

PRESS RELEASE

Gothenburg, May 17, 2001

Natural connective tissue has replaced the surgical implant

Study shows good joint stability after three years

Today, at the ISAKOS Congress currently going on in Montreux, Professor Lars Peterson is presenting the results of a 20-patient pilot study for the treatment of anterior cruciate ligament injuries. Three years after the operation, it can now be seen that the implant has been replaced by natural connective tissue that the body itself has built up.

- After a 30-36 month follow-up, the implant has been replaced by naturally built up connective tissue, the same tissue that forms the body's own ligaments. The patient has regained the same degree of stability as with an uninjured knee, says Professor Lars Peterson.

In the study, twenty patients underwent operations using the so-called augmentation technique where one takes tendon tissue from the patient's own patella and strengthens it with Artimplant's implant.



Cruciate Ligament Injuries

Every year approximately a million people in the Western world are impacted by anterior cruciate ligament injuries. In Sweden, a torn anterior cruciate ligament is responsible for 85 percent of all debilitating knee injuries that affect athletes involved in team sports and downhill skiing. Half of the injured cruciate ligaments are not operated on, but rather treated with physiotherapy to compensate for the joint's lost stability. The long-term results have often been poor because of increasing wear and tear injuries to the cartilage and other structures in the joint.

Artimplant

Artimplant focuses on problem solutions in the field of reconstructive surgery. Artimplant is active in research and development, manufacturing and marketing biologically degradable implants with the goal of recreating active lives. The material the company has developed builds on a new technology that opens up new markets in the field of orthopedic surgery and a variety of other specialized fields where there are significant medical needs. After many years of development work, Artimplant is now entering a marketing phase.

Among other things, Artimplant has developed and patented a number of different decomposable ligament implants, which are going through clinical trials. The company is now focusing on three prioritized areas with the degradable material: augmentation device for anterior cruciate ligament reconstruction, hand surgery and augmentation sutures.

Artimplant is listed on the OM Stockholm Stock Exchange's O-List.

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BiographyLars Peterson, Professor

Lars Peterson is Clinical Director at Gothenburg Medical Center, GMC, associated company to Artimplant AB.

Lars Peterson has together with Professor Anders Lindahl and Anders Nilsson, MD developed a method for cartilage replacement, which Harvard Medical School in 1994 appointed to be one of the ten most significant medical progresses. Lars Peterson has published more than 150 research publications within orthopaedic and sports injuries and has also been co-author in a large number of literature works, amongst others "Sports injuries" that has been translated into 10 different languages.

In 1981-86 Mr. Peterson was the President of Swedish Society of Sports Medicine.

During 1984-90 he was chief physician for the Swedish soccer team and he also served as chief physician during the World Championship in soccer in France 1998.

Lars Peterson is presently the President of the International Cartilage Repair Society and the Chairman of AISAB, Artimplant Scientific Advisory Board.



Artimplant Corporate profile

Background – The Company

Artimplant focuses on solving problems in the field of reconstructive surgery. The company's innovative and degradable material supports the body's unique ability to repair and regenerate itself. The specifically designed products give patients new chances to return to a healthy and active life.

A prioritized product, close to being launched on the market, is an augmentation device for reconstruction of the anterior cruciate ligament, a so-called ACL (ACL - Anterior Cruciate Ligament) augmentation device. This product is currently in the certification phase to receive a CE-Mark from the "Notified Body" and approval is expected during summer 2001.

In the next few years, Artimplant anticipates being able to certify a number of other products for orthopedics and hand surgery. In the field of hand surgery, studies with Artimplant's material are being conducted for arthrosis and ligament injury in the thumb. The company is planning to start clinical trials with augmentation sutures for thorax surgery during the fall of 2001.

Anterior Cruciate Ligament Injuries

The importance and functioning of the knee

The functioning of the knee is of the utmost significance in everyone's daily life. The knee is a joint that combines strength and motion in a way that none of the body's other joints do. Whether it is a matter of taking a walk, jogging, running or jumping, the knee is the strong, stable basis for motion. The anterior cruciate ligament is the most important stabilizing structure in the knee joint.

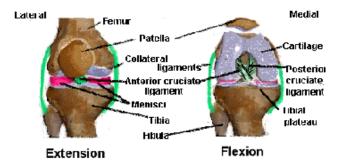
A ruptured anterior cruciate ligament in the knee is the most commonly occurring ligament injury. The condition affects leading athletes, and in particular, athletes who play soccer, handball, and basketball as well as downhill skiers. An injured anterior cruciate ligament limits opportunities for a physically active life. In the long run, a torn



anterior cruciate ligament often leads to disabling wear and tear injuries to other structures in the knee. Anterior cruciate ligament injuries in the knee also entail significant costs for the society.

Ligament Structure

The Anterior cruciate ligament is made of collagen (a fibrous, connective tissue), which is positioned intra-articularly, i.e. inside the knee joint. The anterior cruciate ligament is approximately 10 mm wide and 40 mm long.



The Function of the Cruciate Ligament

The anterior cruciate ligament is the ligament that stabilizes all the specific motion that occurs in the knee. The ligament prevents the tibia – the shinbone – from sliding forwards in relation to the femur – the thighbone. For the most part, the anterior cruciate ligament stabilizes the motion so that we cannot rotate, twist, or hyperextend the knee joint. The anterior cruciate ligament also protects the knee joint's ability to bend inwards and outwards when the other ligaments are missing.

The Consequences of an Injury

When the anterior cruciate ligament is injured and cannot perform its protective functions, movements in the knee become unstable and uncontrolled. This leads to an inability to do all the daily activities that require movement in the knee joint. It is also well known that an anterior cruciate ligament injury speeds up the process of wear and tear to the joint cartilage, which then leads to decreased movement and pronounced pain problems for those who are affected. Surgical reconstruction offers the best prognosis for those who are affected by an anterior cruciate ligament injury.



Competing Methods

Conservative Treatment

Conservative treatment entails doing without surgical measures and trying to compensate for lost joint stability with ongoing physiotherapy and adapted muscular exercises. The long-term results of this treatment method are often unsatisfactory because of successively increasing wear and tear injuries to the other structures in the knee.

Reconstruction with Transplantation

Patellar Tendon

At the present time, the most common operative technique in anterior cruciate ligament reconstruction is to replace the injured ligament with a portion of the patient's own patellar tendon. One of the disadvantages to this method is that the elasticity and strength of the tendon tissue decreases after a few weeks, which increases the risk of rupture or stretching and thereby unsatisfactory joint stability during rehabilitation and afterwards. Measurements suggest that the inserted tendon tissue never achieves the strength of a healthy anterior cruciate ligament. Not infrequently, there are also complications at the donor site itself.

Hamstring

Approximately 25 % of the anterior cruciate ligament operations that occur today use tendon from the inside of the rear portion of the thigh – from the hamstring – instead of a portion of the patellar tendon. The advantage to this method is that it causes fewer problems at the donor site. The disadvantage is that these tendons are harder to connect to bone in the patellar tendon.

Clinical Results

The long-term follow-ups that were performed after cruciate ligament reconstruction with autograft tissue have shown a significant complication frequency. A study that was performed at Sahlgrenska University Hospital in Gothenburg and that was presented at the Swedish Society of Medicine Convention in 1999 evaluated functional and objective observations four to seven years after surgery and compared them with clinical results after a two-year follow-up. The conclusions included the fact that the results four to



seven years after reconstruction were worse than those obtained after two years. One in four patients had had another operation before the monitoring performed four-seven years after the first operation.

Other larger compilations of long-term results that have been performed have shown that, on average, in almost 40% of the cases complications in the form of pain, limited mobility or wear and tear in the autograft material arise 4.5 years after the operation.

Non-degradable Implant

The non-degradable implants that were used previously as prostheses in anterior cruciate ligament reconstruction have not been able to fulfill the requirements that were placed on them and have therefore to a large extent been withdrawn from the market. None of these prosthetics were manufactured from material that was developed for the principal purpose of being used in cruciate ligament reconstruction.

Artimplant's Augmentation Device for Anterior Cruciate Ligament Injuries

If a ligament or a tendon tears, a biological defect arises. The "ligament cells" are not capable of bridging over defects. On the other hand, a biodegradable scaffold, with the same mechanical characteristics as a healthy ligament, together with autograft tissue can create the requisite conditions for the formation of a new ligament. The scaffold, or implant, replaces the injured ligament so that the joint's function and stability are maintained before the scaffold is successively broken down through the effects of bodily fluids and replaced with endogenous ligament tissue.

While the implant maintains the functionality of the cruciate ligament, the body's own cells have the opportunity to grow into the implant and form a functional biological unit. This is possible because the implant is biocompatible and possesses mechanical characteristics that correspond to a natural cruciate ligament.

Over the long term, the implant loses its strength, being broken down through the effect of water in the body ("hydrolysis") into small molecules that can pass through the body's membranes. It is important that the implant break down at a rate that is as slow as the rate at which the body's cells are able to form new support tissue. As the implant is exposed to mechanical stresses, the cells are stimulated to form a new ligament. A natural ligament consists in large part of connective tissue (collagen) that can be



compared with the fibers of a rope. The collagen is responsible for mechanical characteristics like strength and a certain amount of ductility. As the fibrous material in Artimplant's ligament implant is spun and woven using a tested technology, the resultant strength and elasticity characteristics are equivalent to those found in a natural cruciate ligament. The body's cells infiltrate the ligament implant to build up a natural ligament as the implant is being broken down.

Laboratory studies of Artimplant's cruciate ligament implant have shown that the degradation occurs at a rate that is slow enough to enable the endogenous connective tissue to fill in. Animal testing has shown that the ligament implant is biocompatible and that it recreates satisfactory joint stability. The testing has also confirmed that the implant can handle the mechanical stresses that normally arise in a knee and that the rate of degradation does not fall below the minimum limit (>12 months).



Artimplant's augmentation device for the anterior cruciate ligament

Market Potential

Approximately a million anterior cruciate ligament injuries occur in the Western world every year. Approximately half of all injuries are treated conservatively. The market potential for implants for ruptured anterior cruciate ligaments is estimated at between 10-15 billion SEK globally.



Gothenburg Medical Center

In 1998, Artimplant acquired Gothenburg Medical Center, GMC. GMC is a forum for clinical research, application, and training in the field of orthopedic surgery. GMC was started by Professor Lars Peterson and is one of Sweden's leading sports clinics. Artimplant Clinical Academy, a part of GMC, is a research and marketing strategy initiative to enable Artimplant to develop new applications and maintain closer contact with its primary target groups in the field of orthopedic surgery. The clinic collaborates with selected orthopedic clinics around the world in order to develop and disperse expertise about new treatment methods.

Artimplant Fact Sheet

Founded

1990

Management

Anders Cedronius, CEO
Lars-Erik Nygren, CFO
Hans Bertilsson, Research Director
Ulf Åkerblom, Director Corporate
Communications
Mikael Nordh, Director Sales and Marketing
Ingrid Ekenman, Medical Director
Kristina Lindberg, Director HR
Anders Östin, Director Production and
Logistics

Board

Akbar Seddigh, Chairman Anders Cedronius Per Flodin Helge Ramseng Svante Rasmuson Lennart Ribohn

Number of Employees

77, 33 of whom work for the subsidiary Gothenburg Medical Center

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