Extendible implant solutions for skeletally immature patients
In 1976, the Centre for Biomedical Engineering designed and fabricated the world’s first extendible massive replacement. At that time, the mechanism consisted of a worm drive mechanism. After 4 implantations, this extension method was abandoned because of mechanical problems with the worm-drive mechanism.

Ball bearing mechanism was the growing option selected from 1982. 59 growing prostheses incorporating this mechanism were implanted. This mechanism was then abandoned as ball bearing fractured and the mechanism jammed.

In 1988, the “C collars” were introduced, acting as spacers to gain extension of the device. Because of extensive exposure, high infection rate and long rehabilitation courses, another method was investigated and developed.
Implant Solutions for Skeletally Immature Patients

Minimally Invasive Mechanism

Based upon its experience and follow up, in April 1992, Stanmore Implants introduced a re-engineered worm drive mechanism made from different material. The worm drive mechanism is encased within the shaft of the prosthesis thus preventing soft tissue invading and jamming the extending mechanism.

Using an Allen key, the telescopic implant is extended typically by 6-8 mm at each lengthening episode depending upon the soft tissue tension and length required.

The length of the incision is typically 1-2 cm and lengthening procedures can often be undertaken as day cases leading to significant reduction in rehabilitation and in-patient duration benefiting the patient and reducing healthcare costs.

Advantages

- Minimal incision to access the key-port reduces the risk of infection and aids rapid rehabilitation following limb lengthening
- Fast and straightforward technique
- Custom made device with minimal bulk helps soft tissue closure
- Dependable drive mechanism enclosed within the implant shaft prevents tissue invading the mechanism
- Barrel can be exchanged whilst the intramedullary stem remains in situ when maximum extension is obtained

Growers as a good option

Retaining one’s limb following limb salvage surgery for young patients is paramount but maintaining limb length equality is of great importance to these patients. The success of a reliable extendible replacement is an important element of the quality of life for these young patients.

Although there is still controversy over the use of extendible endoprostheses to maintain leg length in the skeletally immature, it has now become the most acceptable method of treatment. In comparison to adult endoprosthetic replacements, it is acknowledged that there is an increased risk of revision with an extendible implant as a result of a failing mechanism or insufficient extension obtainable from the implant to accommodate all the growth required. The reliability of the extending mechanism depends upon the design. Plus, the type of mechanism impacts on the patient’s quality of life.

There are a number of alternative techniques such as rotationplasty, fusion of contra-lateral growth plates, bone transport, amputation or using non-extendible implants that would be replaced with an extendible version on completion of chemotherapy. With the exception of bone transport, all alternatives offer one definitive surgery but limb length equality at skeletal maturity cannot be achieved.
Introducing the 5\textsuperscript{th} gen

In the mid 80s, Professor John T. Scales of the Centre for Biomedical Engineering (Institute of Orthopaedics), the pioneer of much of the limb salvage implant technology and Mr Rodney Sneath, a leading orthopaedic oncology surgeon, originated the concept of a non invasive extendible implant. During the late 80s, the project was begun and the technology platform selected.

Throughout the 1990’s, the project continued and was supported with generous contributions from Action Research for the Crippled Children and BUPA; following the formation of Stanmore Implants in 1996, the project was funded by income received from its sales of custom made implant service.

The concept

The shaft of the prosthesis is constructed in two parts allowing length to be telescoped by a power screw which jacks the two halves apart where one turn of the power screw extends the shaft by 1mm. The power screw is driven by a epicyclic gearbox diam. 21.5mm by 18.5mm long, producing an overall speed reduction of 13061:1 and an output torque of 4Nm. The input shaft of the gearbox is connected to a rare earth NdFeB toroidal magnet.

Parts of the prosthesis

- The lead screw has 1mm pitch,
- Load bearing capacity is 1350 N,
- Rate of expansion is 0.23mm per min,
- Recommended 3 to 4mm of extension at each sitting.
- Output shaft of the gearbox is made of CoCrMo Alloy and has two ‘O’ Ring seals,
- Remaining gearbox parts are made of Stainless Steel,
- Gearbox parts are lubricated with liquid paraffin.
**The drive unit**

Once the prosthesis is implanted, it is extended by placing the limb with the implant inside an external circular drive unit. By passing an electric current into an electric coil, the drive unit produces a rotating magnetic field at a speed of 3000 rpm and has field strength tuned to generate a predefined torque coupling with the implant magnet. As the magnetic field is turned on, it captures the implant magnet causing it to rotate in synchronisation.

At full speed, the implant grows at a rate of 0.23mm per minute (1mm in 4 minute).
One of the most challenging cases presented to Stanmore Implants was of a young patient aged 2 years and 9 months with an osteosarcoma of his right femur. The tumour was extensive and the options were hip disarticulation or a total femoral replacement.

Following discussion and design considerations, the endoprosthetic solution was selected. The design was of a total femoral replacement. Due to the immaturity of the hip and knee joints, a hemi-femoral head and a hemi-knee replacement were designed. A 22mm diameter femoral head was used as the femoral hemi-arthroplasty and the femoral knee component was fabricated from a block of titanium alloy. This knee component was ion-implanted to improve the wear characteristics. In March 1994, the extendible replacement was implanted. This young boy recovered rapidly and was soon running and playing.

The implant was lengthened repeatedly but, due to the small overall length of the implant, the longest extension that could be obtained was 50mm.

In June 1996, the primary implant was replaced by a new, longer total femoral replacement. Unlike the first, this implant also included a tibial component. The longer implant permitted a total of 90mm of extension and, over the next 5 years, multiple lengthening procedures were performed. By the age of 11, this young boy had undergone over 20 surgical procedures (mostly lengthening). A significant leg length discrepancy had developed and all parties were determined that the next extendible replacement would have a sufficient length capability to ensure that, at skeletal maturity, leg length equality could be obtained.

Our engineers designed and produced an implant that could be extended by an incredible 150mm. It will still be 2 or 3 years before skeletal maturity will be reached.

In early 2004, at a clinical review, the patient is progressing very well and is still undergoing regular lengthening procedures.

This case study demonstrates that even very young patients can benefit significantly from limb-salvage. From a design point of view, these cases are extremely challenging and it is incredibly frustrating that, as designers, we are not able to provide a solution that can provide more if not all the extension required for these young patients.
We report the case of a young female whose chronological age was 13 at the time she was diagnosed with an Osteosarcoma grade 2B of her left distal femur. The expected remaining growth was 40mm. We designed a JTS non invasive custom-made distal femoral endoprosthesis with a passive sliding tibial component and a precision fit, HA coated IM stem. The JTS distal femur was implanted in November 2002. In January 2003, the first lengthening procedure was performed and obtained growth was 4mm. Second lengthening episode was performed in March 2003 with another 4mm extension obtained. Since November 2002, the patient has undergone 9 lengthening episodes and has been extended by 25mm, reaching skeletal maturity. The lengthening is now complete and the patient has leg length equality.
Although there is still controversy over the use of extendible endoprostheses to maintain leg length in the skeletally immature, it has now become the most acceptable method of treatment. In comparison to adult endoprosthetic replacements, it is recognised that there is increased risk associated with the lengthening and the mechanical reliability of extendible implants. This study's aim was to assess the reliability of various types of extending mechanism and to identify the major forms of implant-related failure.
With respect to extending mechanism related problems, the telescopic component of the ball-bearing type jammed as a result of fracturing of the ball-bearings. Ball-bearing fracture was due to high point loading during insertion of the ball-bearing or during ambulation. Only 1 patient with a “C” collar type had an extending mechanism problem and this was dislocation of a “C” collar. With respect to the 2nd generation worm type, 7 implants were revised as a result of the extending mechanism reversing and in 2 cases the mechanism jamming.

Revising the implant as a result of the maximum extension of the mechanism being obtained and more lengthening still required was common to all types of mechanism.

Aseptic loosening was predominantly associated with implants that utilised cemented intramedullary stem fixation compared to those that were secured using a precision-fit uncemented hydroxyapatite coated intramedullary stem (introduced in 1992).

The status of 540 implants with respect to grower mechanism type.

The percentage of implant related failure with respect to grower mechanism type.

The probability of surviving an implant related failure with respect to grower mechanism type.

The probability of surviving aseptic loosening with respect to mode of fixation. (Total femoral and total humeral replacements were excluded).

This study reviewed an evolution of extending mechanism designs that spanned nearly 3 decades and each extending mechanism type had specific advantages and disadvantages.

The “closed” mechanism types (1st & 2nd generation worm-drives and the ball-bearing) had significantly greater problems with the mechanism, than the “open” and much simpler “C” collar design. Although this mechanism was virtually trouble-free in terms of the mechanics, the significant disadvantage was the amount of surgical exposure required to lengthen the implant.

In-patient stay following a lengthening of the “C” collar type was on average 5-6 days. Plus it has also been considered that there was a greater risk of infection due to the larger exposure although the data does not strongly support this. The “closed” mechanism types required minimum surgical exposure to lengthen the implant and in-patient stay for those patients with a 2nd generation worm-drive was typically reduced to an overnight stay and this has important impact on the quality of life of the young patients who require multiple lengthenings.

Surprisingly, aseptic loosening of the cemented IM stemmed implants was a greater cause of implant related failure, but with the introduction of a press-fit design the incidence has been reduced and the early to mid-term results are encouraging.

There is an increased risk of revision with an extendible implant as a result of a failing mechanism or insufficient extension obtainable from the implant to accommodate all the growth required.

The reliability of the extending mechanism depends upon the design. Plus, the type of mechanism impacts on the patient’s quality of life.
Financial cost efficiency

Non-invasive growers are more expensive than minimally invasive. But, in the longer term, they are a cost-effective solution for those patients that will require multiple lengthening procedures.

If the patient is nearing skeletal maturity and the expected extension required is less than 25mm, a non-invasive mechanism would not be the most cost-effective solution financially, unless there was an increased risk of infection.

The risk of infection is ever-present and there are documented cases of infection that can be directly related to the extension procedure. The cost to revise an infected prosthesis to both the patient and health service provider is significant. Minimising surgical intervention minimises the risk of infection.

Non-financial cost efficiency with respect to quality of life.

Limb-salvaging is predominantly about minimising the decline in the quality of life for the patient. The simplest solution for many patients would be amputation but, in today’s society, this would be unacceptable. And now, after many years of research and development, there is the technology available.

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Surgeons say...

The non invasive grower will transform the lives of our children who need extendible replacements. The knowledge that the lengthening can be done painlessly and without an operation or an anaesthetic will be of immense value to these children. The minimally invasive procedures have been remarkably successful but they still have major complications such as infection which should now be a thing of the past.

Mr Rob Grimer, Royal Orthopaedic Hospital, Birmingham, U.K

I have been using the SIW extendible implants for over a decade now. The minimally invasive grower has been in routine use for 13 years and is simple and reliable needing only a small incision and a day case admission. The extendible barrel is obviously only as long as the resection allows, so in a few cases the barrel may have to be changed, but this is a small consideration. The non invasive grower is simply wonderful, although it is early days, there is no pain and no scar during lengthening at all. The only problem is that it is that bit longer, so even more bone needs resection, but the smile on the face of the children (and their mums) when they realize that they don't need an operation to be lengthened has to be seen to be believed. The other huge strength of the SIW system is the modularity of the system: the range of fixation in the metaphysis and diaphysis is extensive: cemented or not, cutting flutes or not, fully or partially coated, with or without side plates. All these options are discussed and plans emailed making the decision making easier, and the operation less stressful. If anyone ever wants an extendible implant, a telephone call to Neil or Sarah in the design office will sort out the details in minutes, and the implant is ready in days. What a service" 

Mr Justin Cobb, The Middlesex Hospital, London, UK

Easy to implant, easy to extend, good prosthetic function, very good support from Stanmore Implants who provide fast and professional communication”

Mr Otte Brosjö, the Karolinska Hospital, Stockholm, Sweden
A part of the team in limb salvage.