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AN ENGINEERING EVALUATION OF ANKLE PROSTHESES FAILURES

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ABSTRACT

There are a wide range of different types of ankle replacements on the market today each with a different mechanical design. Unfortunately the results of ankle replacements are not as good as hip and knee replacements; this is due to the complexity of the ankle joint. In the early days of ankle replacements some of the prosthetics only lasted 4 months. Recent developments have improved the longevity of the replacements although, there are still many complications and failures of the replacements, these include; the prosthetic components migrating into the bone, the components failing due to stresses induced by the forces and the surgery itself i.e. the incision site.

This paper will analyse the documented medical failures of the replacements from a mechanical engineering perspective. Three ankle prosthetics are investigated in this paper: the Buechel-Pappas, the Scandinavian Total Ankle Replacement (STAR) and the Hintegra ankle replacement. Medical publications are examined to isolate the mechanical failure mechanisms of the replacements and to categorise and quantify these failures in engineering terms. These failures will include wear complications and also dislocations of the prosthetic parts among other failures. The paper will conclude by comparing the mechanical reliability of the four prosthetics examined.

Keywords.

Ankle, Failure, Engineering.

INTRODUCTION

Lord and Marotte were the first to attempt to replace the ankle joint with an inverted hip prosthesis in 1970 (Anderson et al 2003). Since then there have been thirty-seven different designs for the ankle prosthesis. Some of these designs include; Irvine, TPR, Mayo, TNK, STAR, Agility, Buechel-Pappas, SALTO, Ramses, Hintegra and the Mobility total ankle replacement. The first generation of total ankle replacements were generally two component cemented designs that were either constrained, semi-constrained or non-constrained. The results with the first generation total ankle replacements were poor and less than satisfactory and had high failure rates (Vickerstaff et al 2007). The short term results of the first generation designs were promising but the medium to long term results were very poor. These failures were due to many reasons but principally the following.

- Use of cemented fixation.
- Over/lack of constraint.
- Subluxation of components.
- Component loosening.
- Inappropriate surgical instruments.
- Excessive bone removal.
- Insufficient surface area to distribute the load at the bone-implant interface.

As a result of these problems, all of the first generation ankle prostheses designs are disused.

(Vickerstaff et al 2007) and (Hintermann B. 2005)

“Those who had persisted with ankle replacement had identified the problems of the first generation and designed new implants with attention to reproducing normal ankle anatomy, joint kinematics, ligament stability and mechanical alignment”. (Vickerstaff et al 2007). Second generation designs of ankle replacements are generally three component cementless designs that have a mobile bearing and a coating of Hydroxyapatite on the surface of the prosthesis; which encourages bone ingrowth to the prosthesis. The designs are generally semi constrained which allows for multi-axial motion.(Bell et al 2006) According to Hintermann 2005 in his book there are two main design philosophies in second generation designs; the constraint type and the congruency type. *“Mobile bearing implants attempt to overcome this constraint conformity conflict by offering two separate fully conforming or congruent articulations that function together to reduce axial and shear constraint at the bone implant interface.”* (Hintermann 2005). The majority of the second generation ankle replacements have three components and a mobile bearing element apart from the Agility ankle and the TNK ankle prostheses which only have two components. (Vickerstaff et al 2007). Examples of three component mobile bearing designs are the Hintegra total ankle replacement, the STAR ankle prosthesis, the Buechel-Pappas total ankle replacement and also the Ramses total ankle replacement. Ankle prostheses can fail for a number of reasons, including the following:

1. Implant not sized properly
2. Malpositioning of the prosthetic components
3. Loosening (aseptic) of the prosthesis
4. Wearing of the prosthetic components
5. Dislocation of inlay or bearing
6. Migration of the tibia and talus prosthetic parts
7. Loss of movement of ankle
8. Surgical procedure – incision
9. Fracture of the medial or lateral malleolus
10. Ruptured tendons i.e. Achilles

THE PROSTHESES

This paper investigates the performance of the following prostheses:

1. Buechel-Pappas total ankle replacement
2. Hintegra total ankle replacement
3. S.T.A.R prosthesis

The reason for choosing these prostheses is because they are widely used in Europe and an example of this would be in Sweden where 83% of the prostheses fitted used the above three prostheses. Also in Norway 84% of the replacements fitted were the STAR prostheses.

The Mobility ankle is the most recent of all ankle prosthesis and has only been in use since 2005. As this is a relatively new prosthesis, there is not much published data on the results, thus this prosthesis is not included in the study. One thing to note about the Mobility prosthesis and the Buechel-Pappas prosthesis is that they are very similar in design. Both have the same type of tibial component with a stem and the talar components have the same features as well. Also the PE bearing is the same design in both prostheses.

Buechel Pappas Total Ankle Replacement.

The Buechel-Pappas total ankle replacement is an improved version of the New Jersey Low Contact Stress ankle prosthesis, which was designed by the same people; Drs. F.F Buechel and M.J Pappas. The Buechel-Pappas prosthesis is a three component, mobile bearing, fully conforming titanium, porous coated cementless design. *“It combines mobility and full conformity in an effort to achieve low wear and low contact stresses”* (Hintermann book 2005). There are three components that make up the Buechel-Pappas prosthesis; the tibial component, the meniscal bearing and the talar component. There have been two different models of the Buechel Pappas replacement. The mark 2 (figure 1) is used nowadays and was designed in 1989. The mark 2 BP prosthesis includes dual fins, a deeper sulcus and a thicker tibial loading plate. The ultra high molecular weight polyethylene (UHMWPE) meniscal bearing has a flat upper surface which lies flush with the lower surface of the tibial loading plate. The lower surface of the bearing conforms to the talar dome with a longitudinal sulcus and this provides control of medial-lateral (left-right) translation and prevents dislocation and provides some inversion and eversion without producing edge loading to the bearing(Hintermann book 2005).

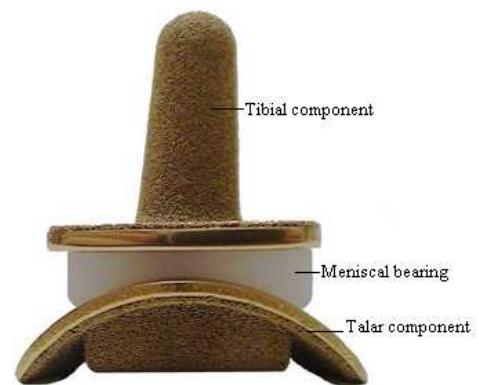


Figure 1: Buechel-Pappas Prosthesis

The Hintegra Total Ankle Replacement.

The Hintegra total ankle replacement (figure 2) is a three component, non-constrained, mobile bearing design. *“This ankle was developed as an attempt to specifically address the needs of minimal bone resection, extended bone support, proper ligament balancing, and minimal contact stresses within and around the prosthesis”*. (Hintermann et al 2004). The tibial and talar components are made from a cobalt-chromium alloy with two layers of a porous coating. Talar component has a smaller radius medially than laterally and is anatomically shaped to match the trochlear of the talus. The tibial component’s anatomically sized flat surface allows for optimal contact to the to the subchondral bone and optimal support for the cortical bone ring, providing a maximal load transfer area. The UHMWPE mobile bearing consists of a flat surface to the tibial side and a concave surface perfectly matching the talar surface. *“The replacement provides 50° of congruent contact flexion and extension and 50° of congruent contact axial rotation, thus providing congruent contact”*. (Hintermann et al 2004). Also there is little contact stress between the articulating surfaces of the prosthesis because there is an increased contact area compared to other designs.[5] The Hintegra prosthesis is one of the only second generation designs that uses fixation screws to secure the prosthesis in place.

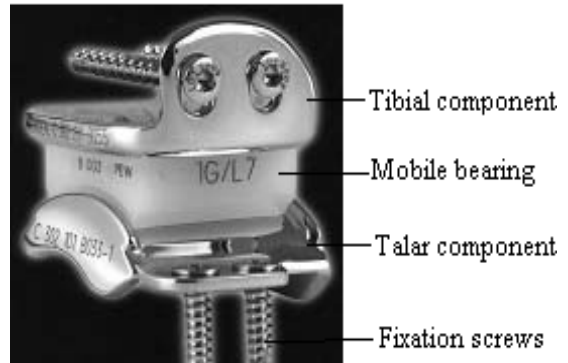


Figure 2: Hintegra Total Ankle Replacement [7]

Scandinavian Total Ankle Replacement (S.T.A.R.).

The S.T.A.R. prosthesis (figure 3) is a three-component, full congruency, mobile-bearing cementless prosthesis. The tibial and talar components are made from a cobalt-chromium alloy and the mobile bearing is made from UHMWPE. The mobile bearing is fully congruent and articulates superiorly with the flat tibial glide plate and inferiorly with a longitudinally ridged convex talar component. This design allows 10 degrees of dorsiflexion, 30 degrees of plantarflexion and finally 15 degrees of rotational movement. (Hintermann 2005) The talar component has wings that replace the medial and lateral facets and allows additional load transfer. There is a contact area of 600mm² on the tibial surface and 320mm² on the talar surface. The coating on the non-articular surface of the talar and tibial implants is a dual coating, consisting of vacuum plasma sprayed and commercially pure titanium. (Hintermann 2005)

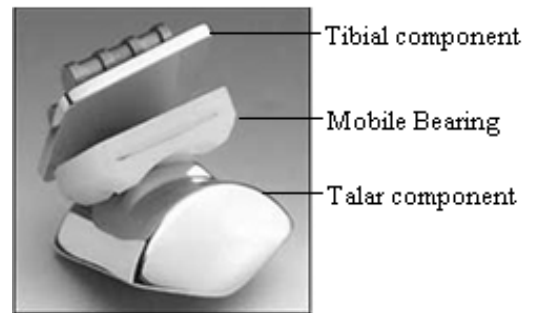


Figure 3: S.T.A.R prosthesis [8]

RESULTS

The following section of the paper will analyse the engineering/mechanical failures of the three different prostheses as published in a range of papers, see figure 4. The first chart shows the percentage of ankle prostheses that mechanically failed, other failures and also the percentage where no revision had to be carried out. The prostheses were considered a failure if a revision had to be made or an ankle arthrodesis had to be carried out. Other failures include, malpositioning of the prosthetic parts, delayed wound healing, migration of the parts, implant not sized properly and fracture of the malleoli among others. Figure 5 shows a breakdown of the 8% of engineering failures. Figures 6, 7 and 8 show the engineering failures for the Buechel –Pappas ankle replacement, Hintegra ankle prosthesis, and the S.T.A.R. prosthesis.

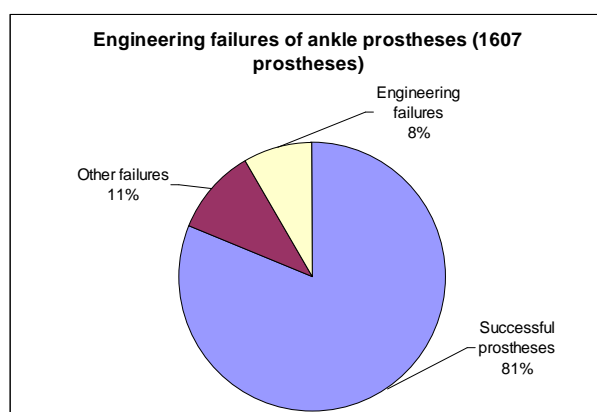


Figure 4 The percent of engineering failures [5], [11], [12], [13], [14], [15], [16], [17], [18], [19], [20], [21].

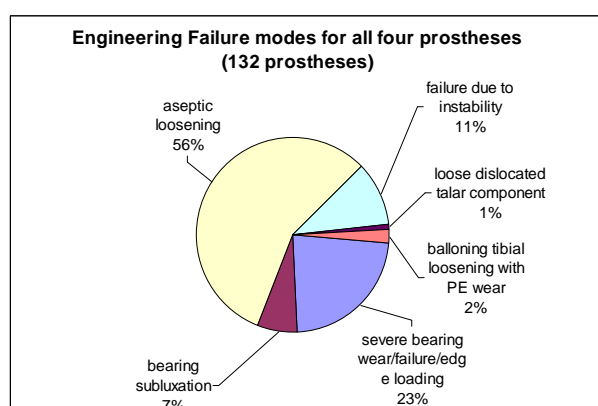


Figure 5 Engineering failure modes [5], [11], [12], [13], [14], [15], [16], [17], [18], [19], [20], [21].

Failure Mode	Name	Description
1	Aseptic Loosening	The mechanical theory of aseptic loosening is the repeated cyclic stresses and movements imposed on the joint cause the prosthesis to loosen overtime. Bauer et al stated that that aseptic loosening can result from large bone resection and also the geometry of the ankle replacement
2	Severe bearing wear and edge loading	This is caused by the prosthesis being positioned wrong in the patient, whether it be a valgus or varus malpositioning. From this malpositioning, edge loadings will occur on the PE bearing from the tibial/talar components. This increase in load will increase the stresses and over time may result in catastrophic failure of the component.
3	Instability	This is where the prosthesis becomes loose and as a result of this the PE bearing may dislocate due to the increased movement from the loosening.
4	Bearing Subluxation	This may occur from sudden movements of the ankle and the PE bearing slipping out of position between the tibial and talar components. This may be a caused by a design issue of the prosthesis
5	Ballooning tibial loosening with PE wear	This is where cavities occur behind the component causing it to loosen overtime and also causing the PE bearing to wear.
6	Loose / Dislocated Talar components	The talar or tibial components once they become loose they can dislocate. However this is a rare phenomenon and was only seen once during the review of the literature.

Table 1 Description of Engineering failures

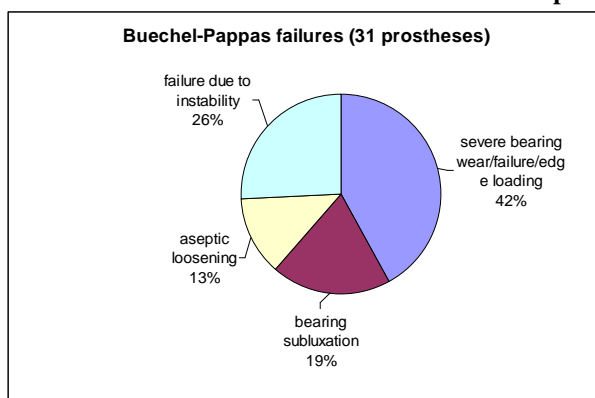


Figure 6 Buechel-Pappas engineering failures [11], [13], [14], [15], [16].

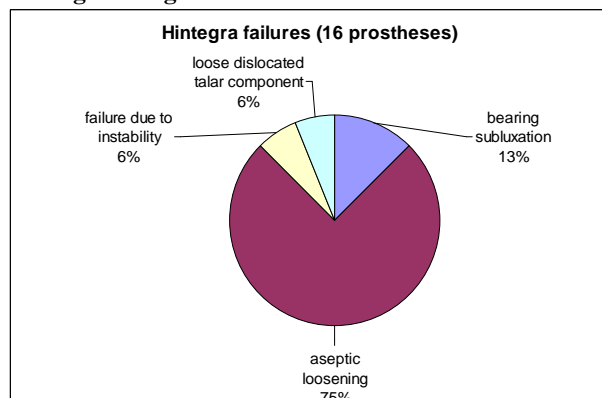


Figure 7 Hintegra engineering failures [5], [11], [12], [17].

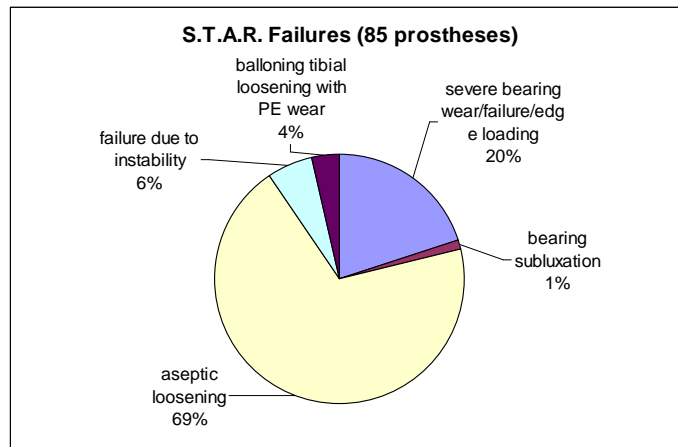


Figure 8 STAR engineering failures [11], [12], [18], [19], [20], [21].

DISCUSSION AND CONCLUSION

Eight percent of ankle prostheses failed due to mechanical or engineering reasons, figure 4. The major cause of engineering failures is aseptic loosening, figure 5. The Hintegra and the STAR prostheses main failure mode was aseptic loosening with 75% and 69% failing respectively, whereas with the Buechel-Pappas prostheses aseptic loosening was the least cause of engineering failure with only 13%. This is due to the design of the prosthesis and the method in which the Buechel-Pappas is fixed in place. The dual fin fixation of the Buechel-Pappas seems to give a stable platform for the prosthesis and is kept secure at the bone-prosthesis interface. The tibial stem on the Buechel-Pappas possibly prevents the aseptic loosening from occurring.

Severe bearing wear, failure and edge loading is the second most common engineering failure of 23%. The major cause of failure for the Buechel-Pappas prosthesis is problems with the PE bearing, whether it is wear, cracks or edge loading of the bearing with 42%. With the Hintegra prosthesis none of the prostheses failed due to this problem but with the STAR prosthesis it was the second most common engineering failure with 20%. The Hintegra may have performed very well because there is little contact stress between the articulating surfaces of the prosthesis due to the increased contact area of the surfaces. [5].

Another problem is the PE bearing subluxing or dislocating and accounts for 7% of the engineering failures. The Buechel-Pappas and the Hintegra prostheses had a higher rate of failure for bearing subluxations 19% and 13% respectively than the STAR prosthesis which only had 1% of failure due to this problem. The STAR prosthesis had very few failures for bearing subluxations and this is possibly due to the ridge in the talar component and the mobile bearing which may keep the bearing in position during ankle movement. 11% of engineering failures were caused by instability with the Buechel-Pappas prosthesis having the highest % of instability failures with 26%. The Hintegra and the STAR prostheses instability failure rates were both below the 11% instability failure rate at 6% for both prostheses.

The Hintegra was the only prosthesis to have failures due to a loose or dislocated talar component. Also the STAR prosthesis was the only prosthesis to fail due to ballooning tibial loosening with PE wear. These two problems should not be of much concern as these failures were very rare.

It is clear that each of the three prostheses have their own pros and cons. Some prostheses are better mechanically than others. There were 374 Buechel-Pappas, 297 Hintegra and 913 STAR prostheses covered in the research. This means that 8% of the Buechel-Pappas failed due to engineering problems, 5% of Hintegra failed due to engineering problems and finally the STAR had 9% of engineering failures. Overall the Hintegra prosthesis performed the best with the least amount of engineering failures with aseptic loosening as the major cause of failure. The Hintegra prosthesis is the best with the bearing problems as it only had a small number of failures due to bearing subluxation and encountered no problems with bearing wear and edge loading. Next was the Buechel-Pappas and this prosthesis main failure mode was due to problems with the polyethylene bearing. The Buechel-Pappas results were very promising for aseptic loosening with only 13% failing due to this problem which is a vast improvement on the results of the STAR and the Hintegra aseptic loosening. The STAR was the least successful with aseptic loosening as the major problem. In conclusion, it would appear from carrying out this study that the following features would yield a more mechanically reliable ankle prosthesis. The first would be the bearing design from the Hintegra prosthesis which would reduce failures with the bearing. The second design feature would be the Buechel-Pappas fixation methods i.e. the dual fins and the tibial stem and this in turn should improve aseptic loosening results.

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