Implementation of an implantable joint-angle transducer

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Abstract—An implantable joint-angle transducer (IJAT) was implemented to provide command-control information from the wrist for functional neuromuscular stimulation (FNS) neuroprostheses. The IJAT uses the Hall effect to sense joint angle. The objectives of this study were to evaluate (1) chronic functionality, (2) safety and biocompatibility, (3) repeatability of the implantation procedure, and (4) clinical feasibility. Accelerated bench testing projected an operating period of over 50 years. In chronic animal experiments, stable output was obtained from three of four IJATs for periods of 10 to 19 months. Histology revealed acceptable osseointegration of the implant. The device has been implanted in human subjects for over 2 years and provides an excellent control signal for hand grasp. We conclude that this device is safe and effective for chronic human use as a control input for an implanted hand neuroprosthesis.

Key words: *animal, biocompatible materials, electrical stimulation, forelimb, human, implants, joints, paraplegia, pathology, physiology, physiopathology, prostheses, rehabilitation, surgery, transducers.*

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INTRODUCTION

Functional neuromuscular stimulation (FNS) restores function in individuals with tetraplegia or paraplegia by stimulating muscles with upper motor neuron paralysis [1,2]. In upper-limb applications in subjects with tetraplegia, hand grasp and release have been successfully achieved with the use of an implanted stimulator system. Paralyzed hand muscles are activated in selected sequences, allowing the hand to open and close in functional grasp patterns. A first-generation implantable system has undergone multicenter clinical trials [3], culminating in Food and Drug Administration (FDA) approval and commercial availability. A second-generation system was developed that employs implanted sensors for control (**Figure 1**) and an implantable stimulator telemeter (IST) [4,5].

A user has voluntary control of a neuroprosthesis through the acquisition of a command control signal. Signals that have been used for mid-cervical-level spinal cord injured individuals include wheelchair-mounted control, shoulder movement, head movement, wrist movement, myoelectric signals, hand switches, voice control, and EEG (electroencephalogram) signals [6–12]. The use of wrist angle as a command control source has a number of advantages over many other sources of command control [9,13]. Wrist position has a natural synchronization with hand opening and closing and emulates the action of the natural weak tenodesis grasp [14]. This natural relationship between the wrist and hand suggests
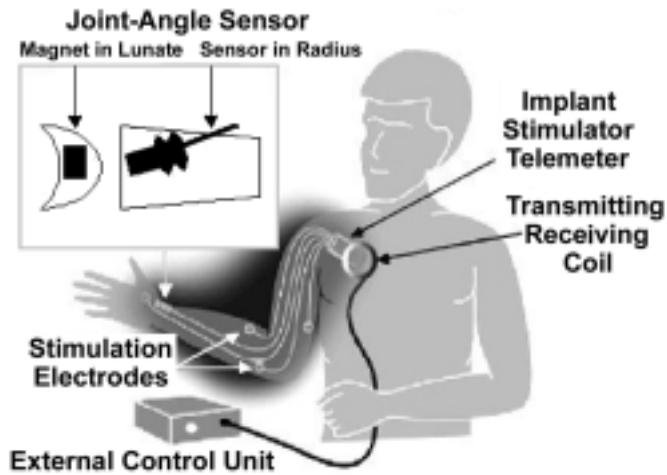
Figure 1.
FES hand-grasp system with implanted joint-angle sensors. Schematic of implant stimulator telemeter (IST), external control unit (ECU), and implantable joint-angle transducer (IJAT).

an ideal control relationship. Wrist control can also be used as a bilateral control source, allowing two-handed manipulation.

Active wrist extension is required to use the wrist for control, although active wrist flexion is not required [9]. Therefore, wrist control is generally targeted for subjects with C6 or lower injuries. However, many C5 subjects can gain voluntary wrist extension through tendon transfer of the voluntary brachioradialis muscle [15]. This procedure often provides sufficient voluntary wrist extension for control and widens the target population [15].

Externally mounted transducers have been viable for first-generation systems, but have inherent limitations [6]. They require donning and doffing, provide inconsistent signal quality because of changes in mounting, are not cosmetically appealing, may encumber some activities, may become dislodged during use, and inherently have external cabling, which may become entangled and break.

To overcome these limitations, we have developed an implantable joint-angle transducer (IJAT), capable of sensing movement of the wrist (C5- or C6-level injuries). Johnson et al. showed a prototype design of the IJAT that was feasible with the use of computer simulations and bench-testing [16]. A prototype IJAT was designed for push-fit insertion into a rectangular slot cut into the dorsal surface of the radius, but it proved difficult to insert accurately. Histology from an animal study showed

excessive fibrous tissue formation around the implant. Therefore, the mechanical aspects of the IJAT package were redesigned as threaded cylinders, which could be surgically inserted with modifications of standard orthopaedic fracture and prosthetic surgery techniques. This allowed precise surgical placement and short- and long-term positional stability.

The objectives of the present study were to demonstrate (1) chronic functionality, (2) safety and biocompatibility, (3) repeatability of the implantation procedure, and (4) clinical feasibility of the redesigned IJAT.

Device Specifications

The inset in **Figure 1** shows a schematic of the IJAT. The IJAT senses relative movement between two opposing bones across a joint. Magnet movement produces a changing magnetic field, which is transduced by the Hall sensors, as fully described in a paper by Johnson et al. [16]. The IJAT uses an array of three Sprague UGN-3503C linear Hall effect sensors, with nominal sensitivities of 1.3 mV/G and an LM336-5.0 V voltage regulator assembled into a hybrid circuit on an alumina substrate. The substrate is mounted and hermetically encased within a laser-sealed titanium capsule. The capsule is a smooth cylinder, which has a threaded collar bonded to its proximal face around the lead feedthroughs. Lead wires are connected to the circuitry within the capsule via a hermetically sealed pacemaker-grade hexapolar feedthrough (Hittman Materials and Medical Components, Columbia, MD). The IJAT sensor connects to the IST and is pulse-powered at a nominal 34 mA. The magnet is a cylindrical neodymium-iron-boron (NdFeB) permanent magnet, mounted and hermetically encased within a laser-sealed titanium capsule. In this paper, IJAT sensor refers to the sensor device in its package, while the magnet capsule and sensor capsule specifically refer to the titanium enclosures.

Insertion Tools

The IJAT sensor signal amplitude is particularly sensitive to the distance of the sensor from the magnet, varying as the inverse of the distance cubed [17]. It was therefore vital to place the sensor and magnet capsules accurately in the targeted bones. The surgical implantation of the IJAT was designed with cannulated instrumentation, commonly used in orthopaedic procedures (**Figure 2**). In this method, a narrow guide wire was first
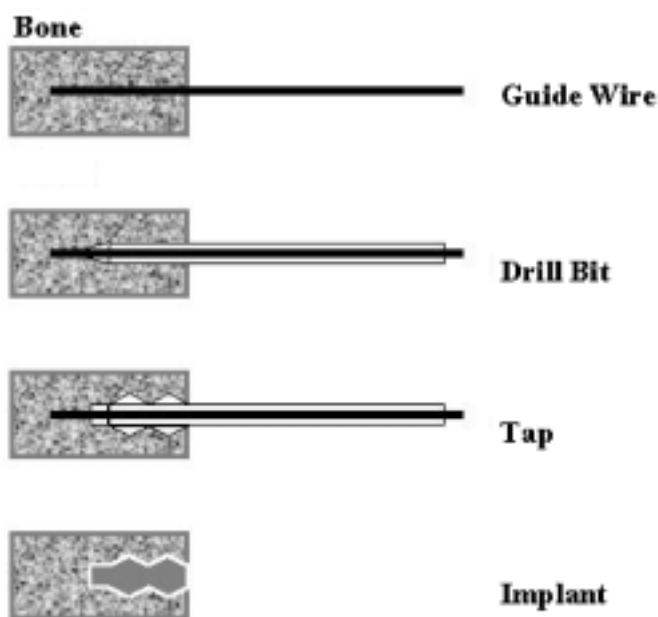
Bone

Figure 2.
Cannulated procedure for implant insertion into bone, reading from top down: Guide wire inserted, cannulated drill bit, tap used over guide wire, and guide wire removed and implant inserted.

inserted in the target bone. The guide wire position could be adjusted under fluoroscopy without undue bone damage. Once the position was judged satisfactory, the bone was drilled and tapped with the use of cannulated tools that slid over the guide wire [17].

We used standard tools (Synthes©) for some steps in the procedure and custom-modified some tools for non-standard sizes. Other custom tools, necessary to hold the magnet and sensor capsules during final insertion, were designed to fit in standard tool handles (Synthes©), thus making the tools simpler to manufacture. Surgical guides were designed to enable accurate relative placement of the IJAT components, which is essential for achieving optimal signal strength from the sensors. One guide allowed placement of the lunate guide wire accurately and safely; the second allowed the radius guide wire to be drilled with the use of lateral fluoroscopy only, thus avoiding turning the forearm multiple times to obtain two-axis views [17].

Neuroprosthetic Implementation

Existing implanted neuroprosthetic systems rely on external signal processing and powering. Therefore, to use an implanted sensor such as the IJAT, one must transmit the sensor signal out of the body to the external-processing device. We accomplished this by developing an IST device that could both stimulate and transmit a bidirectional signal [4]. We performed signal and power transmission using a transcutaneous inductive link. Signals were transmitted from the implant to the external-processing device by modulating the impedance of the IST coil [18]. These impedance modulations were detected by the external coil and the raw IJAT sensor data recovered [4,18].

METHODS

Chronic Functionality

We demonstrated chronic functionality of the IJAT through accelerated soak testing of four instrumented IJAT capsules. The test capsules were manufactured with feedthrough pins but without the IJAT sensors. Because no electronics were placed inside the device, current leakage measurement during testing could be attributed to problems with the external packaging rather than with the internal electronics. The sensors were immersed in a 0.9 percent saline bath at 90 °C, which provides an acceleration factor of 32 relative to body temperature based on the Arrhenius equation [19]. The sensors were powered at 60 ms intervals for 100 μs with a nominal 32-mA current, which corresponds to constant daily use in a neuroprosthetic system. The resistances between each IJAT lead and bath and between leads were recorded daily.

Safety and Biocompatibility

We studied safety and biocompatibility in an animal model by measuring the chronic performance of the IJAT and by examining the tissue surrounding the implant. The IJAT was implanted in the right wrists of four dogs. Three dogs also were implanted with the IST and one without the IST. The implantation for the animal studies was done under general anesthesia, under full aseptic procedures. All procedures followed institutional guidelines for animal care.

Implantation Procedure

We inserted the magnet into the radiocarpal bone in the dogs and in the lunate in human subjects. A single long dorsal incision was used to expose both the carpal bone and the radius. The implantation sites were first targeted with guide wires under fluoroscopic control. We

then followed this by drilling and tapping over the guide wire using cannulated instruments. The sensor was inserted in the radius so that its face abutted the subchondral bone. Next, we connected the IJAT leads to the IST temporarily. IJAT data were displayed in real time on a computer screen as the magnet was slowly inserted. The displayed data showed both the baseline offset of the three sensors and the optimum position of the magnet. We optimized the offset to be near the center of the 12-bit analog-to-digital (AD) range by aligning the magnet axis correctly. The sensor and magnet insertion tools were removed, and the IJAT was disconnected from the IST. Then we implanted the IST in front of the shoulder. The IJAT leads were routed subcutaneously and connected to the IST, and lead wires were capped for the IJAT-only implant (dog 1) or tunneled subcutaneously and attached to an implanted IST (dogs 2 to 4).

At the end of the procedure, sensor baseline data were collected along with flexion-extension range of motion data with the use of an external potentiometric goniometer. Three static trials at five wrist positions (0°, 30°, 60°, 90°, and full flexion) and three dynamic extension-flexion trials were collected. Anteroposterior (AP) and lateral X rays were taken of the wrist and the scapular area for the IST. We closed all surgical wounds and applied a plaster cast to the animal's foreleg and chest. The cast was maintained for 6 weeks. One animal (dog 1) was implanted with only an IJAT. The ends of the IJAT leads were sealed with silicone caps before wound closure. Data for this IJAT were gathered through a breadboard IST. The remaining three animals had full system implants, with IJAT, IST, and ten epimysial electrodes (four in the triceps, two in the biceps, and two each in wrist extensor and flexor).

Histological Analysis

At the terminal experiment, tissue including the distal radius (containing the IJAT sensor) and all the carpal bones (including the magnet) was dissected and processed for histology. We used hard-tissue techniques for undecalcified bone histology with toluidine blue as a surface stain to differentiate between nonmineralized cartilage, calcified cartilage, fully calcified bone, and incompletely calcified bone [20]. We studied sections under a microscope (Olympus BX-60) with surface lighting and photographed with an overlying scale (grid size = 0.1 mm) at a magnification of 3.75. The photographs were scanned and digitized, and the percentage of the perimeter of each sectioned implant that directly contacted the bone was measured. We performed statistical analysis on the bone contact percentages using analysis of variance (ANOVA). We also made contact radiographs (Faxitron; model number 8050-010) of each histological section to show mineralized bone around the implant.

Repeatability of Implantation Procedure

Accuracy of the surgical placement was measured in postimplant X rays in both animals and human subjects. We performed a radiographic assessment of the accuracy of surgical placement by measuring deviations of the components from the optimal position. The optimal position was defined in presurgical template X rays. The magnet capsule was required to be positioned centrally in the lunate, and the sensor capsule was required to abut the subchondral bone of the radius. We minimized measurement errors caused by X-ray magnification by measuring the diameter of the magnet capsule (physically = 4.5 mm) on the X rays and using that as a correction factor. The following parameters were measured:

- Magnet-sensor distance measured from the center of the magnet to the center of the face of the sensor.

- The distance of the center of the magnet from the carpal center, measured on AP X rays (carpal center defined by the intersection of two orthogonal diameters).

- The distance of the center of the face of the sensor from the intramedullary boundary of the radial subchondral bone.

- The IJAT sensor range, normalized for a range of wrist movement, was also calculated. This range was computed as the average of the three sensors in the IJAT for a 90° wrist movement. Since the IJAT output is very sensitive to the magnet-sensor distance, this computed sensor value was selected as another measure of optimal surgical placement of the device.

Characterization of Sensor Output In Vivo

In both the animal model and in the human subjects, we recorded IJAT data with external electrogoniometry. Sensor noise, sensor output versus external wrist angle, and sensor outputs over time were analyzed.

Animal Model

Device Assessment. Every 2 weeks, with the three dogs under sedation, we measured sensor data using the telemeter. In dog 1 with only an IJAT, sensor recordings were made only at implantation and at explantation. With the use of an external reference goniometer, one static trial at five wrist positions (0°, 30°, 60°, 90°, and full flexion) and three dynamic extension-flexion trials were taken. X rays of the limb were taken at 6 weeks, 6 months, and at explantation.

Data Analysis. We analyzed chronic IJAT data to determine the stability of the sensor signals. Sensor noise was evaluated by computing the root mean square (rms) value of noise for static trials, where the wrist was held in a steady position. For the animals, we compared IJAT values for wrists at 0° extension. This was feasible because the dog wrist had almost no radial or ulnar deviation. The sensor output was also averaged for the three sensors and normalized to a 90° flexion range to allow comparisons across animals.

Implementation in Human Subjects

Subjects. Two human subjects, who sustained tetraplegia at the C6 level, secondary to spinal cord injury (clinical summary shown in **Table 1**), were recipients of the IJAT. The surgical procedure was similar to that used in the animal studies; except that in human surgeries, a tourniquet was used and the forearm was casted for 4 weeks followed by physical therapy to strengthen wrist movement. These procedures were approved by the

Table 1.
Clinical summary of two human subjects.

Variables	Subject	
	1	2
Age at injury	21	28
Cause of injury	Fall	Diving Accident
Injury Level:	Right: C6[OCu:2]	Right: C5[O:0]
	Left: C6[OCu:3]	Left: C6[OCu:2]
Age at IJAT Implant	23	48[*]
Years postinjury	2	20[*]
Side on which IJAT & IST implanted	Right	Left[†]

[*]Had 8-channel stimulator on left side at age of 37, 9 years postinjury. This was changed to 10-channel IST and IJAT at age of 48.
[†]Also has 8-channel stimulator on right side implanted at age of 47.

Institutional Review Board, conducted under an Investigational Device Exemption. Postimplantation X rays are shown in **Figure 3**.

Control Signal Assessment. Sensor signals were recorded approximately monthly. The range of the sensor was recorded for a full, voluntary extension from a position of gravity-aided wrist flexion, with the elbow at 90° and the forearm fully pronated. We found this a reproducible measure in contrast to trying to hold the wrist at an intermediate static position. Wrist angle was measured with an external, biaxial electrogoniometer (Penny-Giles®). Data for some trials were also obtained from a three-dimensional (3-D) optical tracking device (OPTOTRAK®).

RESULTS

Chronic Functionality

The accelerated life tests for all the IJAT capsules have demonstrated no leakage for periods estimated to be over 50 years. This lifetime exceeds that anticipated for human subject use.

Safety and Biocompatibility

All the animals regained full range of wrist motion (equal to the opposite limb) and were fully weight-bearing within 6 weeks of removal of the plaster cast. Six months after implant, dog 2 developed a flank sinus following a cage trauma. The IJAT signals, which were stable until this time, started to decline because of a current leakage at the lead connector site that was near the sinus. The sinus eventually was tracked to the IJAT sensor site at the wrist. There were no other clinical complications in the animals.

There were no clinical complications in the human subjects. Presurgery joint movement was restored within 8 weeks of cast removal and has remained stable for over 2 years. Follow-up radiography did not reveal any signs of orthopaedic complications. We were particularly aware of the possibility of avascular necrosis in the lunate. This was not observed radiographically.

As for the histology of the study, all four magnet capsules implanted in the dogs showed excellent osseointegration. The bone staining with toluidine blue was an even blue color across the whole section, implying that the peri-implant bone was stable without any ongoing
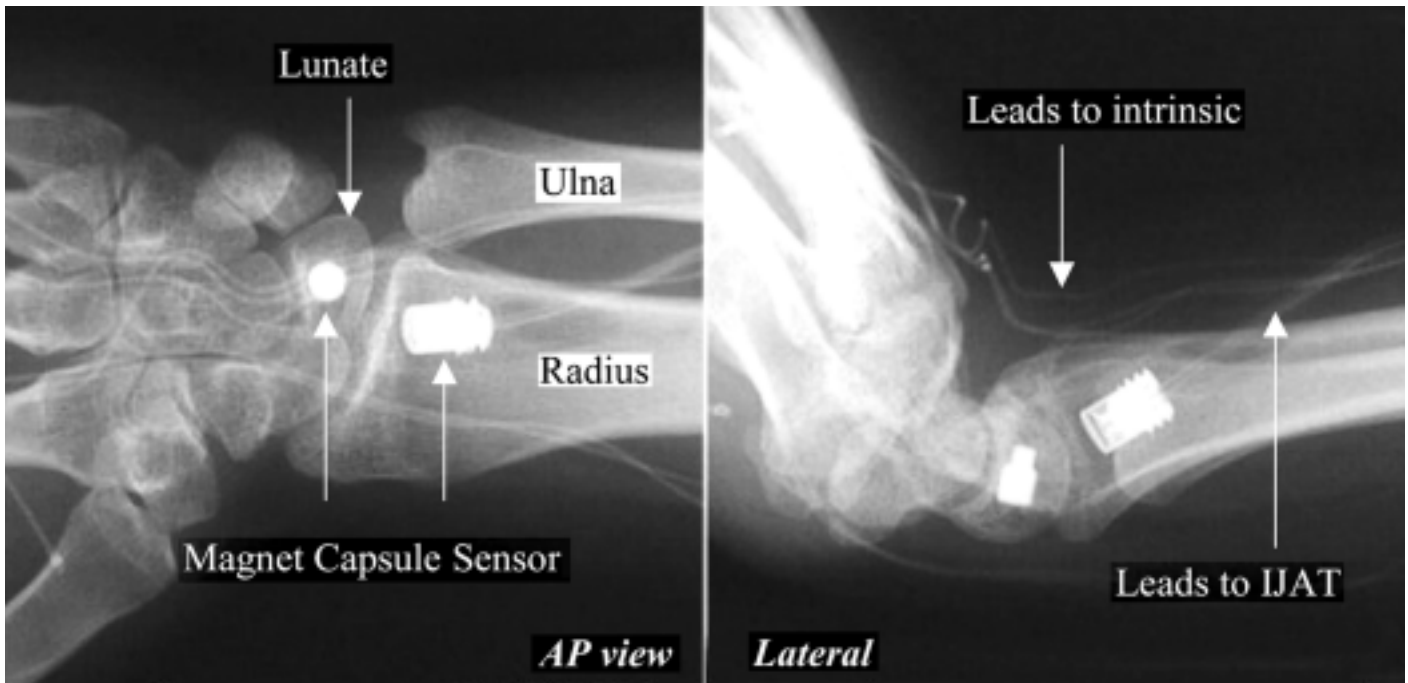
Figure 3.
Radiographs of implanted IJAT. Electrode leads to intrinsic muscles are also visible.

new bone formation. Bone had grown into the thread interstices and behind the head of the magnet capsules (**Figure 4**). There were no fibrous tissue-filled gaps, implying a chronic, stable implant. The entry points on the dorsal surface of the carpal bones were healed in all four animals. We noticed no abnormalities in the joint cartilage of the carpal bone or the radius. The percentage of bone-to-implant contact was 50 percent.

Two of the four sensor capsules (dogs 1 and 3) had similar histology to the magnet capsules. The bone was

stable and had grown into the threads and closed in around the shoulder of the device (**Figure 5**). The exiting leads were tightly surrounded with bone. There were no fibrous tissue gaps between the implant and bone. The percentage of bone-to-implant contact was 21 percent.

Dog 2 had a cage injury 6 months following implantation. This led to a sinus infection, which tracked down the leads to the IJAT sensor after the sixth month. The chronic infection (pseudomonas aeruginosa) caused a chronic subclinical osteomyelitis, which
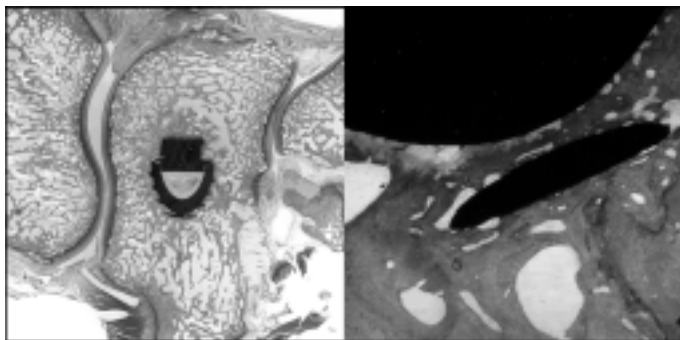

Figure 4.
Microscopy of magnet (magnification ×5 and ×20).

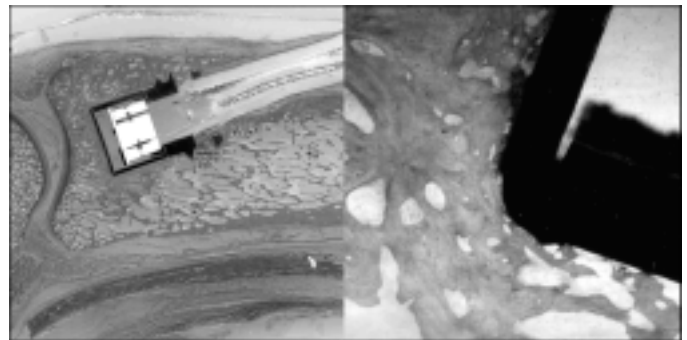**Figure 5.**
Microscopy of sensor (magnification ×5 and ×20).

resulted in bone dissolution. Bone buttressing could still be seen behind the implant shoulder, which suggested that originally the implant had healed well. A paucity of bone around the sensor capsule had a fibrous tissue gap that measured between 0.2 to 0.5 mm. Direct bone-to-implant contact was present in some areas and averaged 4 percent. Dog 4 had a sensor that was not inserted deep enough into the radius. This sensor also showed a fibrous tissue gap of 0.1 to 0.5 mm with bone-implant contact of 3 percent. An ANOVA of the bone contact percentages showed a significant difference between the devices (p value approximately = 0) and the dogs (p value = 0.031). In spite of the lower bone contact in these two sensor capsules, contact radiography of the sensor capsules for all four animals did not reveal any evidence of implant migration, and the IJAT functioned properly.

Repeatability of Implantation Procedure

All six magnet placements were judged accurate, and four of the six sensor placements were accurate. The placement parameters for both the dogs and humans are presented in **Table 2**. Magnet capsule insertion was accurate to within ±1 mm. The sensors in dogs 1 and 4 were not at the optimal depth. In dog 4, this shallow insertion led to one corner of the sensor abutting on the radius cortex. In our first human subject, the sensor was not inserted deep enough at surgery, resulting in lower IJAT sensor outputs. This was a result of the learning curve for the surgery. The IJAT was positioned optimally in the second human subject.

Characterization of Sensor Output In Vivo

Sensor noise varied from 0.1 to 0.6 mV rms across all static trials, including both hard-wired and radio-frequency-linked data recovery. The sensor voltage noise was normally distributed (R value > 0.997 on a Q-Q statistical plot). These values compared well with previous data on the IJAT [21].

In the chronic animals, the changes in the average of all three sensor values for each IJAT at 0° wrist, between implant and explant, are shown in **Figure 6**. The data were normalized on the y-axis to the output range for a 90° wrist movement. Thus, in dogs 2, 3, and 4, the offset changes are less than three times the functional range over periods of 10 to 19 months. Dog 1 had a larger drift in sensor offsets. This was the first IJAT capsule manufactured, and it had some epoxy cavitation. This offset drift was attributed to capsule leakage. All future IJATs, including those bench tested, were made with an improved manufacturing technique. At explantation, 11 out of 12 sensors from the four IJATs were functional. One sensor in dog 4 was not working. The cause for this could not be investigated without jeopardizing the histological preparation and was therefore not done. **Table 3** shows the time course and major events for the four implants.

The IJAT sensor output was stable in the two human subjects. **Figure 7** shows the maximum and minimum values for all three Hall sensors in the IJAT in subject 2 (JHJ). **Figure 8**, for the same subject, shows the mean range of the IJAT for voluntary wrist extension and gravity-assisted wrist flexion with the forearm pronated, over time. These graphs demonstrate the low shift in the sensor offsets and the stability of the output signal range
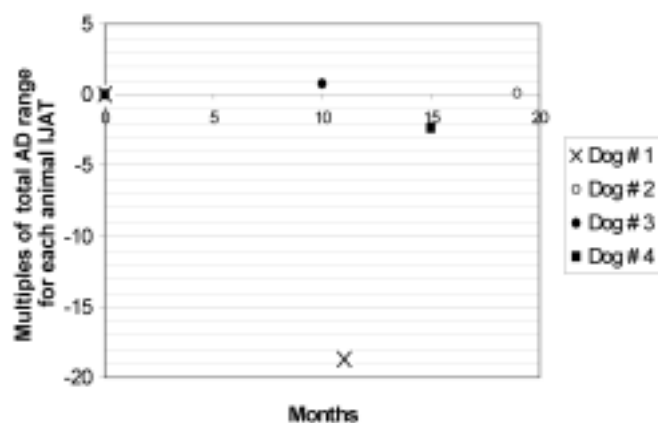
Table 2.
Placement parameters of IJAT in animals.

Parameters	Animals				Humans	
	a1	a2	a3	a4	h1	h2
Magnet-sensor distance (mm)	13	11	11	13	15	9
Distance of sensor from ideal position (mm)	4	2	1	3	5	0
Distance of magnet from ideal position (mm)	2	0	1	0	2	1
Sensor Output/90° ROM (mV)	5	12	1	3.8	4	30

Figure 6.
IJAT data from in vivo study. Offset changes normalized to 0 at implant surgery and mean AD range.

Table 3.
Summary of animal implants.

Major Event	Animal			
	1	**2**[*]	**3**[†]	**4**[‡]
Implant Type	IJAT	IJAT + IST	IJAT + IST	IJAT + IST
Total Implant Time (Mo.)	11	19	10	15
IJAT Status at Explant	Functional	Functional	Functional	2 sensors functional

[*] Sinus @ 6 months postimplant
[†] IST failure @ 3 months
[‡] IST failure at 6 weeks

for a reproducible range of voluntary wrist movement. **Figure 9** shows the range of the three IJAT sensors for the mid-range value of voluntary wrist flexion and extension for subject 1 (CHJ) over time. In this subject, an iatrogenic injury at surgery produced leakage from the IJAT connectors (where the IJAT leads are attached to the IST). This resulted in the decline of the sensor output over time. At a subsequent date, we repaired the connectors using a custom designed silastic sleeve [22]. IJAT sensor values were restored and have been stable since this repair (more than 1 year).

Figure 10 shows IJAT output as a function of voluntary wrist extension-flexion angle (wrist angles were obtained with OPTOTRAK®). The nonlinear output is shown for all three sensors. The output can be linearized as is shown for sensor 1. This linearization allows use of a simple two-way lookup table to assign wrist angles from IJAT data during functional use of the neuroprosthesis.

DISCUSSION

We developed an implantable joint-angle transducer that can be safely implanted in the human wrist and provide adequate output for use in neuroprosthetic systems. We were able to demonstrate chronic functionality, device safety, and device biocompatibility by a combina-
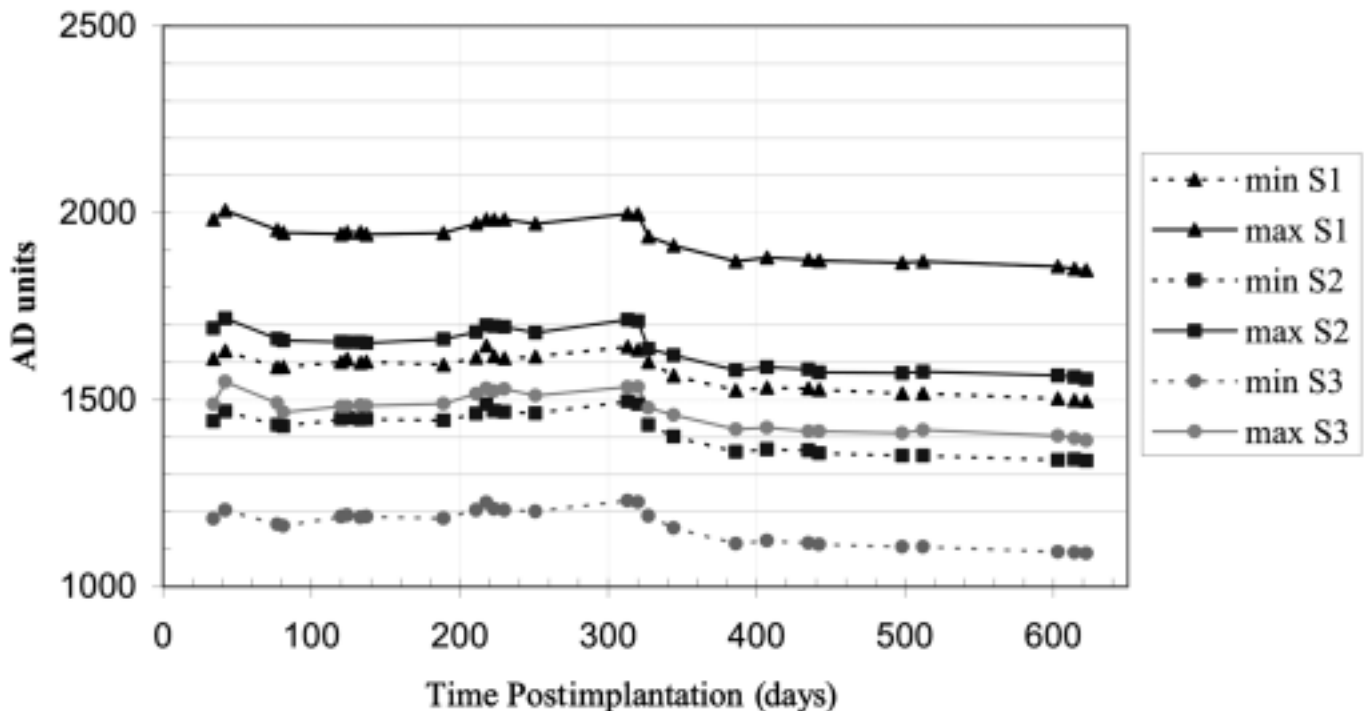

Figure 7.
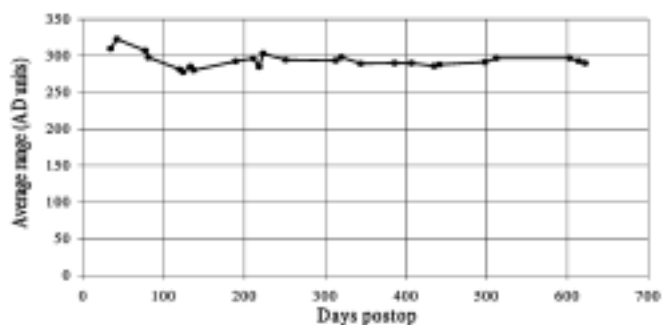Maximum and minimum values of all three sensors over time for human subject 2 (JHJ).

Figure 8.
IJAT sensor output range for voluntary wrist extension over time in human subject 2 (JHJ) (average maximum-minimum range of all three sensors).

tion of bench tests and in vivo experiments. The implantation procedure was accurate and resulted in secure placement of the implanted components in the target bones.

The sensor output from the IJAT had a nonlinear relationship to wrist angle, as would be expected from a magnetic sensor with a rotating magnetic field. The output depended not only on the magnetic field angle but also on the changing magnet-sensor distance caused by screw-axis movements of the carpal bones [23]. In spite of these complexities, the sensor output could be linearized over a functional wrist angle range and the resultant output used for command control with the use of a lookup table. The critical factor was the resolution of the device, and this depended primarily on the output range. The signal range was larger where the magnet-sensor distance was minimized. This implied that it was important to position the sensor close to the subchondral bone of the radius. This is shown in **Figure 11**, where the normalized IJAT output for a 90° range of motion is plotted versus magnet-sensor distance for both animal and human implants. This graph shows the critical relationship between IJAT sensor output and the magnet-sensor distance achieved at implantation. Functionality of the implanted sensor has been demonstrated in both human subjects. In human subject 2 (JHJ), the sensor
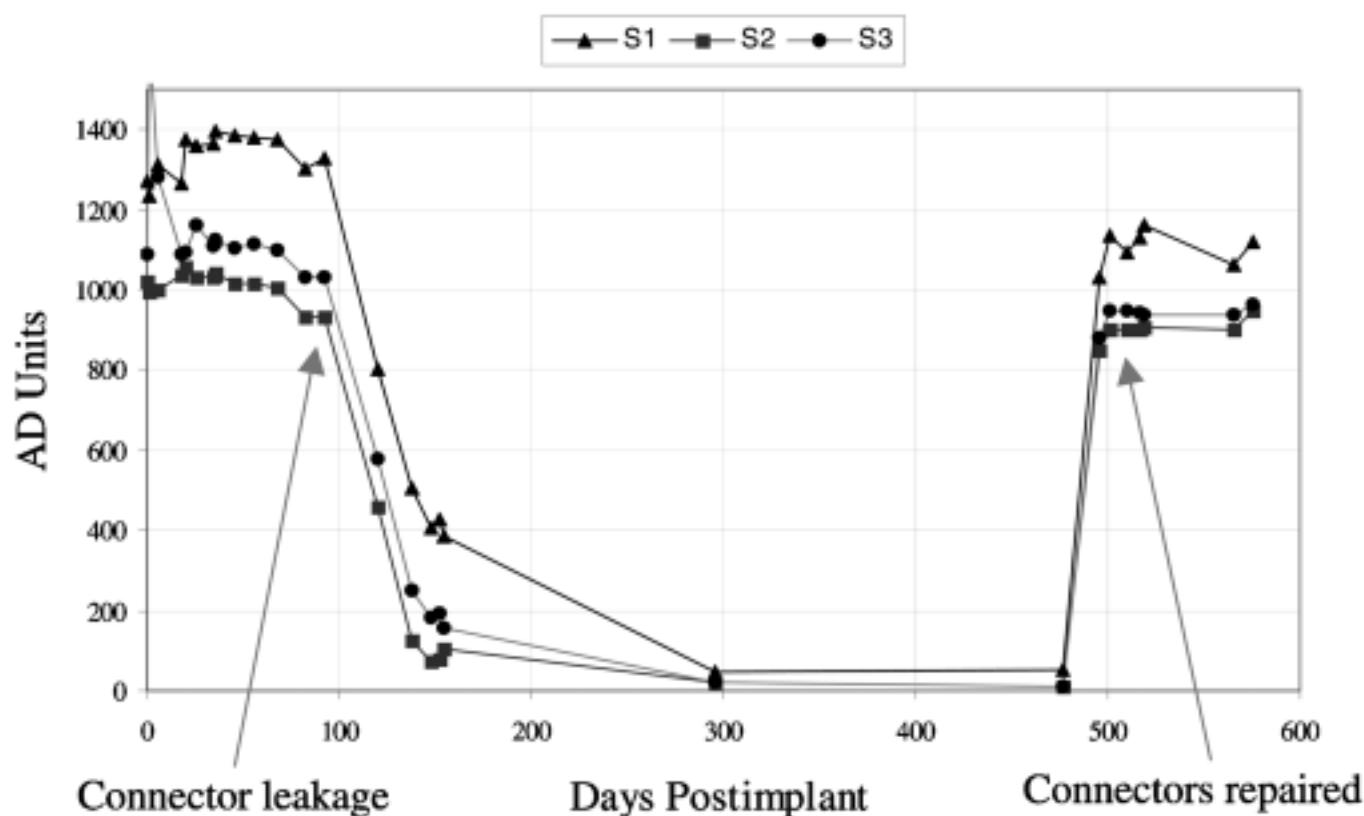

Figure 9.
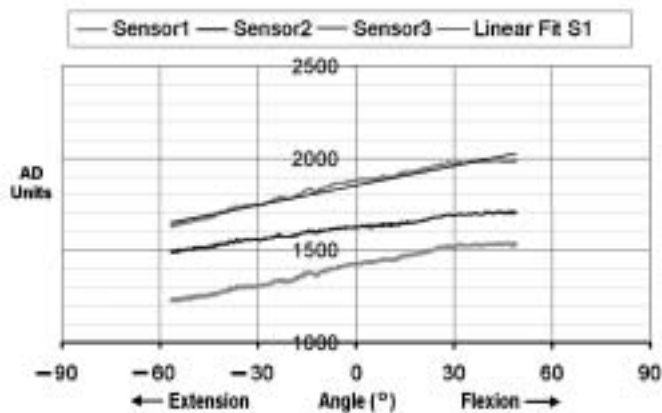Sensor values over time in human subject 1 (CHJ).

Figure 10.
IJAT output over wrist extension-flexion in human subject 2 (JHJ).

signals have excellent range and have been stable for over 2 years. There are approximately 30 control levels available. In human subject 1 (CHJ), the magnet-sensor distance was not minimized and the resulting signal range provided approximately four potential control levels. The best-case angle resolution has been 3°.

Stability of the implant in the bone was demonstrated. Five out of six implants showed stable sensor offsets over 10 to 26 months. This is a very sensitive indicator of stability of the implants, since the sensor output would be markedly changed by minimal changes of distance between the magnet and the sensor. The histology showed excellent bone-implant interface, implying absence of movement of the implant.

The nonlinearities of the sensor output changes from radial-ulnar deviations have not affected implementation of the IJAT in command control. Voluntary movement in
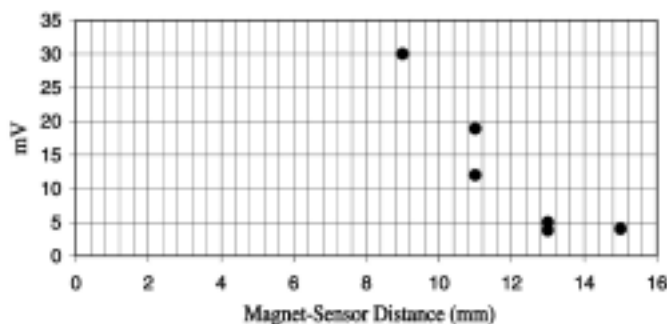

Figure 11.
IJAT output (mV) normalized to 90° range of motion versus magnet-sensor distance for all six IJAT implants.

the subjects was essentially uniaxial. The functional range of wrist movements used for control is 30° flexion to 45° extension, which is within the range of the IJAT.

Could the IJAT provide sufficient resolution for feedback control? Crago et al. give estimations of required performance and suggest 0.5° is required, [24] but this is very demanding and perhaps not justified clinically. One could possibly increase resolution by using sensors with higher sensitivities, either Hall sensors or alternate magnetic sensing technologies, such as magneto-resistive sensors. Signal averaging of the sensor outputs will also increase the signal-to-noise ratio. Increased sensitivity of the sensors also implies that the magnet-sensor distance could be increased. This sensitivity may allow placement of the magnet on the capitate (the movement of which has a linear relationship to wrist angle) and would improve the functionality and applications of this device to other joints of the body.

Not one of the six implantations had surgical complications, and usable IJAT output was obtained in all cases. The threaded design resulted in a stable implant, which could be precisely positioned. Since the implants were not weight-bearing, surgical grade titanium without special surface preparation or coatings was believed to be adequate for the packages. The potential risks and complications in the IJAT procedure were addressed in this research, for example, infection, restriction of joint movement, avascular necrosis of the lunate, pathological fracture of the radius, and sensor failure. The precautions we used against infection were aseptic surgery and the use of prophylactic antibiotics. If late infection occurred, one or both IJAT components would be removed and aggressive orthopaedic treatment for bone infection instituted. Though the radius remodels around the lead hole, pathological fracture was a possibility in our subjects because of their osteoporotic bones. Any fracture would have been treated with standard fracture techniques with removal of the sensor, if necessary. Interventional surgery following infection or fracture may have required additional bone grafts in the radius. If the sensor had failed, we would not have attempted to remove it, since it would have been destructive on the radius. Alternate command control schemes would have then been used for control. The entry point of the magnet encroaches on the articular surface of the lunate and results in fibrous scarring. Joint restriction was minimal, since this part of the lunate contributes only a small percentage of the extension movement. There have been no functional

extension deficits in either human subject. We minimized the risk of joint damage on the radial side by ensuring the sensor capsule did not transgress the subchondral bone of the distal radius.

The IJAT has been specifically designed for the wrist joint. Further work has to be done if this type of transducer is to be used around other joints. The main obstacle is the sensitivity of the IJAT to the magnet-sensor distance, which is constrained by magnet size and Hall sensor sensitivity. Improved Hall sensor technology and/or alternative magnetic sensing sensors (for example magneto-resistive) would allow smaller magnets and more flexible placement of the two components. Future designs could even allow attachment of flat capsules to cortical surfaces of bone, which would largely simplify the surgical procedure.

CONCLUSION

An IJAT has been developed that can be safely implanted in the human wrist and can provide adequate output for use in neuroprosthetic systems. The transducer has been successfully implanted in two human subjects as part of an implanted neuroprosthesis. The best-case angle resolution of the sensor is 3° and the expected lifetime is over 50 years.

ACKNOWLEDGMENTS

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