CHAPTER 2

DESIGN OF NOVEL THR IMPLANT COMPONENT

In this section novel cementless THR component designs are exhibited which utilizes unique thermomechanical properties of nitinol to address the issue of implant loosening, and migration because of osteoporosis. These nitinol actualized improved total hip components are believed for better results and conquer the loosening and migration issues for results benefit. The designs which will be talked about here are specially created for THR, rather, it can likewise be executed to different implants, where loosening occurs because of degradation of bone.

The aspect of these designs are concentrated on two basic implant components of press-fit THR i.e. 1) Acetabular screw design 2) Press-fit acetabular cup design. It involves the theoretical and computational assessment along its experimental validation by comparing it to its commonly used and clinically proven predecessor using the developed test protocol.

2.1 Novel acetabular screw design

As discussed earlier, this novel design of acetabular screw is to address the issue of pullout strength of screw. Design feature includes the nitinol elements with principle constitutive modeling and simulations.

2.1.1 Executing expandable nitinol thread inserts to screw

This innovative screw and its insert gets together which is relied upon to augment the procurement of screw and bone interface. The core idea involves two things, firstly is the use of adapted, modified screws and the second is the use of nitinol inserts. Basic inspiration for the use of modified screws was its higher pull out strength (as discussed in previous section) and the core idea for the implementation of nitinol inserts was aroused from the use of insert where the nut or threaded part is made up of soft material like copper or aluminum.

For better understanding, it is clarified as; nut frequently utilize plastics and milder metals. One of the intrinsic complications with soft material is applying nut without deforming the threaded holes. This deformation can be caused by repeated installation and removal of nut, or by the required torque for the nut exceeding the strength of the soft material threads.

To compensate for the short comings an oversized hole is drilled and tapped in soft materials, and a thread insert is placed in the hole. The outside diameter of the insert is threaded to fit into the tapped hole. The inside diameter is tapped to receive a standard screw. Figure 2.1 shows thread inserts and one typical installation procedure.

The thread insert can be held into the hole in a number of ways. Some are used with a liquid thread bonding adhesive, some use a nylon block embedded in the side to bind against the receiving threads; some are self-tapping, to be forced into a blank drilled hole; and, most commonly, the insert itself will have little steel wedges which are driven in around the perimeter after it is installed to hold it in place, which is shown in figure 2.1 (b) (Campbell, 1959).

Furthermore, if standard V-shaped thread screw will be used without insert, then frequent loosening and tightening of screw will cause rapid wear of mild material from which the screw is made (Oberg et al., 2012). Load and tension distribution might not be even without insert, and maximum load is distributed only on the first two or three threads. Ideal distribution of loads, tension and better wear quality between the threads can be achieved by using inserts (Figure 2.2).

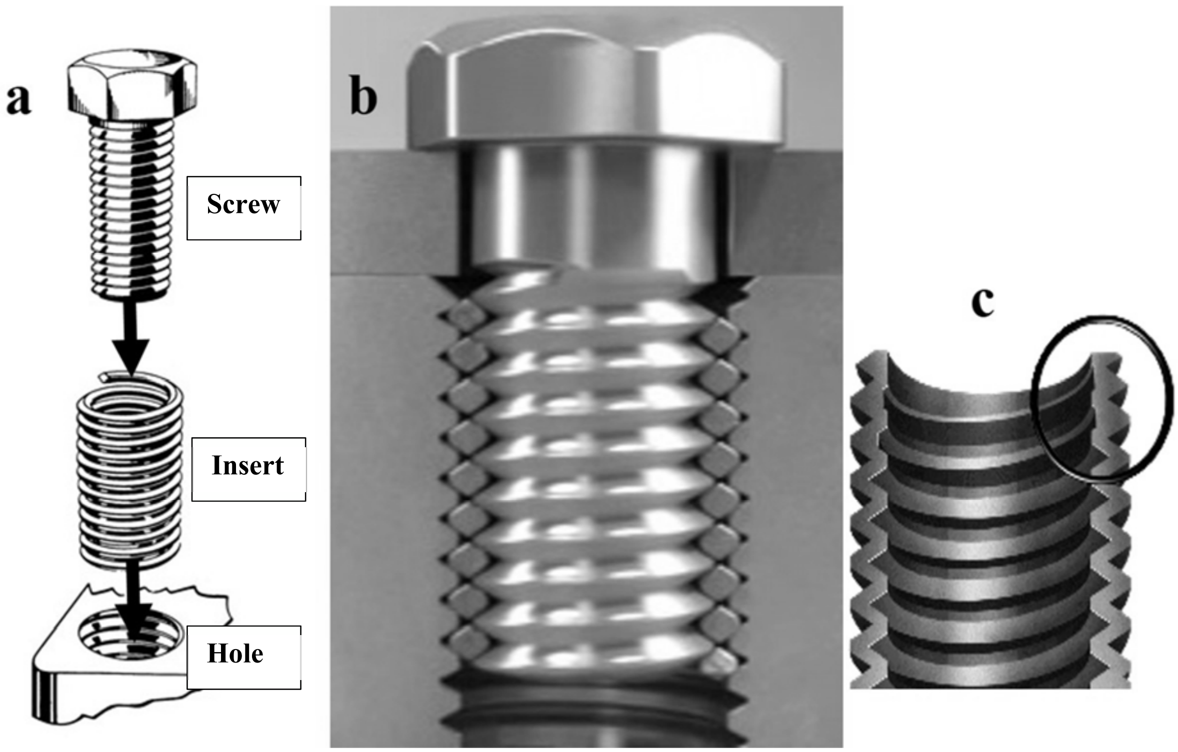

Figure 2.1: Thread insert and installation procedure a) Thread inserts are always necessary when applying threaded fasteners in soft metal detail component. Typical procedure shown to place these inserts into oversized holes b) Cross sectional view of inserts after placement in hole. c) Cross sectional view of a type of insert made from hard material like stainless steel.

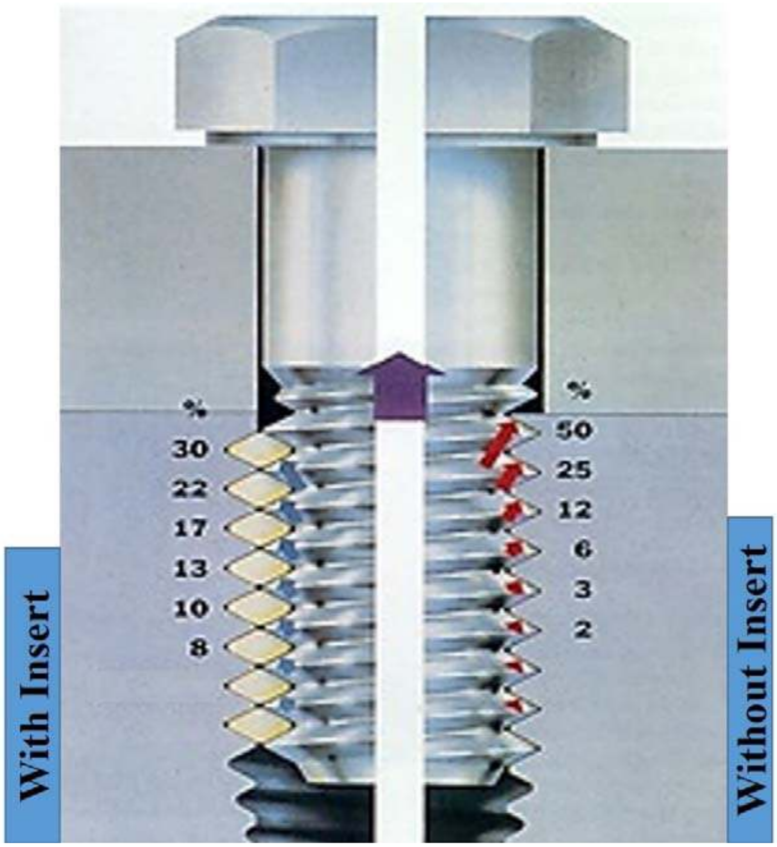

Figure 2.2: Typical load distribution on threads with inserts and without inserts in screw.

The introduced acetabular screw comprises of modified screw thread to hold the insert which possess unique behavior of nitinol (Figure 2.3). These nitinol assemblies are designed such that the end goal to produce two stable shape. Both shapes are acknowledged at two temperatures; low temperature shape, high temperature shape. The low temperature shape is accomplished outside the body or before embedding into the hip and high temperature shape is accomplished when it is set into the body (internal body temperature) or when it comes in contact to pelvic bone. In low temperature, nitinol insert retract on the acetabular screw as indicated in figure 2.4. At high temperature the nitinol insert extend itself as appeared in figure 2.5. These retraction-expansion program are reversible by which it can be withdrawn again by cooling from high temperature to low temperature. This feature serves to pullout the screw from bone when revision is required.

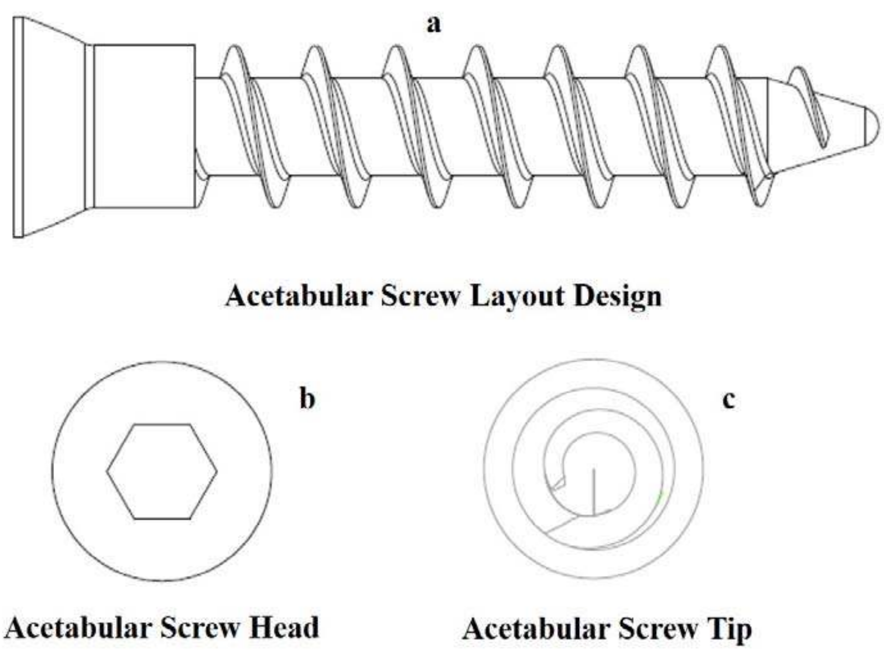

Figure 2.3: Draft view of screw (a) Standard acetabular screw layout design (b) Hexagonal head of screw to anchor with acetabular cup (b) Blunt tip of acetabular tip to prevent vascular injury

This innovative nitinol insert consist of two nitinol elements, both elements use pseudoelastic and shape memory properties of nitinol. These two nitinol elements are assembled in such a way, so it can force each other in opposite direction when activated. In these two elements, one is pseudoelastic (PE) in both the outside body (low temperature) (T_{vitro}) and inside body (High temperature) (T_{vivo}) condition. Usually, the pseudoelastic (PE) phenomena occurs above the austenite final (A_f) temperature, so the pseudoelastic nitinol element's final temperature is lower in both outside and inside body ($A_f^{PE} <$

T_{vitro} *and* $A_f^{PE} < T_{vivo}$). The other element is shape memory (SM) when kept outside body (T_{vitro}) and it transforms to austenite phase when placed inside the body (T_{vivo}). To this element of the insert assembly, nitinol is selected in such a way that its martensite final temperature (M_f^{SM}) be higher than the outside body temperature (T_{vitro}) and its austenite final temperature (A_f^{SM}) should be lower than inside body temperature (T_{vivo}) $M_f^{SM} > T_{vitro}$ *and* $A_f^{SM} < T_{vivo}$).

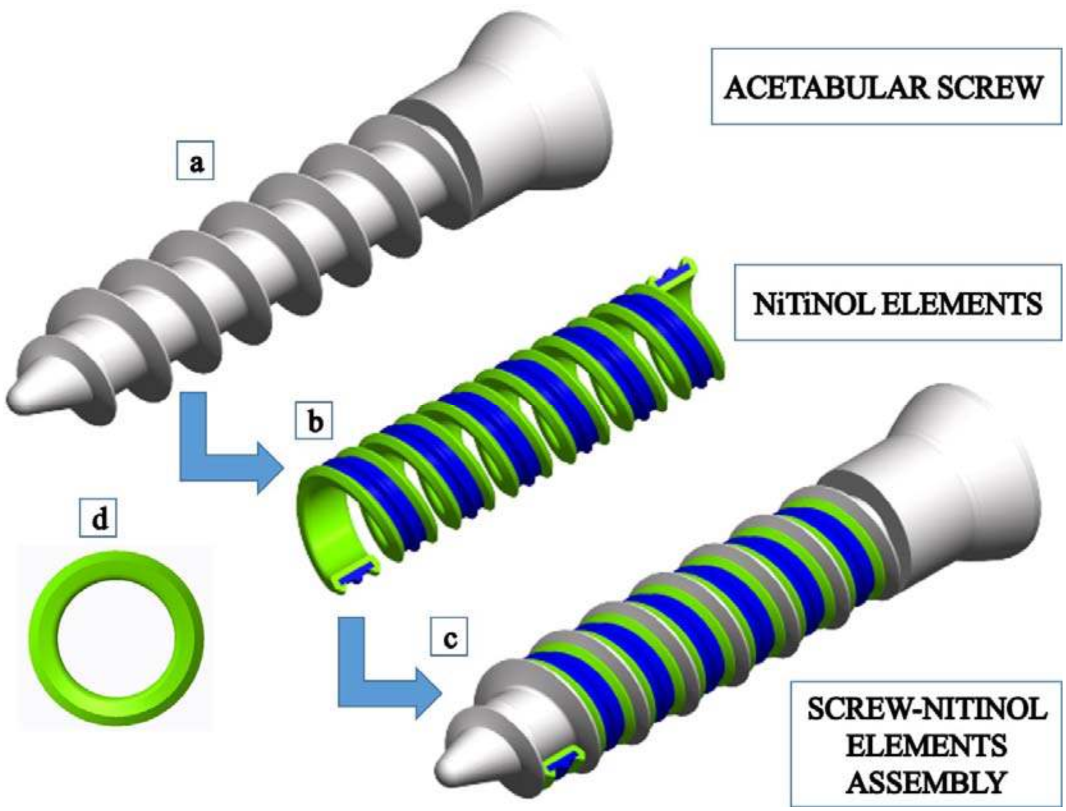

Figure 2.4: Schematic of screw-nitinol insert system outside the body (T_{vitro}) (a) 3D view of acetabular screw (b) Nitinol components assembly, which comprises of pseudoelastic (PE) and shape memory (SM) elements (c) Screw-insert assembly showing actuation of nitinol elements insert -screw framework outside the body (d) Top view of insert

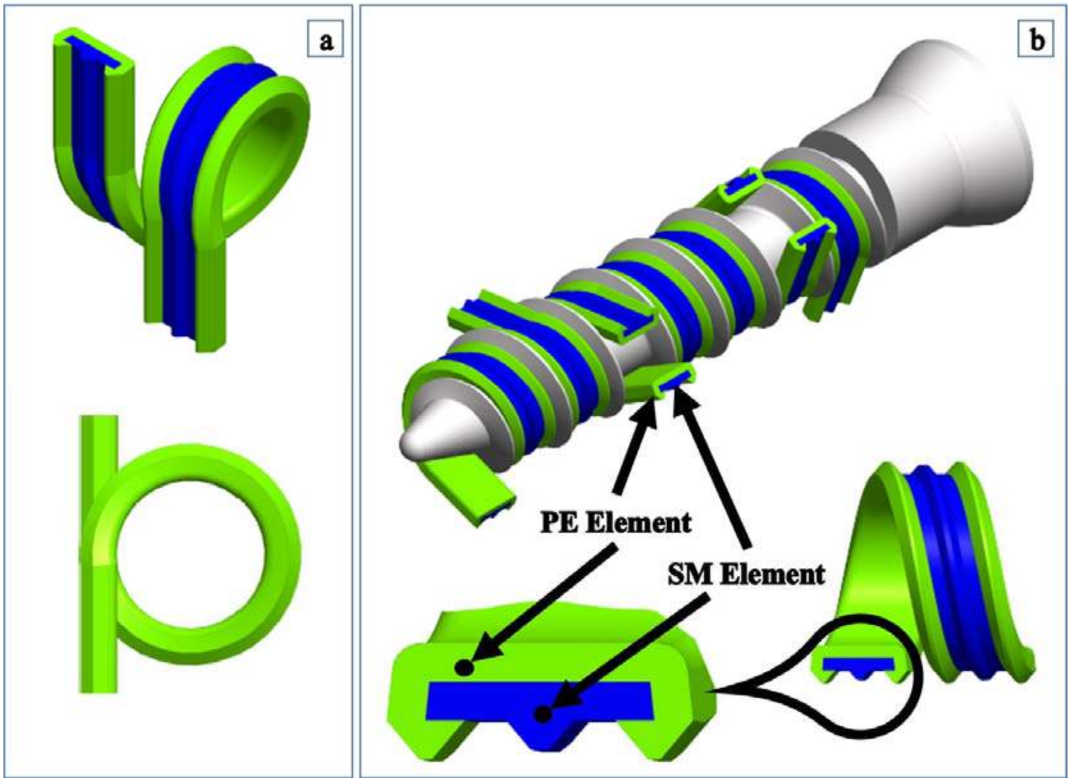

Figure 2.5: Schematic of screw-nitinol insert system inside the body (T_{vivo}) (a) Schematic view of expanded/original form of nitinol insert (b) Screw-nitinol insert assembly after placement inside the hip during THR and enlarged view of nitinol elements which is pseudoelastic (PE) and shape memory (SM) respectively.

This assembly makes the inclination of the SM component be more toward its original shape at body temperature. Both pseudoelastic (PE) and shape memory (SM) components original shape is set with the end goal that in low temperature, the SE component is stronger and the assembly remains toward the SM component, which is set to be the retracted form of the screw. At the point when the screw is placed inside the body, both the screws and its nitinol components, temperature will achieve internal body temperature. At internal body temperature, the SM component passes its austenite temperature and pushes the assembly toward its original shape that is set to be the extended form. This extended form is with the end goal that lone a part of each nitinol insert from both end elongates while the rest of the insert has a tendency to immovably hold the screw body as shown in Figure 2.6 (b). On the off chance that for any reason a specialist chooses to remove the acetabular screw, he can cool down via supercool saline solution, the acetabular screw which enables the temperature down to the nitinol elements, to accomplish the retracted shape again by folding back the protrusions, and pullout the acetabular screw out of the bone as shown in figure 2.6 (a). Temperature by which insert deforms or retracts back to hold the screw threads can be adjusted by modifying the element alloys and heat treatment. Cooling the complete device to lower the temperature be such that it does not harm the surrounding pelvic bone, tissues and vascular structures. The reported range of temperature that is dangerous for bone, tissue and vascular structures is -4 to 10°C. Minimum temperature below which cold injury will occur is -4°C, and duration of exposure is also the leading factor for cold injury (Mcintosh et al., 2011; Zafren 2013).

The nitinol thread insert design is to such an extent that the PE and SM elements can be fabricated by means of procedures, for example, extrusion or rolling (Kalpakjian et al, 2005). In addition, the SM and PE elements must be shape-set to their desirable high temperature and low temperature configuration respectively. Shape setting is a procedure of heat treatment by which we gradually but firmly establish a desired memorized shape in a nitinol component. At last, the SM element can be glided into the SE and the nitinol insert assembly is wrapped around a traditional screw.

Action of this screw and nitinol insert assembly in healthy pelvic bone is such like the standard screw with insert which distributes the loads on all threads evenly. In the case when there is loss of bone mineral density around the screw or severe osteoporosis occurs, the insert which has been expected to reach to steady state body temperature, expand to compensate the bone loss and finally avoiding the screw loosening with its maintained pullout strength.

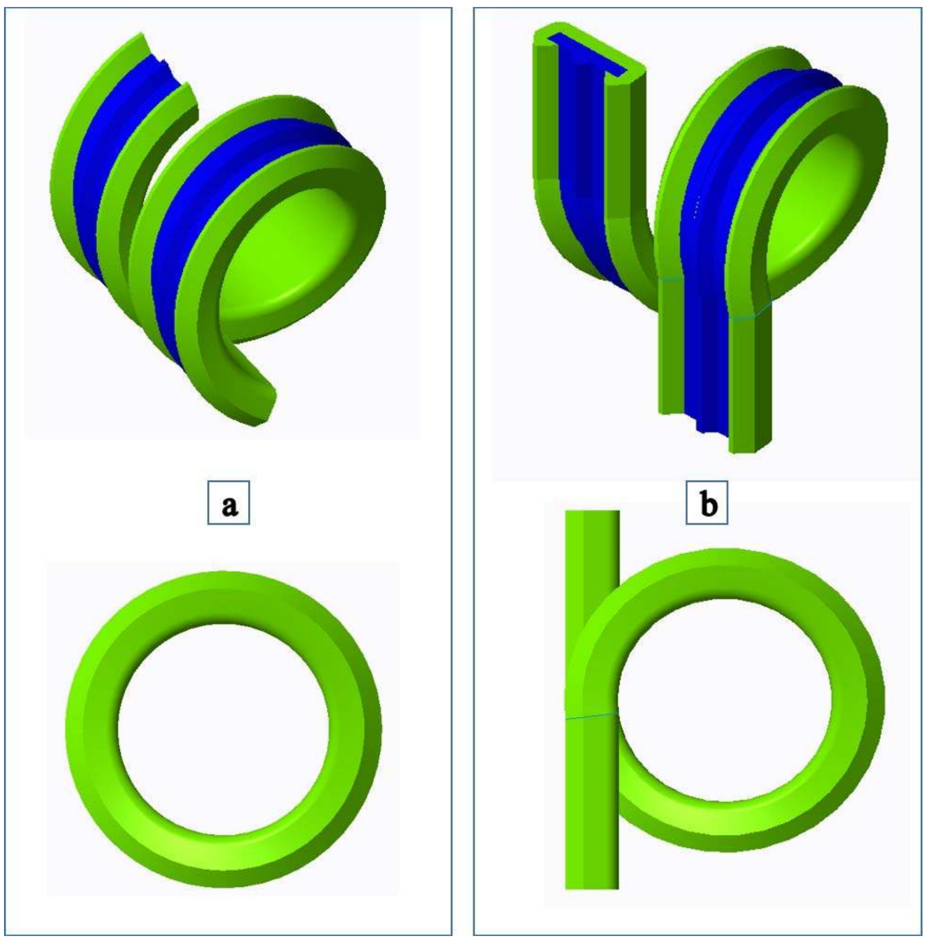

Figure 2.6: Nitinol insert with retractable and expandable components (a) figure above is 3D perspective of retracted form of insert and below is its top view (b) figure above is the 3D view of expanded form of insert and below is its top view

2.2 Acetabular cup and femoral stem

2.2.1 Press-fit acetabular cup with expandable rig

The second novel THR component is press-fit acetabular cup (PFAC) which is anchored with nitinol sprigs assembly to prevent the cup migration and loosening when bone goes in osteoporotic condition. The sprigs are designed in previous fashion like expandable screw inserts, includes both retractable and expandable nitinol components. This novel PFAC differs from the conventional press fit acetabular cups anchored with three additional parts 1) shape memory interior (SM) 2) pseudoelastic exterior (PE) and 3) a metal cage to hold the nitinol elements as shown in figure 2.7 (b)

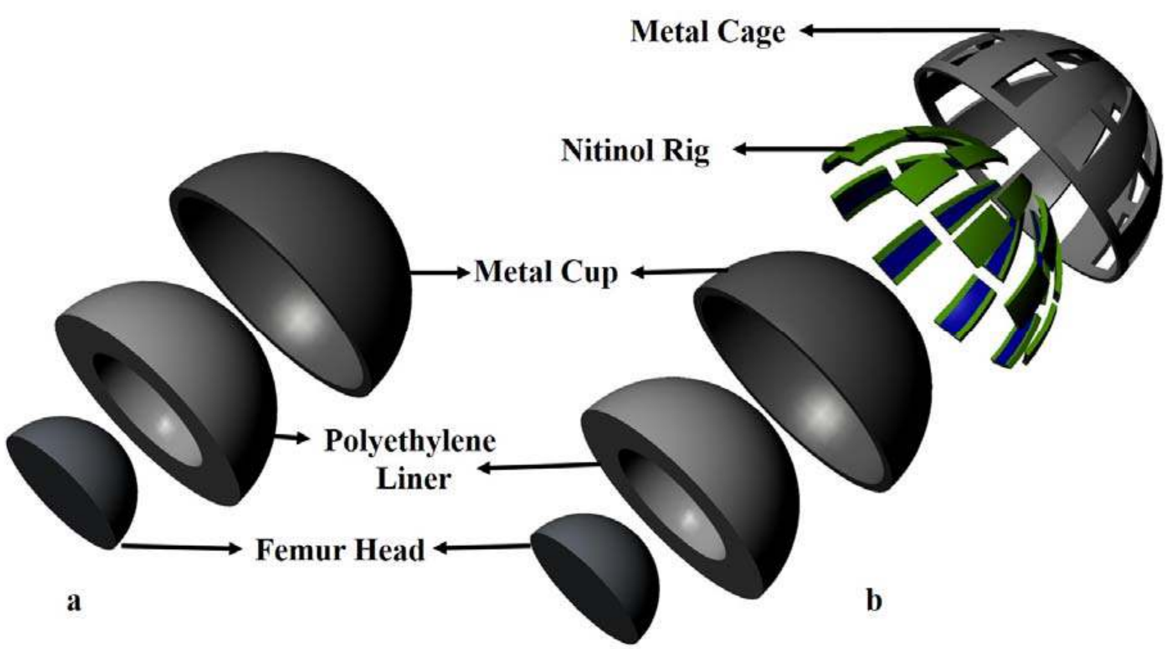

Figure 2.7: Exploded view of press-fit acetabular cup a) Conventional press-fit acetabular cup b) Novel press-fit acetabular cup with nitinol rig and metal cage

This design of nitinol rig is composed of both shape memory interior (SM) and pseudoelastic exterior in 10 nos. The inner part of rig has each a circular trimmed ledge that can be guided through same shaped slots in the exterior part (See Figure 2.8) which prevent any relative rotation of the two components. Nitinol rig assembly is fixed in the metal cage, which consists of same shaped slots to hold the nitinol rigs. Concept behind using this metal cage is tow fold; firstly, the outer surface area of cage is exposed to bone, which can be coated with hydroxyapatite (HA) to give the good bone to cup interface. Secondly, as the nitinol is malleable in its martensite phase, which will not give such strength to bear the hip joint load, so nitinol rigs are fixed with metal cage to bear large loads.

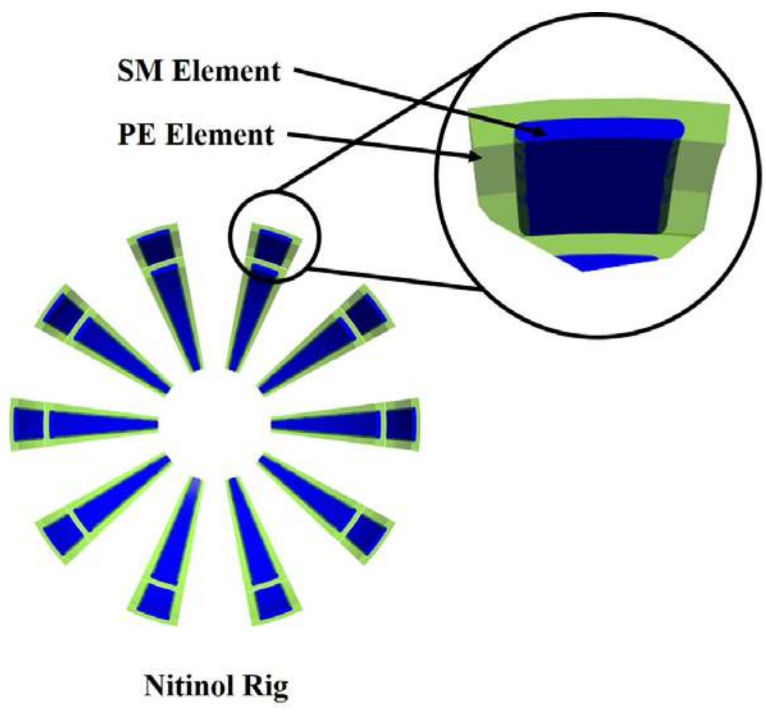

Figure 2.8: Bottom view of nitinol rig assembly which is composed of shape memory element (SM) and pseudoelastic element (PE).

Functioning of this rig is similar to the novel design of screw with nitinol inserts (as discussed in section 2.1.1). The interior has shape memory characteristic meaning that upon heating to body temperature will tend to recover its high temperature original form. As shown in figure 2.9 and 2.10, at its memorized shape all the rigs are expanded.

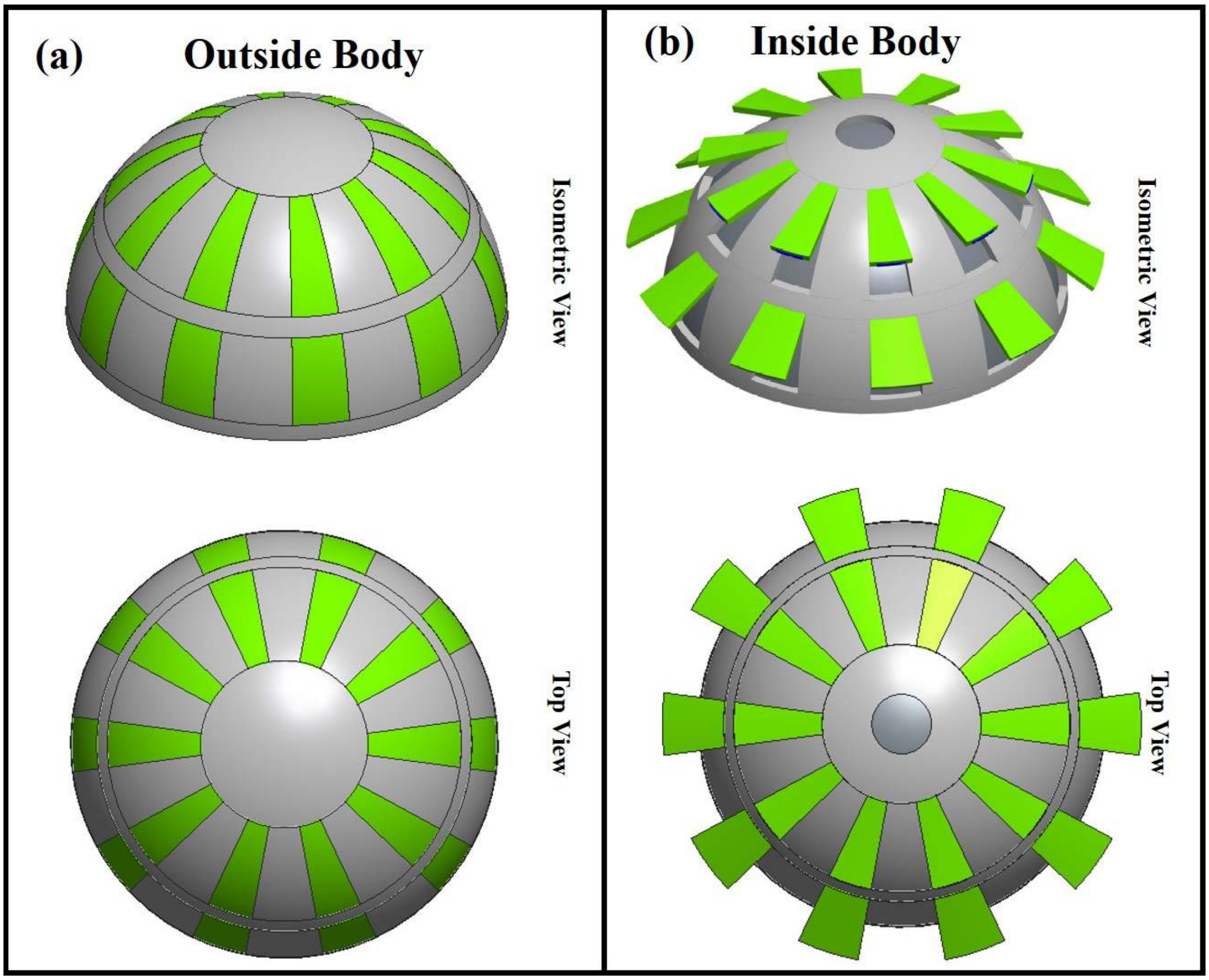

Figure 2.9: Activation of expandable-retractable rig (a) Superelastic Exterior part of the acetabular cup with expandable rig at initial form outside the body. (b) high-temperature austenite form of the acetabular cup with expandable rig inside the body.

The exterior is superelastic with austenite high temperature form as shown in figure 2.9 (a) wherein all rigs are closed. The transformation temperature of the interior part is adjusted near 37 ºC and that of the exterior well below 37ºC.

This assembly is placed similar to regular press fit acetabular cups in the bone despite the fact that it should be kept at a low temperature. After placement, the structure will gradually reach to the body temperature upon which the inner piece activates and forces to open the rig exterior fins with it. In case the bone encompassing the acetabular cup, degrades and loses strength, this feature causes the assembly to retain the purchase via extending outwards (Figure 2.9 b and Figure 2.10 b).

The proposed acetabular cup is easily removable in any revision surgeries. As mentioned earlier, the exterior is superelastic with closed original shape therefore (after pulling the interior out by means of cooling down with supercool saline solution) will retract its fins and can be easily extracted out of the bone.

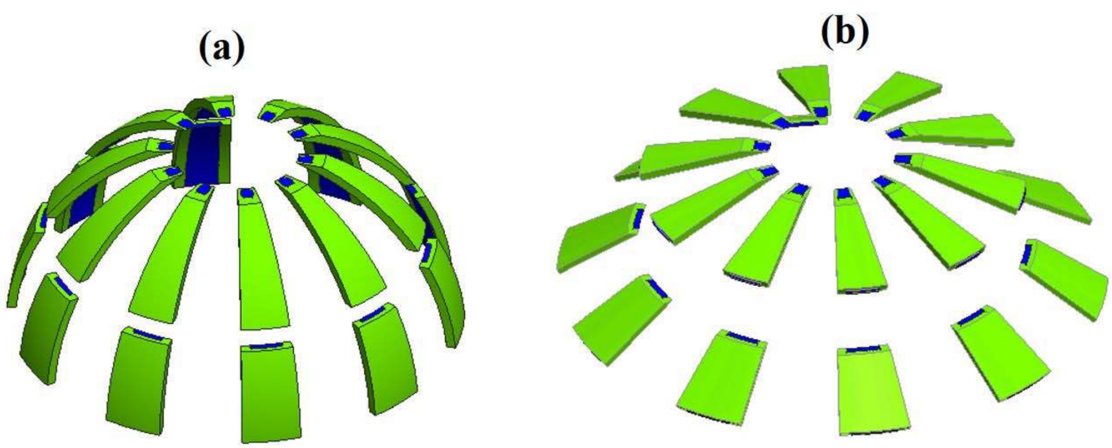

Figure 2.10: Expandable-retractable nitinol rigs in a) retracted form and b) expanded form.

One important aspect in designing shape memory devices is the maximum strain imposed. The maximum strain that can be recovered through shape memory effect in nitinol is approximately 6-8%. Moreover, the fatigue properties of nitinol will diminish drastically if the maximum sustained strain in the component passes 3% under cyclic loading.

In conclusion based on the above descriptions, the prominent advantages of this novel acetabular screw and PFAC with nitinol rigs can be listed as below:

a) The screw and cup is intended to address the issues related to osteoporotic bone degradation and cup migration and loosening.

b) Moreover, this configuration of the screw and cup that enables uncomplicated removing and revision without the damage of surrounding bone.

Below are listed some research questions related to the improvement of this primary design up to an ultimate final outline:

A. What are the optimum transformation temperature ranges for the both SM element and PE elements in the screw insert design and in the PFAC with nitinol rigs?
B. What is the best possible section profile of the insert so that the SE element and PE element can antagonistically act against each other and perform the desired folding and unfolding displacements, considering the effect of the surrounding trabecular bone?
C. Does the partial expansion of the insert enhance the bone-implant interface purchase?

D. Does the partial gripping effect of the squeezing section of the insert provide required friction and strength with the screw in order to withstand various biomechanical loadings?

E. Does the cooling of the system downgrade its temperature to the desired level consistently and evenly through whole structure? Is that level of temperature injurious to the adjacent live tissue?

F. What is the best and safest approach to cooling the device apart from cold saline solution?

In order to address these questions a finite element model is developed to evaluate the effect of different geometrical and material characteristics on the performance of these novel THR implant.