may not be able to be constructed fast enough to meet the patients’ needs. Because the majority of patients with spinal damage are in critical condition in the emergency room, they need to receive medical condition very soon following their injury. For the ProTHOR to be fully effective, the technology behind 3D printing has to become quicker and more efficient.

**Design Process**

In order to benefit the technologies and overall design of ProTHOR, several crucial decisions had to be made regarding the things we wanted to implement in the device. ProTHOR
ProTHOR: Prosthetic Thoracic Vertebral and Disc Technology  

was originally proposed as a full-spine replacement, using an interlocking mechanism where different portions of the spine could be locked together to be used as a whole or used separately. Every portion of the spine would be covered, as opposed to the current strict focus on the thoracic region seen with ProTHOR. We realized that the complexities of creating this interlocking technology were beyond us-- in addition, there was no need to cover the whole spine when full-spinal injuries are uncommon.

In order to make the ProTHOR replica as accurate as possible, a visual guide of sorts must be provided-- a scan of the spine, so the problem areas ProTHOR must address are well documented. There are two primary ways to produce an image of the body: a computed tomography (CT) scan, which utilizes X-rays to assemble an image, and magnetic resonance imaging (MRI), which utilizes a strong magnetic field instead. We had to select the process that the ProTHOR would use to create its dimensions and parameters. Ultimately, the CT scan was discarded in favor of using the MRI scan. The x-rays a CT scan emits are more harmful than the magnetic field of MRI, and can lead to many medical complications.

We considered using ball joints in lieu of a replica of the actual spinal discs. It was assumed that this would be improving upon the actual design of the discs found naturally in the human body. The idea wasn’t followed up on, and we instead decided to utilize the normal design of spinal discs with artificial materials in ProTHOR. The idea of using ball joints was ambitious, but the design naturally doesn’t fit with the rest of the spine. In addition to that, a ball joint has more potential for extemporaneous movement. The traditional spinal disc structure works better, as it allows for less reckless movement and cushions the rest.
Consequences

With ProTHOR technology, the damaged sections of the spine would be able to be replaced with new, functional pieces, allowing the regaining of function to be a possibility. The development and use of the ProTHOR will pave the way for future prosthetics for different bones throughout the body. Medical breakthroughs will take place and further the knowledge regarding the spinal region and prosthetics. With additional surgical techniques, ProTHOR’s use will transcend that region and be applied further, to the rest of the spine.

Consequences of our new technology could include being cost prohibitive, inducing the discovery of new technologies, and helping individuals with paraplegia. With every surgical procedure comes inevitable risks, and the implantation of the ProTHOR is no exception. Patients receiving the surgery risk death, paralysis, and further damage to the spinal area if the surgery does not go as planned.

Due to the expenses coming from the surgical procedure, equipment needed, and materials needed, the ProTHOR will not be immediately accessible to everyone. As it becomes more widely accepted, costs will go down and health insurance plans are more likely to cover the procedure. The goal of the ProTHOR is for it to be utilized by everyone, which would not be realistic as long as individuals do not have the means to afford such a procedure. People with monetary benefits may also choose to replace a healthy vertebral column with a prosthetic, giving them unfair advantages. Despite potential short-term negative consequences, ProTHOR technology will become more widely accessible, significantly increasing the quality of life and affected individuals and their loved ones.
Works Cited


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ProTHOR: Prosthetic Thoracic Vertebral and Disc Technology

Shaping the World: One Bone at a Time

ProTHOR is a prosthetic for thoracic vertebrae and vertebral discs in patients with damage to the region.

In the space below, please describe any special effects that might be applied to your web page.

Sample Web Page #1 of 5 (must include 5 forms)
**ProTHOR: Prosthetic Thoracic Vertebral and Disc Technology**

<table>
<thead>
<tr>
<th>Home</th>
<th>Our Technology</th>
<th>Past &amp; Present Technology</th>
<th>Design Process</th>
<th>Breakthroughs &amp; Consequences</th>
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</thead>
</table>

### Past & Present Technology

<table>
<thead>
<tr>
<th>History</th>
<th>Today</th>
</tr>
</thead>
<tbody>
<tr>
<td>First 3D Printing technology was developed in the 1980s</td>
<td>3D printers are used everywhere and have many purposes</td>
</tr>
<tr>
<td>MRI scans were created in the late 1970s</td>
<td>MRI scans are often used today in hospitals</td>
</tr>
<tr>
<td>Artificial vertebral discs were created around 30 years ago</td>
<td>Artificial discs are now used commonly in spinal fusion procedures</td>
</tr>
</tbody>
</table>

In the space below, please describe any special effects that might be applied to your web page.

Sample Web Page # 2 of 5 (must include 5 forms)
ProTHOR: Prosthetic Thoracic Vertebral and Disc Technology

Our Technology

Individuals with major trauma in the thoracic region of the spine now have the ability to replace the damaged area with a sturdy, functional prosthetic, the ProTHOR. The vertebral disc component consists of a protective outer layer of collagen mimetic peptides and an amicid alginate hydrogel interior. In addition, the vertebrae are composed of sturdy Grade-5 titanium alloy.

In the space below, please describe any special effects that might be applied to your web page.
### ProTHOR: Prosthetic Thoracic Vertebral and Disc Technology

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</table>

#### Design Process

<table>
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<tr>
<th>Accepted</th>
<th>Rejected</th>
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</table>
| • Pedicle screws to hold the newly inserted vertebrae and spinal discs in place  
  • Prevents disks from slipping  
  • Using MRI scans to produce images of the spinal column  
  • More accurate images  
  • Is less harmful  
  • Sticking with the design of the natural spinal disc  
  • Other designs don’t fit with the designs of other bones within the body | • Focusing on a full-spine prosthetic  
  • Focusing on the thoracic region narrowed our focus  
  • Using CT scans to produce images of the spinal column  
  • More harmful  
  • Using ball joints in lieu of a replica of the actual spinal discs  
  • Does not fit with the body’s design |

In the space below, please describe any special effects that might be applied to your web page.
**ProTHOR:** Prosthetic Thoracic Vertebral and Disc Technology

**Breakthroughs & Consequences**

Thousands of cases of spinal cord injuries occur annually. There is a constant threat of extremities surrounding the spinal cord being damaged, potentially leading to paralysis. With this new development, individuals with major trauma in the thoracic region of the spine have the ability to replace the damaged area with a sturdy, functional prosthetic, the ProTHOR.

**Breakthroughs**
- Improved surgical technique as the arthroplasty
- Quicker 3D Printing to decrease delay for the patient

**Consequences**
- Material availability may be limited to certain countries
- Cost prohibitive
- ProTHOR will allow for future technologies to be developed

In the space below, please describe any special effects that might be applied to your web page.