Design of High Viscosity Cement Gun for Vertebroplasty

Pranjal Gupta

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Delft University of Technology

Faculty of Mechanical, Maritime and Materials Engineering

Department of Biomechanical Engineering

Author:

Pranjal Gupta

1532111

Professor

Prof. Dr. Jenny Dankelman

Supervisors:

Dr. Ir. Edward Valstar

Ir. Gert Kraaij

Preface

The design of high viscosity cement gun for vertebroplasty is my graduation project for M.Sc Biomedical Engineering at Delft University of Technology. This is a research project for developing an improved design of cement gun for injection of high viscosity bone cements inside the vertebra during vertebroplasty. The project was done in collaboration with Leiden University Medical Center. This study contains the design process used to create a novel cement gun which is suitable for injection of high viscosity bone cements.

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P. Gupta

Department of Biomechanical Engineering

Faculty of Mechanical, Maritime, and Materials Engineering

Delft University of Technology

Abstract

Vertebroplasty is a minimally invasive procedure performed to treat vertebral compression fractures, benign tumors, and metastatic cancers of spine. In this procedure, bone cement is filled inside the vertebra for stabilization of the spine. There are complications due to leakage of bone cement in the surrounding area. High viscosity bone cements are required to minimize leakage but these are difficult to be injected using the current cement guns, as they require excessively high injection forces. Requirements for the design are made after discussions with surgeons. Different options in various domains are investigated and five concepts are generated. The concepts are evaluated based on the requirements and a final concept is chosen. A new design of the cement gun is made which is capable of reducing the injection forces with high viscosity bone cements during vertebroplasty.

I. Introduction

Osteoporosis is one of the main causes of vertebral compression fractures occurring worldwide. Every year 1 million people in Europe and more than 700,000 people in the USA are affected from osteoporosis [1], [2]. Osteoporosis makes the bone weak and vulnerable to fractures, resulting in vertebral fractures particularly in elderly people.

Vertebroplasty is a minimally invasive procedure for the treatment of vertebral compression fractures. Along with that vertebroplasty is also used to treat benign tumors and metastatic cancers in the spine. In vertebroplasty, bone cement is injected inside the vertebra to stabilize the fracture, hence providing pain relief.

Vertebroplasty was introduced in 1984 by Galibert and Deramond in France [3], and it is a safe procedure with effective outcomes. Cement leakage commonly occurs but is mostly asymptomatic. Based on the findings from different studies the occurrence of cement leakage varies from 30% - 72.5% of patients. [4]. Complications due to cement leakage are rare but severe: cement leakage can cause pulmonary embolism [1], intervertebral disc leakage leading to new fractures, paraplegia [2], and even death. Cement leakage may be prevented by replacing low viscosity bone cements with high viscosity ones. The disadvantage herein is that high viscosity bone cements require high forces to be injected [5], [6], [7] and such forces are impossible to be manually applied by the current cement guns used for vertebroplasty. Moreover, injection of high viscosity bone cements may result in sudden events such as injection of large lump of bone cement inside the vertebra leading to complications. The goal of this study is to design a cement gun suitable for manually injecting high viscosity bone cements. In section II design requirements are explained, the function of the current cement gun is described in section III. Possible solutions, concepts and evaluation of concepts are discussed in section IV, V, and VI. Section VII describes the final design followed by discussion and conclusion in section VIII and IX.

[1] Clotting of bone cement in vascular system of lungs.
[2] Impairment in motor or sensory function of the lower extremities.

II. Design Requirements

The design requirements were defined based on a series of discussions with Dr. Sander D.S. Dijkstra who is one of the surgeons performing vertebroplasty at Leiden University Medical Center (LUMC). The requirements are shown in Table 1 and explained hereunder.

Table 1: Set of requirements for high viscosity cement gun

S. No.	Requirements
1	20 – 200N injection forces
2	30cm separation of surgeon from X-rays
3	15cc of Bone Cement
4	Controlled injection
5	Easy handling

Injection forces: The injection forces should be low while injecting high viscosity bone cements as the procedure is done in close vicinity of the spinal cord. The range of injection forces was difficult to be quantified by the surgeons and was therefore defined based on a study which measured grip forces in different arm positions (at 90° and 180°). The grip forces were divided in levels of 2 (weak), 5(strong), 7 (very strong), and 10 (extremely strong); a mean grip force of 410N on level 10 was measured on the CR-10 scale[3] [8]. Considering that in extreme conditions maximum forces up to 400N can be applied, a range of injection forces between 20 – 200N was selected to be comfortable for the surgeons. It is obvious that the injection forces will rise after a certain period of time due to increasing viscosity of the bone cement. The comfortable range of forces is much narrower than the current injection forces using high viscosity bone cements (approximately 100 – 1300N).

Length over Radius ratio: Vertebroplasty is done under X-ray guidance and the focus of the radiation is on the vertebra to be treated. The surgeon wears lead coat to protect himself from the scattered radiation but his hands are directly exposed to radiation. To prevent that, the length of the cement gun should be such that it provides protection to the surgeon from X-Ray radiation. Moreover, the volume of the cement gun should be such that it contains sufficient amount of bone cement for the operation. After discussions with the surgeons it was made clear that the cement gun should be able to hold a volume of 15cc of bone cement to allow treatment of multiple vertebrae in one procedure and it has to maintain a distance of 30cm to keep the surgeon out of the radiation focus.

Controlled injection: The injection rate of bone cement varies, depending on the filling pattern of the vertebra. From past experiences of the surgeons there have been complications by using conventional syringes which have push plungers; as there can be sudden burst of bone cement inside the vertebra due to loss of pressure in the syringe causing leakage and thereby resulting in severe complications. To prevent such events from happening it is important that the cement gun injects a controlled volume of bone cement, that is, a fixed volume of bone cement in each injection cycle.

Handling: Easy handling is an important requirement for the design of cement gun, although it cannot be defined with strict boundaries. Handling refers to assembling of cement gun before use, holding of the cement gun by the surgeon during injection, orientation of the cement gun with respect to the patient and the surgeon, and usability of the cement gun with existing components such as the cannula. The cement gun has to be disposable as the bone cement will render it unusable for reuse.

III. Overview of the Cement Gun

This section describes the functional principle of the current cement gun that is currently used in vertebroplasty. A comparison between the ranges of injection forces encountered during injection of low and high viscosity bone cements when using such a gun is also made.

A typical cement gun consists of a syringe with a plunger, a connecting tube, and a cannula (Figure 1).

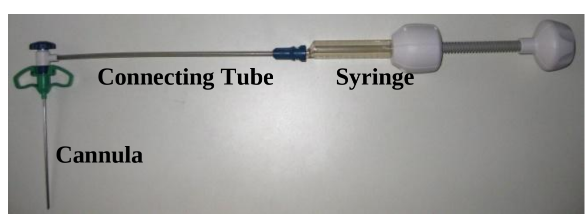

Figure 1: Current cement gun

[3] CR-10 scale also known as Borg scale measures perceived exertion.

The total pressure required to inject the bone cement consists of two parts; the extravertebral pressure required to inject the bone cement out of the cement gun and the intravertebral pressure required to infiltrate the bone cement inside the vertebra. Approximately 95% of the total pressure is extravertebral and less than 5% is intravertebral pressure [9]. Therefore, the focus of this design is on reducing the extravertebral pressure and the resulting forces.

In previous studies, the Hagen-Poiseuille's law for Newtonian fluids was used to estimate the pressure drop for bone cements during injection [10]. According to this law, the pressure drop of a fluid flowing through a tube is given by:

$$\Delta P = \frac{8Q\mu L}{\pi r^4} \qquad (1)$$

where Q is the volumetric flow rate in m^3/s; μ is the viscosity of the bone cement in Pa.s, L is the length of the tube in m, and r is the radius of the tube in m. The assumptions for this equation are that the flow is laminar through a constant circular cross-section, the length of the tube is substantially greater than its diameter, and the fluid flowing is incompressible. Although bone cement is a non-Newtonian fluid, the estimated pressure values has been shown to correspond well with experimentally measured values [9], [11].

A syringe model for calculating the injection forces is described in equation 2 and Figure 2. In this model F_{ax} is the axial force required to inject the fluid, P_S is the fluid pressure inside the syringe and is analogous to extravertebral pressure, and r_S is the radius of the plunger [12]:

$$F_{ax} = (P_S).(\pi r_S^2) \qquad (2)$$

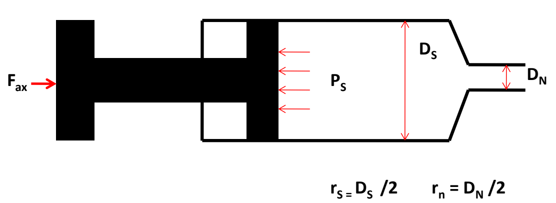

Figure 2: The model of a syringe is used to see how the force is applied to inject the fluid out of the syringe [12]

The syringe model is modified according to the cement gun and the total pressure difference $\mathbf{\Delta P_{total}}$ required to inject the bone cement is described by equation 3.

$$\Delta P_{total} = \Delta P_S + \Delta P_{CT} + \Delta P_C \qquad (3)$$

$\mathbf{\Delta P_S}$, $\mathbf{\Delta P_{CT}}$, and $\mathbf{\Delta P_C}$ are the pressure drops happening in the syringe, connecting tube, and the cannula which constitutes the extravertebral pressure. Subsequently the respective injection force can be calculated by multiplying ΔP_{total} by the internal surface are of the syringe which is also the surface area of the plunger (equation 4).

$$F_{ax} = \left[\left[\frac{8Q\mu}{\pi}\left(\frac{L_S}{r_S^4} + \frac{L_{CT}}{r_n^4} + \frac{L_C}{r_n^4}\right)\right].\pi r_S^2\right] + F_F \qquad (4)$$

where F_{ax} is the applied axial force on the plunger (N); F_F is the friction force between the plunger and the syringe wall; L_S, L_{CT}, and L_C are the lengths of the syringe, connecting tube, and cannula respectively (m), and r_S and r_n are the radii of the syringe and the needle (m). The radii of the connecting tube and the cannula are same with that of the needle. In the analysis, the volumetric flow rate was kept constant to a value of 1cc/min which is equivalent to $1.6x10e\text{-}08m^3/s$. The friction force F_F is very small as compared to the force encountered during injection of bone cement. The conventional syringes used in medical applications are coated with silicone oils to minimize the friction between the plunger head and the syringe wall. Thus, the static friction value will be less in case of a syringe. The dynamic friction value will be lesser than the static friction value and can be thus neglected.

The viscosity of bone cement increases with time and for the calculations discrete data points are taken from the literature. A comparison of high and low viscosity bone cements is shown in Figure 3. The dimensions of the current cement gun are shown in Table 2. The pressure drop was calculated for the respective parts of the cement gun by equation 1. From Table 2 it can be seen that in the current system the maximum pressure drop occurs in the connecting tube and the cannula, due to their very small radii. The pressure drop in the syringe is approximately

0.03% of the total pressure drop, which can be easily neglected.

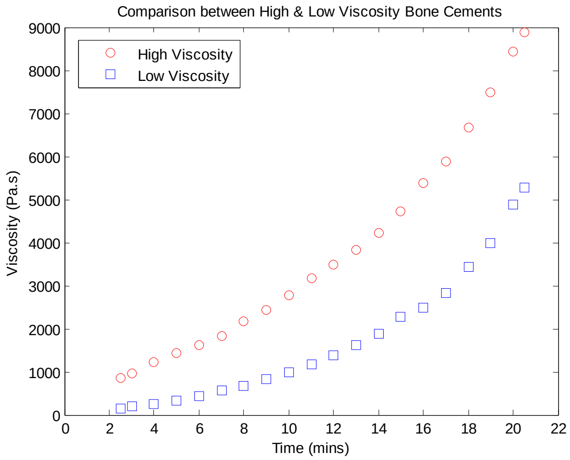

Figure 3: Change of viscosity with time for high and low viscosity bone cements. Vertaplex HV (red) is high viscosity bone cement and Vertaplex (blue) is low viscosity bone cement

Table 2: Dimensions of current cement gun along with %age pressure drops in the respective part of the cement gun.

	Length (m)	**Radius (m)**	**Pressure Drop (%)**
Syringe	0.1	6.6x10e-03	0.03
Connecting Tube	0.3	1.35x10e-03	65.19
Cannula	0.16	1.35x10e-03	34.76

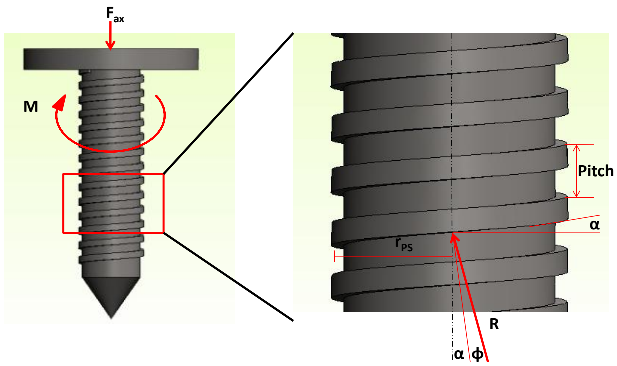

Figure 4: Schematic diagram of a screw showing axial force, moment, and dimensions

The current cement gun uses a screw plunger to inject the bone cement. To calculate the injection forces using current cement guns dimensions of the screw have to be considered. A schematic diagram of the screw plunger indicating axial force, moment, and dimensions is shown in Figure 4. The angle α and φ are dependent on the dimensions of the screw and the material of the screw and are calculated by equation 5.

$$\alpha = \tan^{-1}\left(\frac{\text{Pitch}}{2\pi r}\right) \qquad (5)$$

where Pitch is the distance from the crest of one thread to the next and r is the radius of the screw. The angle of friction (φ) is dependent on the material property of the screw and can be calculated by taking the inverse tan of ε, where ε is the friction coefficient between the interacting screw and threads of the plunger [13]. In this case the ε was taken to be 0.8 as the screw and the threads are made of acrylic [14]. The pitch of the screw was measured to be 3.5mm and the screw radius 5.5mm. The angle α was calculated to be 5.7° and φ to be 38.65°. The moment and injection force by the surgeon is calculated by equations 6 and 7 [13].

$$M = F_{ax} r_{PS} \tan(\alpha + \varphi) \qquad (6)$$

$$F_{in} = \frac{F_{ax} r_{PS} \tan(\alpha + \varphi)}{r_K} \qquad (7)$$

where F_{in} is the injection force by the surgeon, F_{ax} is the axial force from equation 4, r_{PS} is the radius of the plunger shaft, r_K is the knob radius, α is the pitch angle, and φ is the friction angle. The efficiency of the screw can be calculated by equation 8:

$$\eta = \frac{\tan \varphi}{\tan(\alpha + \varphi)} \qquad (8)$$

φ will be constant for a given material, to have maximum efficiency it is important that α remains small. As angle α increases the efficiency of the screw decreases and vice versa. However, α<φ to prevent the screw from unwinding by itself [13].

Figure 5 shows the range of injection forces using both low and high viscosity bone cements with the current cement gun as calculated by equation 7.

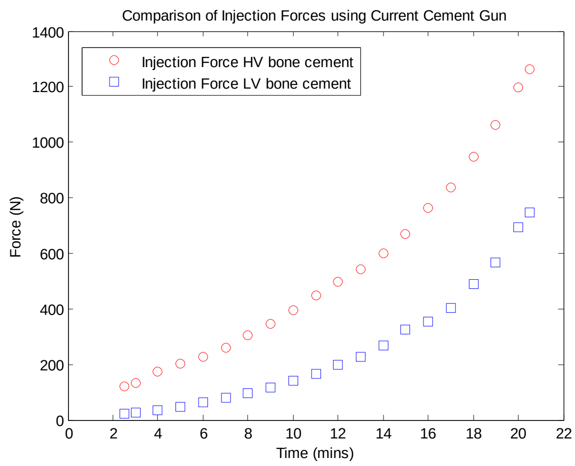

Figure 5: Comparison of injection forces between high (red) and low (blue) viscosity bone cements using current cement gun. Vertaplex HV (red) is high viscosity bone cement and Vertaplex (blue) is low viscosity bone cement

From the calculated data it can be seen that the resulting injection forces with high viscosity bone cements is within injectable range in the beginning of the procedure but increases quickly with the hardening of bone cement in time. The range of injection forces as approximated by the calculations is between 100–1300N for high viscosity bone cements, which implies that the current cement guns cannot be used for this purpose. Different concepts for improving the cement gun design are described in the next section.

IV. Overview of Solutions

It is essential to see the options which can be used for designing a high viscosity cement gun for vertebroplasty. Table 3 describes the morphological table in which different options for applying injection force are mentioned. The options for injection forces are described in terms of energy types that can be transformed to apply injection force.

Radiation, nuclear and chemical energy are eliminated as they are complex and can be hazardous considering the fact that the design of the instrument has to be used on a patient by a surgeon. Electrical and magnetic energies such as photoelectric/magnetic and piezoelectric/magnetic effect are also eliminated as it would make the design complex and difficult to materialize. The cement gun design has to be manual, so the electrical and magnetic energies are eliminated as well. That leaves us with the option of mechanical energy only.

The injection forces under mechanical energy are subdivided into two types: direct transmission and indirect transmission (Table 4). In direct transmission, the force is applied to the bone cement without any intermediate medium, whereas in indirect transmission, an intermediate medium is used to apply the injection force on the bone cement. The medium could be either gas (pneumatics) or liquid (hydraulics). Option for gas (pneumatics) is eliminated as gas is a compressible medium. Part of the injection forces would be used in compressing the gas and would render the option inefficient.

For both direct and indirect transmission, pushing, pulling, and rotating can be used to generate injection forces. For each of these three options, possible mechanisms are shown at the lower part of Table 4. The option pulling and the related mechanism of pulleys and cables is eliminated as it requires multiple pulleys and lengthy cables to reduce the injection forces, making the cement gun design complex. This leaves us with the mechanisms of push plungers, lever, gears, and screws. All these mechanisms are possible to be applied with or without an intermediate medium. The concepts of these mechanisms are described and evaluated based on the design requirements in the next section, after which the final concept will be chosen.

Push Plunger

A push plunger is one of the simplest mechanisms that are used to inject a fluid out of a syringe. The applied force is directly translated into the forward motion of the plunger thereby injecting the fluid out of the syringe.

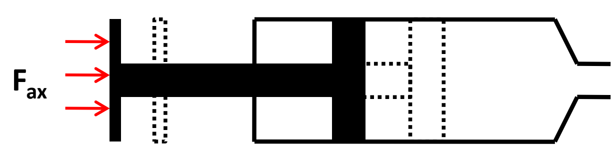

Figure 6: Schematic diagram of conventional syringe with push plunger

Table 3: Morphological table with options for applying injection force

Functions	**Options**													
Injection Forces	Mechanical Energy			Electrical Energy			Magnetic Energy			Chemical Energy	Nuclear Energy		Radiation Energy
	Push	Pull	Rotation	Current/ Voltage	Piezoelectric Effect	Photoelectric Effect	Magnetic Flux	Piezomagnetic Effect	Photomagnetic Effect	Chemical Reaction	Fusion	Fission	Radiation Spectrum

Table 4: Morphological table with options for applying injection forces by means of mechanical energy

Functions	**Mechanical Energy**					
Injections Forces	Direct Transmission (without intermediate medium)			Indirect Transmission (with intermediate medium)		
				Gas (Pneumatics)	Liquid (Hydraulics)	
	Push	Pull	Rotation	Push	Pull	Rotation
Mechanisms	Push Plunger	Pulleys & Cables	Lever Gears Screw	Push Plunger	Pulleys & Cables	Lever Gears Screw

Initially vertebroplasty was done using syringes of 1 and 2cc [15]. This mechanism gives a good force feedback to the operator as there is a direct translation of the applied force to the movement of the plunger. However, by using these syringes the operator was directly under the radiation. According to the literature manual thumb injection forces on the plunger up to 100N can be applied to inject bone cements using conventional syringe [16]. The injection force is proportional to the axial force and there is no magnification of the injection force. The mechanical advantage offered by this mechanism is little less than 1 (axial force/injection force) due to friction between the interacting surfaces. Figure 7 shows the range of injection forces using push plunger with a current cement gun. The injection forces are calculated using equation 4.

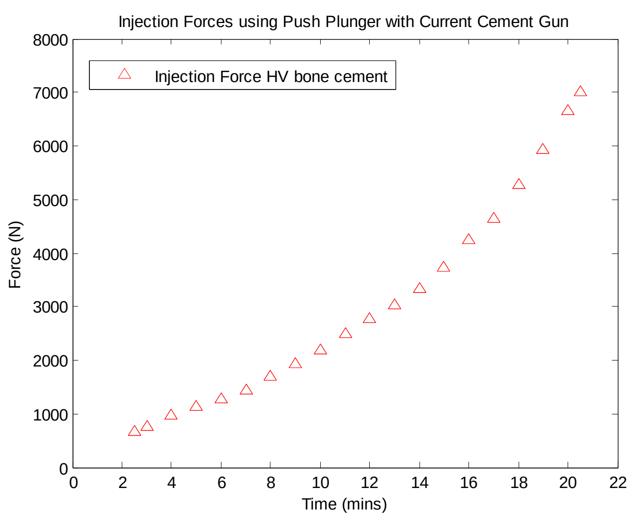

Figure 7: Injection forces using push plunger with current cement gun. With push plunger there is no amplification injection force and therefore it is equal to the axial force

The encountered range of injection forces is between 670N – 7000N which is excessively high. A manually operated push plunger mechanism is thus unsuitable for high viscosity bone cements.

Lever

By using a lever, the applied force on one end can be magnified to exert a much higher force on the other end. This mechanism allows magnification of the injection force. The magnification factor depends on the length of the two arms of the lever, the effort arm and the load arm. For the lever to be effective in amplifying the force the effort arm has to be longer than the load arm (Figure 8).

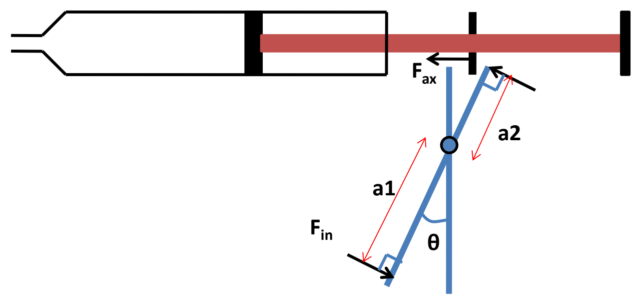

Figure 8: A schematic diagram of the lever

The axial force (F_{ax}) is applied to push the plunger. The injection force applied by the surgeon F_{in} is the injection force applied by the surgeon. F_{in} can be calculated by equation 9.

$$F_{in} = \frac{F_{ax} a_2}{a_1 \cos \theta} \qquad (9)$$

where a1 and a2 is the respective effort arm and load arm, and θ is the angle between the arms and the fixed bar which forms the fulcrum. F_{ax} will be maximum as θ tends to zero. The displacement of the plunger in horizontal direction is d and is calculated by equation 10.

$$d = a_2 \sin \theta \qquad (10)$$

This mechanism allows injecting a controlled volume of bone cement, the distance d moved by the plunger will inject a quantum of bone cement in every cycle. A comparison between the axial force and the injection force using lever mechanism is done. For exerting a constant horizontal force the applied force at θ=45° will be greater than at θ=0°. Figure 9 shows the comparison of axial and injection forces using a lever.

The mechanical advantage offered by lever depends on the ratio of the arm lengths a1 and a2. The longer the effort arm (a1) the lesser the injection forces. However, the lever has to be held in the surgeon's hand and there is a limitation of length for the effort arm due to the size of the hand. The lever mechanism is also one of the possible mechanisms that can be used in developing a new design for cement gun but feasibility of this mechanism will be discussed in the discussion section.

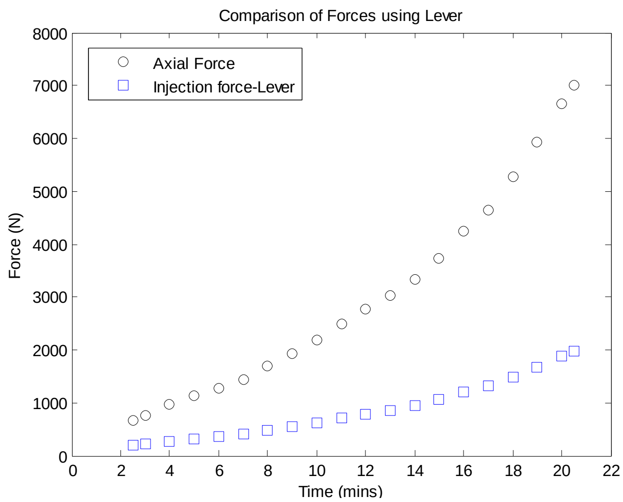

Figure 9: Comparison of axial and injection forces using a lever

Gears

By using gears torque can be transmitted to other parts of a system. The gear ratio (gr) is the number of teeth on output/driven gear divided by number of teeth on input/driver gear. Since the number of teeth is proportional to the circumference of the gear wheel the gear ratio can also be expressed in terms of the pitch circles of the gears.

$$gr = \frac{D}{d} \qquad (11)$$

where D is the pitch diameter of the output gear and d is the pitch diameter of the input gear. There are different types of gears used in various engineering applications with which different gear ratios can be achieved. For the cement gun, rack and pinion gear system is used as the moment (M) has to be translated into the axial force (F_{ax}) to inject the bone cement. Figure 10 shows a schematic diagram of rack and pinion gear system.

The moment can be calculated by multiplying the axial force (F_{ax}) with the radius of the pinion driver (r_G). The injection force (F_{in}) in this case can be calculated by equation 12.

$$F_{in} = \frac{F_{ax} r_G}{r_K} \qquad (12)$$

r_K is the radius of the plunger knob (Figure 11). Injection forces using rack and pinion system for current cement gun are approximated by equation 4 and 12 which is shown in Figure 12.

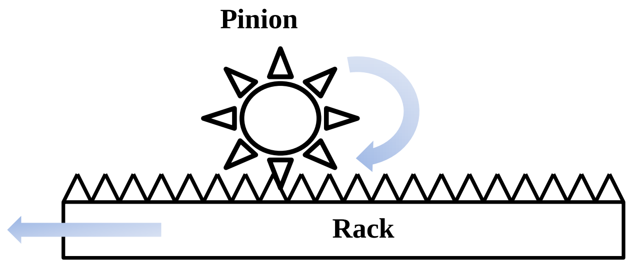

Figure 10: Schematic diagram of rack and pinion gear system

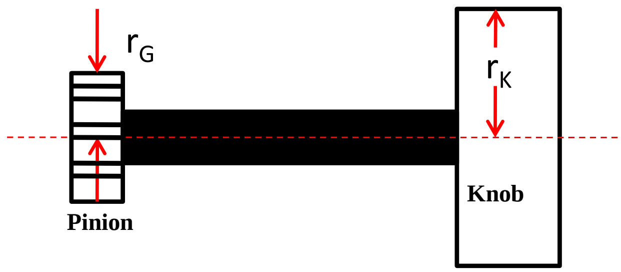

Figure 11: Schematic side view of pinion along with the plunger shaft and knob

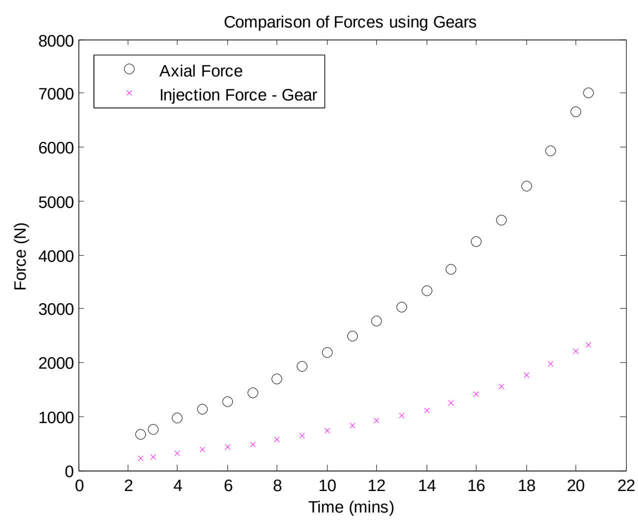

Figure 12: Comparison of axial and injection forces using rack and pinion system

The injection force will decrease as the radius of the knob increases. This mechanism allows controlled injection of bone cement with every rotation of the plunger knob.

Screw

Screws are used for translating rotational motion into linear motion, fastening, and transmitting power. The current cement gun makes use of screw plunger; in this mechanism the moment applied by the surgeon is translated into forward motion of the plunger thereby injecting bone cement. The required injection forces using screw mechanism lies between 100N – 1300N, as already estimated in section III.

In section V, the mechanisms described above will be used to generate design concepts. Before that, the dimensions of the syringe will be described in the following paragraph.

Dimensions

An essential requirement of the cement gun is to keep the surgeon at a safe distance from the X-Ray radiation. The current cement gun does that by using a long connecting tube of small diameter. Removing the connecting tube in the current cement gun will reduce the required injection forces significantly will bring the surgeon under direct radiation. Thus, the connecting tube must be kept and modifications of the syringe dimensions are required to reduce the injection forces.

The length over radius ratio for different dimensions is calculated for a fixed volume to see the effect of forces at a certain viscosity of bone cement. The length and radius is normalized to see the effect of changing dimensions on the injection forces. In this analysis a length range of 0.1 – 2m is considered and the respective radii are calculated for a fixed volume of 15cc using equation 13.

$$r_S = \sqrt{\frac{V}{\pi L_S}} \qquad (13)$$

where L_S is the length and r_S is the radius of the syringe. V is the volume of bone cement which is constant in this case (15cc). The pressure required to inject the bone cement is calculated using equation 1, the required pressure is then multiplied by the surface area of the syringe to calculate the injection force. As the length increases, the radius decreases to keep the volume constant. From Figure 13 it can be seen that there is a range of L_S/r_S ratios where the injection forces will be low (dashed ellipse in Figure 13) for a given viscosity. Decreasing or increasing the ratio beyond this range will result in increase of injection force.

In the requirements it is made clear that the distance of the surgeon from the radiation has to be 0.3m. This length of the syringe allows the surgeon to maintain sufficient distance from the radiation and be close enough to monitor the real-time injection on the fluoroscopes.

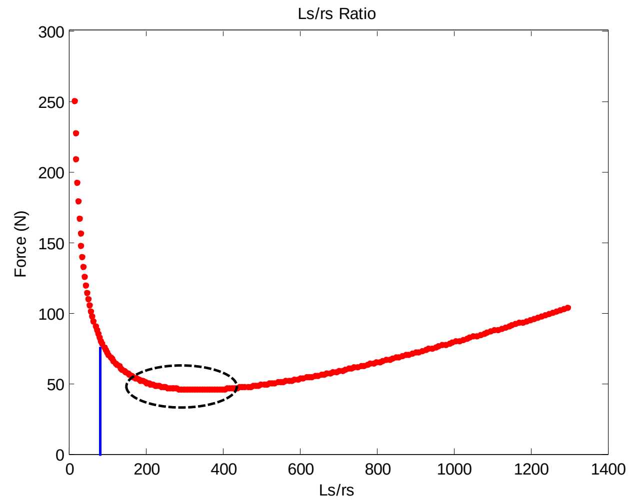

Figure 13: Injection forces at different L_S/r_S ratios with constant volume of bone cement. L_S and r_S are the length and radius of the syringe. Blue line indicates the dimensions of the syringe (0.3m) for concepts and black ellipse shows the plateau where minimum forces are achieved by syringe lengths of 0.78–0.86m

Four design concepts will be described in section V, all assuming length of 0.3m. However, this length requires an injection force of about 85N (blue vertical line in Figure 13), whereas injection forces as low as 50N can be achieved with the syringe length of 0.78–0.86m For generating concepts, a length of 0.3m is taken in consideration (blue line marked in Figure 13). However, based on the L_S/r_S ratio analysis the minimum injection forces are achieved with the syringe length of 0.78 – 0.86m. Although syringes with such lengths may be difficult to handle, this range is still kept in consideration and a fifth concept implemented with such syringe length is also presented in section V.

V. Concept Mechanisms

The functions mentioned in Table 4 are used to make the concepts which can be used for improving the cement gun design. The analysis of the mechanisms described in the previous section showed that a push plunger mechanism requires excessively high injection forces and therefore is not used in making the concepts. There are three concepts chosen from the direct transmission option making use of lever, screw, and gear mechanism. One concept is generated from the indirect transmission option using hydraulics; the three mechanisms (lever, gear, and screw) are combined separately for this concept.

Lever Mechanism

Based on the requirements, the length of the syringe is 0.3m and the corresponding radius is 4x10e-03m. Equation 4 is modified to calculate axial force (F_{ax}) as there is no connecting tube present, and is mentioned hereunder:

$$F_{ax}=\left[\left[\frac{8Q\mu}{\pi}\left(\frac{L_S}{r_S^4}+\frac{L_C}{r_C^4}\right)\right].\pi r_S^2\right]+F_F \qquad (4a)$$

The mechanism used in this concept is lever mechanism. The injection forces for lever mechanism are calculated using equation 4a and 9. Lever mechanism is shown in Figure 14.

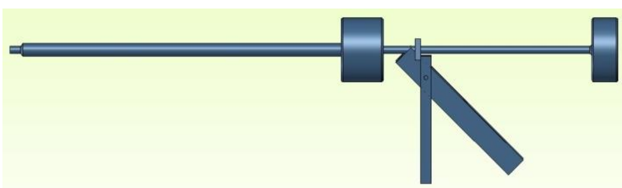

Figure 14: Design of lever mechanism

The injection forces using lever mechanism are shown in Figure 15.

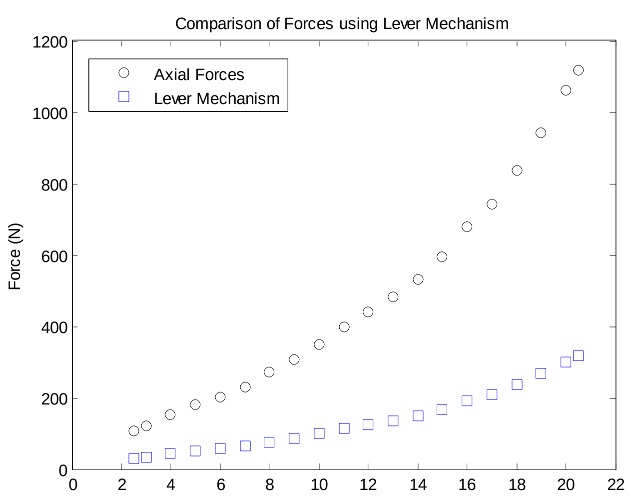

Figure 15: Comparison of axial and injection forces using lever mechanism

The axial forces lie approximately between 100N–1100N. The range of forces using this concept is approximately between 30N–320N. The distance moved by the plunger is multiplied by the cross-sectional area of the syringe to determine the volume of bone cement injected in each cycle. The volume of bone cement injected per cycle is 0.7cc.

Gear Mechanism

The dimensions of the syringe for this concept are same as that of lever mechanism. A rack and pinion system is used in this concept to inject the bone cement. The rack acts as the plunger and the pinion is the driver which translates the moment into linear force. The axis of the syringe and the axis of the pinion are orthogonal. Gear mechanism is shown in Figure 16.

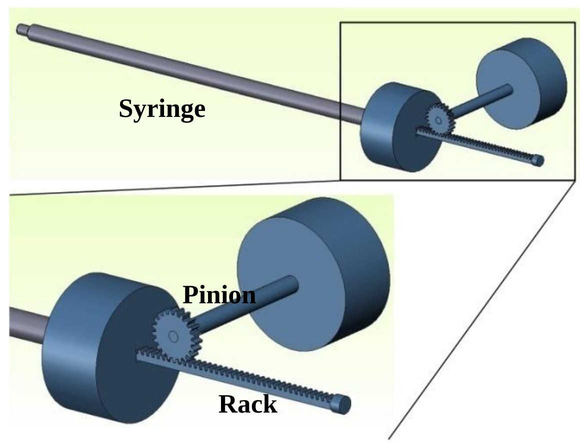

Figure 16: Gear mechanism using rack and pinion, the axes of pinion and rack are orthogonal

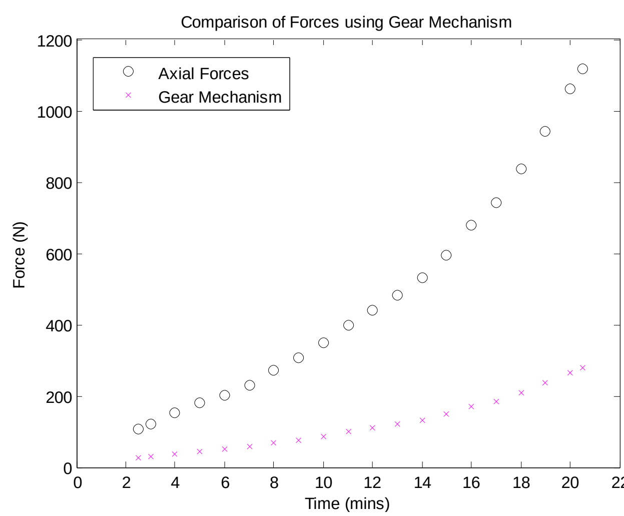

Figure 17: Comparison of axial forces and injection forces using gear mechanism

The axial forces are calculated using equation 4a and the injection forces are calculated using equation 12. The radius of the pinion shaft (r_G) is 7.5x10e-03m and the knob radius (r_K) is 30x10e-03m. The injection forces using this concept are shown in Figure 17. The range of injection forces using rack and pinion system is approximately between 25N – 280N. The injection forces with gear mechanism are slightly over the manual range for injection. The volume of bone cement injected in each cycle is determined by the distance moved by the rack in one rotation of the pinion; this distance is circumference of the pinion. The distance moved multiplied by the cross-sectional area of the syringe gives the volume per cycle. The volume injected in each cycle using gear mechanism is 2.3cc.

Screw Mechanism

The dimensions of the syringe for this concept are same as that of lever mechanism. Screw plunger is used in this concept for injection of bone cement. The axial forces are calculated using equation 4a and the injection forces are calculated using equation 7. Screw mechanism is shown in Figure 18 and range of injection forces using this concept is shown in Figure 19.

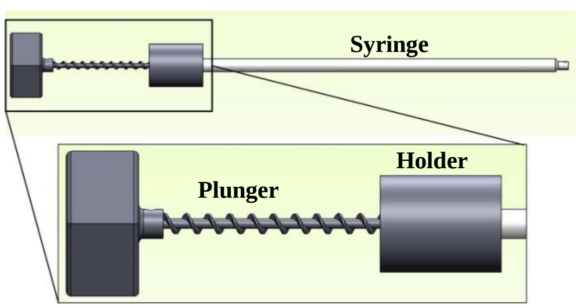

Figure 18: Screw mechanism

The approximate range of injection forces for this concept is between 15N–180N. This range of forces is within the manual range of injection. The volume of bone cement injected in each cycle is calculated by multiplying the pitch of the screw by the cross-sectional area of the syringe. It is calculated to be 0.3cc for screw mechanism.

Hydraulic Mechanism

The hydraulic lever works on the principle that the applied pressure to a confined fluid at any point is transmitted undiminished throughout the fluid in all directions. In hydraulic lever the transmission of applied force is done by using an incompressible fluid. The idea is to apply less force on one end and exert high force on the other end. A schematic figure of hydraulic lever is shown in Figure 20.

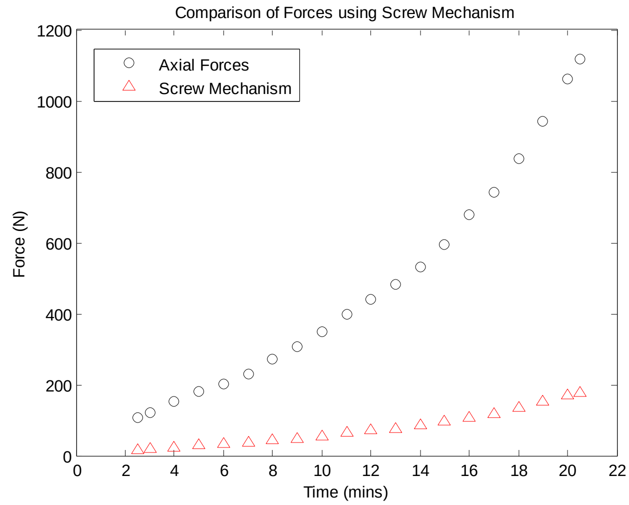

Figure 19: Comparison of axial forces and injection forces using screw mechanism

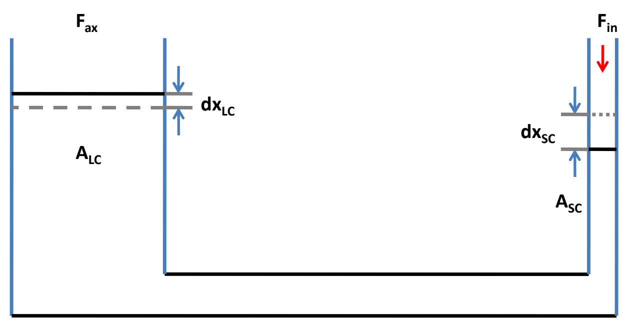

Figure 20: Schematic diagram of hydraulic lever

A larger load can be lifted by applying small force; however, the injection force has to be applied over a larger distance in the smaller chamber to move the bone cement through a small distance in the larger chamber. The relation between forces, distance moved, and respective area is shown in equation 13.

$$\frac{dx_{LC}}{dx_{SC}} = \frac{\mathrm{F_{in}}}{\mathrm{F_{ax}}} = \frac{A_{SC}}{A_{BC}} \tag{13}$$

where dx_{LC} and dx_{SC} are distance moved in the larger chamber and smaller chamber, F_{ax} and F_{in} are forces applied on larger and smaller chambers, and A_{BC} and A_{SC} are the respective areas of the larger and smaller chamber. In hydraulic mechanism there are two chambers, the fluid chamber and the bone cement chamber corresponding to the smaller and larger chamber in Figure 20.

The dimensions of the fluid chamber are same as the dimensions of the syringe in previous three concepts. The bone cement chamber is a syringe with a plunger; the plunger is connected to the fluid chamber. The dimensions of the syringe chamber and fluid chamber are mentioned in Table 5 and Figure 21 shows hydraulic mechanism.

Table 5: Dimensions for hydraulic mechanism

	Length (m)	Radius (m)	Area (m^2)
Bone Cement Chamber	0.1	7x10e-03	1.5x10e-04
Fluid Chamber	0.3	4x10e-03	5.0x10e-05

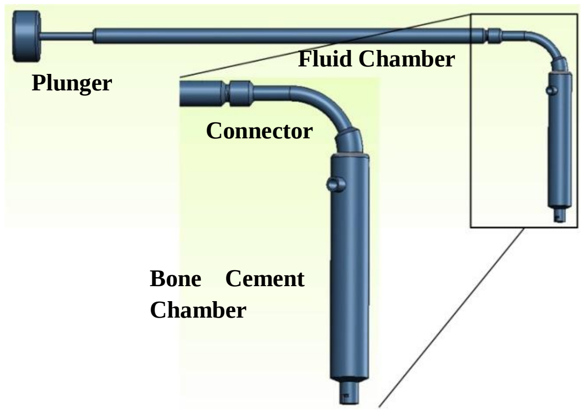

Figure 21: Hydraulic mechanism making use of fluid chamber and bone cement chamber for injection

The hydraulic mechanism is capable of reducing the injection forces. The axial forces are calculated using equation 4a. Bone cement can only be injected with the help of an injection mechanism. The mechanisms that can be used in hydraulic mechanism are lever, gear, and screw. The required injection forces for this concept using the three injection mechanisms are calculated using equation 4a, 7, 9, and 12. Figure 22 shows the range of forces using different mechanisms.

From Figure 22 it is clear that hydraulic concept in combination with lever, gear, and screw is capable of reducing injection forces as compared to the axial forces. The injection forces using lever lie approximately between 30N–310N, with gear approximately between 25N–280N, and with screw the range of injection forces is approximately between 15N–180N. The volume of bone cement injected per cycle for lever, gear, and screw is same as described in the previous concepts. However, more number of parts is used in hydraulic mechanism in comparison to the other concepts. Also, it has to be made sure that there is no presence of impurities or air in the fluid chamber as it will hamper the functioning of the device.

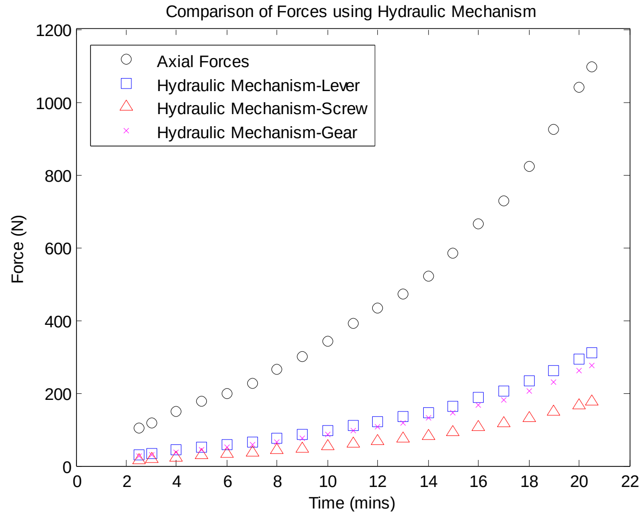

Figure 22: Comparison of axial forces and injection forces with hydraulic mechanism using lever, gear, and screw

Helix Mechanism

From the L_S/r_S ratio analysis presented in section IV it was found that there is a range of L_S/r_S ratios where the injection forces are minimal and increase only slightly by changing the dimensions; this plateau phase is marked in dashed blue ellipse in Figure 13. This particular point of minimum has respective length and radius of 0.82m and 2.4x10e-03m. A syringe as long as 0.8m will be difficult to handle. By configuring the tube in a helical form, however, a length of 0.8m can be compressed to 0.3m. The helix mechanism is shown in Figure 23.

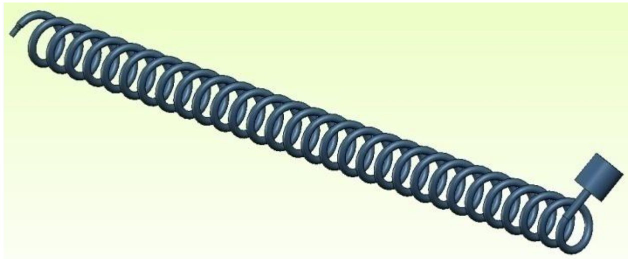

Figure 23: Helix mechanism with a helical tube and a helical plunger

The helical tube requires a helical plunger to inject the bone cement. The pressure required to inject the bone cement can be calculated using equation 1 and the subsequent axial forces by equation 4a. The length of the tube (L_S) is taken as 0.8m. The axial force is applied by the moment on the helical plunger. The relation is mentioned in equations 14 and 15.

$$M=F_{ax}r_{hlx} \qquad (14)$$

$$F_{in}=\frac{F_{ax}r_{hlx}}{r_k} \qquad (15)$$

where M is the required moment to apply F_{ax} by the helical plunger, r_{hlx} is the radius of the helix, and r_K is the radius of the knob. The injection force F_{in} is applied by the surgeon on the knob of the helical plunger. The required injection force will be lesser than axial force as $r_K>r_{hlx}$. The injection forces using helix mechanism are shown in figure 24.

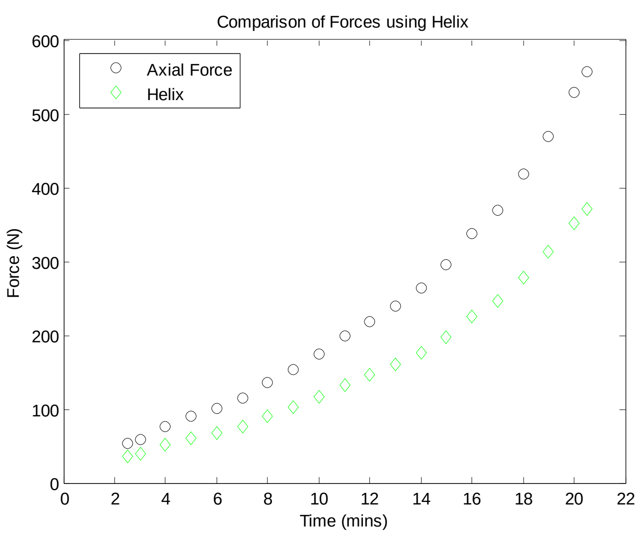

Figure 24: Comparison of axial and injection forces using helix mechanism

The range of injection forces for helix mechanism is between 35N–370N. The volume injected in every cycle is the distance moved by the helical plunger multiplied by the cross sectional area of the helical tube. The volume per cycle is 2.2cc for helix mechanism.

VI. Evaluation of Concept Mechanisms

In this section, the design concepts are evaluated based on their advantages and disadvantages. All the concepts in the previous section are capable of reducing the injection forces to certain extent and provide a minimum separation of 0.3m from the radiation focus. Table 6 shows the range of injection forces and the volume injected per cycle of injection for all the five concepts. From the concepts using mechanical energy with direct transmissions screw mechanism has the minimum range of injection forces followed by gear mechanism and lever mechanism. In all the three concepts there is controlled injection of bone cement. However, the volume injected per cycle differs. The injection forces for lever mechanism are higher than the injection range mentioned in the requirements and therefore it is not considered for making the final design of the cement gun. The range of injection forces for gear mechanism is slightly higher than the injection forces defined in the requirements.

Based on the handling criteria, the injection devices are better held when the axis of the plunger is at an angle of approximately 45° with the frontal plane of the surgeon. Screw and lever mechanisms can be held by the surgeon in such position during injection of bone cement. In gear mechanism the axes of the plunger and syringe are orthogonal which makes the handling difficult and due to these reasons gear mechanism is not considered for the final design of the cement gun. In the direct transmission category the screw mechanism is better than other two concepts in terms of injection forces, controlled injection of bone cement, and handling.

In hydraulic mechanism which uses indirect transmission of mechanical energy, three mechanisms can be used to inject the bone cement. The screw option under hydraulic mechanism concept has the minimum range of injection forces. The volume of bone cement injected per cycle for hydraulic mechanism is same as in the three concepts mentioned under direct transmission category. The handling criteria for the mechanisms used in hydraulic mechanism are same as the concepts mentioned under the direct transmission category.

In the helix mechanism the range of injection forces is higher than the manual range of injection defined in the requirements. The inner surface of helical tube and the helical plunger will have greater amount of friction between them during injection. The helix mechanism will allow controlled injection of bone cement with every turn of the plunger. This concept is not suitable for the design of cement gun based on the injection forces criteria.

Table 6: Comparison of concepts based on injection forces and injected volume/cycle

	Direct Transmission			Indirect Transmission (Hydraulics)			
	Lever Mechanism	**Gear Mechanism**	**Screw Mechanism**	**Lever**	**Gear**	**Screw**	**Helix Mechanism**
Injection Forces (N)	30 - 320	25 - 280	15 - 180	30 - 310	25 - 280	15 - 180	35 - 370
Volume/ Cycle (cc)	0.7	2.3	0.3	0.7	2.3	0.3	2.2

Table 7 describes the criteria for grading the concepts. The concepts are graded in the form of (+), (-), and 0 based on how well they perform in their respective individual functions. Based on the argumentation above, an evaluation table is made to grade all the concepts (Table 8). In comparison of the concepts the functions are stated in the order of their priority.

The screw mechanism and the hydraulic mechanism are eligible for the final design. Both concepts have similar injection forces and volume injected per cycle. However, based on the handling criteria the hydraulic mechanism has more number of parts to be assembled before use in comparison to the screw mechanism and therefore scores less in Table 8. Also, in this concept the fluid chamber has to be filled with the fluid such that there is no presence of air bubbles and there is no leakage in the fluid chamber.

The disadvantage with screw mechanism is that the volume of bone cement injected in every turn is 0.3cc; this means that the surgeon has to turn the knob 50 times to inject 15cc of bone cement if required i.e. 3 turns for 1cc of bone cement. A tradeoff between the injection forces and number of turns has to be made, and in this case it is made in favor of the injection forces based on the priority. Screw mechanism is a suitable concept based on the evaluation of concepts. It offers low injection forces, controlled injection of bone cement in every cycle, good separation from X-rays, and satisfactory handling. The final design is discussed in section VII.

VII. Final Design

In the evaluation, screw mechanism scores the best out of five concepts and is chosen for the final design. The final design consists of 5 components namely; syringe, plunger shaft, holder, knob, plunger head and a flexible connector (Figure 25).

The material used for making the parts is medical grade acrylic except the plunger head which is made up of medical grade latex rubber. The connecting ends of the connector as shown in Figure 25 are made up of medical grade acrylic and the tube is made up of flexible material. A standard luer lock connector can be used for making a secure connecting between syringe and cannula. The handling of the final design is similar to the current design of the cement gun. Additional components like cannula and cement mixers can be connected with this design.

The assembling of the final design has to be done in a specific order. First step includes tight fitting of plunger shaft with the knob, after which the plunger shaft is screwed inside the holder. The plunger head is tightly fitted on top of the plunger shaft. Finally the syringe is fitted tightly with the holder. The luer lock connector comes as a separate component which is attached with the cement gun at the time of operation. After assembling, the syringe encapsulates the plunger head and shaft shown in Figure 25 (full view). Detailed technical drawings of the final design are mentioned in appendix C. Section VIII is presented with the discussion and recommendations.

Table 7: Criteria for grading the concepts

Injection forces

(+) → signifies less than or equal to 200N	(0) → signifies slightly higher than 200N, between 200 – 300N	(-) → signifies greater than 300N

Volume/cycle

(+) → between 0.5 – 1.0cc	(0) → greater than 1.0cc	(-) lesser than 0.5 cc

Separation from X-rays

(+) → distance of separation equal to 0.3m	(-) → distance of separation less than or greater than 0.3m

Handling

(++) → for less number of parts and comfortable holding position	(+) → for less number of parts or comfortable holding position	(-) → for more number of parts or uncomfortable holding position	(--) for more number of parts and uncomfortable holding position

Table 8: Evaluation of concepts

Concepts → **Functions ↓**	**Lever Mechanism**	**Gear Mechanism**	**Screw Mechanism**	**Hydraulic Mechanism**	**Helix Mechanism**
Injection Forces	**0**	**0**	+	+	-
Volume/Cycle	+	**0**	-	-	**0**
Separation from X-rays	+	+	+	+	+
Handling	+	-	++	-	-

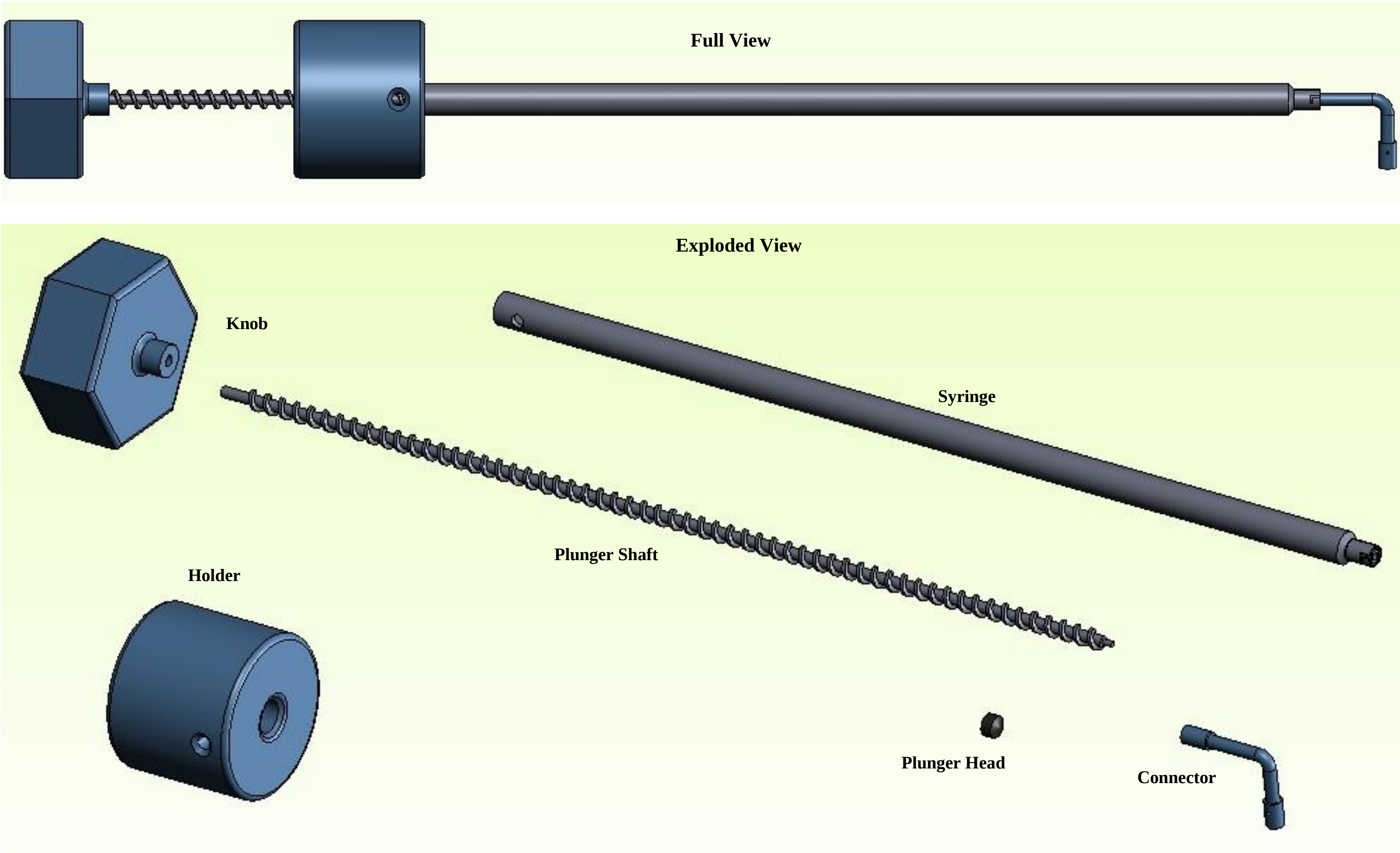

Figure 25: Full view and exploded view of final design consisting of syringe, plunger shaft, holder, knob, plunger head, and a flexible connector

VIII. Discussion

A methodological approach was taken to investigate the possibilities for designing a cement gun for injection of high viscosity bone cements. The result was the design of a cement gun that employs high viscosity bone cements; it expectedly requires injection forces that can be applied manually, while also allowing controlled injection, good separation from radiation, and satisfactory handling.

Different concepts were made which were capable of reducing the injection forces and then evaluated based on their advantages and disadvantages. In the evaluation of concepts screw mechanism is the best out of all the concepts. A tradeoff between the less injection forces and more number of turns has to be made, and in this case it is made in favor of the injection forces based on the priority. One limitation of this study is that the pressure drop was calculated by using the Hagen-Poiseuille's law, which assumes that the fluid is Newtonian, whereas the bone cement exhibits non-Newtonian behavior. Despite this discrepancy, however literature has shown that estimated values of pressure drop correspond well with the experimental values for bone cements.

Another limitation is that the study is focused on manually operated cement guns only. In the literature it was found that automated systems also exist which are capable of injecting bone cement without the need of surgeon handling the cement gun. By automating the system the surgeon is out from the loop and becomes a monitor instead. In discussions with the surgeons at LUMC it was made clear that the surgeons had a strong preference to be kept inside the loop, i.e. to operate the device manually. Therefore, automation was not considered in this study.

A final note may be made on the working times of the cement gun. High viscosity bone cements reach the working phase in lesser time as compared to low viscosity bone cements. With this design the surgeons can work with high viscosity bone cements as soon as the working phase of the bone cement begins. This reduces the overall time of the procedure and minimizes the risk of leakage inside the vertebra. Longer working time duration of 18 minutes is considered in the study. However, in discussions with the surgeons it was mentioned that the time window in actual vertebroplasty procedure is between 10 – 12 minutes. This is an advantage for the surgeons as the injection forces in this time duration are approximately 85N with the final design. The design of cement gun is capable of providing efficient force reduction. The working of this design is close to the current cement gun, this makes it is easier for the surgeons to adapt to the new design which provides much easier injection of high viscosity bone cements.

Recommendations

For future work, the final design has to be prototyped and tested with high viscosity bone cement. The injection forces have to be measured in time by keeping the flow rate of bone cement constant. The prototype of the final design has to be tested in operating room conditions by the surgeon on cadavers. The injection forces and handling of the prototype has to be verified objectively by the surgeons.

IX. Conclusion

The aim of the research was to reduce the injection forces when using high viscosity bone cements in vertebroplasty. Various domains were investigated to seek for the possible solutions to achieve this goal. Different concepts were generated and evaluated and a final design was chosen. The design of high viscosity cement gun developed in this study is expected to reduce the injection forces, allow controlled injection, good separation from radiation, and satisfactory handling.

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Appendices

A. Anatomy

The vertebral column or the spine is a part of the axial skeleton which extends from skull to the pelvis. The vertebral column consists of vertebrae that are divided by intervertebral discs. The intervertebral discs are made up of cartilage and acts as a vertical shock absorber between adjacent vertebrae. The vertebral column is divided into five parts known as the cervical, thoracic, lumbar, sacral and the coccyx. The vertebral column encloses and protects the spinal cord. Apart from protection, it supports the skull and facilitates its movement, articulates with the rib cage, and also provides attachment for trunk muscles. The size of each vertebra differs from the cervical region to the coccyx.

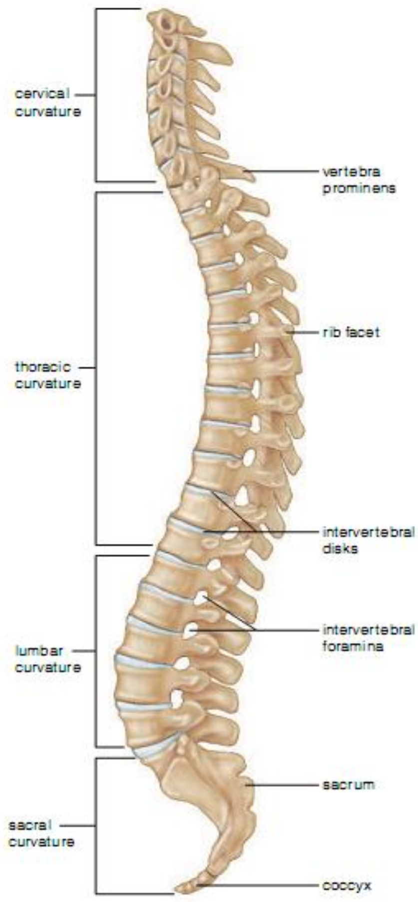


Figure 26: The human vertebral column showing different regions and curves of the spine [17]

There are total of 33 vertebrae in the vertebral column namely:

- 7 cervical vertebrae C1-C7
- 12 thoracic vertebrae T1-T12
- 5 lumbar vertebrae L1-L5
- 5 sacral vertebrae S1-S5, the sacral vertebrae fuse to form the sacrum
- The coccyx is composed of 3-4 small vertebrae.

Figure 26 shows the vertebral column with different regions as previously mentioned and different curvature of the spine. The cervical and lumbar curvatures are convex and the thoracic and sacral curvatures are concave in shape.

The overall shape of the spine gives stability to the structural framework of the body while standing, sitting, and performing daily activities.

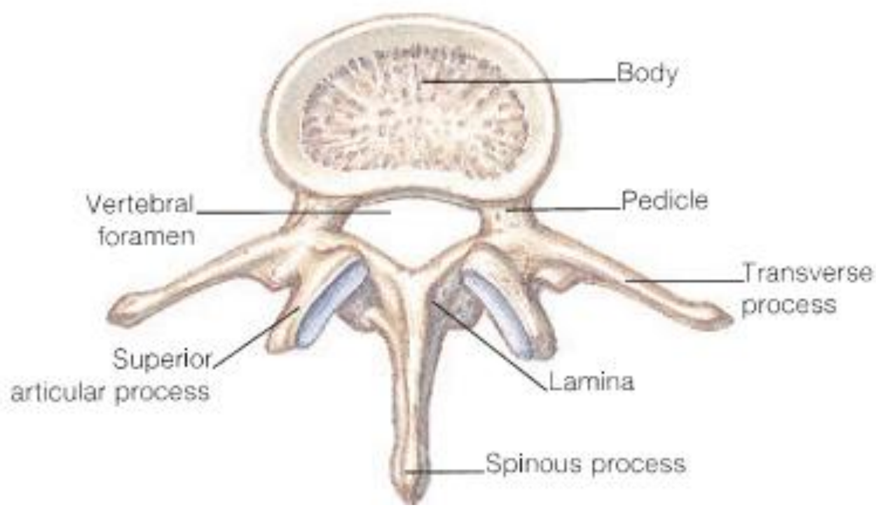


Figure 27: A typical transverse section of a vertebra from the lumbar region [18]

The vertebra is composed of a drum shaped body which is padded above and below by the intervertebral discs. Figures 27 and 28 show the transverse section and the lateral view of a lumbar vertebra and its parts. The pedicles, laminae, and the posterior surface of the body form the vertebral foramen, through which the spinal cord passes. The spinal nerves branch off from the spinal cord and emerge through the spaces between two adjacent pedicles called the intervertebral foramina. A typical vertebra has seven processes arising from it (Figures 27 and 28), namely:

- The spinous process
- Two transverse processes
- Two superior articular processes
- Two inferior articular processes.

The spinous process and transverse processes help in attachment of muscles. The superior and inferior processes limit the twisting of the vertebral column. In the following section the five regions of the vertebral column are discussed in detail.

Cervical C1-C7

The cervical region of the vertebral column consists of seven vertebrae which supports the head and makes the basic framework of the neck. Cervical vertebrae can be identified by transverse foramen in each transverse process; these spaces are formed for the arteries and veins supplying blood to the head.

Thoracic T1-T12

The twelve thoracic vertebrae articulate with the ribs, and are larger than cervical vertebrae. The size of the thoracic vertebrae increases from T1 to T12. Thoracic vertebrae have facets for attachment of ribs. Figure 29 shows the general structure of thoracic vertebra from T1 to T10.

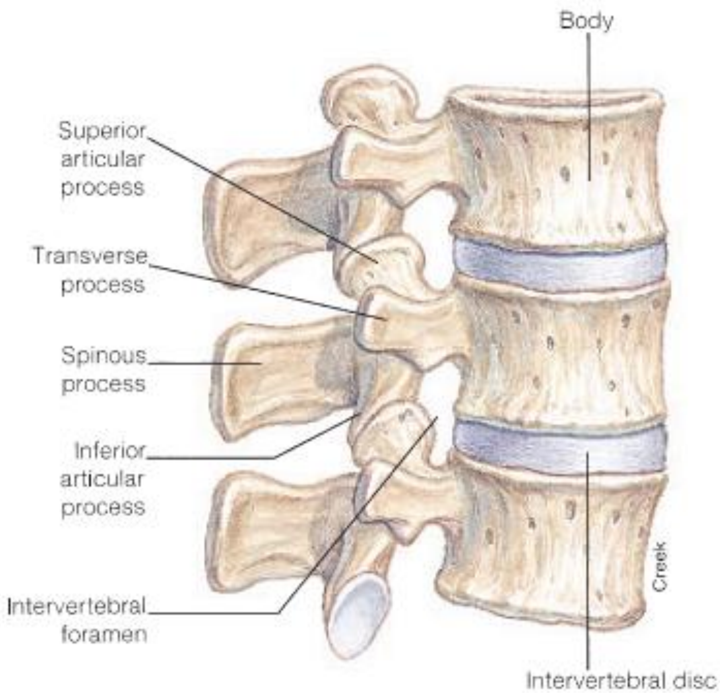


Figure 28: Lateral view of the lumbar vertebrae [18]

Lumbar L1-L5

After the thoracic region, comes the lumbar region which consists of five vertebrae L1 to L5, Figure 27 and 28 shows the lateral view and transverse section of lumbar vertebra. The lumbar vertebrae are the largest of the vertebral column and are identified by heavy vertebral bodies with thick and blunt spinous processes. These spinous processes serve for the attachment of back muscles.

Sacral and Coccyx

Figure 30 shows the anterior and posterior view of the sacrum and coccyx. The five sacral bones fuse to form a wedge-shaped structure at the lower region of the vertebral column. The five sacral bones fuse at a later stage in life, generally after age 26. The lateral side of the sacrum has an extensive auricular surface which forms the sacroiliac joint with the ilium of the hip. Posterior sacral foramina on either side of the sacrum are spaces for the passage of nerves from the spinal cord. The tubular sacral canal is the continuation of the vertebral canal. In the end there are 3-4 small bones fused together making the coccyx also known as the tailbone [18], [17]. The vertebral column may suffer from diseases as a result of progressing age and sometimes tumors. In the following section vertebroplasty procedure is discussed in detail.

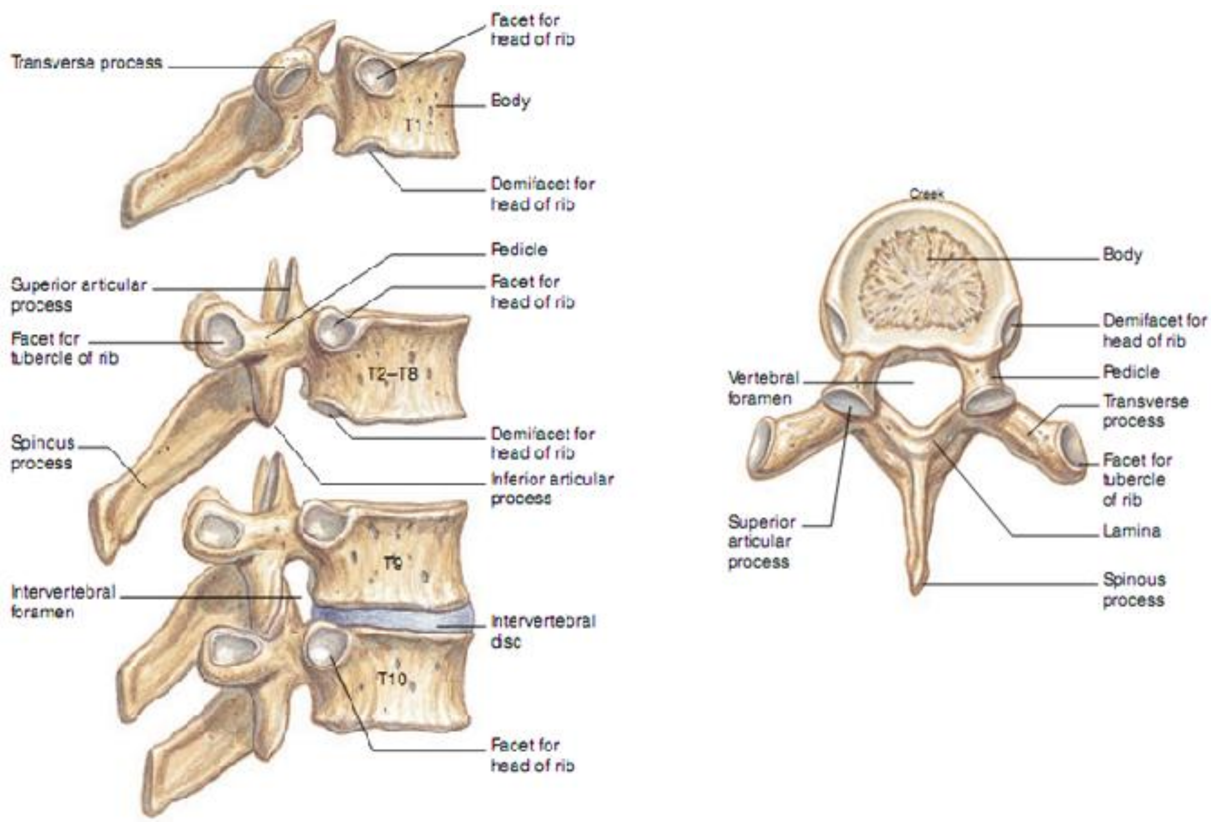


Figure 29: General structure of thoracic vertebrae. Lateral view from T1 to T10 (left), transverse view (right) [18]

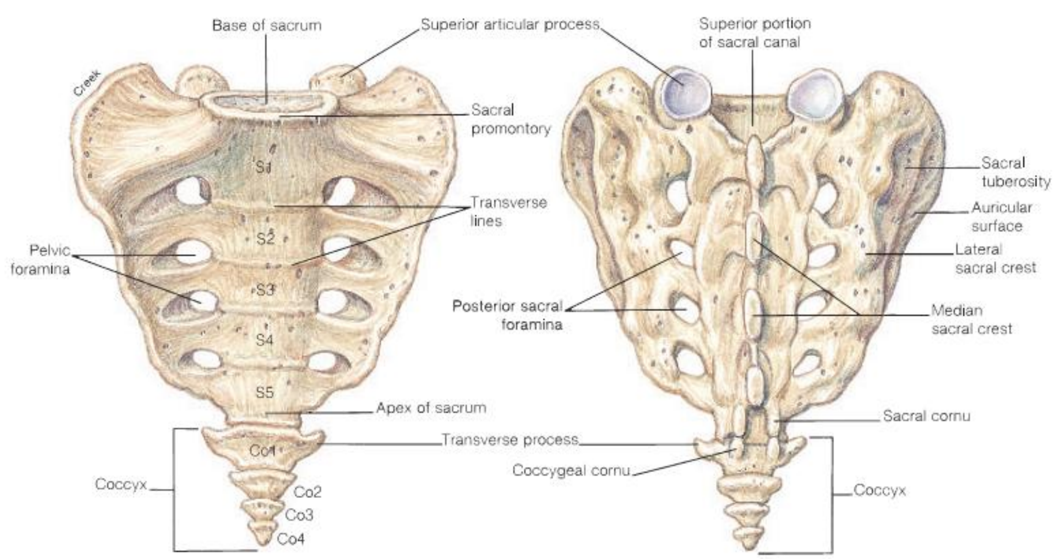


Figure 30: The anterior and posterior view of the sacrum and coccyx [18]

B. Vertebroplasty Procedure

Vertebroplasty is a minimally invasive procedure done for relieving pain by stabilization of the vertebra. The bone cement is injected into the cancellous bone of the affected vertebra under fluoroscopic guidance. The following steps are carried out in vertebroplasty procedure.

- Patient positioning
- Anesthesia
- Cannula needle positioning
- Cannula needle insertion
- Bone biopsy
- Cement mixing and cement delivery

PVP is an outpatient procedure and requires less time as compared to the conventional open surgery. CT scans and radiographs of the affected vertebra are taken prior to the procedure. Preinterventional imaging is important and is done to provide the accurate details of the anatomy. Initially, the patient is positioned in the biplanar imaging setup to obtain a clear view of the affected vertebra in 2-Dimension i.e. lateral and anteroposterior (AP) views. The need for a biplanar imaging is necessary to see the exact position of the cannula needle inside the vertebra in two dimensions [19].

Anesthetic drugs are administered to provide local anesthesia, the needle positioning is done after the region is anesthetized. Figure 31 shows the patient positioning along with the biplanar imaging setup, the two C-arms are visible through which biplanar imaging is done.

Figure 31: Patient positioning and the biplanar imaging setup (Courtesy LUMC)

The needle is first placed on the spine superficially (Figure 33A) and X-ray image in AP and lateral view is taken to ensure the optimal position of the cannula needle (Figure 32) [20]. After the position is fixed, the cannula needle is inserted and guided under the fluoroscope; the surgeon is able to view both the lateral and AP views while guiding the cannula needle inside the vertebra (Figure 32). The cannula needle is steered with the help of a small hammer to reach the desired position inside the vertebral body (Figure 33B). The needle is taken out after positioning and the cannula remains in position. A biopsy needle is then inserted in the positioned cannula to take bone biopsy for pathological examination (Figure 33C) [21]. Multiple levels of vertebra can be treated in the same procedure (Figure 33D).

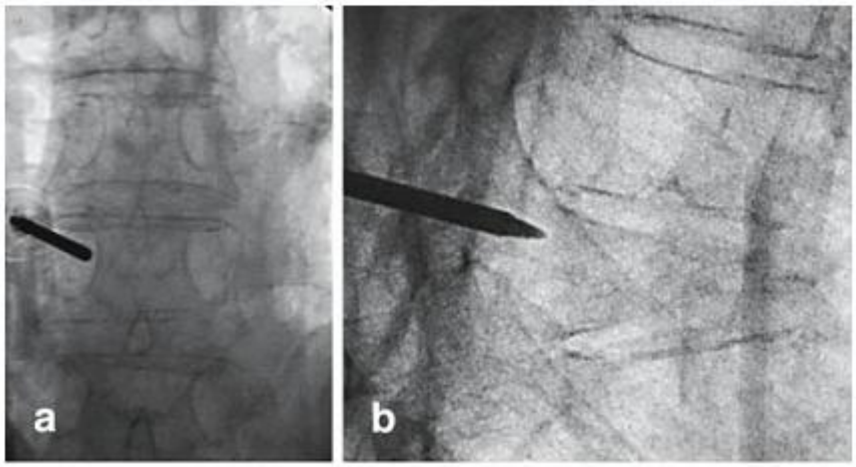


Figure 32: Needle positioning under fluoroscopic guidance, (a) AP view, (b) Lateral view [20]

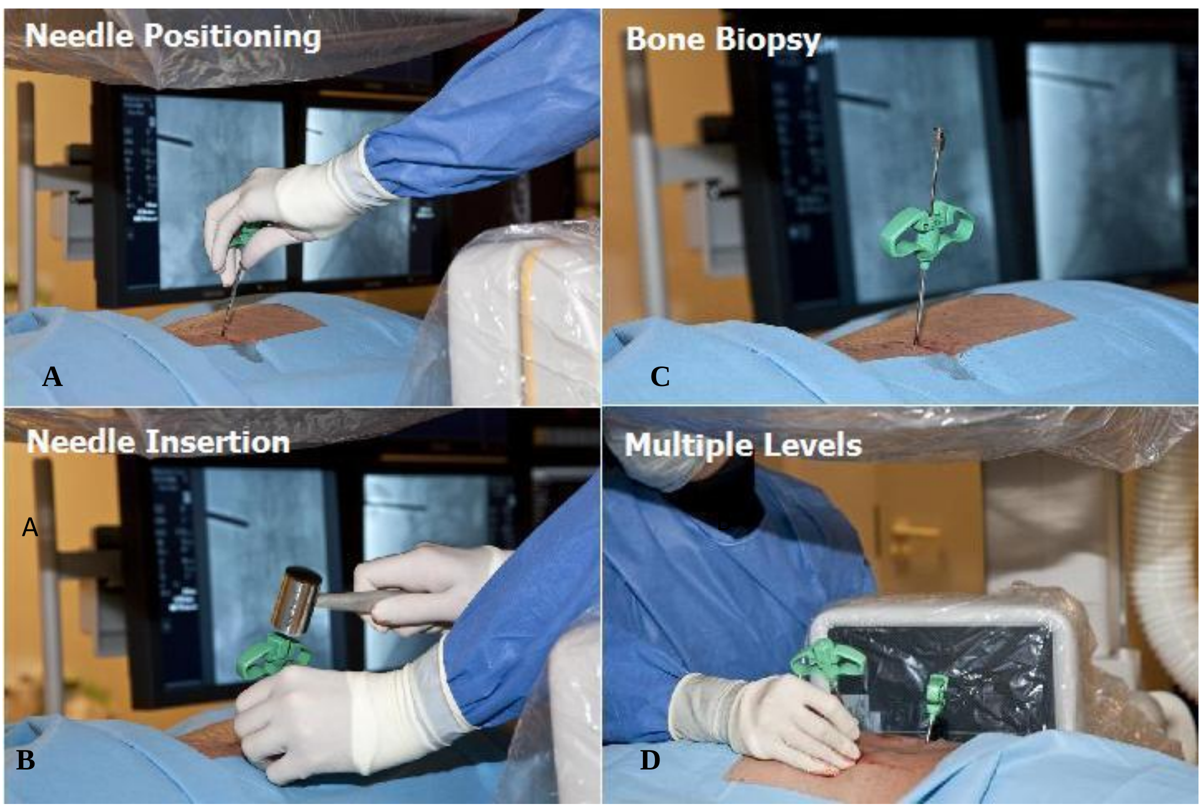


Figure 33: (A) Needle positioning, (B) Needle Insertion, (C) Bone Biopsy, and (D) Multiple levels of vertebra treated in same procedure (Courtesy LUMC)

There are different approaches used to place the cannula needle in the vertebral body. The approach is selected by the operator based on the condition of the vertebra and on the operator's experience with a specific approach. The approaches used for placing the cannula needle are as follows:

- Extrapedicular
  - Posterolateral
  - Intercostovertebral
- Transpedicular
  - Unilateral – using one pedicle
  - Bilateral – using both pedicles

The extrapedicular approaches are used in cases where the pedicles are too small due to which the needle cannot be inserted through it or the anatomy of the pedicles is destroyed or have lesions. The posterolateral approach (Figure 34) is used essentially in the lumbar region if the tumor lesion involves the pedicles.

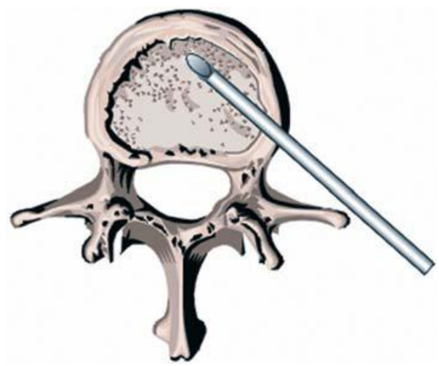


Figure 34: Posterolateral approach in the lumbar vertebra [22]

The intercostovertebral approach (Figure 35) is taken in case of thoracic vertebrae where the pedicles are inapproachable or destroyed by tumor. It is to be taken care that the intercostovertebral approach bears high risk of pneumothorax and paraspinal bleeding [23].

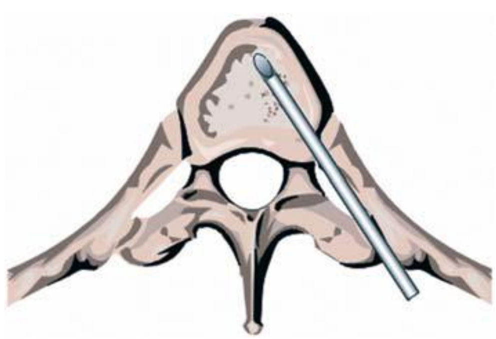


Figure 35: Intercostovertebral approach in the thoracic vertebra [22]

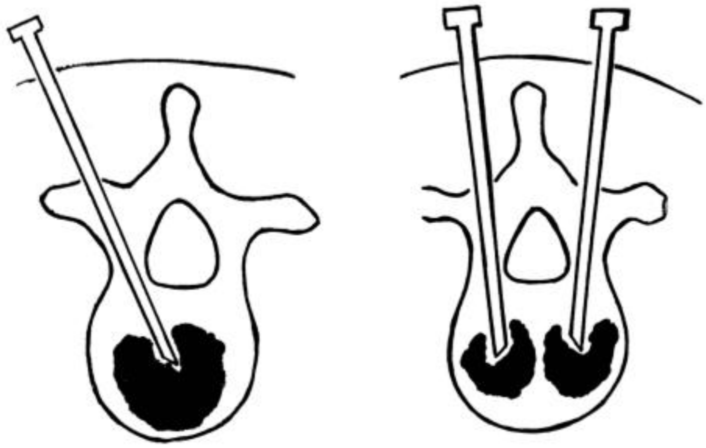


Figure 36: Transpedicular approach for filling vertebral body, (Left): Unilateral approach, (Right): Bilateral approach [4]

Figure 36 shows the unilateral and bilateral approach. In the transpedicular approach the cannula needle is inserted through the pedicles to reach inside the vertebral body. In unilateral approach only one pedicle is used, in bilateral approach both pedicles are used to insert the cannula needle and deliver PMMA inside the vertebral body. Once the needle is positioned and the bone biopsy is taken, bone cement is prepared and injected inside the vertebra (Figure 37).

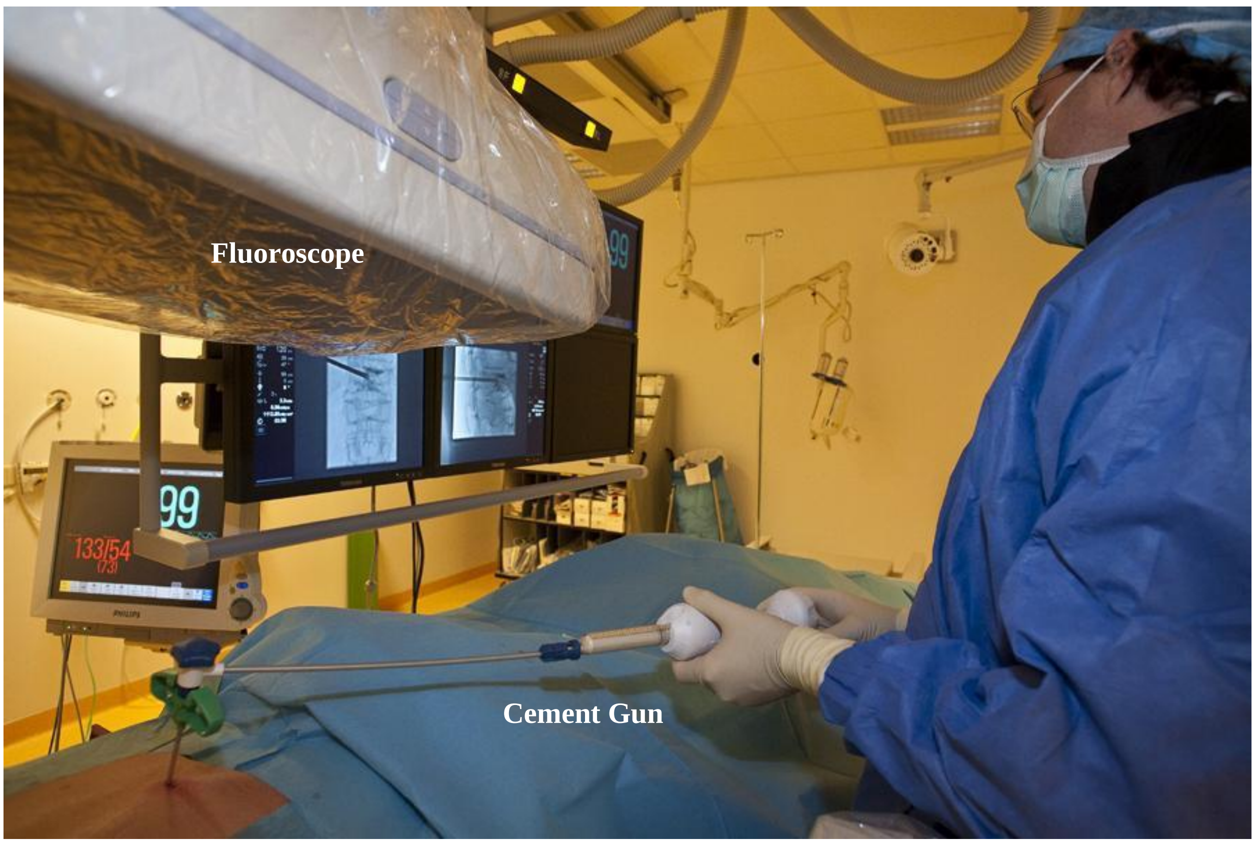


Figure 37: Injection of bone cement by the surgeon (Courtesy LUMC)

The cement injection is done under constant fluoroscopic guidance to ensure the right amount of PMMA is delivered. After the cement is delivered, the cannula is kept in place until the cement polymerizes completely and becomes hard. The waiting time is approximately 10-15 minutes after injection. The cannula is taken out by first twisting it and then retracting it, the puncture wound is covered and the patient is sent for post-operative scans. Post-operative scans are important to see the leakage and ensure the efficacy of the procedure.

Bone cement is injected to stabilize the affected vertebra. The selection of the bone cement is usually based on the patient diagnosis and condition of the affected vertebra. The bone cement is offered as a two-component system (powder and liquid). The polymer powder component consists of PMMA and/or methacrylate copolymers. Additionally, it contains benzoyl peroxide (BPO) as initiator of the radical polymerization. The liquid phase is methyl methacrylate. Both components are mixed together, which initiates the chain formation to achieve a consistent paste of bone cement; due to this chain formation of polymers the bone cement hardens in time [24]. Low viscosity bone cements are usually used for vertebroplasty but now the surgeons want to use high viscosity bone cements to reduce leakage. The bone cement has four phases namely; mixing phase, waiting phase, working/application phase, and setting phase [24]. The mixing phase is the mixing of powder polymer and liquid monomer, in the waiting phase the bone cement is left for few minutes so that it can achieve a suitable viscosity for injection, the working/application phase is the time in which the surgeon injects the bone cement inside the vertebra, and setting phase is the time in which the bone cement hardens inside the vertebra.

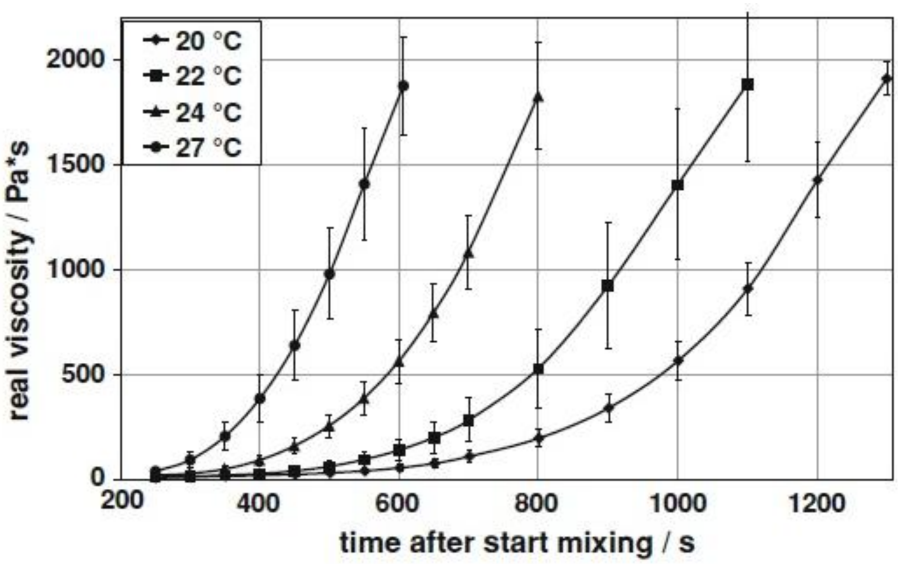
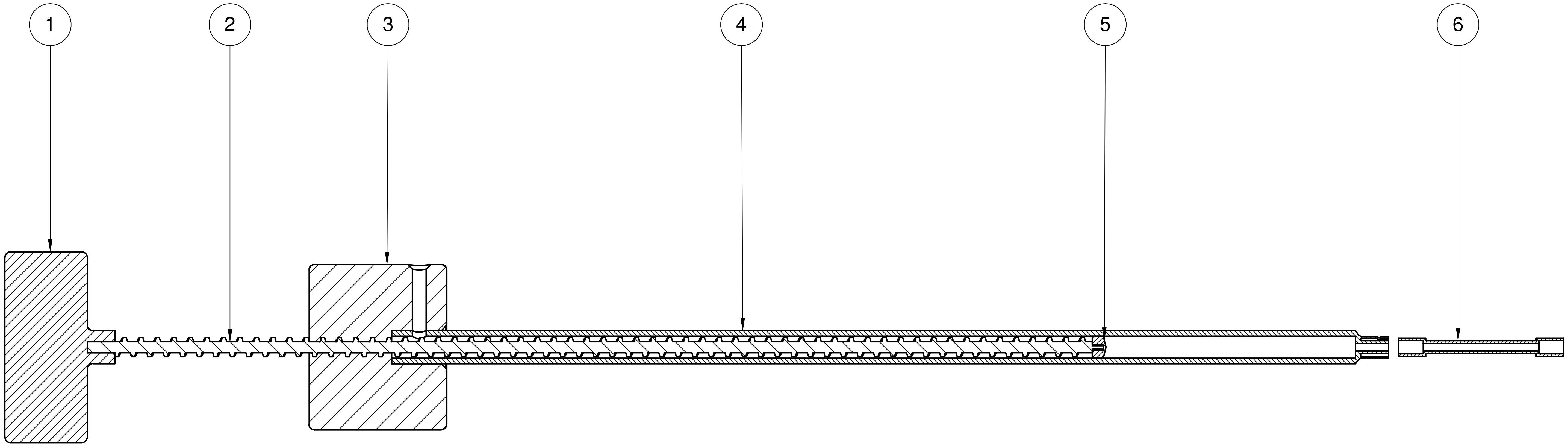


Figure 38: Effect of ambient temperature on the curing of bone cement [11]

It is desirable that the rate of hardening stays low during the working phase and not in the waiting phase of the bone cement. The bone cement is highly temperature sensitive; the higher the ambient temperature the faster the rate of hardening [11]. From Figure 38 it is evident that as the ambient temperature rises the rate of hardening of bone cement also increases. Increment of temperature by roughly 1°C reduces the working time and setting time by 30 seconds [25].

C. CAD Drawings of Final Design

Detailed drawings of the components of final design are shown in the following pages.



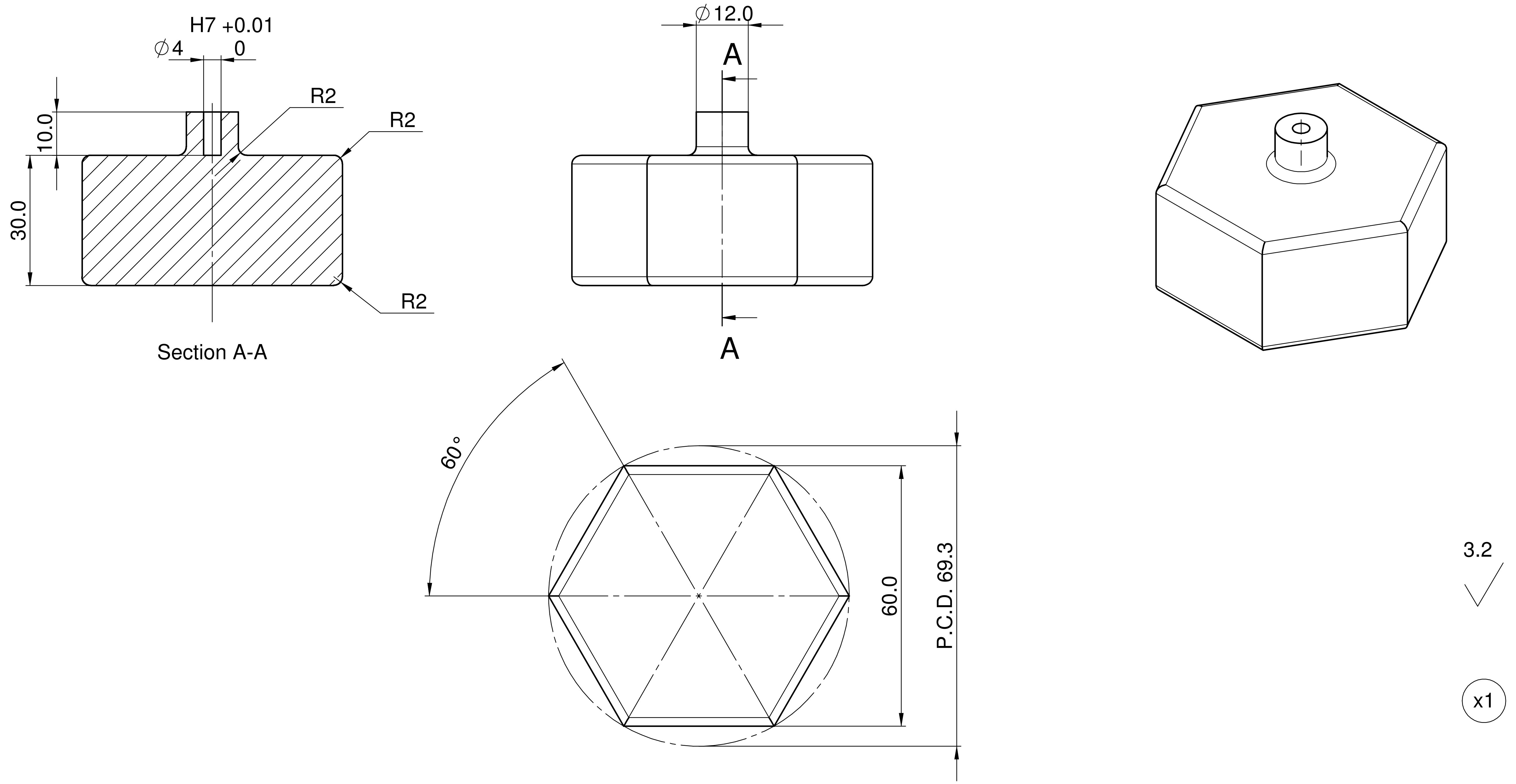
ITEM NO.	PART NUMBER	MATERIAL	QTY.
1	Knob	Medical Grade Acrylic	1
2	Plunger Shaft	Medical Grade Acrylic	1
3	Holder	Medical Grade Acrylic	1
4	Syringe	Medical Grade Acrylic	1
5	Plunger Head	Medical Grade Latex Rubber	1
6	Connector	Standard Luer Lock Connectors	1

scale	1:1.5	date	comments
unit	mm	8/10/2011	
name	Pranjal Gupta		
group	MISIT		
title	Assembly Drawing		

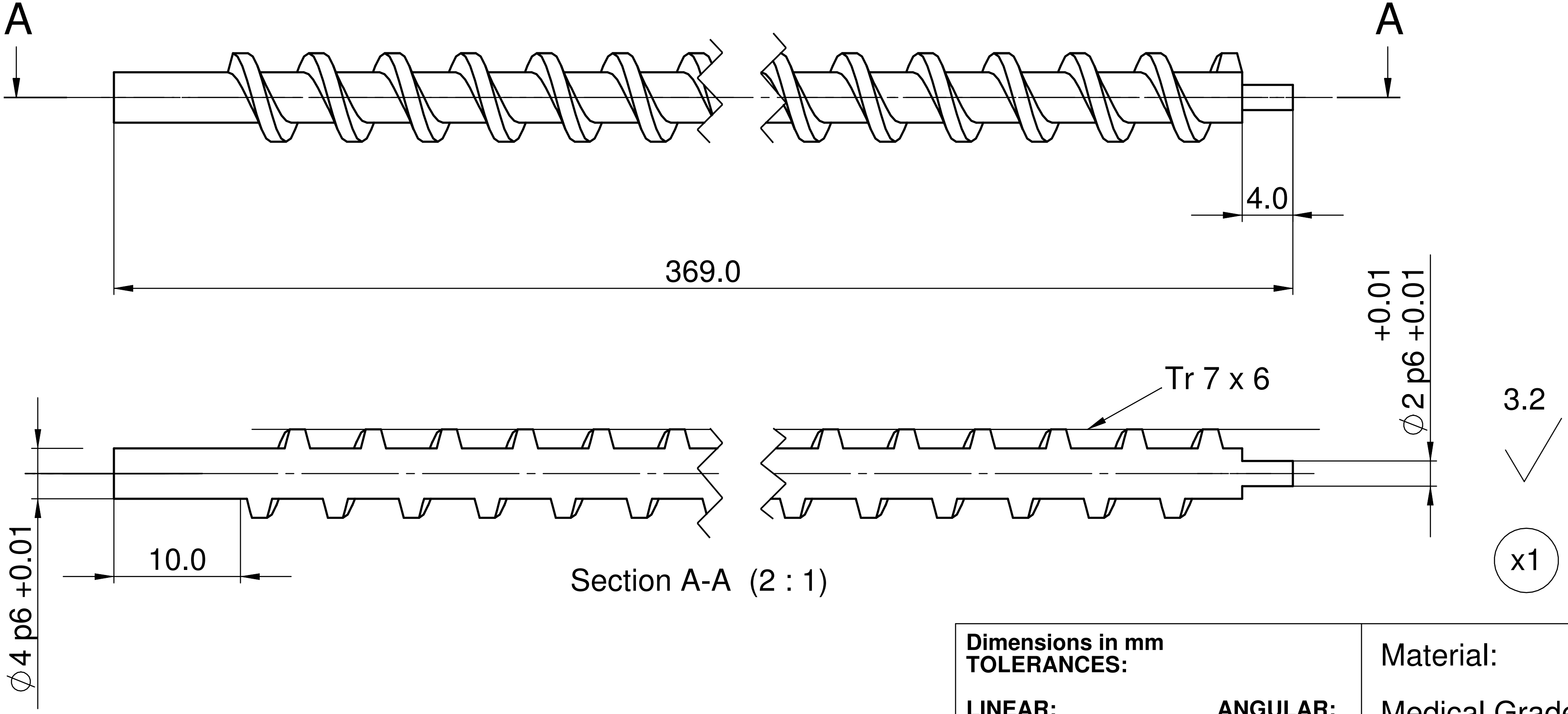
TU Delft
Biomechanical Engineering

format A3

part number



Dimensions in mm TOLERANCES: LINEAR: .X --> 0.1mm .XX --> 0.01mm .XXX --> 0.001mm ANGULAR: .X --> 0.1°	scale 1:1 unit mm name Pranjal Gupta group MISIT	date 8/10/2011	comments Debur sharp edges
	title Knob		
Material: Medical Grade Acrylic	TU Delft Biomechanical Engineering	format A3	part number 01



Section A-A (2 : 1)

Dimensions in mm
TOLERANCES:

LINEAR:
.X --> 0.1mm
.XX --> 0.01mm
.XXX --> 0.001mm

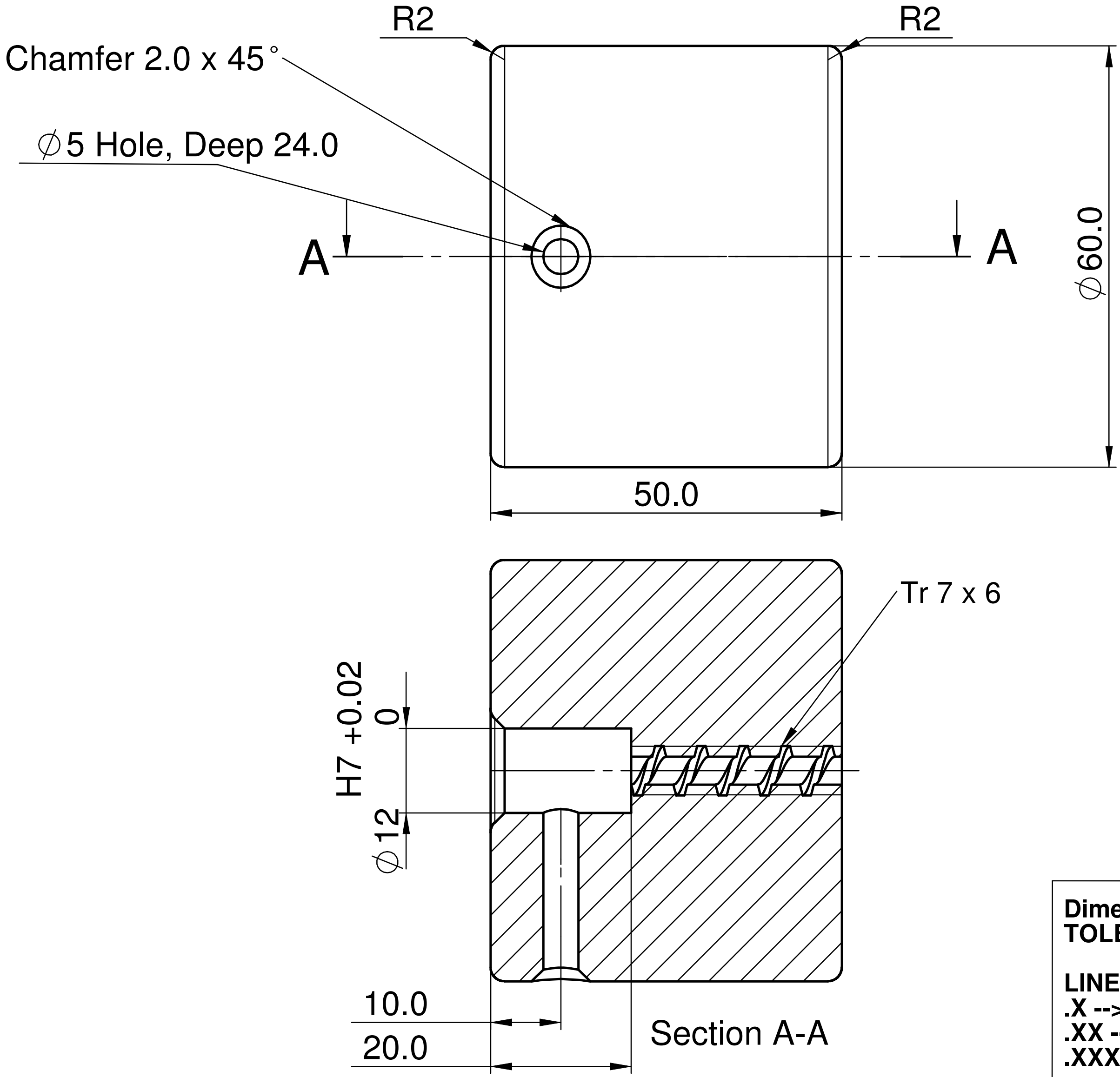
ANGULAR:
.X --> 0.1°

Material:

Medical Grade Acrylic

Debur sharp edges

TU Delft Biomechanical Engineering	title: Plunger Shaft		date: 8/10/2011	unit: **mm**
		scale: **2:1**	group: **MISIT**	formaat: A4 / part number: 02
		name: **Pranjal Gupta**		



3.2

x1

Debur sharp edges

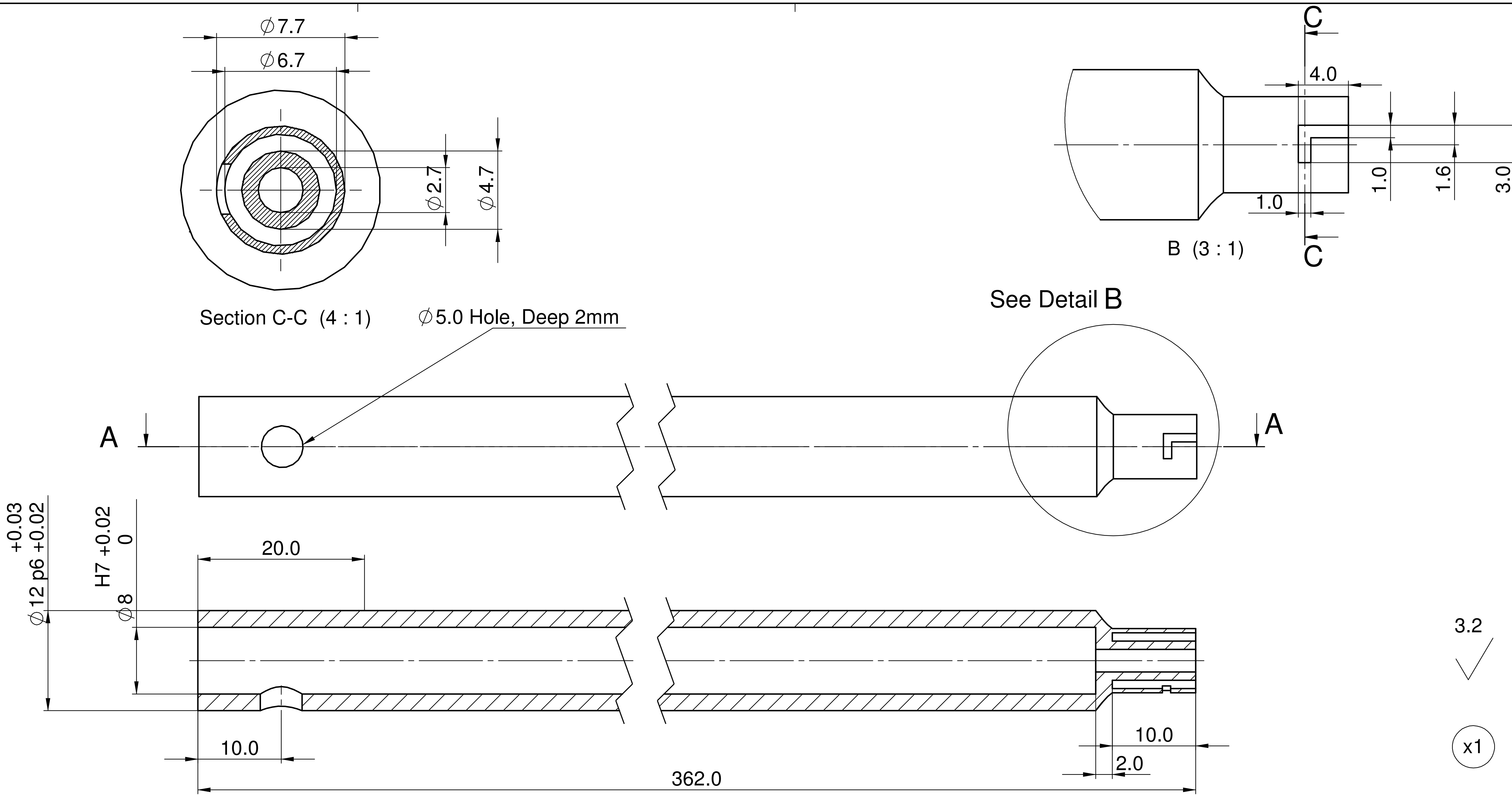
Dimensions in mm
TOLERANCES:

LINEAR:
.X --> 0.1mm
.XX --> 0.01mm
.XXX --> 0.001mm

ANGULAR:
.X --> 0.1°

Material:
Acrylic

TU Delft Biomechanical Engineering	title: Holder		date: 8/10/2011	unit: **mm**
		scale: **1:1**	group: **MISIT**	format: A4
		name: **Pranjal Gupta**		part number: 03



Section A-A (2 : 1)

Dimensions in mm
TOLERANCES:

LINEAR:
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.XX --> 0.01mm
.XXX --> 0.001mm

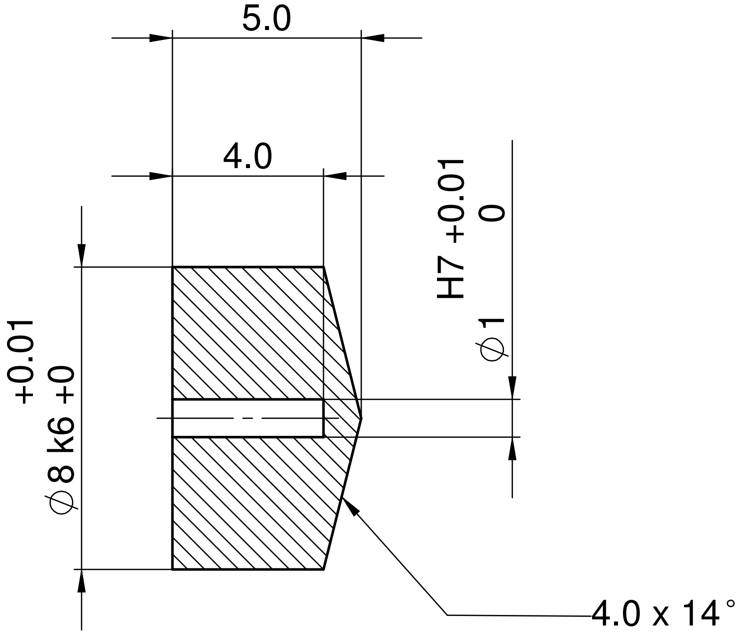
ANGULAR:
.X --> 0.1°

scale	2:1	date	comments
unit	mm	8/10/2011	Debur sharp edges
name	Pranjal Gupta		
group	MISIT		
title	Syringe		

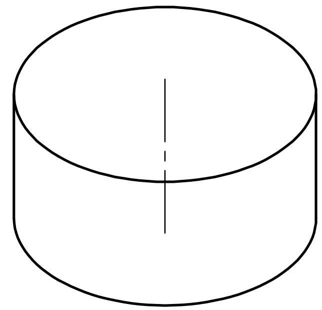
Material:
Medical Grade Acrylic

TU Delft
Biomechanical Engineering

formaat	part number
A3	04



Section A-A (5 : 1)



1.6

x1

Plunger Head made of elastic material
to accomodate ∅2 Plunger Shaft

Dimensions in mm
TOLERANCES:

LINEAR:
.X --> 0.1mm
.XX --> 0.01mm
.XXX --> 0.001mm

ANGULAR:
.X --> 0.1°

Material:

Medical Grade
Latex Rubber

TU Delft Biomechanical Engineering	title Plunger Head		date 8/10/2011		unit **mm**
		scale **5:1**	group **MISIT**	format A4	part number 05
		name **Pranjal Gupta**			