

Design Rationale and Clinical Review of a New Compliant Bearing Material for Acetabular Reconstruction

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Abstract: Wear and the generation of particulate debris continue to be a significant problem in the longevity of total joint devices. Metal on metal bearings started in the 1930s with Philip Wiles and progressed with McKee, Ring and Sivash through the 1960s. Sir John Charnley convinced that M-O-M could not be used to reduce the frictional torque began his search into the field of polymers in the early 1950s. Polyethylene and metal has been the material of choice for THA since the 1960s. Continued problems with wear and the generation of particulate debris has increased the use of ceramics and a renewed interest in M-O-M. This paper will review the design and clinical results of a new compliant bearing material (PCU) implanted in humans for total hips since 2006. This material and system design possess features significantly different from traditional acetabular bearing materials. This new system is having encouraging clinical results and may open up a new way of thinking about acetabular reconstruction.

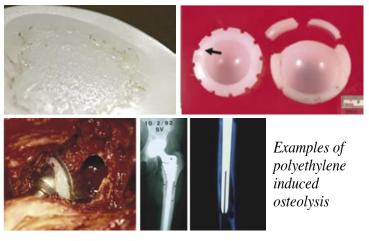
Introduction

Total hip arthroplasty is one of the most effective orthopaedic procedures with a very high success rate as measured by pain relief, improved function and patient satisfaction. It has been almost three decades since Willert first describe the problem of polyethylene wear leading to peri-prosthetic inflammation, granuloma, bone resorption and implant loosening. Wear has and continues to be a significant problem. We are now seeing third and fourth generations of polyethylene along with work being done on alternative hard on hard bearing trying to reduce the generation of wear debris.

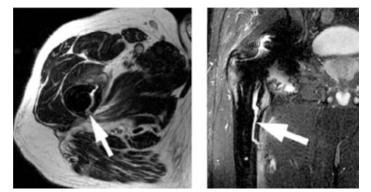
Examples of polyethylene failures

Hylamer Poly

XLPE Poly



Over the past few years as hard on hard bearings have increased in usage, clinical issues have been raised as to squeaking, fatigue strength in ceramics to short term aseptic loosening, high trace elements, and metal sensitivity in metal-on-metal bearings.



Bone Necrosis (E. Smith) M-O-M bearing

Ceramic on Ceramic is recognized for low wear and no metal ion release, however, fatigue issues can be a problem resulting in component fracture, intraoperative chipping, and now reported articulation noise in the form of squeaking.



From the Joint Implant Surgery & Research Foundation 46 Chagrin Plaza #118, Chagrin Falls, Ohio 44022 Non-Profit Founded in 1971 www.jisrf.org

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Currently, the scientific community has not yet reached consensus as to which of the currently available bearing surfaces options are optimal for total hip arthroplasty.

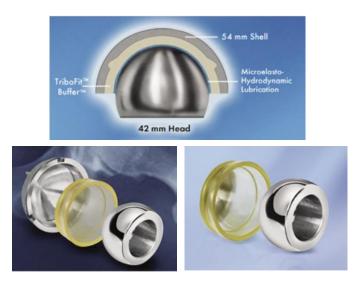
Ideally, the surfaces for articulation will be made from materials having high strength, low wear, corrosion resistance and low friction moments. Polycarbonate urethane (PCU) has been developed into a new approach for replacement of the polyethylene side of the bearing surface.



Material & Methods

Polycarbonate urethane (PCU) has been extensively tested in a number of animal and biomechanical models and began clinical evaluation in Europe as a bearing surface in the hip socket for THA in patients with femoral neck fractures.

A retrospective analysis of patients who underwent primary THA with a compliant bearing material (PCU) TriboFit® acetabular Buffer[™] Implant by Active Implants Corp. Memphis TN was undertaken. The inclusion period was between February 2006 and May 2009.

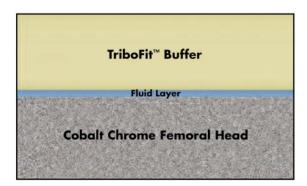


Two styles of TriboFit® acetabular Buffer[™] implants were reviewed. One being just the Buffer implant used as an acetabular cartilage replacement placed directly into the boney acetabular socket and a second style where the Buffer implant is used as an acetabular insert placed into a traditional cementless acetabular metal component. A total of 408 acetabular devices made of this material have been implanted at 70 different sites in Italy, Germany, Israel, Spain and Australia. A total of 84% have been implanted as cartilage replacements (meaning only the Buffer implant was used on the socket side). A variety of femoral stem components have been used all with a metal CoCr femoral modular head component with a standard 12/14 Euro-headneck taper junction. All femoral heads were large diameter (meaning greater than 32 mm).

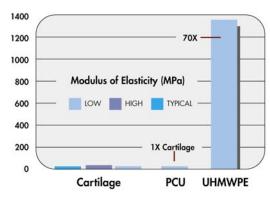
This review of the results to date was limited to indication for use, infection, and revision rate of the acetabular component for dislocation and loosening.

Design Rationale

The TriboFit® acetabular Buffer[™] implant has significantly different design goals as compared to conventional polyethylene, ceramic and metal bearings.



Microelasto-hydrodynamic Lubrication



Soft compliant polycarbonate urethane is designed to function more like the natural hip at least on the acetabular side of the hip joint. Articular cartilage, along with the synovial fluid layer, provides a natural buffer to the bone and surrounding soft tissues in the hip, so that there is reasonable stress transmission at the joint due to the shock absorbing



characteristics of the cartilage and fluid layer.

Previous implant systems provide poor shock absorption, due in part, to the significant difference in mechanical properties of the materials used-specifically, the modulus of elasticity. All prior commercial systems eliminated nature's buffer.

Polycarbonate urethane (PCU) is a hydrophilic material which attracts fluids. This property helps to establish the full fluid-film layer between the Buffer implant and the femoral head in order to provide microelasto-hydrodynamic lubrication.

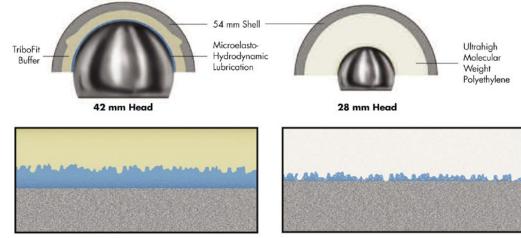
and possible generation of metal debris and increase in ion levels.

Another factor with MoM bearings is the occurrence of breakaway wear that is generated during mechanical wear testing.



Example of run away wear

LLUMC has demonstrated in wear simulators that 1 out of 6 MoM bearing test samples can and do generate break away wear regardless of manufacture and regardless of head



TriboFit® Buffer[™] Implant cross section showing fluid film layer as compared to polyethylene

Scientific studies have demonstrated PCU to provide better full fluid lubrication in terms of enhanced wear reduction compared to conventional UHMPE, and testing is underway comparing cross-linked UHMWPE and hard on hard bearings to PCU.

We have seen in MoM bearings that manufacturing tolerance is a critical factor to the generation of a fluid film level and this fluid film level is necessary to reduce the material frictional properties of MoM bearings.





In motion

If tolerance is too tight < 100 microns - risk of pinching head and equatorial bearing, resulting in more friction

diameter.

This is a concern since this has yet to be explained. What if anything does this mean to the clinical setting? Only more testing and closer follow-up to clinical studies may some day show clinical correlation.

The Buffer™ Implant

Since this PCU implant is designed to function more like cartilage it has the distinct advantage of being low profile from a surgical preparation point of view. The BufferTM implant

is 3 mm thick so it requires very little bone removal. It has a novel snap fit locking mechanism that provides ease of insertion, positive locking stability with ease of retrievability in mind. It is designed at this point to articulate with a CoCr head.

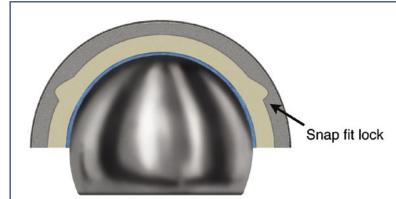
In cases where it is needed, an acetabular shell is also available that is designed to be inserted with this snap fit Buffer implant.

This novel design provides

versatility to be used as a stand alone acetabular cartilage replacement or it can be used as a standard acetabular component replacing the polyethylene bearing surface. While it is too early in clinical evaluations to determine if



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one approach is better than the other over the long term, it is certain that a PCU bearing used as a stand alone cartilage implant has the advantage of less bone removal.

Surgical Technique "Buffer™ Implant without acetabular metal shell

The TriboFit system is designed for all standard surgical approaches and requires no special instruments for exposure.

If the Buffer implant is to be used as a stand alone cartilage replacement a few patient requirements are necessary. The first is shape of the socket. The face of the natural acetabulum is closer to 55° not 45°. This implant is designed for full bony containment so preparation and insertion techniques are significant factors.

All soft tissue is removed but it

is not necessary to remove all remnants of articular cartilage. Ensuring you have a hemispherical shaped socket light reaming can be done but it is not required to go to bleeding bony bed.

Note: This is different that the standard surgical preparation for conventional acetabular components.

Do not ream to bleeding bed as with standard socket preparation. Leaving any remnants of articulate cartilage will aid load transfer and reduce bone/ implant interface wear generation.



Trial gauges are available for sizing. Sizing and implantation is line to line. It is the locking groove feature that provides implant stability.

A special groove reamer similar to the original Charnley grooved reamer is then used to cut a locking channel into the acetabular wall.

One complete revolution is required.

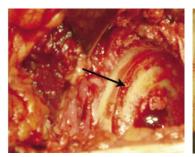
Do not over ream you may compromise the locking capability of this channel.

Then the Buffer implant is snapped into place with finger pressure. It is important to ensure full containment of the implant within the acetabular cavity. If the implant is hanging out in any direction,

edge loading and deformation of the material can increase the risk of wear.



Because containment is required the use of large heads and proper restoration of femoral offset is critical to a successful outcome.





Locking groove

Buffer™ implant snapped into place



Surgical Technique "Buffer™ Implant with acetabular metal shell

This implantation is a standard surgical technique as used with any cementless hemispherical metal shell component. Progressive socket reaming is carried out with standard implant orientation of 45-50° of abduction and 15-20° degrees of version. Press fit of the metal shell is recommended between 1-2 mm. The metal shells are available with two fins and no screw holes.

Once proper reaming and sizing is carried out the Buffer implant is snapped into place and can then be inserted as a monoblock acetabular component.





Implantation and component insertion is carried out as with any standard cementless conventional acetabular component.

Femoral stem selection is the decision of the surgeon. Any cemented or cementless stem design may be used as long as the head neck taper is compatible with the femoral head supplied by Active Implants (12-14 Euro taper).

TriboFit® Modular Femoral Heads are packaged with the Buffers to ensure proper sizing and tolerance. Wear testing to-date has been with cobalt chromium (CoCr) heads and although ceramic heads might reduce wear generation equal to or better than CoCr heads, ceramic has yet to be tested with the Buffer[™] implant.

Neck adaptors are available for adjusting vertical height and are selected based on the size of the modular head. The neck adaptor is inserted into the femoral head and is locked together via a taper interference fit.







The Goals of Total Hip Arthroplasty (THA)

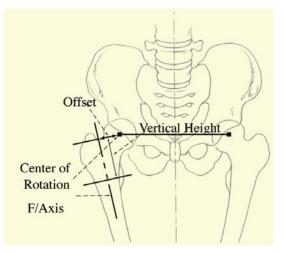
Remember the goals of THA.

Elimination of Pain

• New Hip

Restoration of Function

- Reproduce Hip Mechanics
- 1 Femoral Offset
- 2 Neck Length
- 3 Version Angle

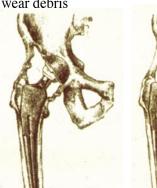


Selection of femoral stems that provide for multiple corrections of femoral offset can and do reduce biomechanical loads that are placed on the bearing surfaces.

The advantages to increased offset:

- Decreased load on the hip joint
- Increased Joint Stability
- Reduction of wear debris

The newer stem designs available provide features that reduce the risk of increasing femoral offset like increased torsional loads and increased bending moment. Many of the newer stems provide proximal



Regular offset

Increased offset

modularity and neck sparing features that can provide additional benefits when used with the Buffer[™] implant.

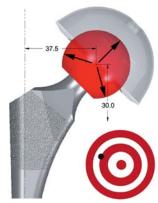
Example of Target Restoration with a modular neck stem design:



Instability - What should be done? Trial reduction demonstrates joint instability with slight increased leg length.



Modular Heads allow length adjustment, unfortunately increase head length increases leg length.



Big Heads! Theoretically, a bigger head is more stable... At the extremes of motion when the neck impinges In this case, intrinisic stability is unchanged (Head center stays the same).



er Biomechanical Solution Modular Neckl Add offset for joint stability ck reduce length for proper gait.

Newer stems designs like this Tissue Sparing Implant[™] (TSI[™] stem) saves all of the femoral neck. It is very conceivable that the combination of this and the Buffer[™] implant provides the most tissue (hard & soft) conservation of any current combination available for THA.





The use of this PCU material as a bearing material in THA has a number of potential advantages. It is 70 times less stiff than the traditional UHMWPE used and its stiffness is similar to that of cartilage. The material allows for fluid film lubrication similar to cartilage and has shown improved wear resistance as compared to UHMWPE. Because of the improved wear resistance, the Buffer[™] implant can be made thinner (3mm). All of these features allow less bone to be removed and allows for large head technology that will help reduce hip dislocations.



Photograph of the TriboFit BufferTM and a post-op xray with large head and Buffer implant in position in a patient.



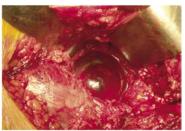
Prof. A. Moroni Buffer™ implant used with Hip Resurfacing

These features have considerable appeal in younger, more active patients who will have a higher probability of needing additional surgery in their lifetime. The thinner component conserves more bone and the novel locking design feature makes both insertion and removal if necessary simpler with less bone loss as compared to cemented or current cementless porous metal components.

This use also has potential benefits to the elderly that receive these devices for femoral neck fractures. Publications have demonstrated that patients do better with THA as compared to Endo or Bi-Polar heads. Reducing the potential of secondary surgery in this patient population can significantly improve the quality of their life and reduce health care cost by reducing or eliminating the costly revision surgery.

Example of typical post-op radiographic views for femoral neck fractures:

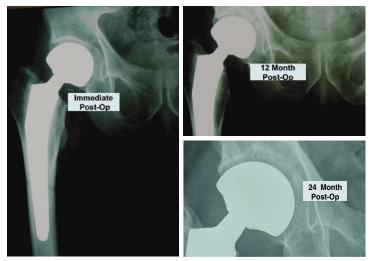
- male, caucasian
- 71 years old
- 90 Kg Weight
- R femoral neck fracture
- 56 mm Tribofit[™] Buffer
- 50mm Head + Zimmer 10 mm Stem



Prof. A. Moroni Buffer™ Implant in place



Buffer TM implant with stem and head in place



Prof. A. Moroni case example

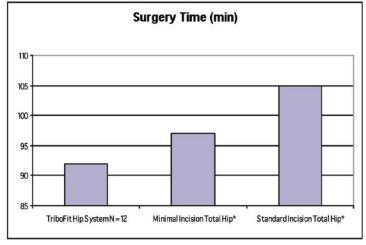


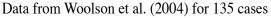
Results

Surgical Time

The literature describes a study of 135 THA patients implanted with either a minimal or standard incision. The average surgical time for the Buffer[™] component and associated implants was approximately 5 minutes on average shorter than primary THA utilizing minimal incision approach and 10 minutes on average shorter than primary THA utilizing a standard surgical approach as reported by Woolson et al. for 135 cases.

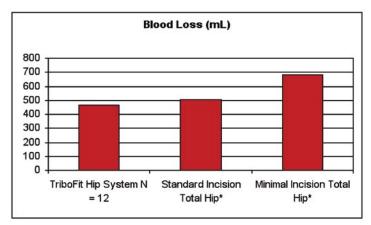
Surgical Time for the TriboFit[™] Buffer Hip System





Surgical Blood Loss

With the same or shorter operative times blood loss for the TriboFit[™] System as compared to standard surgical incision were comparable (approximately 480 ml, respectively) and on average almost 700 ml less blood loss as compared with MIS in 135 cases. (Woolson et al. 2004)



^{*} Data from Woolson et al (2004) for 135 cases

A total of 13 elderly femoral neck fracture patients were part of a pre-clinical study. Of these, 2 were revised, 1 died, and 6 were either lost to follow-up or were bedridden for comorbidity, non-device related reasons. The two revisions were the first two implanted patients at two different sites. One was revised at 10.5 months and the other at 12 months. The first was revised because of artifact seen on a computerized tomography (CT) image that made it appear that the Buffer component had disappeared. At revision it was found that the Buffer component was still well fixed and intact. The other component was revised because the patient complained of hip pain. After revision the pain remained and was later determined to be the result of spinal involvement. That Buffer component was intact, well fixed, and the articulating surface still pristine upon removal. Neither revision turned out to be device related or was considered a device failure.

Other than the first two patients (both of which were later revised) that had problems with the grooving instrument for insertion of the Buffer component, all of the remaining patients had the TriboFit PCU Buffer component implanted without any issues at the time of surgery. A key advantage of the TriboFit surgical technique is that the acetabular component does not need to be impacted into position, but rather is snapped by hand into the grooved acetabulum. With traditional UHMWPE acetabular cups, press fit impaction of acetabular components is reported by Haidukewych et al (2006) to cause fracture of the acetabular bone in 0.4% of the cases. No acetabular fractures have occurred intraoperatively with the TriboFit System and bone fracture is impossible or extremely unlikely if acetabular cup impaction is not used.

Of the more than 45 patients in May 2009 with more than 3 months clinical follow-up, 20 patients had femoral neck fractures and 25 patients had osteoarthritis (OA). In aggregate, 32 patients had 3 to 6 month follow-up, 15 had 6 to 9 month follow-up, 20 had 12 month follow-up, and 4 had 18 to 24 month follow-up. The maximum number of patients with 12 month follow-up is 78. In other words, 291 TriboFit patients have had implants less than one year.

Harris Hip Scores

Harris Hip Scores (HHS) could be recorded pre-operatively for the osteoarthritis (OA) patients and had an average value of 41.0 in 23 patients. Ten OA patients had an average value of 78.8 at 3 months. Six OA patients had an average value of 88.3 at 6 months. Six patients had an average HHS at 12 months of 81.8. These HHS results are shown in Figure 4 for



osteoarthritis patients where it can be seen that the averages were similar to or better than for patients undergoing a traditional UHMWPE total hip replacement for osteoarthritis as reported in the literature.

Patients with Buffer Only

Pre-Op HHS	3 - 6 Months	9 - 12 Months
n = 7	n = 3	n = 5
Avg. = 42.57	Avg. = 91.3	Avg. = 83

Patients with Metal Shell

Pre-Op HHS	3 - 6 Months	9 - 12 Months
n = 17	n = 12	n = 6
Avg. = 41.04	Avg. = 80.3	Avg. = 89.7

Retrievals

The overall removal rate after over three years of clinical experience of the TriboFit® Hip System is 2.0% (8 out of 408). Even without any explanation this value, on the face of it, compares favorably with the literature that reports a 2.0% removal rate of cementless total hips within the first three years (Simbanda et al 2008). However, it is important to note that the seven of the eight removals were not found to be related to the implant itself and were not related to any of the usual reasons for revisions of acetabular components— wear, loosening, or fracture. Since this subject is so important, each of the non-device related removals will be described in order of time from surgery, followed by the device related one.

One TriboFit Buffer removal was for trauma in the hospital within the first 3 days of surgery caused by a pelvic fracture after the patient fell out of bed. To repair the pelvic fracture, the Buffer component had to be removed.

The second removal occurred shortly after surgery when the patient dislocated their hip. To repair the dislocation the surgeon surgically removed the Buffer component and femoral head component to create a longer neck construct.

The third removal also occurred shortly after surgery when the patient became infected. To treat the infection the surgeon surgically removed the Buffer component and femoral head component.

A fourth removal occurred at 1 month after a dislocation. During the removal operation to repair the dislocation an infection was discovered and an antibiotic bone cement block was inserted to treat the infection. The fifth removal occurred at 4.8 months in another Buffer alone case. This patient complained of pain, which was the reason for removal, but the pain did not resolve after removal.

The sixth removal was at 10.5 months because of pain and what was later determined to be CT artifact that made it appear as though the Buffer component had disappeared. Revision to a traditional hip design that was 2 mm larger than the device removed did resolve the pain. More details concerning this removal are contained in a publication by Wippermann et al 2008.

A seventh removal was for a patient at 12 months who had pain. Removal and replacement did not resolve the pain which was subsequently correctly diagnosed as caused by spinal stenosis that was causing hip pain. More details concerning this removal have also been published by Siebert et al 2008.

The eighth removal, the only one that turned out to be device related, occurred at 10 months in a patient that had an apparent immediate dislodgement of the Buffer component from the acetabular bed.

Discussion and Summary

All of the existing bearing materials used in total hip replacement have known issues and reasons for concern. The design rationale for clinically trying out a new plastic material to replace the acetabular component is that this new material will not have any of the known drawbacks of existing bearing materials.

After over three years of clinical use of this bearing material in over 400 cases it can be said that the results to date are encouraging. Even though most of the uses were for femoral neck fractures it can be concluded that the dislocation rates are lower probably because of the larger head size. The clinical results, infection rate, loosening rate, and revision rate appear to be in line with other total hip system bearing materials.

Perhaps the most telling information from this clinical series is from the implantations and the revisions of this new bearing acetabular cup system. Unlike most implanted acetabular components, the Buffer component could be easily and quickly inserted and easily removed with a minimal, if any, loss of acetabular bone stock while being implanted or removed. It can also be concluded that the reaction to the material seen clinically and at these revisions has so far been equal to or better than other bearing materials, especially



since no cases of synovitis were observed. Except for one case which was a loosening caused by surgical technique, all of the surgically removed Buffer components were found to be intact, in the original position, and well fixed up to 12 months. Except for this one case the Buffer acetabular implant was revised with the same size acetabular component or a 2 mm larger one than the Buffer size removed. In other words, in nearly every case the new revision acetabular component removed.

In the beginning all total hip femoral stems were single piece components. Over time nearly all femoral stems have become modular so as to allow for more surgical options for the next surgery. Just as femoral stems became "next surgery" stems, so too should surgeons begin to think about using "next surgery" acetabular cups. The use of this new PCU material as an acetabular bearing allows this "next surgery" concept to be extended to the acetabular prosthesis by allowing through the use of a novel material and unique design, minimal bone removal at the time of implantation, no risk of acetabular fracture from impaction, minimal risk of recurrent dislocation, and minimal risk for a revision to a cup size larger than the primary surgery. All of these "next surgery" features in this new system either decrease the chances of an acetabular revision, allowing for the acetabular revision to occur easier, and/or permitting for more acetabular bone at the time of revision which in an of itself will allow for more "next surgery" options in an area that doesn't have much bone stock to begin with. All of these "next surgery" advantages are in addition to eliminating the known risks of using current acetabular bearing materials.





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Notes



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