

# Moonshot R&D MILLENNIA\* Program

\*Multifaceted investigation challenge for new normal initiatives program

# "Research on technological and social issues related to social implementation of embedded cyborg technology and its impact on social systems"

# Initiative Report

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# I. Concept of Proposed MS Goal

1. Proposed MS Goal

1.1 Title of Proposed MS Goal

"Realizing a society in which everyone can be who they want to be by 2050, through technologies for augmenting body, brain, and neural functions"

#### 1.2 Desired Vision of Society in 2050

In a society realized by means of embedded cyborg technology, anybody can become who they want to be in real life.

Congenital as well as acquired disabilities in limbs or organs can be solved by technology that combines organisms and artificial objects. In addition, bodily functions, including limbs and organs, as well as brain / neural functions, including cognitive and autonomic nerve functions, can be not only recovered when lost, but also augmented and enhanced with the same technology. As a result, it will become possible to share and select human capabilities, from hardware, such as muscle strength, to software, such as skill.

An increase in the production of added value brought about by embedded cyborg technology will be regarded as an increase in the individual's productivity, so that it will not generate a trade-off between increase in the production of added value of organizations and destabilization of employment of the individual, which is a problem in technologies that belong to organizations as assets, such as robots and AI. For this reason, by combining deeper social implementation of robot and AI technologies, which is already inevitable, with the introduction of embedded cyborg technology, it will become possible to enhance both the welfare of individuals and the creativity of society as a whole.

People living in such a society would be able to challenge themselves to play the roles they want to play in the real world and to exert standardized and shared creativity that is beyond their abilities, without being bound by physical constraints.

2. 2. Targets (Scenarios in which the MS Goal is achieved. What will have been realized by 2050 (and 2030))

Examples of scenarios in which the proposed MS goal is achieved are shown in Figure 1. By achieving this goal, people living in 2050 will be able to augment and enhance their physical functions



Figure 1: Example of scenarios in which the proposed MS goal is achieved

beyond what they were born with, by means of embedded devices. As a result, people will not only be able to recover lost functions, but also acquire further abilities and skills to become who they want to be, even in old age. This, in turn, would allow people to aim for self-actualization at any time, and to spend their long sunset years fruitfully. As for society as a whole, it will secure a population that participates in society, increase the production of added values, and revitalize society.

- 3. Reasons for setting the MS goal and social significance of achieving the goal
  - 3.1 Reasons why it is necessary now to set and achieve the MS goal

At present, a problem shared by various countries around the world is "how to secure a large a population that participates in society and to increase their production of added value and welfare." In particular, for developed countries such as Japan, the problem of demographic composition has been an urgent issue for many years, and social changes caused by the Corona pandemic have accelerated future population decline. Moving toward a vision of the future realized by embedded cyborg technology proposed in this report means addressing the following requirements.

# Social demand:

- 1. Solving the social participation population (working population) problem by means other than population growth (solution by improving the rate of participation in social activities by prolonging healthy life expectancy)
- 2. Increasing production of added value and creativity as a group (increasing GDP per capita)
- 3. Eliminating congenital and acquired disabilities (realization of a fully active society)
- 4. Reducing significant disparities in individual abilities associated with income (improving QOL by solving the problems of meritocracy and hypermeritocracy)
- 5. Reducing physical gender differences in employment and social participation (reducing disadvantages of gender differences)
- 6. Creating new and derivative industries, as well as creating technologies whose benefits and assets belong to individuals, unlike AI and robots (solving problems related to new technologies and employment)

Academic research demand:

- 7. Since embedded cyborg technology has an extensive technological area, spin-off research in all fields will be promoted by setting a large goal, mobilizing all fields of science and technology, such as biomedical science, materials science, and electronic machinery.
- 8. By setting themes that require total mobilization of both the humanities and social sciences as well as obtaining social consensus, such as redefining the body and changing how we view human beings, the social value of science will be re-examined from a national perspective, and universities and academia will be seen in a new light within its relation to society and institutions.
- 9. Currently, research in Japan is on the decline and hurdles for invasive clinical research have become extremely high with the enforcement of the Clinical Trials Act; by setting, as the goal, "vision of society in which everyone can be who they want to be, brought about by research and development focused on embedded cyborg technology," which is a major goal for all fields in the academic field, it will become possible to revitalize research in all of Japan, including spin-off and derivative research as well as research and development in innovative related industries.

3.2 Social significance of achieving the goal

- Solving the social participation population (working population) problem by means other than population growth (solution by improving the rate of participation in social activities by prolonging healthy life expectancy)
- Increasing production of added value and creativity as a group (increasing GDP per capita)
- Eliminating congenital and acquired disabilities (realization of a fully active society)

- Reducing significant disparities in individual abilities associated with income (improving QOL by solving the problems of meritocracy and hypermeritocracy)
- Reducing physical gender differences in employment and social participation (reducing disadvantages of gender differences)
- Creating new and derivative industries, as well as creating technologies whose benefits and assets belong to individuals, unlike AI and robots (solving problems related to new technologies and employment)

## 3.3 Outline of society-wide efforts to achieve the MS goal

Embedded cyborg technology is not only an invasive operation, but also a technology that eliminates the difficulties in disabilities that human beings have suffered thus far, so in a society that accepts it, how we view human beings will change profoundly. As a result, all current social and legal systems that presuppose "flesh-and-blood human beings" will become subject to re-evaluation. Specifically, even trying to change prostheses that are closely combined with the human body from "property" to "part of the human body" will generate a large amount of procedures in legislation and administration as well as scrutiny of laws and legal practice. In the production of employment and labor, matching the current state of the industry, i.e., the employers, with the system that should be realized, is essential.

In addition, since it will become one of the indispensable elements of life maintenance by being closely combined with the human body, the medical community will also need to work to establish safety standards therefor as medical devices as well as to standardize surgery, maintenance, and management. As a flip side to safety standards involving human lives, when considering the social danger of unrestricted expansion and enhancement of functions, it is likely that some restrictions will be institutionalized, and compliance thereto will be subject to international ratification in order to prevent medical tourism as a means of evading the law.

In this manner, there will be a society-wide demand for "changing how we view human beings" brought about by embedded cyborg technology. Therefore, with regard to ELSI, i.e., ethical, legal, and social issues, acceptance of the technology will be based on social agreement, including its degree and phased measures, and its use by individuals will be based only on the person's decision making, in principle. In the academic world, it could become a major common theme, not only for science and technology researchers, who are responsible for the technological development, but also in the fields of humanities and the social sciences, and all players in society such as industry, legislature, administration, consumers, and citizens will be involved in the social decision making of to what extent to accept a "society in which everyone can become who they want to be."

4. Changes in social and industrial structure that would be brought about by achieving the goal

The biggest statistical change will be the working population. People whose physical functions, as well as neural functions including cognitive functions, are assisted by this technology will not only have a longer life expectancy, but will also be ensured a prolonged healthy life expectancy, and they will be able to carry out social activities for a longer period of time. In other words, minorities for whose equal and equitable social participation is currently being promoted, such as the elderly, women, and those with physical or mental disabilities, will be able to blend in with the majority without any inconvenience.

In addition, inconveniences that can be solved and routine work that can be greatly improved in efficiency by receiving electronic and mechanical assistance will be reduced in terms of human load, and it will become possible to distribute human resources to high-value-added production activities and innovation. The difference from AI, robots, etc., which are not combined with the human body, is that while AI and robots are not assets belonging to individuals, embedded cyborg technology can produce added value as an asset belonging to the same, flesh-and-blood individual. In this case, "AI taking over jobs (= assets of a company or organization replacing the production of added value, thereby reducing the production of added value by individuals, who end up losing the job or social participation)" could not happen, so that problems of employment and social participation are unlikely

to occur. In other words, by socially combining assets that belong to companies, such as AI and robots, with assets that belong to individuals, such as embedded cyborg technology, it becomes possible to achieve both digital transformation of the industry and gradual changes in employment; as a result, people will be able to expand their creative production activities.

Products such as artificial limbs and organs that are based on embedded cyborg-related technology and their introduction and operationalization themselves have an economic impact as a new industry. In addition, routine but socially essential work, and creative, high value-added work can be separately solved while avoiding social conflict, i.e., the problem of employment, so that there will be increased efficiency in the production of added value for society as a whole.

#### **II.** Statistics / overview analysis

1. Issues (scientific, technological, and social issues) and necessary efforts for achieving the MS goal

In this research, we set a "society in which one can become who they want to be" as a vision of society that we should aim to achieve by 2050, and held a workshop by experts to better clarify this vision. Please refer to the attached document for the analysis results of the workshop. Here, we first describe the vision of society as clarified as a result of the workshop, and then describe the technical and social problems that need to be solved to realize that vision.

#### [Vision of Society]

In order to become the person who one wants to be, in the case that a bodily function was lost due to some kind of illness or injury, recovering that function goes without saying, but education and training are also required. The range of selectable professions may be determined to some extent by the choice of a major in college, and it is sometimes said that it takes 10 years to attain some kind of craftsmanship skill, or that one should steal, rather than learn, skills from a master. Only a handful of people can play an active role as an athlete.

In this manner, it usually takes a lot of time, effort, and in some cases money, to become the person who one wants to be, and changing courses or returning to school in middle and old age can be disadvantageous compared to learning at a young age. Returning to school in middle and old age is mentioned as recurrent education in "Basic Concept of Human Resources Development Revolution" of the Japanese Government's 100-year-life Era Concept Conference (Reference 1), and there is already some institutional support (Reference 2), but it still takes time and effort to do.

Therefore, in order to realize a society in which one can become who they want to be, technology



Figure 2: Neurointerface, which is a core technological objective of the proposed MS

for acquiring abilities on demand or augmenting the body is required in addition to technology for recovering bodily functions lost due to some kind of illness or injury. Ultimately, body augmentation will allow people to selectively gain distinct personalities.

#### [Technical Problems]

In the proposed MS goal, we focus on intervention in the nervous system that controls each part of the body in order to realize this vision of society, instead of focusing on the musculoskeletal system, joints, and individual organs, as has been the case in the past. In this way, one can aim to comprehensively strengthen their body.

The nervous system is roughly divided into the central nervous system consisting of the brain and spinal cord and the peripheral nervos connecting the central nervous system and each part of the body, and the peripheral nervous system is further classified into the somatic nervous system and the autonomic nervous system. The somatic nervous system consists of nerves that interact with the external environment by receiving sensory information from receptors and transmitting motor commands, and include afferent nerves (sensory nerves) and efferent nerves (motor nerves). The autonomic nervous system is a nervous system that involuntarily controls organs and regulates the internal environment, such as heartbeat, respiration, and secretion.

Previous studies on neuromodulation and brain-computer interface (BCI) were mainly aimed at recovery and intervention of the central nervous system and information communication. However, in order to become the person who one wants to be, it is necessary to intervene not only in the functions of the central nervous system but also in the peripheral nervous system, which controls the whole body.

The peripheral nervous system consists of motor nerves, sensory nerves, and autonomic nerves. In terms of bodily functions, they correspond, respectively, to movement, sensation, and internal organs. In other words, there is a demand for technology that augments A-1. motor function, A-2. sensory function, and A-3. visceral function, through intervention not only in the central nervous system but also in the peripheral nervous system. In this manner, the development of an interface for connecting devices to the A-0. nervous system of the whole body, is a core technological problem of the proposed MS goal, and its realization could become a breakthrough.

If this technology is realized, as shown in Fig. 2, interfaces would be connected to various parts of the body, and information could be exchanged between the device and the body; it would thereby become possible to stimulate the peripheral nervous system to enhance motor and visceral functions, or transmitting enhanced sensory information to the brain.

#### [Social Problems]

In a society where the proposed MS goal is realized, 1) ethical issues regarding social disparity and equality between people who have embedded devices and those who do not, 2) pharmaceutical issues, and 3) other legal and philosophical issues can be assumed to arise.

These issues will be presented in an organized manner in Section III.5.

#### 2. Overview of research and development that should be undertaken to achieve the MS goal

In this section, we consider what kind of technology should be specifically used in order to achieve a "society in which one can be who they want to be", that is, how to freely change one's body and expand its functions.

Here, the technology is organized on two axes. The first axis is which function of our body is to be prostheticized or functionally augmented, which is classified into mental function (mental) and physical function (physical). Augmentation of mental function refers to enhancement of memory and cognitive function, and augmentation of physical function may include enhancement of motor function, cardiopulmonary function, or muscle strength. Sensory functions depend on sensory organs such as eyes and ears, so they should be included in physical function. The second axis is invasiveness. In other words, it distinguishes between a device or orthosis worn outside the body and an embedded device.

Figure 3 shows a technological overview in which existing technologies are mapped using this classification. Technologies for medical purposes are indicated by red circles, and technologies for



Figure 3: Overview of technology to be developed based on the proposed MS goal

purposes of augmentation are indicated by green circles.

According to this figure, there are many non-invasive devices that are worn outside the body for both mental and physical functions, and many are for augmentation purposes as well as medical purposes. In addition, although technologies that are invasive and relating to mental function are primarily for medical purposes, vagus nerve stimulation (VNS) and BCI can also be used for purposes of augmentation. BCI is also listed as a research and development theme in the existing MS Goal 1 "Realization of a society in which human beings can be free from limitations of body, brain, space, and time by 2050."

On the other hand, there are many invasive devices for physical function for medical purposes, but devices for augmentation purposes have not been introduced at this time. Therefore, as a technology for augmenting bodily functions, newly developing invasive devices for physical augmentation, which have not been introduced, i.e., a new technology for embedded cyborgs, would greatly contribute to the realization of a "society in which one can become who they want to be."

As described in the previous section, the technical problem of the proposed MS goal is to develop an interface for bidirectional information exchange between embedded devices and the nervous system of the whole body, including the peripheral and central nervous systems, such as the brain and spinal cord, the realization of which would become a breakthrough.

At present, there are ethical issues in using an invasive device to augment the function of a healthy person. However, in recent years, many people, especially in Scandinavia, have implanted microchips subcutaneously as a means of identification or contactless payment (Reference 3). In addition, implantable electrocardiographs used for arrhythmia diagnosis that has a length of about 45 mm and a thickness of about 4 mm have been introduced (for example, three products such as Reference 4 have already been approved in Japan), which can be implanted through a 10-minute surgery under local anesthesia, requiring a skin incision of about 1 cm. In this manner, even for invasive devices, devices and surgical methods that have a low burden on the body have been developed, and an environment is being established in which even healthy people can actively implant devices for the purpose of functional augmentation.

Thus, now is a good opportunity to start development of an interface for bidirectionally exchanging information with the nervous system of the whole body as a MS-type R&D program.



Figure 4: Japan's share of literature in related fields

3. Overall trends in research and development relating to the goal, overseas trends, and Japan's strengths

In this section, we used the SciVal literature database to investigate research trends and the position occupied by Japan in technologies related to the proposed MS goal clarified in Section II.2.

Figure 4 visualizes Japan's share of the number of articles published in academic journals that have keywords of related technologies between 2016-2020. It can be seen that the shares of three items – CMSO image sensor, artificial organ, and optogenetics – are relatively high. In particular, CMSO image sensors and optogenetics are also used in France in clinical applications for vision recovery in people who are completely blind (Sahel et al, Nature Medicine, 2021), expected to become important in future physical augmentation technologies, and it is considered important for our country to be in a technologically advantageous position in this field.

Although Japan was not necessarily dominant in terms of the number of cited articles, it was confirmed that Japan occupies a particularly dominant position in terms of artificial retina, retinal regeneration, and optogenetics. This is likely because Japan has traditionally had a strong foothold in the image sensor field, as well as a high level of research, such as producing Nobel laureates for the development of LEDs necessary for light stimulation.

We also investigated the share of the number of citations in patents, and found that for CMOS image sensors it was 25.7%, which is a very high value similar to citations in the literature, and the share of citations for artificial organs in patents was 12.2% worldwide, which is higher than the share of citations in the literature at 5.9%. This indicates that research results in Japan have reached a level that could lead to practical application and social implementation. Thus, it can be said that Japan has sufficient potential for the development of technology related to the proposed MS goal.

According to information published by the Cabinet Office e-CSTI, Japan has invested in research fields that are related to the proposed MS goal. The Ministry of Education, Culture, Sports, Science and Technology promoted the "Brain Science Research Promotion Program (2008-2015, annual budget: 3,500 million yen)," which was transferred to AMED in 2015. According to the administrative project review sheet, these projects are evaluated to have achieved certain results. The Ministry of Internal Affairs and Communications has been subsidizing the development of brain information and

communication technology that contributes to solving social issues, such as support for the elderly and persons with disabilities, in an initiative titled "R&D and Social Implementation of New Brain Information and Communication Technology (annual budget of 210 million yen)". The Ministry of Economy, Trade and Industry has also initiated "Project to Promote the Development and Standardization of Robotic Devices for Nursing Care (annual budget of 11 million yen)" (transferred to AMED in 2018), to continue support for the development of robotics for nursing care and livelihood support for the elderly and disabled people.

The JST ERATO Inami JIZAI Body Project is also conducting research and development for human augmentation using wearable technology and robotics, and is also trying to investigate the effects of these augmented bodies on the nervous system.

Therefore, although the technology to be developed according to the proposed MS goal is a wideranging technical system that includes various efforts so far taken in Japan, at the same time, since the foundation for its technological development already exists, the results of these existing projects can be combined with international cooperation to promptly and appropriately kick off research and development for an all-Japan system.

Looking at trends overseas, although R&D is progressing in each country, including Japan, for medical purposes or as individual elemental technologies, as mentioned in Section II.2, the physical function augmentation technology using invasive devices itself has not been introduced to the public so far. It however should be noted that there is the possibility that research and development have just not been made public but are proceeding privately.

A report entitled "Beyond Therapy: Biotechnology and the Pursuit of Happiness" published by the Presidential Commission for the Study of Bioethical Issues in 2003 (Reference 5) discusses research and development of physical function augmentation by means of biotechnology, but also mentions technology for the military and soldiers, so a dual-use way of thinking is presented. In fact, in 2019, the U.S. Army's Edgewood Chemical Biological Center published a report entitled "Cyborg Soldier 2050: Human/Machine Fusion and the Implications for the Future of the DOD" (Reference 6), which describes cyborg technologies for military purposes that they aim to realize by 2050. Thus, it became clear through the literature search that there is research on physical function augmentation technology for military purposes that has not been made public.

Although it would be possible to interview the authors of these reports to obtain further non-public information, access to military personnel is not easy and it is unlikely that anything that is classified as military secret will be disclosed. In addition, Nagoya University, to which the team leader Fujiwara belongs, has confirmed in "Basic Policy on the Handling of Military Security Research" (2018) that it will not conduct research aimed at military use, so we have not contacted the authors of the report.

# III. Scenarios for realizing the vision of society

1. Fields / areas and research issues for bold R&D

#### (1) Fields and areas for bold R&D

In this research, Section I.1 presented a "society in which one can be who they want to be" as the ideal vision of society for 2050. Furthermore, we showed in Section II.1 that a technology to freely augment the body is necessary, and in Section II.2 that an area that should be developed with the proposed MS goal is embedded cyborg technology, using a technological overview. We also stated that a breakthrough would be the development of an interface for exchanging information not only with the central nervous system, such as the brain and spinal cord, but also with the nervous system of the whole body, including the peripheral nervous system (A-0 Infrastructure Technology and A-1 Motor Function Enhancement). As a related existing technology, there is neuromodulation, which aims to improve symptoms by stimulating abnormal nerve functions with electricity or magnetism.

Figure 5 is an overview of neuromodulation technology. The numbers in the figure indicate the reference numbers summarized in Attachment 1. Until now, the mainstream of neuromodulation technology has been the development of stimulators for the central nervous system, such as the deep brain and vagus nerve. In addition, in BCI, the main research target is decoding core brain information, and there are few examples that have realized bidirectional communication, including Decoded



Figure 5: Technological map of neuromodulation technology

Neurofeedback (DefNef), which is being researched and developed mainly in Japan.

However, as shown in Fig. 5, various neuromodulation technologies have been put into clinical practical use, not only in terms of devices that give non-invasive stimulation from outside the body, such as transcranial magnetic stimulation (TMS), but also in terms of many invasive devices, such as deep brain stimulation (DBS) devices. Although these are for medical purposes, they have been reported to be effective in improving concentration and cognitive function, such as TMS and vagus nerve stimulation (VNS), some of which are being eyed for application to functional augmentation in the future. Furthermore, it can be seen that there are already cases where modulation (SNM) that give electrical stimulation to peripheral nerves have already been clinically applied, but bidirectional communication with peripheral nerves has not been realized thus far.

Figure 6 is a map that gives an overview of the technology related to artificial vision as a representative example of A-2 sensory function enhancement. As can be seen, not only implantation of a device near the retina but also implantation of devices in the optic nerve and cortex is being attempted. Artificial vision technology differs from other technologies in that there is a technology for not only implanting a single device, but also for implanting multiple devices and operating them in cooperation with each other. Considering the degree of invasiveness, it is desirable to implant as few devices as possible, but it is thought that there are many things that cannot be achieved by only stimulating a single site. Therefore, although the degree of invasiveness will increase, the fact that embedding of multiple devices and their cooperation with each other have already been realized in artificial vision technology could become a foundational technology when developing embedded cyborg technology in the future.

Furthermore, Fig. 7 is a map summarizing the technological trends of devices that can treat cardiovascular diseases and strengthen cardiovascular function as technologies related to enhancing A-3 visceral function. It can be seen from this figure that there are many pacing devices for treating arrhythmias as invasive devices, and there are also devices that are implanted in highly invasive sites such as the inside of a cardiac blood vessel. Of note here is a type of device called cardiac contractility



Figure 6: Technological map of artificial vision technology (cooperation: Nidek Inc.)

modulation (CCM). CCM stimulates the heart with leads placed in the heart and enhances the contractile force of the heart, that is, cardiac output. Currently, it is indicated for recovery of cardiovascular function in patients with heart failure, but it may be possible to enhance the contractile force even if adapted to a healthy heart. In addition, CCM has the advantage of increasing cardiac output without increasing myocardial oxygen consumption (without increasing cardiac work) as tends to happen with cardiac stimulants (Butter et al., 2007). CCM is able to strengthen the circulatory function as reversibly as possible without burdening the heart, which would become important if it is to be used for the purpose of strengthening the circulatory function of healthy people in the future. Thus, enhancing cardiovascular function by stimulating the heart is no longer a pipe dream.

In this manner, it is expected that technology used for medical purposes will also come to be used for augmentation purposes in the future, and if Japan does not start developing this technology now, sooner or later, an interface technology for connecting with the nervous system of the whole body will undoubtedly emerge from another country. For example, blue LED developed by Amano et al. is widely used in optogenetics, but unfortunately the world's first clinical application of optogenetics was performed in France as vision treatment, as shown in Fig. 6 (Sahel et al, Nature Medicine, 2021).

Furthermore, there are cases where medical devices, even when they are products developed in Japan, are first launched overseas. A carotid artery stent for the treatment of carotid artery stenosis developed by a domestic medical device manufacturer was first put into practical use in Europe due to regulatory restrictions, and was only approved in Japan after a delay of about 7 years. Thus, there is a problem that current Japanese regulation is not always in line with the speed of research and development.

Therefore, in order for Japan to lead in the development of bidirectional communication interface technology with the nervous system of the whole body, it is necessary to promptly start research and development as an MS goal, as well as evaluation of the institutional aspects for social implementation, with a sense of urgency.

#### (2) Research problems for achieving the goal



Figure 7: Technological map for cardiovascular treatment / enhancement devices

In order to achieve the proposed MS goal, A-0. bidirectional communication interface technology with the nervous system of the whole body would be the core technology, and based on this, it is necessary to develop various technologies in order to augment each of A-1. motor function, A-2. sensory function, and A-3. visceral function.

Attachments 2-4 show roadmaps for the development of motor function augmentation technology. In these roadmaps, changes in the vision of society and the values of the people who live there, which is the social level, are broken down, showing the expected changes at the market level, product level, and technology level.

Here, it is assumed that the basic technologies at the social level and the technological level are common to all the roadmaps A-1 to A-3. In other words, the target vision of society is set to be the same in all technological aspects, and the target vision of society is assumed to be attainable via any roadmap. In addition, the underlying technology is common to all of A-1 to A-3, and this constitutes A-0. bidirectional communication interface technology with the nervous system of the whole body. Then, by combining this infrastructure technology and elemental technology, it should be possible to realize products and services that satisfy specific required functions.

In this manner, in the proposed MS goal, by setting a common core technology A-0, it becomes possible to proceed with research and development in an organically related manner, rather than developing A-1 to A-3 individually, so that an efficient R&D system can be constructed.

The infrastructure technology A-0 and roadmaps A-1 to A-3 will be described in detail below.

#### A-0. Nervous system interface

Realizing an interface with the nervous system of the whole body including the peripheral nervous system is the core technology of this MS goal, and is represented as an infrastructure technology in the roadmaps. It consists of the development of materials necessary for long-term placement of electrodes in peripheral nerves, percutaneous power supply, and processors capable of performing

communication and signal processing.

# A-1. Motor function augmentation technology

The ultimate technological goal of this MS goal in terms of motor function augmentation is to be able to smoothly master specific movements with an embedded device, rather than with muscle strength, which can be strengthened with an orthosis that can be worn outside the body. These movements that one would want to master are called skills, and in this research, we created a roadmap focusing on how one could freely acquire skills.

A technique for causing muscles to perform specific movements by stimulating peripheral nerves has already been developed in Japan and demonstrated in animal experiments (Takeuchi et al. 2020). Therefore, by stimulating peripheral nerves through peripherally arranged neurointerfaces, it is possible to cause muscles to perform specific actions. In other words, if stimulus signals that realize the target motion are recorded in advance and then reproduced to stimulate the peripheral nerves, the motion can be reproduced with a certain degree of accuracy. Based on this, it is expected that a person will be able to acquire "skills" more efficiently than before through further practice. Ultimately, if the stimulus signals for such skills are packaged and made downloadable, one would be able to quickly learn a skill, with practice, as if installing the skill in the body and making additional settings after installing a piece of software.

For this purpose, in addition to the neurointerface developed with A-0 (infrastructure technology), a technology to digitally record, and decode, neural signals of a person who has already acquired the skill is required as an elemental technology. Therefore, in A-1, development of modulation technology for recording, decoding, reproducing, and overwriting neural signals is required.

#### A-2. Sensory function augmentation

In the roadmap for the augmentation of sensory functions, we decided to focus on artificial vision because (1) cochlear implants are already widespread and (2) somatic sense is included as part of motor function augmentation technology. The ultimate goal is to acquire, by means of artificial vision, visual functions allowing visual recognition of subjects that cannot be seen with general visual functions, such as small objects, objects in blind spots, and invisible light.

In order to achieve such a roadmap, neurointerface technology developed with A-0 (infrastructure technology) is required for both artificial vision and neural signal reproduction / overwriting. In addition, ability to be chronically used and improved sensitivity would be demanded of optogenetics technology. On the other hand, once a technology for connecting devices and nerves is established, improvement in resolution, expansion of the field of view, acquisition of invisible light, etc. are problems that can be solved on the side of the camera included in the device, so feasibility is expected to quickly increase.

#### A-3. Visceral function augmentation

Regarding the enhancement of visceral function, devices that are used by being implanted in the body such as under the skin of the chest or in the thoracic cavity are already being used clinically, and it is thought that cardiovascular devices whose significance is widely recognized will continue to be the main focus in the future. Therefore, we focused on these in this roadmap. These technologies are for measuring and stimulating muscles and nervous systems such as the myocardium, conduction system, and autonomic nervous system, sharing the foundation with the above-mentioned nervous system-related technology A-0. In addition, it is expected that heart-related technology will pave the way ahead of other visceral function augmentation technologies. One of the challenges for realizing a new cardiac implant device targeted in this roadmap is to establish an interactive connection between the heart and the autonomic nervous system.

In order to realize this technology, we believe it is necessary to newly tackle multi-channel, multifunctional myocardial stimulation technology for more accurate heart rate control. In addition, closedloop control between the autonomic nerves and the heart is required to realize blood perfusion meeting the needs of the living body. This can actually affect emotional control as well as heart rate control, as it is known that heartbeat affects emotions, and proper closed-loop control is considered essential from the perspective of long-term outcomes, including psychological impact.

2. Goals (milestones) to be achieved by 2030, 2040, and 2050, research and development to achieve the milestones, and ripple effects thereof

# (1) Goals (milestones) for 2030, 2040, and 2050, respectively

<u>Milestone 5 years after the start of research and development based on this MS goal: Development of</u> a neural signal collection / stimulation system capable of bidirectional connection with nerves

As a milestone to determine go/no go five years after the start of R&D by calculating back from the milestone setting of 2030, first, a neural signal collection / stimulation system capable of bidirectional connection with nerves by means of an invasive method will be developed.

#### Milestone for 2030: Realization of high-resolution neurointerface

We will develop a neural signal collection / stimulation system that enables bidirectional connection with nerves in a non-invasive / minimally invasive manner, and that can decode / encode neural signals with the resolution of nerve fascicles / neural function units.

As a result, it becomes possible to continuously stimulate and collect signals with respect to the nervous system of the whole body including the peripheral nervous system for a long period of time, and to monitor and intervene in physical and mental functions.

# Milestone for 2040: Hardware implementation of autonomous neural signal modulator / demodulator (encoder / decoder) "Cyborg Core AI"

A system, which has the function of modulating the target nerve / organ by decoding signals measured from the peripheral nerves and central nerves by means of AI and autonomously outputting an appropriate response, will be implemented on hardware of a material and form that can be chronically placed in the body.

As a result, humankind will obtain a means to expand functions beyond their own innate capabilities, such as appropriately feeding back information perceived by one's own sensory organs to muscle contraction, and appropriately breaking down command information from the central nervous system relating to higher level physical activities into activities of the muscle, viscera, and sensory organ units and modulating them.

# Milestone for 2050: Realization of highly reliable updater for the Cyborg Core AI and a neural connection interface that can autonomously and plastically switch connections.

In order to realize various functions with embedded cyborgs, it is necessary to store, as a library, as many encoding / decoding functions as there are required functions, and enhancement thereof becomes an objective. Furthermore, since there are different nervous systems that control these functions, adaptive switching is required to connect to the target nervous system. Implementing this feature in a chronic indwelling system will be the final milestone for the realization of an embedded cyborg.

## (2) Specific R&D themes to be tackled to achieve the milestone

## R&D themes for achieving the 2030 milestone

• Development of electronic neural connection devices with high biocompatibility using semiconductor microfabrication technology and functional organic / polymer materials

• Search for materials and charge / discharge control technology for secondary batteries that are stable and reliable over a long period of time

• High-efficiency percutaneous wireless power supply (charging) technology

# R&D themes for achieving the 2040 milestone

· Realization of long-term constant cyborg mechanics (robot arm, artificial muscles, invisible light

camera) connection / operation and functional electrical stimulation from brain activity through animal experiments

• Constant monitoring of neural activity and motor / sensory / visceral functions and modeling of the relationship therebetween

• Implementation of a small and extremely low-power-consumption hardware for AI equivalent to the model described above

· Formulation of secure and robust internal and external wireless communication protocols

#### R&D themes for achieving the 2050 milestone

· Adaptive switching technology for cyborg-nerve connections

• Establishment of high-speed and highly reliable maintenance (read / write) method for the Cyborg Core AI

# (3) Effects of achieving the milestones on society

The effects of achieving the 2030 milestone on society

The ability to constantly take recordings from the nervous system makes it possible to monitor abnormal EEG in patients with severe epilepsy. In addition, the possibility of long-term continuous stimulation will lead to neural circuit reorganization technology, and it will become possible to restore motor and sensory functions, promote learning effects in rehabilitation, and adjust visceral functions. As a result, utilization of these will begin to spread in medical applications. In addition, academic spillover effects will also be brought about to society, such as

• Use as a new tool for measurement and experimental intervention in neuroscience research; and

• Establishment of a method for decoding motor / sensory information by combining constant monitoring of neural activity and measurement of user / environmental information.

#### The effects of achieving the 2040 milestone on society

The autonomous neural signal modulator / demodulator (encoder / decoder) "Cyborg Core AI" will be able to execute skills acquired with cyborg technology in terms of motor function, and its application to people with severe disabilities will begin to be considered. It also leads to recovery from disorders and use as an alternative sensory input method for sensory functions. These changes will open the way for people with disabilities to become independent. In epilepsy patients, electrical intervention will be conducted when abnormal brain activity that is a precursor to seizures occurs, leading to the development of new seizure prevention methods. In addition, for those who repeatedly faint due to significant autonomic neuropathy, it will become possible to prevent fainting by modulating the autonomic nervous system.

# The effects of achieving the 2050 milestone on society

By 2050, an interface will have been constructed that enables the combination of the innate human body and nerve functions with various devices (for example, artificial hands, exoskeleton type assist suits, electric wheelchairs, cameras, microphones, etc.), which means that the core embedded system portion of the cyborg technology will have been completed. Not only will it be possible to operate these devices and obtain information from these devices, but it will also be possible to easily obtain skill sets without cumbersome education or training. Experiences so far unknown to humans, such as flying with bird wings, are no exception. Cyborg technology that can bring about such diverse functions will be an infrastructure technology that can also bring about social change.

Furthermore, the predicted market size of typical equipment brought about as each of the abovementioned enhancements is projected to be:

- Neural signal control type prostheses: about \$370 million / year in japan, and about \$35 billion / year globally
- Artificial visual device: about \$107 million / year in Japan, and about \$1.6 billion / year globally

• New pacemaker: about \$220 million / year in Japan, and about \$21 billion / year globally

These are only for typical devices, and there is a good chance that other applications and advancements will be made. New functions could be added to existing technologies, such as cochlear implants and deep brain stimulation. In addition, since application as a new method for treating organs that have dysfunction due to spinal cord injury, such as in the lungs and the bladder, is also expected, the projected amount could further increase.

#### 3. Ideal form of international cooperation to achieve the goal

While a society free from physical restrictions and discrimination would become increasingly borderless, it was predicted in a workshop conducted by the team that it could cause a large disparity depending on whether the embedded cyborg technology can be adopted. This also indicates that differences in regulations, legislation, social welfare, etc. between countries can cause large disparities, which may result in international problems that lead to the outbreak of cyborg refugees, large-scale migration, and even conflict between countries. In order to prevent such international problems, it is necessary to develop international standards and rules regarding cyborg technology as soon as possible, and it is essential to create international rules that each country ratifies, accompanied by a certain degree of their enforcement.

International standards such as those mentioned above have been discussed by organizations such as ISO and IEC, consisting of industry groups and academia, and it is conceivable to expand the areas covered by the aforementioned standards and organizations so that they could function even in the coming cyborg society and with respect to technology for interfacing with the nervous system of the whole body. On the other hand, in terms of international regulations, it is necessary to further expand the framework and capacity of current international laws and organizations such as the United Nations.

For international cooperation in technological development, it is possible to leverage international cooperation that so far has been carried out between academia and companies, and, as the abovementioned multilateral standards and regulations are being developed, and as multilateral standards and regulations are developed as mentioned above, it is expected that cooperation will be further promoted if differences among cooperating countries are eliminated, such as in the Pharmaceutical and Medical Devices Act and the Foreign Exchange Law.

Particularly for embedded devices, as shown in Section III.3, Japan is already carrying out pioneering research and development along with the United States, and it has been shown through internationally co-authored papers and co-authored review papers that a system of international joint research has already been established with renowned research institutes in Europe and the United States. If Japan could proceed with the development of the above-mentioned standards and regulations without delay from other countries, and if the research areas and the above-mentioned international teams were provided with continuous and evolving budget measures as a result of this goal being adopted, we can expect a generation of strong collaborative relationships and research results.

# 4. Ideal form of cooperation across fields and sectors to achieve the goal

The proposed MS goal requires cross-disciplinary/sector collaboration in both research and technology development and social implementation. Therefore, in order to enable the system of cooperation to be put into operation promptly when this proposal is adopted, cooperation was established in this research for the following three layers: 1) direct cooperation through interviews with prominent researchers related to elemental technologies, 2) direct cooperation with ELSI-related centers at Osaka University and Kyoto University, and 3) indirect cooperation through the cooperation platform of the Research University Consortium.

1) Direct cooperation through interviews with prominent researchers related to elemental technologies In this survey, we produced the most detailed technology roadmaps possible in 2021. This is not only for visualizing the overall picture of the future direction of R&D and technology, which is the original purpose of the roadmaps, but also for carrying out interviews with research leaders who are expected to play major roles regardless of how the roadmaps are changed in the future, in order to lay the foundation for collaboration through deepening discussions on the proposed MS goal. As a result, the team succeeded in building a relationship of trust in the team's vision with the research leaders listed in Form 2: Final Report Meeting Supplementary Materials.

#### 2) Direct cooperation with ELSI-related centers at Osaka University and Kyoto University

Through workshops and discussions within the team, it was determined that the proposed MS goal would bring a great deal of choice to human society, and at the same time, it will question the transformation of the human image (what it is to be human?) that society presupposes. As a result, not only achievements of technological development but also the ELSI aspect could become a bottleneck toward its social implementation. In this research, we propose to (1) incorporate ELSI in research, and (2) collaborate with ELSI experts not only as independent researchers but also organizationally.

First, regarding (1), it was pointed out in the workshop by people from various standpoints, including lawyers and creative professionals, such as those in the field of science fiction, that the proposed MS goal would demand a re-examination of the human image in current society, values of the people living there, and the legal system that puts those values in the statutory form. It is necessary to mobilize all the existing knowledge of a wide range of fields of the humanities, such as philosophy, as well as the social sciences, including law. This mobilization is not limited to receiving comments from experts, but also needs to be conducted as work that brings about new knowledge to humanity, i.e., research. From the inception of the plan, our team assumed that ELSI would be incorporated as a part of research rather than simply gathering comments from experts, and two core experts in ELSI research are participating as team members.

First, in each ELSI-related community, we exchanged opinions with ELSI experts who are involved in ongoing problems such as AI and laid the foundation for cooperation, centered around these two people. Furthermore, based on this foundation, we established cooperation with not only individual researchers but also with the Osaka University Research Center on Ethical, Legal and Social Issues (Osaka University ELSI Center) and Kyoto University, The Center for Interdisciplinary Studies of Law and Policy (Kyoto University Law and Policy Center), where they are systematically conducting ELSI research as centers. This is to secure a wide background for ELSI + and in the ELSI domain, based on the survey results that this ELSI research would become extensive.

With the Osaka University ELSI Center, we jointly held a study group for the Osaka University ELSI center as a means to evaluate the ELSI in this research, and we considered what the proposed MS goal could bring about to society with researches that represent the field in Japan, such as Center Director Atsuo Kishimoto, Professor Ekou Yagi, and Associate Professor Ryuma Shineha Although some members of the Osaka University ELSI Center are already participating in existing goals, this is the first initiative in which the center itself is involved in Moonshot, so the team succeeded in making a connection between the Osaka University ELSI Center and the Moonshot program. The Osaka University ELSI Center has agreed to continue to collaborate with our team, not only on the proposed MS goal, but also in terms of research aimed at social implementation of embedded cyborg technology, on the premise of respecting the respective social roles and perspectives of each party.

In addition, in response to the fact that this survey revealed the importance of the legal system aspect, we conducted an interview, led by the two lawyers participating in this team, with Professor Tatsuhiko Inatani of the Kyoto University Law and Policy Center, which is a stronghold of law and policy research in Japan. Professor Inatani pointed out that it is necessary to delve into not only the legal system itself but also its background ideology, so we proposed an organizational collaboration centered around the center's "Artificial Intelligence and Law" unit, led by Professor Inatani, and we reached an agreement of collaboration to take place after the goal is adopted.

In this way, the concept of the team is to propose and build collaboration on the assumption that ELSI, which is an important requirement for social implementation, will be collaborated upon by both individuals and organizations and incorporated into research.

3) Indirect cooperation through the cooperation platform of the Research University Consortium.

Through 1) and 2), we succeeded in forming a direct, face-to-face collaboration with researchers

responsible for technological development and ELSI researchers considering social implementation. Assuming a situation in which collaboration is further widely solicited, the team obtained agreement to collaborate with the Digital Transformation Platform for university researchers to collaborate across institutions and sectors, currently under construction by the Research University Consortium, which includes Nagoya University to which the present representative belongs. This platform is being constructed by the National Institute of Natural Sciences as a part of the Research University Strengthening Promotion Project of the Ministry of Education, Culture, Sports, Science and Technology, and because the expected application state is optimal for top-down research themes, i.e., for the Moonshot program, and also because members of this team are involved in the construction of the platform, we succeeded in obtaining an agreement. If the goal is adopted, Nagoya University will be able to organize, through this platform, joint research in collaboration with university research to be conducted beyond networks unique to the members of this team.

#### 5. ELSI (Ethical, Legal, Social Issues)

(Ethical, legal, and social issues in the efforts to achieve the goal, and solutions thereof)

In a society where the proposed MS goal is realized, 1) ethical issues regarding social disparity and equality between people who have embedded devices and those who do not, 2) pharmaceutical issues, and 3) other legal and philosophical issues can be assumed to arise as issues related to ELSI.

1 ) 1) Ethical issues regarding social disparity and equality between people who have embedded devices and those who do not

Issues from the perspective of social disparity and equality between people who have embedded devices and those who do not are broadly divided into the problem of disparities, etc., between individuals, and the problem of disparities, etc., between societies. The former are issues of fairness regarding the handling of various aspects such as employment between embedded people and non-embedded people, the problem that the current economic disparity would become entrenched or widened, and the like. The latter is the problem caused by disparity in accessibility to these technologies for groups of people, such as countries. All of these issues vary depending on the accessibility of device embedding technology (prevalence status).

The aim for our team is for "everyone" "to be who they want to be," but it can be assumed that during the process of its popularization, only the rich (individuals, countries) would be able to go through the process of becoming "who they want to be." This is an issue similar to that of universal health coverage in health care; that is, when designing a health system that ensures access to medical care for all citizens, how much of advanced medical care and services related to medical care should be publicly supported, using a system of high-cost medical treatment costs and welfare aid, while being able to secure financial resources to enable all citizens to participate in and enjoy services as health insurance, etc.?

Alternatively, as in the case of educational disparity caused by differences in access to private education at tutoring schools and preparatory schools besides public school education, final fairness and justice should be realized by determining, on a case-by-case basis, whether it is an example of ensuring simple equality of access (application of technology within the scope of individual freedom) or an example of seeking equal results (equity) (for example, example belonging to the category of public medical insurance), while clearly separating what should be supported publicly and what should be simply permitted as individual freedom with respect to this technology. Therefore, in relation to disparity between individuals, it is necessary to be fully aware of the difference between the use of this technology for "patients" who require it as medical treatment and the use of this technology by "healthy persons".

In order to achieve a fair result, it is also important to make a comparative assessment of whether there are other measures that are less invasive to the target individual, and whether barriers should be eliminated on the side of society rather than the individual in the first place, in order to achieve a fair result. Regarding the issues of disparity between societies, we recognize that there are many issues in common with various efforts in the international community and their solutions, and that this is an important research topic to be considered in parallel with the technological development of the present MS goal.

# 2) Regulatory issues

The Pharmaceutical and Medical Devices Act is one of the laws that are currently considered to be relevant to the social implementation of embedded cyborg technology. In the Pharmaceutical and Medical Devices Act, medical devices are defined as "devices, specified by government ordinance, used for the diagnosis, treatment or prevention of human or animal diseases, or that affect the structure or function of the human or animal body," and we believe embedded cyborg technology, at least that which is used for therapeutic purposes, falls under this category. In addition, in the case of an embedded cyborg device, it is thought that its "purpose is to affect the structure or function of the human or animal body," so that it would also be a medical device.

On the other hand, if the benefit-risk balance of embedded cyborg technology for individuals and society changes significantly, that is, if the technology matures and invasiveness to the body is minimized and development and maintenance become easier, it is assumed that the embedded cyborg technology would come to be used in a manner not limited to treatment, in which case there is a possibility of distribution outside the scope of regulation. For example, a myoelectric prosthetic hand, already in practical use, is a welfare device (non-medical device) when used as a rehabilitation prosthesis / orthosis (although it is a medical device when it is regarded as a device used for treatment); therefore, it can be distributed without being regulated by the Pharmaceutical and Medical Devices Act.

In addition, even if it corresponds to a medical device, there is a possibility that it will be distributed without the intervention of a medical professional. For example, Apple's "ECG app" and "irregular heart rhythm notification feature", which were approved by the US FDA in 2018 and in Japan in 2020, are regulated as medical devices but can be obtained by the user in the form of ordinary circulation without going through a medical institution or a specialized wholesaler. In this way, there already are several medical devices available through ordinary circulation placed in the category of "home medical devices".

In view of such cases, embedded cyborg technology would also be subject to distribution regulation as a medical device if it is used in therapeutic practice when interpreted within the scope of the current Pharmaceutical and Medical Devices Act; otherwise, it may be treated as a non-medical device. However, even if it is not considered as a medical device, it would be necessary for a doctor to perform the invasive act of implantation, in the case that the user does not perform the implantation themselves. For example, medical devices that are not approved in Japan for use in surgery may be used in the field of self-financed cosmetology, but these are used at the discretion of the doctor, and may only be used by physicians. There is no legal problem with conducting invasive acts to one's own body. For example, it is still legal to open a piercing hole by oneself.

For devices within the scope of the Pharmaceutical and Medical Devices Act, companies are obliged under law for their maintenance and management after manufacturing, sales, and post-sales, but for a device outside the scope of the Pharmaceutical and Medical Devices Act, the company has no responsibility under the law. Even if the invasiveness during the implantation procedure is minimized, subsequent follow-up and maintenance are necessary from the viewpoint of safety, so that a new discussion will be needed on how to socially deal with cases that are not subject to the Pharmaceutical and Medical Devices Act. Specifically, it is thought that a system for managing safety would become required, including post-implantation maintenance / management, removal, and replacement.

It is also necessary to discuss how the procedures and treatments associated with cyborg technology should be handled in Japan, which has a universal health insurance system. For example, in modern times, cosmetic medicine, which is one option for realizing "who one wants to be", is not covered by insurance, and even if cosmetic medicinal treatment causes aftereffects or complications, the treatment thereof is also not covered by insurance (the Ministry of Health, Labor and Welfare states that cosmetic medicine complications are not covered by insurance in accordance with "Health Insurance Act Article

116 Analogy," "Prohibition of mixed medical treatment," and "Third-party acts," etc.).

According to the current thinking of the insurance system, at the time that cyborg technology permeates society for the purpose of functional augmentation, it is highly likely that cyborg implantation for the purpose of functional augmentation will not be covered by insurance. Furthermore, cyborg technology requires maintenance even after implantation, and unexpected cyborg-related disorders could occur after the implantation, in which case they also would likely not be covered by insurance.

However, when cyborg technology has permeated society and becomes indispensable in the activities of social life, it would become necessary to reconsider the insurance system itself and how it should be, i.e., whether we should, as a nation, have a system of redress and compensation for disadvantages caused as a result of individual choice in a "society in which one can be who they want to be" or to deal with them through private insurance services.

#### 3) Other legal and philosophical issues

There are enormous legal issues to be considered when socially implementing embedded cyborg technology. Here, regarding the liability for damages caused by cyborg technology, we summarize the points of discussion relating to problems that arise from increasing divergence from a "human" as assumed by the conventional legal system, and problems that arise from the fact that an embedded cyborg is a device embedded in humans.

[Reasonable allocation of liability for possible damage]

In the process of research and development, manufacturing and distribution, and implantation, the first thing that is indispensable is the rational allocation of liability for damages that could occur due to embedded cyborgs.

Let's assume a case of an accident in which a mistake in the design and development stage and a mistake made by the embedded person conflict with each other and causes another person's injury. First, considering civil liability, under the current system of civil liability which is based on the principle of liability arising from negligence, the victim bears the burden of proof regarding a mistake in the design and development stage or a mistake made by the embedded person, so unless the victim can explain and prove such a mistake in the design and development stage or a mistake made by the embedded person, so unless the victim can explain and prove such a mistake in the design and development stage or a mistake made by the embedded person, the damage cannot be compensated. However, given that cyborg technology is extremely advanced and that there is a wide variety of technologies depending on the embedded person, it would be extremely difficult for a victim who suffered accidental damage to obtain the necessary information for the establishment of facts, to identify the cause, and to prove it to thereby receive compensation for the damage.

Such a structure is not limited to embedded cyborg technology, but is a common problem for social implementation of advanced technologies, but since this may appear prominently and widely particularly with respect to embedded cyborgs, evaluating the legal control thereof is necessary. Otherwise, negative externalities will not be properly allocated to cyborg vendors or embedded individuals, leading to the circulation of many dangerous embedded cyborgs in society.

With regard to criminal liability, according to the current criteria for negligence in criminal practice, designers / developers may be subject to widespread criminal liability, which may impede development research or social implementation of embedded cyborgs; therefore, some measure is required. Until now, procedures for review and approval have been taken for types of products that have a certain probability of causing serious consequences. This includes the type approval system for automobiles and the approval review of pharmaceutical products. It is precisely because the safety of a product is confirmed in the process of these reviews and approvals, and it is determined that risk has been minimized to the degree that there would normally be no danger, that companies have been exempted from being subject to criminal proceedings, except for cases in which the risks identified after the fact have been left unaddressed beyond a reasonable period of time. The system of approval review has the effect of clearly showing the standards by which criminal negligence will not be questioned.

Embedded cyborgs also need a mechanism that can clearly indicate the criteria for not being

criminally liable in some way. It should be noted that the approval review is given only as an example, and it is not meant to suggest that an approval review should also be required with respect to embedded cyborgs. It is, however, necessary to consider some kind of safe and efficient mechanism.

[Problems that arise from increasing divergence from a "human" as assumed by the conventional legal system]

Currently, human death is said to be determined by means of the so-called three-symptom theory. That is, human death is determined based on irreversible respiratory arrest, irreversible cardiac arrest, and dilatation of the pupil. The treatment of brain death as human death is only adopted in limited situations such as in the case of organ transplantation. Therefore, if an embedded cyborg with mechanized cardiopulmonary and visual functions appears in the future, problems could occur in which it becomes difficult to determine if a person can be said to be alive. This is a standard that presupposes a limit of a human being as a living organism that if the breathing stops, the heart stops, and the visual function is lost, then it means death. However, embedded cyborgs could break the premise of this standard. Although this is just the most extreme and easy-to-understand example, even in less extreme cases, various systems are set up on the premise of what is possible for a person as a living body.

For example, Article 34, Paragraph 2 of the Building Standards Act stipulates that "buildings with a height of more than 31 meters (excluding those specified by Cabinet Order) must be equipped with an emergency elevator. " but, of course, the law does not presuppose the existence of people who can fly (perhaps the ability to fly becomes more serious in relation to standards for penal detention facilities). Articles 604 and 605 of the Ordinance on Industrial Safety and Hygiene stipulate ensuring a certain level of illuminance, daylighting, and lighting, but do not assume that a person might acquire night-vision.

In this way, if these provisions are applied to embedded cyborgs as is, situations may arise in which the abilities acquired by an embedded cyborg cannot be fully utilized. Since it is easy to expect inconveniences for various systems that have been designed on the assumption that human bodies and abilities are within a certain range, what kind of attitude we should have toward these and what kind of system should be designed will come into question.

[Problems that arise from the fact that an embedded cyborg is a device embedded in humans]

The mechanical parts of an embedded cyborg are expected to cause various legal problems because they are embedded in the human body in a form that is difficult to separate.

For example, suppose a case in which a mechanical part of a cyborg embedded in a human body is hacked from the outside, preventing its normal operation. If any part of the living body is impaired in its physiological function, it will be considered as a crime of injury, but if it merely interferes with the normal operation of a mechanical part, under the current law, it can only be discussed within the purview of property damage crime. However, when assuming various types of cyborgs, the question arises whether this is a sufficient degree of protection.

In response, it is conceivable to give the part embedded as a cyborg the same degree of protection as that for injury crimes, but on the other hand, if the cyborg part can be easily detached and repaired, according to the current metaphor, it could be an infringement akin to breaking someone's eyeglasses, in which case weighing it as similar to an injury crime may not be consistent with the current criminal law system.

In addition, there is also the issue of whether information perceived by a person and stored in a mechanized part can be searched and seized (note that using a so-called truth serum by warrant in criminal proceedings is thought to be prohibited for the reason that it would constitute an infringement of the right to remain silent or that it violates the dignity of a person.).

Both of these two problems are problems of whether a mechanized part of a cyborg should be regarded as a part of, or be treated in the same way as, a human body, and what kind of protection should be given to it. Embedded cyborgs can raise unique legal issues, whether they are treated as part of the human body by some standard or are not at all recognized as a human body.

Furthermore, the above-mentioned problem arises from the combination of humans and mechanical parts of the embedded cyborg, but apart from this, the difficulty of separation also causes various legal

#### problems.

As an easy-to-understand typical example, assume a case of the appearance of an embedded cyborg with a high risk of harm to others. Obviously, such entities would be prohibited and measures such as restricting implant surgery would be taken, but let us assume that such an embedded cyborg, created in a country where such regulations do not exist, ends up in Japan.

A question could be whether the dangerous mechanical parts of this embedded cyborg can be forcibly confiscated (or, could an order be issued to stop their function, as a conceptual partial confiscation). Although it probably should be possible to do so, if the mechanical part of the embedded cyborg is to be regarded as the human body by some standard, the question arises of how to consider the fact that the current legal system (and the laws of almost all developed countries) prohibits corporal punishment. Also, depending on the explanation for this problem, another argument arises that if separation can be legally enforced, then combination could also become legally enforceable. Since this is something related to the core of the way of being of embedded cyborgs, it is necessary to thoroughly consider the legal aspects in advance.

#### [Legal and philosophical issues related to the foundation that includes the above legal issues]

What we have described regarding legal issues so far mainly has the Japanese legal system in mind. Meanwhile, from the viewpoint of achieving the MS goal, it is not sufficient to consider only Japan with respect to legal and ethical issues. If Japan's cyborg technology is not accepted in other countries, not only will the technology not be exportable, but it may hinder the flow of people who become cyborgs (cyborgized) using Japan's cyborg technology. In addition, it is necessary to have some guidelines on the criteria by which Japan accepts foreign cyborg technology and people who are cyborgized by means of said technology.

Cyborg technology has elements inseparable from how we view human beings, how we view the body, how we view life and death, views on religion, and the like, which may bring about gaps in cyborg legislation between countries that cannot be filled. As an easy-to-understand example, there are considerable differences between countries in the way of thinking about the influence of the body on the mind, the way of thinking about the influence of the mind on the body, and the way of thinking about life and death and how to treat it. In Japan, the point that the body affects the mind is accepted to the degree of it being a given assumption, but this is not always the case in other countries. In Japan, corpses are generally cremated, but in other countries this is not always the case. Such differences can make a difference in cyborg legislation of foreign countries through the sensibilities of the people of said countries. In particular, issues, such as to what degree the body can be cyborgized and whether cyborgization that affects the mind should be allowed, will be strongly influenced by differences in how human beings are viewed in each country. Therefore, it is necessary to consider how to deal with these differences as a premise of internationally acceptable legal and ethical issues.

Obviously, it is not feasible to take an approach to fill all the gaps between countries to establish a single unified standard. Since the expected differences come from the hard-to-change aspects of the people of each country, forcing a unified standard would inevitably cause backlash.

Therefore, what should be considered is laying a foundation of dialogue and coordination on how to handle the differences between countries, for which it is essential to establish the possible modes of dialogue, after considering what kind of views of human beings exist.

#### **IV. Conclusion**

The shrinking of society due to Japan's rapid population decline is an unavoidable "future that has already occurred." In order to alleviate the shock caused by this change in population composition and to even leverage it as a curious opportunity to revitalize the society and the economy, an environment is required in which each citizen can exert abilities exceeding what they innately possess. For that purpose, not only social institutional reforms but also technological innovations are necessary, as described in Chapter I of this report.

On the other hand, in this research, we presented a "society in which one can be who they want to

be" as the ideal vision of society in 2050, and held a workshop with experts to further clarify it and to dig deeper. As a result, in order to realize this vision of society, that is, in order to realize a society in which one can become who they want to be, technology for acquiring abilities on demand or augmenting the body is required in addition to technology for recovering bodily functions lost due to some kind of illness or injury.

More specifically, the proposed MS goal focuses on interventions in the nervous system that control each part of the body, with an aim to comprehensively enhance the body. That is, in order to become who one wants to be, there is a demand for technology that augments A-1. motor function, A-2. sensory function, and A-3. visceral function, through A-0. intervention not only in the central nervous system but also in the peripheral nervous system, and it was made clear that, for this purpose, the development of an interface for connecting devices to the nervous system of the whole body is the technical problem and the breakthrough technology of the proposed MS goal. Then, in this research, we created roadmaps referring to interviews with, and advice received from, researchers who lead each field, and showed that a "society in which one can be who they want to be" can be ultimately realized regardless of which roadmap is followed.

If we can realize a "society in which one can be who they want to be" through these technological developments, it will become possible to enhance both the welfare of individuals and the creativity of society as a whole. People living in such a society would be able to challenge themselves to play the roles they want to play in the real world and to exert standardized and shared creativity that is beyond their abilities, without being bound by physical constraints. In this way, it can be said that the vision of society and technological development themes presented in this research are sufficiently inspiring and meet the criteria for MS goal development.

Ultimately, if human beings are released from physical constraints in a "society in which one can be who they want to be," the innate and acquired physical differences that are now the source of discrimination and prejudice will become meaningless. It will promote independence of persons with disabilities and the elderly, who will no longer need to feel indebted to caregivers. From the perspective of care and welfare, a major social shift that frees people from suffering will undoubtedly occur. In other words, innovation of values associated with the body will occur. This is sufficiently imaginative and meets the criteria for MS goal development.

As a concrete technology development approach to realize the above, in Chapter III, we described the importance of development of an interface for bidirectional information exchange between the central and peripheral nerves and embedded devices for the realization of this vision of society and presented the milestones therefor. Furthermore, Sections II.2 and II.3 detailed the current status of these technological development themes. From the foregoing, it can be seen that the R&D theme proposed in this research is highly feasible, the achievement status can be objectively evaluated, and it is sufficiently credible as an MS goal.

Furthermore, regarding the ELSI side, in addition to organizing points of discussion regarding pharmaceutical affairs and legal issues, we held a symposium with the Osaka University Research Center on Ethical, Legal and Social Issues (ELSI Center) and discussed the ethical issues surrounding embedded cyborg technology. Furthermore, through an interview with Professor Tatsuhiko Inatani of the Faculty of Law, Kyoto University, who is conducting research on the ideal form of criminal responsibility for the development and use of artificial intelligence, it became clear that cyborg technology has elements inseparable from how we view human beings, how we view the body, how we view life and death, views on religion, and the like, which may bring about gaps in cyborg legislation between countries that cannot be filled, and that discussion on these issues is an important research topic inseparable from the development of embedded cyborg technology.

In this way, in this research, we not only conducted research on the technology development side, but also organized the points of discussion assuming problems from the ELSI perspective that can be expected with respect to augmentation of human beings by means of embedded cyborg technology. It is thereby possible to avoid social turmoil when embedded cyborg technology is introduced and to lay a foundation for its smooth social implementation.

#### V. References

1. Summary of the 100-year-life Era Concept Conference "Human Resources Development

Revolution, Basic Concepts", 2018

- 2. Ministry of Education, Culture, Sports, Science and Technology "University Recurrent Education Promotion Project for Supporting Employment and Job Change" https://www.mext.go.jp/a\_menu/ikusei/manabinaoshi/mext\_01127.html
- 3. BBC Feature, Life with a Microchip, <u>http://www.bbc.com/storyworks/future/innovation-at-the-edge/the-microchip-revolution</u>
- 4. Fukuda Implantable Electronic Electrocardiography Recorder BIOMONITORIII, https://www.fukuda.co.jp/medical/products/icm/biomonitor3.html
- 5. The President's Council on Bioethics: Beyond Therapy: Biotechnology and the Pursuit of Happiness, 2003
- The U.S. Army Combat Capabilities Development Command Chemical Biological Center: Cyborg Soldier 2050: Human/Machine Fusion and the Implications for the Future of the DoD, 2019